In patent law, the first paragraph of 35 U.S.C. § 112 is currently interpreted to include a written description requirement that is distinct from the requirement of enabling a person skilled in the art to make and use an invention. However, analyses of patent specifications under the "written description requirement" have relied on determinations of whether one skilled in the art would comprehend the scope of the claimed invention in view of the description provided, in effect continuing use of enablement as the statutory threshold for description purposes. The Court of Appeals for the Federal Circuit in University of Rochester v. G.D. Searle & Co., 358 F.3d 916 (Fed. Cir. 2004), cert. denied, 125 S. Ct. 629 (2004) (No. 04-476) departs from considerations of enablement to assess the adequacy of the written description in a patent specification. The decision by the court in Rochester and Judge Rader's vigorous dissent may well represent not only departures from legal precedent, but also the seeds of a split in authority within the Federal Circuit.
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N. SCOTT PIERCE

INTRODUCTION

The first paragraph of 35 U.S.C. § 112 is currently interpreted to include a written description requirement that is distinct from the requirement of enabling a person skilled in the art to make and use an invention. Opinions differ as to whether a distinction between these requirements has always existed or whether it is a recent development. From the early nineteenth century, courts relied on knowledge of one skilled in the art to identify a “principle” or “mode of operation” to distinguish an invention and to establish the limit of an inventor’s exclusive right. During this time, the understanding of one skilled in the art as applied to patentability and infringement was closely linked to “interchangeability” and “equivalence” in view of the written description of a patent specification.

Subsequent to enactment of the Patent Act of 1952, courts began to distinguish between a statutory requirement of a description of the invention and a statutory requirement of enablement by one skilled in the art to make and use it, the former necessitating sufficient demonstration to one skilled in the art that the inventor “possessed” or “invented” the invention. Analysis of a specification under the “written description requirement” relied on a determination of whether one skilled in the art would comprehend the scope of the claimed invention in view of the description provided, in effect employing enablement as the statutory threshold for description purposes. The Court of Appeals for the Federal Circuit (“CAFC”) in University of Rochester v. G.D. Searle & Co. departs from considerations of enablement to assess adequacy of the written description in a patent specification. Further, opinions issued in a decision denying a petition to rehear this case portend a fundamental split in authority in the CAFC that, depending on the panel, will severely limit or deny patent protection.

I. SUMMARY OF UNIVERSITY OF ROCHESTER v. G.D. SEARLE & CO.: NO PROTECTION FOR THE "PHILOSOPHER'S STONE"

The CAFC in Rochester II affirmed a decision by the United States District Court for the Western District of New York invaliding U.S. Patent No. 6,048,850
(hereinafter "the '850 patent") for failure to provide a written description of the claimed invention as required by the first paragraph of 35 U.S.C. § 112. The claims were directed to a method for selectively inhibiting mammalian prostaglandin H synthase-2 ("PGHS-2," or "COX-2") in a human host by administering a non-steroidal compound that selectively inhibits activity of a PGHS-2 gene product. The invention was based on a discovery by scientists at the University of Rochester of the existence of PGHS-2 and its association with inflammatory stimuli responsible for pain and inflammation, and that PGHS-2 has functions distinct from PGHS-1, which provides benefits such as assistance in protecting the stomach lining. Known pain relievers employed to inhibit activity of PGHS-2 also inhibited PGHS-1, potentially causing stomach irritation. Having identified the distinct functions between PGHS-1 and PGHS-2, the scientists developed an assay for identifying a non-steroidal compound that would selectively inhibit PGHS-2. The '850 patent described that assay, but did not include any compounds identified by its use.

The district court stated that:

Id.

1 35 U.S.C. § 112 (2000). The pertinent section states:

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.

Id.

5 Independent claims 1, 5 and 6 of the '850 patent are as follows:

1. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product to a human host in need of such treatment.

5. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the activity of the non-steroidal compound does not result in significant toxic side effects in the human host.

6. A method for selectively inhibiting PGHS-2 activity in a human host, comprising administering a non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product in a human host in need of such treatment, wherein the ability of the non-steroidal compound to selectively inhibit the activity of the PGHS-2 gene product is determined by:

a) contacting a genetically engineered cell that expresses human PGHS-2, and not human PGHS-1, with the compound for 30 minutes, and exposing the cell to a predetermined amount of arachidonic acid;

b) contacting a genetically engineered cell that expresses human PGHS-1, and not human PGHS-2, with the compound for 30 minutes, and exposing the cell to a predetermined amount of arachidonic acid;

c) measuring the conversion of arachidonic acid to its prostaglandin metabolite; and

d) comparing the amount of the converted arachidonic acid converted by each cell exposed to the compound to the amount of the arachidonic acid converted by control cells that were not exposed to the compound, so that the compounds that inhibit PGHS-2 and not PGHS-1 activity are identified.

U.S. Patent No. 6,048,850 (issued April 11, 2000).

7 Id.
8 Id. at 224.
[The real issue here is simply whether a written description of a claimed method of treatment is adequate where a compound that is necessary to practice that method is described only in terms of its function, and where the only means provided for finding such a compound is essentially a trial-and-error process.\(^9\)

Comparing the non-steroidal compound of the ‘850 patent claims to the “philosopher’s stone,” the court found that, without the compound, the patentees could not have possession of the claimed method of its use.\(^10\) The court stated that, to be an inventor or patentee, one must demonstrate possession of the invention,\(^11\) and that failure to provide such a description rendered the patent merely a “wish or plan”\(^12\) which was “an attempt to preempt the future before it has arrived.”\(^13\) The district court held that the written description of the specification, as a matter of law, failed to comply with the written description requirement of 35 U.S.C. § 112 and granted defendants’ motion for summary judgment because no compound was identified by the assay.\(^14\) The court also granted a motion for summary judgment of patent invalidity for

\(^9\) Id. at 221.

\(^10\) Id. at 229–30. The court noted:
In effect, then, the ‘850 patent claims a method that cannot be practiced until one discovers a compound that was not in possession of, or known to, the inventors themselves. Putting the claimed method into practice awaited someone actually discovering a necessary component of the invention. In some ways, this is reminiscent of the search for the so-called “philosopher’s stone,” eagerly sought after by medieval alchemists, which supposedly would transmute lead into gold. While the Court does not mean to suggest that the inventors’ significant work in this field is on a par with alchemy, the fact remains that without the compound called for in the patent, the inventors could no more be said to have possessed the complete invention claimed by the ‘850 patent than the alchemists possessed a method of turning base metals into gold.

\(^11\) Id. at 218. The court stated that:
An “inventor” or patentee is entitled to a patent to protect his work but only if he produces or has possession of something truly new and novel. The “invention” he claims must be sufficiently concrete so that it can be described for the world to appreciate the specific nature of the work that sets it apart from what was before. The inventor must be able to describe the item to be patented with such clarity that the reader is assured that the inventor actually has possession and knowledge of the unique composition that makes it worthy of patent protection.

\(^12\) Id. ("The patent here does not do that. What the reader learns from this patent is a wish or plan or first step for obtaining a desired result.").

\(^13\) Id. (quoting Fiers v. Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

\(^14\) Id. at 224. The court stated:
Applying these principles to the case at bar, I conclude that, as a matter of law, the ‘850 patent does not comply with the written-description requirement of § 112, and that defendants are therefore entitled to summary judgment on that issue. The patent does no more than describe the desired function of the compound called for, and it contains no information by which a person of ordinary skill in the art would understand that the inventors possessed the claimed invention. At best, it simply indicates that one should run tests on a wide spectrum of compounds in the hope that at least one of them will work.

\(^{14}\) Id.
non-enablement on the basis that a person of ordinary skill in the art would have to engage in undue experimentation, without assurance of success, in order to identify a compound that would selectively inhibit PGHS-2 gene product activity, as claimed.\footnote{15} On appeal, the CAFC affirmed the district court's decision granting summary judgment invalidating the '850 patent for failure to meet the written description requirement. The analysis by the CAFC under 35 U.S.C. § 112 began by partitioning the first paragraph:

Three separate requirements are contained in that provision: (1) "the specification shall contain a written description of the invention"; (2) "the specification shall contain a written description . . . of the manner and process of making and using it [i.e., the invention] 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 (3) "the specification . . . shall set forth the best mode contemplated by the inventor of carrying out his invention."\footnote{16}

The CAFC relied on \textit{Evans v. Eaton}\footnote{17} to aver that the Supreme Court has recognized the existence of separate written description and enablement requirements, providing "two objects" for a patent specification, since at least 1822.\footnote{18} The court distinguished the modern written description requirement from enablement on the basis of a close similarity of the language between the Patent Acts

\footnote{15} \textit{Id.} at 233. The court stated:
\begin{quote}
What the '850 patent does \textit{not} do, however, is provide the necessary link between those two steps: actually finding a compound that works. It provides precious little guidance in the way of selecting a particular compound, or even of narrowing the range of candidates in order to find a suitable compound without the need for undue experimentation.
\end{quote}

\footnote{16} \textit{Rochester II,} 358 F.3d 916, 921 (Fed. Cir. 2004).

\footnote{17} \textit{Evans v. Eaton,} 20 U.S. (7 Wheat.) 356 (1822).

\footnote{18} \textit{Rochester II,} 358 F.3d at 924. The court stated:
\begin{quote}
Indeed, as early as 1822 the Supreme Court recognized the existence of separate written description and enablement requirements:
\begin{quote}
[T]he patent act requires . . . that the party [\textit{i.e., the inventor}] "shall deliver a written description of his invention, in such full, clear, and exact terms, as to distinguish the same from all other things before known[, and to enable any person skilled in the art or science, & c. & c. to make, compound, and use the same." The specification, then has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.
\end{quote}
\end{quote}

\textit{Id.} (quoting \textit{Evans v. Eaton,} 20 U.S. (7 Wheat.) 356, 433–34 (1822)).
of 1793 and 1952.\textsuperscript{19} The court further stated that enablement alone is not sufficient because "an invention may be enabled even though it has not been described."\textsuperscript{20} and presented the following hypothetical: "Such can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B if B were described."\textsuperscript{21}

Without a description of the compound employed in their method, the court found that it would be impossible to practice the claimed method of treatment.\textsuperscript{22} Like the district court, the CAFC stated that the inventor must establish that he was in possession of the claimed invention, even if reduction to practice is only constructive.\textsuperscript{23} Summary judgment for failure to meet the written description requirement of the first paragraph of 35 U.S.C. § 112 was affirmed.\textsuperscript{24} The CAFC specifically declined to consider enablement.\textsuperscript{25}

Petitions for rehearing and for rehearing \textit{en banc} the \textit{Rochester II} decision were denied.\textsuperscript{26} The Order, issued July 2, 2004, was accompanied by two concurring opinions and three dissenting opinions. Judge Lourie, who wrote the majority opinion on appeal to the CAFC, concurred in denying the petitions, stating simply that a written description requirement separate from enablement has always been required and that a revision of its interpretation is not warranted.\textsuperscript{27} Judge Dyk

\textsuperscript{19} \textit{Rochester II}, 358 F.3d at 925 ("Although the patent statutes have been extensively revised since 1822 [when \textit{Evans v. Eaton} was decided], most notably in the addition of the requirement of claims, the language of the present statute is not very different in its articulation of the written description requirement.").
\textsuperscript{20} \textit{Id.} at 921.
\textsuperscript{21} \textit{Id.}
\textsuperscript{22} \textit{Id.} at 925. The court noted that:

Regardless whether a compound is claimed per se or a method is claimed that entails the use of the compound, the inventor cannot lay claim to that subject matter unless he can provide a description of the compound sufficient to distinguish the infringing compounds from non-infringing compounds, or infringing methods from non-infringing methods. As the district court observed, "the claimed method depends upon finding a compound that selectively inhibits PGHS-2 activity. Without such a compound, it is impossible to practice the claimed method of treatment."

\textit{Id.} (quoting \textit{Rochester I}, 249 F. Supp. 2d 216, 228 (W.D.N.Y. 2003)).
\textsuperscript{23} \textit{Id.} ("Constructive reduction to practice is an established method of disclosure, but the application must nonetheless describe the claimed subject matter in terms that establish that the applicant was in possession of the . . . claimed invention, including all of the elements and limitations."(quoting Hyatt v. Boone, 146 F.3d 1348, 1353 (Fed. Cir. 1998)).
\textsuperscript{24} \textit{Id.} at 929.
\textsuperscript{25} \textit{Id.} at 929-30 ("In view of our affirmance of the district court’s decision on the written description ground, we consider the enablement issue to be moot and will not discuss it further.").
\textsuperscript{26} Univ. of Rochester v. G.D. Searle & Co., 375 F.3d 1303, 1304 (Fed. Cir. 2004) [hereinafter \textit{Rochester III}].
\textsuperscript{27} \textit{Id.} at 1305-07 (Lourie, J., concurring).

Contrary to the assertions of the appellant, certain amici, and some of the dissenters, there is and always has been a separate written description requirement in the patent law. The requirement to describe one’s invention is basic to the patent law, and every patent draftsman knows that he or she must describe a client’s invention independently of the need to enable one skilled in the relevant art to make and use the invention. The specification then must also describe how to make and use the invention (i.e., enable it), but that is a different task.
agreed with Judge Lourie that 35 U.S.C. § 112 contains a separate written description requirement and further stated that, although the court has "yet to articulate satisfactory standards that can be applied to all technologies" in enforcing this requirement, *Rochester II* was not the appropriate case for *en banc* consideration of this issue. 28 Judge Newman, in a dissenting opinion, supported the holding, but argued for rehearing the case *en banc* to resolve differences of opinion among the judges. 29

Judge Linn, with whom Judges Rader and Gajarsa joined, dissented, stating, in direct contravention to the opinions of Judges Newman, Lourie, and Dyk, that the sole measure of the written description requirement was whether it enables one skilled in the art to make and use the claimed invention. 30 Judge Linn argued that, without enablement and best mode, there is no standard by which to measure written description and, further, given that the purpose of the claims is to set forth the metes and bounds of the invention, there is no reason to require a written description that is distinct from enablement. 31

Judge Rader, who also dissented, and with whom Judges Gajarsa and Linn joined, provided a much different analysis of the written description requirement. Specifically, and contrary to the court's opinion, Judge Rader asserted that the only

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In sum, I concur in the decision of the court not to rehear this case *en banc*. Our precedent is clear and consistent and necessitates no revision of written description law.

*Id.*

28 *Id.* at 1327 (Dyk, J., concurring).

29 *Id.* at 1304 (Newman, J., dissenting). Judge Newman stated:

I fully share Judge Lourie's understanding of the law. The continuing attack on well-established and heretofore unchallenged decisions such as *Vas-Cath, Inc. v. Mahurkar...* and earlier cases such as *In re Ruschig...* is not only unwarranted, but is disruptive of the stability with which this court is charged. If precedent has become obsolete or inapplicable, we should resolve the matter as a court and again speak with one voice.

*Id. (citations omitted).*

30 *Id.* at 1325 (Linn, J., dissenting). Judge Linn's dissent states in part:

Section 112 of Title 35 of the United States Code requires a written description of the invention, but the measure of the sufficiency of that written description in meeting the conditions of patentability in paragraph 1 of that statute depends solely on whether it enables any person skilled in the art to which the invention pertains to make and use the claimed invention and sets forth the best mode of carrying out the invention.

*Id.*

31 *Id.* at 1326—27. The judge further dissented:

Construing § 112 to contain a separate written description requirement beyond enablement and best mode creates confusion as to where the public and the courts should look to determine the scope of the patentee's right to exclude. Under the panel's analysis, a court looks to the written description to determine the parameters of the patentee's invention—under guidelines yet to be articulated—and then determines if the claims, as properly construed, exceed those parameters . . . . There is simply no reason to interpret section 112 to require applicants for patent to set forth the metes and bounds of the claimed invention in two separate places in the application. That is the exclusive function of the claims.

*Id.* at 1326—27 (citations omitted).
requirement for a written description under the Patent Act of 1952, apart from enablement, was established by Judge Rich in 1967 to ensure that an inventor had possession, as of the filing date of an application, of the subject matter later claimed.\footnote{Id. at 1311 (Rader, J., dissenting). Judge Rader noted in his dissent:
Beginning in 1967, this court and its predecessor applied the written description language to achieve this vital purpose of the Patent Act – tying disclosure to the time of invention. In the words of Judge Rich, the first judge to use the description requirement to police priority, “The function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.”}

Judge Rader stated that the hypothetical\footnote{Id. at 1313 (Rader, J., dissenting) (“In sum, our patent law (and the world’s patent law) has worked well for 200 years because the law already possesses ample remedies for the Rochester hypothetical, which, as a practical matter, never occurs.”).} wherein “a patent can enable an invention that is not described,” which was presented by the panel, “rarely, if ever, happens. No actual case presents the hypothetical.”\footnote{Patent Act of 1790, ch. 7, 1 Stat. 109–12 (Apr. 10, 1790) (repealed 1793) (current version at 35 U.S.C. § 112 (2000)).} He concluded that “ample remedies” exist to address the “Rochester hypothetical” in the absence of a separate written description requirement.\footnote{See id. § 2.}

II. HISTORICAL DEVELOPMENT OF THE WRITTEN DESCRIPTION REQUIREMENT

A. Changes in the Literal Language of the Written Description Requirement Since 1790

Section 2 of the Patent Act of 1790\footnote{See Rochester II, 358 F.3d 916, 921 (Fed. Cir. 2004).} included a requirement that:

[T]he grantee or grantees of each patent shall, at the time of granting the same, deliver to the Secretary of State a specification in writing, containing a description, accompanied with drafts or models, and explanations and models . . . of the thing or things, by him or them invented or discovered. . . .

The Act further required:

[The] specification shall be so particular, and said models so exact, as not only to distinguish the invention or discovery from other things before known and used, but also to enable a workman or other person skilled in the art or manufacture, whereof it is a branch, or wherewith it may be nearest connected, to make, construct, or use the same, to the end that the
public may have the full benefit thereof, after the expiration of the patent term . . . .

According to the literal language of the Patent Act of 1790, therefore, the specification was required to "distinguish the invention or discovery from other things before known and used." Separately from the requirement of distinguishing the invention from other things previously known and used, the specification was required to "enable a workman or other person skilled in the art or manufacture . . . to make, construct, or use the same." The phrase, "to the end that the public may have the full benefit thereof, after expiration of the patent term," follows from the second requirement of the specification, enablement, because distinguishing the invention from other things before known would not be a benefit to the public that would continue after expiration of the patent.

The Patent Act of 1793 retained dual requirements of a description that distinguished the invention from things previously known and of enablement by any person skilled in the art to make and use the invention. Section 3 of the Act stated:

Every inventor . . . shall deliver a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science, of which it is a branch, or with which it is most nearly connected, to make, compound, and use the same.

Therefore, the Patent Act of 1793 still required that the written description distinguish the invention from things previously known and separately enable one skilled in the art to make and use the invention.

In Section 6 of the Patent Act of 1836, the requirement that the specification distinguish the invention from "other things before known" was eliminated, leaving the written description with the sole requirement "as to enable":

He shall deliver a written description of his invention or discovery, and of the manner and process of making, constructing, using, and compounding the same, in such full, clear, and exact terms, avoiding unnecessary prolixity, as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound and use the same . . . .

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38 Id.
40 Id. § 3.
42 Id. § 6.
This change was contemporaneous with the insertion of a requirement, in the same section of the Act, that the inventor “shall particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery.”

Section 26 of the Patent Act of 1870 incorporated language relating to the requirements of a written description nearly identical to that of the Patent Act of 1836:

That before any inventor or discoverer shall receive a patent for his invention or discovery, he shall . . . file in the patent office a written description of the same, and of the manner and process of making, constructing, compounding, and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art or science to which it appertains, or with which it is most nearly connected, to make, construct, compound, and use the same . . . .

The Patent Act of 1870, also like that of 1836, required the inventor to particularly point out what he claimed as his invention or discovery, but included the additional criterion that he “distinctly claim” his invention: “. . . and he shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery . . . .” That the inventor was required by the literal language of the statute to “distinctly claim” the invention, apart from providing a specification that included an enabling written description, is evidenced by the last phrase of Section 26, which separately identifies the specification and claim: “. . . and said specification and claim shall be signed by the inventor and attested by two witnesses.”

Under the Patent Act of 1952, United States Code Title 35, Section 112 (“§112”), the term “specification” embraces both a “written description of the invention,” and “claims,” in the first and second paragraphs, respectively, and includes much of the language of Section 26 of the Patent Act of 1870. The first and second paragraphs of 35 U.S.C. § 112 are as follows:

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.

41 Id.
43 Id. § 26.
44 Id.
45 Id.
46 Id.
47 Id.
The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.\(^4\)

### B. Development of Legal Precedent Pertaining to the Written Description Requirement Under the Patent Acts of 1793, 1836 and 1870

#### 1. Evans v. Eaton as a Basis for a Separate Written Description Requirement

_Evans v. Eaton_,\(^5\) decided in 1822, was cited by the CAFC in _Rochester II_ as recognition by the Supreme Court of a written description requirement separate from enablement since the Patent Act of 1793.\(^6\) Judge Rader, in his dissent from the decision to deny rehearing, stated that the Patent Act of 1793 required that the written description both distinguish the invention from "other things before known" and "enable any person skilled in the art."\(^7\) He suggested that the court overlooked the significance of the fact that in 1822 there was no statutory requirement to separately claim the invention\(^8\) and that omitting the language "to distinguish the same from all other things before known" in later acts, in conjunction with a statutory requirement to include claims, could only mean that "enablement became the sole 35 U.S.C. § 112, ¶ 1 standard for adequate disclosure of an invention."\(^9\)

The literal language of the portion of Section 3 of the Patent Act of 1793 requiring an inventor to "deliver a written description of his invention, as to

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\(^6\) See supra Part I.

\(^7\) Rochester III, 375 F.3d 1303, 1309 (Rader, J., dissenting). In his dissent, Judge Rader reasoned:

In 1793, the Patent Act, 1 Stat. 318, required an inventor to describe the scope of the invention in the body of the specification; the Act did not require any claims. Instead the Act required the inventor to provide a written description of his invention, and of the manner of using, or process of compounding the same, in such full, clear, and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art . . . to make, compound and use the same."

_Id._ (citations omitted).

\(^8\) _Id._ at 1310 ("For obvious reasons, Rochester undertakes no further explanation of the Supreme Court's language. In simple terms, the Supreme Court could not have meant that the written description portion must provide adequate support for the claims as this court's law presently requires. Patents did not even contain claims in 1822.").

\(^9\) _Id_. Judge Rader further explained:

The Supreme Court clearly linked its "other object" of the specification disclosure to the portion of the statute requiring the inventor "to distinguish the same from all things before known." Significantly, that language no longer appears in 35 U.S.C. § 112. Later, in 1870, the Patent Act first articulated the requirement that applicants define their exclusive right in a distinctly drafted claim. Only one logical conclusion flows from this history. When the Patent Act assigned the notice function to claims rather than the written description, enablement became the sole 35 U.S.C. § 112, ¶ 1 standard for adequate disclosure of an invention.

_Id._ (citations omitted).
distinguish the same from all other things before known . . . .” was interpreted in Evans in view of Section 2, which was directed to the rights of inventors of “original discoveries” relative to those who patent “improvements.”

As stated by the lower court in Evans:

If the alleged inventor of a machine, which differs from another previously patented, merely in form and proportion, but not in principle, is not entitled to a patent for an improvement, which he cannot be by the 2d section of the law, he certainly cannot, in a like case, claim a patent for the machine itself.

The lower court and the opinion by the Supreme Court addressed whether, in the case of an improvement on a flour mill called a “Hopperboy,” the inventor was entitled to the improved invention as a whole or only the part of the invention that represents the improvement. Further, both the lower court and the Supreme Court discussed at length whether an improvement must be identified by the inventor as such. The lower court stated the inventor must be aware of the “original,” explaining that to hold otherwise would grant overly broad protection. However, the same obligation to describe the portion or feature of a machine that is an “improvement” is not necessary, according to the lower court, where the invention is an “original machine.”

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Provided always, and be it further enacted, That any person, who shall have discovered an improvement in the principle of any machine, or in the process of any composition of matter, which shall have been patented, and shall have obtained a patent for such improvement, he shall not to be at liberty to make, use or vend the original discovery, nor shall the first inventor be at liberty to use the improvement: And it is hereby enacted and declared, that simply changing the form or the proportions of any machine, or composition of matter, in any degree, shall not be deemed a discovery.

Id.


57 Id. at 367 (“The answer to this is, that an improvement necessarily implies an original, and unless the patentee is acquainted with the original which he supposes he has improved, he must talk idly, when he calls his invention an improvement.”).

58 Id. at 362 (“Because if that superiority amounts to an improvement, he is entitled to a patent only for an improvement, and not for the whole machine. In the latter case the patent would be too broad, and therefore void when the patent is single.”).

59 Id. at 367–68. The court stated:

If he knows nothing of an original, then his invention is an original, or nothing; and the subsequent appearance of an original to defeat his patent is one of the risks, which every patentee is exposed to under our law. As to the supposed distinction between an improvement on a machine patented, and one not so, there is nothing in it. In both cases the improvement must be described, but with this difference—that in the former case it may be sufficient to refer to the patent and specification, for a description of the original machine, and then to state, in what the improvements, or such original consists;—whereas, in the latter case, it would be necessary to describe the original machine, and also the improvement. The reason for this distinction is too obvious to need explanation.

Id.
Counsel for plaintiff, in defense of validity of the patent, argued strenuously that the subject invention of the patent need not be compared to "things before known or used," but rather, that the specification need "merely to distinguish new from old." Plaintiffs counsel stated that Section 2 of the Patent Act of 1793 was directed to rights associated with improvements on previously patented inventions, while Section 3 spoke to substantive requirements of the written description of any patent, regardless of whether it represented an "improvement" under Section 2.

Defendant’s counsel argued the opposite, that if the invention was directed to an improvement, the specification must identify the improvement. Failure to do so meant either that the patent was void either because the invention was not new or because the patent was overly broad by not distinguishing the point of novelty.

Justice Story, writing for the Supreme Court, referenced Section 2 of the Patent Act of 1793, stating that an inventor is not entitled to use an "original discovery" where the invention lies in an improvement of what was previously known, "nor is the first inventor at liberty to use the improvement." Further, the Court stated:

(60) Id. at 375. Plaintiff's counsel asserted:

It was a second error of the Court, to take it for granted, that the improved Hopperboy was not so described in the specification, as to distinguish it from all things before known or used, and to enable a person skilled in the art to make it. It is so described . . . . No one skilled in the art could misapprehend this description or be misled by it . . . . The law does not require of patentees to describe new and old, but merely to distinguish new from old. Otherwise a patent would be more complex and voluminous than a Welsh pedigree.

Id.

(61) Id. at 369–70. The plaintiff's counsel further noted:

Indeed, it may well be doubted whether any discrimination is necessary, where, as in this case, there is but one patent in existence. The second section of the law speaks of the case of a prior patented machine. The Court would have the third section to be substantive, without association with the second and sixth [regarding defenses to infringement such as lack of novelty]. But how can a patentee describe what he never saw?

Id. at 376–77.

(62) Id. at 358. Counsel for the defendant stated:

The patentee ought, in his specification, to inform the person who consults it, what is new and what is old. He should say, my improvement consists in this, describing it by words, if he can, or if not, by reference to figures . . . . All that is contended, and that is fully supported by authority, and by the reason of the case, is, that the specification must, in some way or other, distinguish the new from the old, the improvement from what was known before, so as to show what the patented invention is, or else the patent is broader than the invention, and void.

Id. at 389–90.

(63) Id. at 358. Defendant's counsel further stated:

[It is confidently submitted, that the patent of Oliver Evans must be considered as a patent either for the machine or for the improvement. That if it be for the machine, it is void, because it is fully proved that he was not the original inventor, but the machine was known and used before.

The Court would have the third section to be substantive, without association with the second and sixth [regarding defenses to infringement such as lack of novelty]. But how can a patentee describe what he never saw?

Id. at 394.

(64) Id. at 429. The majority set out that:

The Patent Act of the 21st of February, 1793, ch. 11 upon which the validity of our patents generally depends, authorizes a patent to the inventor, for his invention
that, according to the statute, a mere change in form or proportion will not be considered to be a discovery.\(^5\) The Court also cited Section 3 of the Patent Act of 1793, and stated that the "specification, then, has two objects":

The third section of the patent act requires, as has already been stated, that the party 'shall deliver a written description of his invention, in such full, clear, and exact terms, as to distinguish the same from all other things before know [sic], and to enable any person skilled in the art or science, &c. &c. to make, compound, and use the same.' The specification, then, has two objects: one is to make known the manner of constructing the machine (if the invention is of a machine) so as to enable artizans [sic] to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent . . . . The other object of the specification is, to put the public in possession of what the party claims as his own invention, so as to ascertain if he claim anything that is in common use, or is already known, and to guard against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented.\(^6\)

Sections 2 and 3 of the Act were summarized by stating that the inventor's patent is valid for a whole machine "only by establishing that it is substantially new in its structure and mode of operation."\(^6\)

If, then, the plaintiff was not entitled to a patent to the invention as a whole, the question, according to the Court, became whether the patent was valid as an improvement.\(^6\) Relying again on Section 3 of the Patent Act, which required that the inventor "shall deliver a written description of his invention . . . , in such full, clear and exact terms, as to distinguish the same from all other things before known, and to enable any person skilled in the art or science . . . to make, compound, and use the same," the Court held that the specification must identify the improvements, and to limit the patent to the improvements.\(^6\) The Court affirmed the judgment of the

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\(^5\) Id. ("It also declares that simply changing the form or the proportion of any machine or composition of matter not known or used before the application. It also gives to any inventor of an improvement in the principle of any machine, or in the process of any composition of matter which has been patented, an exclusive right to a patent for his improvement; but he is not to be at liberty to use the original discovery, no[r] the first inventor at liberty to use the improvement.

\(^6\) Id. at 433–34.

\(^6\) Id. at 430. The majority noted:

From this enumeration of the provisions of the act, it is clear that the party cannot entitle himself to a patent for more than his own invention; and if his patent includes things before known, or before in use, as his invention, he is not entitled to recover, for his patent is broader than his invention. If, therefore, the patent be for the whole of a machine, the party can maintain a title to it only by establishing that it is substantially new in its structure and mode of operation.

\(^6\) Id. at 432–33.

\(^6\) Id. at 434–35. The court asserted that:
circuit court invalidating the patent because the patent did not specifically identify the improvements over a previously known Hopperboy, as such.\textsuperscript{70}

Justice Livingston, in a dissenting opinion, disputed the interpretation of the statute by the majority.\textsuperscript{71} Specifically, he stated that the law does not require identifying in what particulars the patented improvement lay.\textsuperscript{72} Justice Livingston stated that, if the improved machine is distinguishable upon comparison with known machines, "the words and the objects of the invention are satisfied,"\textsuperscript{73} and that those objects are limited to guarding the public against violation of the patent and enablement of the public to practice the invention upon expiration of the patent:

The law appears to have nothing else in view, in requiring a specification, then [sic] the instruction of the public: that is, to guard them against a violation of the patented improvement, and to enable them, when the letters patent expire, from the specification filed, to make a machine similar to the one which had been patented. The only inquiry, therefore, ought to be, whether this obvious intention of the legislature has been answered by the particular specification which may be the subject of litigation; and if enough appears, either to prevent a person from encroaching on the right of the patentee, or to enable a skillful person to make a machine which shall

\textsuperscript{70} Id. at 435. The court finally stated:

We do not consider that the opinion of the Circuit Court differs, in any material respect, from this exposition of the patent act on this point: and if the plaintiff's patent is to be considered as a patent for an improvement upon an existing Hopperboy, it is defective in not specifying that improvement, and therefore the plaintiff ought not to recover.

\textsuperscript{71} Id. at 441 (Livingston, J., dissenting).

\textsuperscript{72} Id. In his dissent, Justice Livingston stated:

We have seen already that the law prescribes no precise form of specification, which would have been impracticable, and imposes no obligation to describe, in any particular mode, the machine in question. Not a word is said as to showing in what particulars the improvement patented differs from all other machines for the same purpose then in use.

\textsuperscript{73} Id. ("If, on the whole description taken together, the machine of the plaintiff can be distinguished from other machines when compared with his, the words and the objects of the law are satisfied.").
not only resemble the one patented, but produce the like effect: more ought not to be required.\textsuperscript{74}

The issues presented by \textit{Evans}, then, were whether the plaintiff's patent was directed to a machine that was original or an improvement of a previously-known machine and, if an improvement, whether the specification required delineation of the features that constitute the improvement over previously known machines. The majority held that the plaintiff's invention was an improvement on that which was previously known and that the inventor was obligated to identify in the description where the improvement lay.\textsuperscript{75} The dissent, on the other hand, stated that so long as the invention, as described, was distinct from previously known devices, the specification was adequate because the law did not require a list of features that specifically constitute the improvement.\textsuperscript{76}

Although the majority and dissenting opinions in \textit{Evans} differed as to whether the specification, where the patented invention represents an improvement, must specifically state where the improvement lay, or whether it is sufficient merely to describe an invention that is, in fact, different from that which has gone before, both opinions agreed on the policy objectives of the statute setting the requirements of the specification. In particular, both opinions agreed that the objectives of the statute included enabling the public to benefit from the inventors' discovery after expiration of the patent, and putting the public on notice as to the scope of the invention as a warning against encroachment.

The issue in \textit{Evans} was intimately tied to a statutory requirement that the specification distinguish the invention from "all other things before known." As discussed above, the Patent Act of 1836 did not include this language, but instead required that the inventor "particularly specify and point out the part, improvement, or combination, which he claims as his own invention or discovery."\textsuperscript{77} The explicit requirement in the Patent Act of 1870 that the inventor "shall particularly point out and distinctly claim the part, improvement, or combination which he claims is his invention or discovery,"\textsuperscript{78} met the "other object" of the specification identified in \textit{Evans}, of putting the public in possession of what the party claims as his own invention, so as to ascertain if he claim[s] anything that is in common use, or is already known," and guarding "against prejudice or injury from the use of an invention which the party may otherwise innocently suppose not to be patented."\textsuperscript{79} Further, the requirement of the second paragraph of 35 U.S.C. § 112 that "the specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention" is consistent with denial of protection to an applicant whose specification does not call out which among the listed features constitutes an improvement over things before known, as was the case in \textit{Evans}.

\textsuperscript{74} Id. at 441-42.
\textsuperscript{75} Id. at 435.
\textsuperscript{76} Id. at 441-44.
\textsuperscript{77} See supra Part II.A.
\textsuperscript{78} Id.
\textsuperscript{79} Id.
Contrary to the CAFC’s analysis in *Rochester II*, support for a “separate” written description requirement under the Patent Act of 1952 cannot be found by drawing a parallel with the Patent Act of 1793 because the “other object” of the written description requirement of the specification was met by the introduction of a statutory requirement for claims.


At least as early as 1814, a parallel was drawn between patentability and infringement in view of the “principle” or “mode of operation” of an invention or machine. As stated by Circuit Justice Story in *Odiorne v. Winkley*:

The first question for consideration is, whether the machines used by the defendant are substantially, in their principles and mode of operation, like the plaintiff’s machines. If so, it was an infringement of the plaintiff’s patent to use them, unless some of the other matters offered in the defense are proved. Mere colorable alterations of a machine are not sufficient to protect the defendant. The original inventor of a machine is exclusively entitled to a patent for it. If another person invents an improvement on such machine, he can entitle himself to a patent for such improvement only, and does not thereby acquire a right to patent and use the original machine; and if he does procure a patent for the whole of such machine with the improvement, and not for the improvement only, his patent is too broad and therefore void. It is often a point of intrinsic difficulty to decide whether one machine operates upon the same principles as another ... The material question, therefore, is not whether the same elements of motion, or the same component parts are used, but whether the given effect is produced substantially by the same mode of operation, and the same combination of powers, in both machines. *Mere colorable differences, or slight improvements, cannot shake the right of the original inventor*.

Therefore, the court in *Odiorne* stated that when the “given effect is produced substantially by the same mode of operation” as that of a patented machine, the differences between the machines are “mere colorable differences, or slight improvements” that do not protect against a finding of infringement.

By stating that such differences “cannot shake the right of the original inventor,” the court further suggested that identification of the principle of an improvement was a test of both infringement of the patent and of the patentability of the improvement.

In *Gray v. James*, decided in 1817, the Circuit Court for the District of Pennsylvania held in an infringement action that a claimed invention by Perkins was not shown to operate by the same mode as a machine described in an earlier patent.

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81 Id. at 582 (emphasis added).
82 Id.
83 Gray v. James, 10 F. Cas. 1019 (C.C.D. Penn. 1817).
by Chandler. In particular, the Chandler patent was not a reference against Perkins because the description in the Chandler patent was insufficient to determine whether they operated by the same mode, or principle:

But the important difference is in the mode of operating. Perkins' machine makes the nail by one and the same pressure of the lever, Chandler's, so far as the court can perceive, effects nothing more by the pressure of the lever, than the cutting of the nail rod; but, by what power the side or horizontal levers which form the head, are moved, does not appear, otherwise than as it is stated in the specification, to be by the action of what is called secondary levers, or the axes of a wheel during its revolutions. But, by what power are these secondary levers or wheel[s] worked? . . . In short, the court finds it impossible to discover in what manner the complicated parts of this machine are worked, beyond the pressure of the lever which cuts the nail . . . . The one operates by means of a single power; the other by the aid of more than one power. Or, if this be not so, it behooves the defendants clearly to show the contrary, before the court can listen to a motion to set aside the verdict, on the ground that the two machines are substantially alike in principle.\textsuperscript{84}

Therefore, the general description in an earlier patent to Chandler of forming a nail by an apparatus that, like Perkins' nail cutter, included a lever to cut a nail rod, did not foreclose Perkins' right to a patent. In other words, until the mode of operation by which the device disclosed by Chandler could be shown, the court assumed that the principle of operation was different, thereby obviating the challenge to Perkins' right to a patent to the nail-making machine described.

In \textit{Davis v. Palmer}, decided by the Circuit Court for the District of Virginia five years after \textit{Evans}, Circuit Justice Marshall held, in an action for infringement of a patent directed to a mould-board of a plow, that although the principle of the improvement was clearly stated in the specification as that of working the mould-board "to circular or spheric lines," as opposed to straight lines,\textsuperscript{5} the patentee was limited to the particular embodiment shown.\textsuperscript{86} Nevertheless, the court responded to requests by the defendant to modify jury instructions relating to infringement, to the standard by which patentability of the invention was to be determined, and to sufficiency of the description in the specification of the plaintiff's patent. With respect to infringement, the court stated that:

\textsuperscript{84} Id. at 1020.

\textsuperscript{5} Davis v. Palmer, 7 F. Cas. 154, 157 (C.C.D. Va. 1827) ("[I]instead of working the moulding part, or face of the mould-board to straight lines, my improvement is to work it to circular or spheric lines." (quoting the plaintiff)).

\textsuperscript{86} Id. The court stated:

We are then decidedly of opinion, that a mould-board conforming to the particular description contained in the specification, is the invention which the plaintiff claims, and that instead of being a mere illustration of the principle stated in the introductory part of the specification, it is itself the essential improvement, of which only a general idea was given in the introductory part.

\textit{Id.}
The patent, undoubtedly, covers only the improvement precisely described. But if the imitation be so nearly exact as to satisfy the jury that the imitator attempted to copy the model, and to make some almost imperceptible variation, for the purpose of evading the right of the patentee, this may be considered as a fraud on the law, and such slight variation be disregarded.\(^8\)

Similarly, with respect to patentability, the court stated that not every change in form or proportion is fatal, despite the language of Section 2 of the Patent Act of 1793:

In construing this provision [of Section 2 of the Patent Act of 1793], the word “simply,” has, we think, great influence. It is not every change of form and proportion which is declared to be no discovery, but that which is simply a change of form or proportion, and nothing more. If, by changing the form and proportion, a new effect is produced, there is not simply a change of form and proportion, but a change of principle also.\(^8\)

With respect to the written description, the defendant requested that the jury be instructed that it “must be satisfied that the former mould-board is described with sufficient certainty, to distinguish between it and the improvement claimed.”\(^8\) Contrary to the defendant’s request, the court found that a description that distinguished between a former mould-board and the patentee’s improvement was unnecessary.\(^9\) Rather, only a general reference to mould-boards, or one commonly known, was required, along with a description of patentee’s improvement “as will enable a workman to distinguish what is new.”\(^9\)

Therefore, even under the Patent Act of 1793,\(^9\) which predated any requirement for claims, and subsequent to Evans, the written description requirement was interpreted to require only that patentee provide a description of his improvement “enabling a workman to distinguish what is new.”\(^9\) Moreover, all three modifications to the jury instructions in Davis reflect an underlying policy of protecting an inventor’s right against imitators in exchange for providing to the public notice and an enabling description of his improvement. The defendant’s requested jury instruction requiring more of the written description, i.e., “that the former mould-board is described with sufficient certainty, to distinguish between it and the improvement claimed,” was specifically denied by the court.

\(^{87}\) Id. at 159.
\(^{88}\) Id.
\(^{89}\) Id.
\(^{90}\) Id.
\(^{91}\) Id. The court stated that:

We do not think a particular description of the former mould-board is necessary. A general reference to it, either in general terms which are not untrue, or by reference to a particular mould-board, commonly known, accompanied by such a description of the improvement as will enable a workman to distinguish what is new, will be sufficient

\(^{92}\) Id.
\(^{93}\) See supra Part II.A.
\(^{94}\) Davis, 7 F. Cas. at 159.
Infringement and patentability were explicitly compared in a dissenting opinion in the Supreme Court case of *Hotchkiss v. Greenwood,*\(^4\) decided in 1851, after enactment of the Patent Act of 1836.\(^5\) The majority held that a patent directed to a door knob made of potter's clay was void for lack of ingenuity or skill other than that of an ordinary mechanic.\(^6\) In the dissenting opinion, Justice Woodbury stated that, in his view, "the true test of its being patentable was if the invention was new, and better and cheaper than what preceded it."\(^7\) Further, Justice Woodbury stated that such a test is the same as that employed to determine whether patented subject matter is sufficiently distinct so as to avoid infringement of an earlier patent, thereby applying the same standard to both infringement and patentability: "Whenever the kind of test adopted below is used otherwise than to see if there has been an infringement or not, it is to ascertain whether the invention is original or not, that is, whether it is a trifling change and merely colorable or not."\(^8\)

Among the references relied upon for this proposition by Justice Woodbury\(^9\) was *Lowell v. Lewis,\(^\text{100}\) which, like *Odiorne,* based infringement on whether the accused device was "substantially" the same invention claimed by the patent holder.\(^\text{101}\) In *Lowell,* decided by the Circuit Court of the United States for the First Circuit in 1817, infringement was determined by whether the pump described in a patent to the plaintiff, Mr. Perkins, was substantially the same as that of the defendant, Mr. Baker.\(^\text{102}\) Whether the pumps of Mr. Perkins and Mr. Baker were, in fact, the "same invention" was determined by whether the differences were merely in "form or proportion," because such differences could not be the basis for a "new invention."\(^\text{103}\) The reliance on *Lowell* by the dissenting opinion in *Hotchkiss* means that, as late as 1851, after the patent statute had been changed to delete the explicit requirement

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\(^5\) See supra Part II.A.
\(^6\) *Hotchkiss,* 52 U.S. at 267. The majority stated:

> [F]or unless more ingenuity and skill in applying the old method of fastening the shank and the knob were required in the application of it to the clay or porcelain knob than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention. In other words, the improvement is the work of the skillful mechanic, not that of the inventor.

\(^7\) Id. at 268 (Woodbury, J., dissenting).
\(^8\) Id. at 269.
\(^9\) Id.
\(^\text{100}\) *Lowell v. Lewis,* 15 F. Cas. 1018 (C.C.D. Mass. 1817).
\(^\text{101}\) Id. at 1019–20.
\(^\text{102}\) Id. at 1021.
\(^\text{103}\) Id.

Another (and under the circumstances of this case, probably the most material) inquiry is, whether the defendant has violated the patent right of the plaintiff and that depends upon the fact, whether the pumps of Mr. Perkins and of Mr. Baker are substantially the same invention. I say substantially the same invention, because a mere change of the form or proportions of any machine cannot *per se* be deemed a new invention. If they are the same invention, then Mr. Perkins, being clearly the first inventor, is entitled exclusively to the patent rights, although Mr. Baker may have been also an original inventor, for the law gives the right, as among inventors, to him, who is first in time.
that the written description distinguish the invention from "other things before known," at least one Supreme Court justice (albeit in dissent) was hinging patentability and infringement on whether the invention, as described by the patentee, differed from the prior art (in the case of patentability) or an accused device (in the case of infringement) in ways that were "merely colorable."

In Winans v. Adam,\(^{104}\) the Supreme Court focused on whether a patentee's claim to an invention should be limited to the literal form of the claim or whether it should embrace embodiments that were substantially the same, in principle and mode of operation.\(^{105}\) The plaintiff had requested the circuit court to instruct the jury with respect to infringement, as follows:

[T]hat what they had to look at was not simply whether, in form and circumstances, which may be more or less immaterial, that which had been done by the defendant varied from the specification of the plaintiff's patent, but to see whether, in substance and effect, the defendants, having the same object in view as that set forth in the plaintiff's specification, had, since the date thereof, constructed cars which, substantially, on the same principle and on the same mode of operation, accomplished the same result.\(^{106}\)

This language, according to the plaintiff, "was taken verbatim, nearly" from an instruction to the jury in an earlier case, Walton v. Potter, which was another instance where patentability was compared with infringement.\(^{107}\) The plaintiff then cited several cases where patentability and infringement were determined by ascertaining whether a difference from an earlier device (in the case of patentability), or a difference from a device of a patent (in the case of infringement), were differences in principle and mode of operation, or were merely either colorable differences or a substitution of mechanical equivalents.\(^{108}\) For example, with respect to patentability, the plaintiff referenced Huddart v. Grimshaw;\(^{109}\) Regarding infringement, the plaintiff cited Russell v. Cowley\(^{110}\) and Morgan v. Seaward.\(^{111}\) The

\(^{105}\) Id. at 338-39.
\(^{106}\) Id. at 334 (quoting the request by the plaintiff) (emphasis added).
\(^{107}\) Id. Specifically, as recited by the plaintiff in Winans with respect to Walton:
It is in this case [Walton] that C.J. Tindal says, "That if a man has by dint of his own genius and discovery, after a patent has been obtained, been able to give the public, without reference to the former one, or borrowing from the former one, a new and superior mode of arriving at the same end, there can be no objection to his taking out a patent for that purpose. But he has no right whatever to take, if I may so say, a leaf out of his neighbor's book, &c."
Id. (citations omitted).
\(^{108}\) Id. at 337.
\(^{109}\) Huddart v. Grimshaw, 1 Web. Pat. Cases, 85. "If the tube and the plate were the same, substantially, the difference being colorable only, then the patent was void, otherwise it was good: and the question was left to the jury, who found for the plaintiff." Winans v. Adam, 56 U.S. 330, 335 (1853).
\(^{110}\) Russell v. Cowley, 1 Web. Pat. Cases, 457. "This was the case of a patent for welding iron tubes, by drawing them, at a welding heat, through a conical hole. The infringement was the passing them between rollers; and the question of colorable or substantial difference was referred to the jury." Winans, 56 U.S. at 335.
plaintiff quoted Crossley v. Beverly as follows: “[T]he scientific men, all of them, said, ‘the moment a practical, scientific man has got that principle in his head, he can multiply without end, the forms in which that principle can be made to operate.’”112 This reasoning was applied by the plaintiff to his claimed invention in Winans:

As in the case under discussion: the moment a practical, scientific man is furnished with the idea of giving to the car a shape which will, by dispensing with the framing obdollarily [sic] used, enable him to make it lighter in production to its load, than it has ever been made before, he can multiply without end the forms in which this principle can be made to operate.113

The plaintiff concluded that the test of infringement must be whether the accused railroad cars of the defendant were “substantially, in principle and mode of operation, within the plaintiff’s patent.”114

The defendant, on the other hand, argued that an invention, as claimed, is confined to that form: the principle of the invention and the form of the claim are one and the same.115 In other words, the defendant argued that infringement should be limited to the literal scope of the patent claim.

The majority opinion delivered by Justice Curtis held that the principle and mode of operation established both patentability and the scope of a claim.116 The

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111 Morgan v. Seaward, 1 Web. Pat. Cases, 167. “Therefore, the two machines were alike in principle; one man was the first inventor of the principle, and the other has adopted it; and though he may have carried it into effect by substituting one mechanical equivalent for another, still you (the jury) are to look to the substance, and not the mere form, and if it is in substance an infringement, you ought to find so.” Winans, 56 U.S. at 335 (quoting Morgan).


113 Id.

114 Id. at 332. Counsel for the plaintiff went on to state:
Still the question must always be, whether, whatever the shape he adopts, he is not availing himself of the principle first suggested by the patentee; a question which, in a court of law, is at all times a question not for the court, but the jury: after the former shall have given to the specification that construction which is to govern the latter in determining whether the infringement complained of falls, substantially, in principle and mode of operation, within the plaintiff’s patent. Id. at 336.

115 Id. at 337–38. Defendant’s counsel stated:
But the claim is confined to a single form, and only through and by that form to the principles which it embodies: and if, out of the many forms embodying more or less perfectly the same mode of operation, the plaintiff in error has made his choice of the best, he is confined to that choice and the rejection which it involves of all other forms less felicitous . . . . Where the invention consists of a principle embodied in a single form, the form is the principle and the principle the form, and there can be no violation of the principle without the use of the form. Id. (citations omitted).

116 Id. at 341. The majority wrote:
Under our law a patent cannot be granted merely for a change of form . . . . To change the form of an existing machine, and by means of such change to introduce and employ other mechanical principles or natural powers, or, as it is termed, a new mode of operation, and thus attain a new and useful result, is the subject of a patent. Such is the basis on which the plaintiff’s patent rests.
majority cited *Davis v. Palmer* as an instance where the patent is limited to the particular form “described and claimed.” However, the Court distinguished such cases, not on the basis that the inventor was limited in the scope of protection to what literally was described and claimed, but rather that the form disclosed by the patentee was the only form “capable of embodying the invention.” The court held that the jury must decide infringement according to whether the defendant’s claims were “the same in kind, and effected by the employment of his [the plaintiff’s] mode of operation in substance.”

The dissenting opinion also relied on *Davis v. Palmer*, but argued that the specification and claim determine the limit of an invention. This position was grounded in the concern that failure to confine a patentee’s right to the literal bounds of his claim, in effect, creates no bounds for the claim at all. The danger of not

Its substance is a new mode of operation, by means of which a new result is obtained. It is this new mode of operation which gives it the character of an invention, and entitles the inventor to a patent; and this new mode of operation is, in view of the patent law, the thing entitled to protection . . . .

Now, while it is undoubtedly true, that the patentee may so restrict his claim as to cover less than what he invented, or may limit it to one particular form of machine, excluding all other forms, though they also embody his invention, yet such an interpretation should not be put upon his claim if it can fairly be construed otherwise, and this for two reasons:

1. Because the reasonable presumption is, that, having a just right to cover and protect his whole invention, he intended to do so.

2. Because specifications are to be construed liberally, in accordance with the design of the Constitution and the patent laws of the United States, to promote the progress of useful arts, and allow inventors to retain to their own use, not anything which is matter of common right, but what they themselves have created.

*Id.* (citations omitted).


118 *Winans*, 56 U.S. at 343 (citations omitted) (“Undoubtedly, there may be cases in which the letters-patent do include only the particular form described and claimed. *Davis v. Palmer* seems to have been one of those cases. But they are in entire accordance with what is above stated.”).

119 *Id.* (“The reason why such a patent covers only one geometric form, is not that the patentee has described and claimed that form only; it is because that form only is capable of embodying his invention; and, consequently, if the form is not copied, the invention is not used.”)

120 *Id.* at 344. Justice Curtis Held, in particular:

It must be the same in kind, and effected by the employment of his mode of operation in substance. Whether, in point of fact, the defendants’ cars did copy the plaintiff’s invention, in the sense above explained, is a question for the jury, and the court below erred in not leaving that question to them upon the evidence in the case, which tended to prove the affirmative.

*Id.*

121 *Id.* at 345 (Campbell, J. dissenting). (“We are authorized to conclude, that his precise and definite specification and claim were designed to ascertain exactly the limits of his invention. *Davis v. Palmer*, 2 Brock 298.”)

122 *Id.* at 347. In his dissent, Justice Campbell stated:

The claim of to-day is, that an octagonal car is an infringement of this patent. Will this be the limit to that claim? Who can tell the bounds within which the mechanical industry of the country may freely exert itself? What restraints does this patent impose in this branch of mechanical art?
limiting patent construction was foreseen and provided for, according to the dissent, by the requirement that the invention be described in enabling terms and, separately, that the inventor particularly specify and point out what the inventor claims as his invention:

This danger was foreseen, and provided for, in the patent act. The patentee is obliged, by law, to describe his invention, in such full, clear, and exact terms, that from the description, the invention may be constructed and used. Its principle and modes of operation must be explained; and the invention [sic] shall particularly “specify and point” out what he claims as his invention. Fullness, clearness, exactness, preciseness, and particularity, in the description of the invention, its principle, and of the matter claimed to be invented, will alone fulfill the demands of Congress or the wants of the country.123

The dissent concluded that, “[i]n this case the language of the patent is full, clear, and exact. The claim is particular and specific.”124 In effect, the dissent asserted that the statutory requirements (Patent Act of 1836) for the specification also defined the scope of protection: the specification must include a written description in such full, clear and exact terms as to enable a person skilled in the art to practice the invention; in the case of a machine, the “principle and the several modes” contemplated were to be explained; and the inventor was to particularly “specify and point out” what he claimed to be his invention.125

The Supreme Court case of White v. Dunbar126 was an infringement suit decided following enactment of the Patent Act of 1870, which explicitly required inclusion of claims.127 The Court held that, in a reissued patent, substituting the limitation of “textile fabric” with “enveloping material” between a metal can and shrimp contained within the can, the reissued claim was broadened impermissibly and that, therefore,
Specifically, the Court found that there was nothing in the description to support broadening protection beyond use of a textile fabric, and by limiting the claim to a lining of textile fabric, the patentees were declaring that they claimed nothing more.

The Court stated that, although the specification may be referred to in order to understand the meaning of a claim, it is not to be used to change the claim. The policy behind refusing to interpret a claim beyond its literal scope, as expressed by the Court, was to force the patentee to explicitly define his invention in fairness to the public.

Neither in the case of Winans nor in White was there literal support for the claim scope required to recover for infringement by a competitor. However, Winans was decided prior to the Patent Act of 1870. The Court in that case based its holding on the "mode of operation" of the patentee's invention as compared to that of a defendant's machine. The Court in White, on the other hand, and as just mentioned, was decided after enactment of the Patent Act of 1870. In contrast to Winans, the Court in White made no attempt to derive any principle or mode of

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128 White, 119 U.S. at 52 ("In our judgment the reissued patent in this case was unlawfully granted, and the bill should have been dismissed.").
129 Id. at 49. Justice Bradley wrote for the majority:
   The claim in the original patent was for placing textile fabric between the can and its contents; whilst in the reissue it is for interposing between the metal can and the shrimps an enveloping material for the shrimps. This is certainly, on its face, a very important enlargement of the claim; and we see nothing in the context of the specification in the original patent which could possibly give the claim so broad a construction.
   Id. (emphasis added).
130 Id. at 51. The Court further noted:
   We see nothing in all this to raise the slightest implication that the patentees were the inventors of the process of interposing any and every kind of lining between the cans and their contents; and when their claim is confined to a lining of textile fabric, it is tantamount to a declaration that they claimed nothing else.
   Id.
131 Id. In support of their findings, the Court looked at:
   Some persons seem to suppose that a claim in a patent is like a nose of wax which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express. The context may, undoubtedly, be resorted to, and often is resorted to, for the purpose of better understanding the meaning of the claim; but not for the purpose of changing it, and making it different from what it is.
   Id. at 51–52.
132 Id. at 52. The Court re-established that:
   The claim is a statutory requirement, prescribed for the very purpose of making the patentee define precisely what his invention is; and it is unjust to the public, as well as an evasion of the law, to construe it in a manner different from the plain import of its terms.
   Id.
135 Id. at 344.
operation from the specification and relied solely on the literal language of the specification and original claim, essentially adopting the position of the dissent in *Winans* by requiring not only that the patentee “particularly ‘specify and point’ out what he claims as his invention,” but that he “describe his invention, in such full, clear, concise, and exact terms, that from the description, the invention may be constructed and used.”

*Graver Tank v. Linde Air Products Co.*, held that the defendant, employing silicates of calcium and manganese, infringed a patent claim to a combination of alkaline earth metal silicate and calcium fluoride. In support of its holding, the Court argued that a patentee should be protected from “the unscrupulous copyist.”

The doctrine relied upon by the court was based on *Winans* (referred to by the Court as “*Winans v. Denmead*”) and, according to the Court, could be invoked to enforce a patent against a device “if it performs substantially the same function in substantially the same way to obtain the same result.”

The factors to be considered in determining whether a device was equivalent to claimed subject matter included, according to the Court in *Graver Tank*, knowledge of the “interchangeability” of ingredients by those “reasonably skilled in the art.” Given that manganese and magnesium were considered to be equivalent as components of welding flux, the Court found that failure to provide an explanation or indication of independent research inferred “imitation” by the defendant.

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137 Id. at 52; see also *Winans*, 56 U.S. at 347 (Campbell, J., dissenting).
139 Id. at 607. For the majority, Justice Jackson wrote:

> But courts have also recognized that to permit imitation of a patented invention which does not copy every literal detail would be to convert the protection of the patent grant into a hollow and useless thing. Such a limitation would leave room for—indeed encourage—the unscrupulous copyist to make unimportant and insubstantial changes and substitutions in the patent which, though adding nothing, would be enough to take the copied matter outside the claim, and hence outside the reach of law.

*Id.*

140 Id. at 608. Specifically, the Court further reasoned that:

> The essence of the doctrine of equivalents is that one may not practice a fraud on a patent. Originating almost a century ago in the case of *Winans v. Denmead*, it has been consistently applied by this Court in the lower federal courts, and it continues today to be ready and available for utilization when the proper circumstances for its application arise. ‘To temper unsparing logic and prevent an infringer from stealing the benefit of an invention’ a patentee may invoke this doctrine to proceed against the producer of a device ‘if it performs substantially the same function in substantially the same way to obtain the same result.’

*Id.* (citations omitted).

141 Id. at 609 (“An important factor is whether persons reasonably skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was.”).
142 Id. at 612. The court noted:

> Specialists familiar with the problems of welding compositions understood that manganese was equivalent to and could be substituted for magnesium in the composition of the patented flux and their observations were confirmed by the literature of chemistry. Without some explanation or indication that Lincolnweld was developed by independent research, the trial court could properly infer that the accused flux is the result of imitation rather than experimentation or invention.

*Id.*
In their dissenting opinions, Justices Black and Douglas criticized the court for departing from the precedent of *White*. They also stated that application of a doctrine of equivalents unjustly deprives the public of notice and “emasculates” the portion of the statute that provides that an application shall “particularly point out and distinctly claim the part, improvement, or combination which he claims is his invention or discovery,” and that Congress explicitly provided for errors made by patentees, such as not claiming the full breadth of an invention to which he is entitled, by reissue. According to the dissent, Congress entrusted the U.S. Patent and Trademark Office (“USPTO”), rather than the courts, with “initial authority” to determine whether claim scope should be expanded.

The majority decision of *Graver Tank* continued the doctrine of *Winans*, whereby claim scope was determined by equivalence of the mode or principle of the invention, despite the explicit statutory requirement imposed after *Winans* by the Patent Act of 1870, and despite the post-1870 holding in *White*, limiting claim scope to the explicit embodiments of the specification. The Court found equivalence in the case of *Graver Tank* because the accused product performed “substantially the same function in substantially the same way to obtain the same result,” and stated that the differences between the patent claims and the accused product were “colorable” only.

*Engineering Development Laboratories v. Radio Corp. of America* was an appeal of an infringement suit decided in 1946, prior to *Graver Tank*. In *Engineering Development Laboratories*, Judge Learned Hand, for the U.S. Court of Appeals for the Second Circuit, addressed the question of whether claim amendments filed in a

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143 *Id.* at 614 (Black and Douglas, J.J., dissenting). Justices Black and Douglas noted: Today the Court . . . departs from the underlying principle which, as the Court pointed out in *White v. Dunbar*, forbids treating a patent claim like a nose of wax which may be turned and twisted in any direction, by merely referring to the specification, so as to make it include something more than, or something different from, what its words express . . . .

144 *Id.* at 614–15. Justices Black and Douglas further discussed the “emasculating” of the statute:

In seeking to justify its emasculation of R.S. § 4888 [35 U.S.C. § 33, providing that an applicant “shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery”] by parading potential hardships which literal enforcement might conceivably impose on patentees who had for some reason failed to claim complete protection for their discoveries, the Court fails even to mention the program for alleviation of such hardships which Congress itself has provided. 35 U.S.C. § 64 authorizes reissue of patents where a patent is “wholly or partly inoperative” due to certain errors arising from “inadvertence, accident, or mistake” of the patentee.

145 *Id.* at 615 (“Congress was careful to hedge the privilege of reissue by exacting conditions. It also entrusted the Patent Office, not the courts, with initial authority to determine whether expansion of a claim was justified.”).


147 *Id.*

148 See *supra* text accompanying note 129.

149 *Graver Tank v. Linde Air Prods. Co.*, 339 U.S. 605, 612 (1950) (“Though the infringement was not literal, the changes which avoid literal infringement are colorable only.”).

150 153 F.2d 523 (2d Cir. 1946).
reissue application constituted an impermissible broadening of the invention. The reasoning of the court was very much like the infringement test that would be announced in *Graver Tank* (i.e., whether the device “performs substantially the same function in substantially the same way to obtain the same result”). According to the court, “any patent is entitled to some range of equivalents” and the test for amended claim language was whether the scope would “produce substantially the same result by substantially the same means.” The underlying policy for allowing such amendments to claims was to prevent depriving inventors of protection for embodiments of their invention “they never meant to put in the public demesne,” despite competing interests, such as intervening rights in the case of reissue. Therefore, just as in cases, extending as far back as *Odiorne*, where infringement and patentability were based on identification of substantial similarity to the “principle” or “mode of operation” of an invention, in *Engineering Development Laboratories* support for amendment of a claim was determined by identifying substantial similarity of the amended claim language to embodiments found in the written description as filed.

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151 *Id.* at 524.


153 *Eng. Dev. Labs.*, 153 F.2d at 524–25. The court wrote:

So far as concerns the change of the anode of the “rectifying” tube, we are unable to say on this record that it enlarged the scope of the claims at all, if proper allowance be made for possible equivalents. As we have said, the “grid” had no function: a “rectifier” which left it out would accomplish the same result in substantially the same way; and any patent is entitled to some range of equivalents.

... As to the amendment which substituted “resistance” for “variable resistance” in the heater circuit, the disclosure was of a “series of resistance” in that circuit, and the text did not prescribe that any of them should be variable, but only, as we have said, that “one of these resistances may be a variable resistance if desired” ... But once more, we cannot know whether a “resistance,” properly designed for a heater circuit, does not produce substantially the same result by substantially the same means as a “variable resistance” so set that it will prevent the burning out of the filaments. A priori we should suppose that it did.

*Id.* at 524–25 (emphasis added) (citations omitted).

154 *Id.* at 526. The court further noted:

Nor need we say that, though no excuse is given for the delay [in amending the claim], the doctrine [of intervening rights] applies if the change is not to a “new invention” but involves only a minor change necessary to secure complete protection for what the applicant originally intended to reserve to himself. Possibly he may have as much in spite of “intervening rights.” The doctrine [of intervening rights] is designed to protect the public against abuses, not to deprive inventors of what they plainly never meant to put into the public demesne. It is enough here to say that it certainly does not prevent amendments which go no further than to make express what would have been regarded as an equivalent of an original: or to incorporate into one claim what was to be gathered from the perusal of all, if read together. This is the situation here as it comes to us upon this record.

*Id.*

155 See supra Part II.B.2.

1. Advent of the Modern Written Description Requirement: “Equivalence,” and “Invention” and “Possession” by the Inventor

*Prutton v. Fuller*, which was decided after enactment of the Patent Act of 1952, was an appeal from an interference proceeding wherein entitlement to earlier-filed applications was determined under a general requirement of “sufficiency of disclosure.” Specifically, the question was whether earlier-filed applications would “fairly suggest” a claimed composition to one skilled in the art. The court stated that broad disclosure by an applicant does not necessarily entitle him to claim any specific combination of disclosed elements:

> It is clear, however, that when an applicant cites two or more lists of ingredients and indicates that any one in one list may be combined with any one in another, he is not necessarily entitled to claim any specific combination of elements which may fall within the scope of such a disclosure, and we have so held. As was said in the decision of the board affirmed in the Prutton case, “The statutes require more than a statement of a broad field to be usurped to support claims to a composition of matter.”

In *In re Gay*, Judge Rich, for the Court of Customs and Patent Appeals, reversed a decision by the Patent Office Board of Appeals (“Board”). The Board had rejected claims as being based on “new matter” because the phrase “substantially nonporous” was added to the specification and the claims after filing and because applicants failed to disclose the “best mode” required under 35 U.S.C. § 112. The court stated that, because “appellants’ specification would have indicated to one skilled in the art that all suggested container materials were to be substantially nonporous...insertion of this limitation expressly into the specification and claims did not involve ‘new matter.’” The court also found that appellants met the requirement of disclosing the “best mode” of the invention.

The court stated that the first paragraph of 35 U.S.C. § 112, although including several requirements, has two distinct parts:

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156 Prutton v. Fuller, 230 F.2d 459, 463 (C.C.P.A. 1956) (“The issue thus presented by this appeal is limited to the sufficiency of the disclosure of the earlier Prutton applications.”).
157 *Id.* at 463 (“The determining factor is whether the application would fairly suggest to the skilled worker in the art the particular composition claimed, or whether the desirability of that composition could be ascertained only by extensive experimentation.”).
158 *Id.* (citations omitted).
159 *In re Gay*, 309 F.2d 769, 774 (C.C.P.A. 1962).
159 *Id.* at 770.
160 *Id.* at 772.
161 *Id.* at 771.
162 *Id.* at 771.
163 *Id.* at 774 (“It is manifest that appellant does not consider either perforation size, positioning, or number to be particularly crucial aspects of his invention, and that this fact would be appreciated by one skilled in the art who read the specification.”).
We have set forth the Patent Office position in some detail as we feel that it confuses, and in fact is in part contrary to, two of the several requirements of the first paragraph of 35 U.S.C. § 112. This paragraph reads as follows:

"[A] 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 it [sic] most nearly connected, to make and use the same, and shall

"[B] set forth the best mode contemplated by the inventor of carrying out his invention."\(^{164}\)

The court then stated, with respect to the first part, [A], of the first paragraph that, in essence, the statute requires that a specification enable one skilled in the art to make and use the invention: "The essence of portion [A] is that a specification shall disclose an invention in such a manner as will enable one skilled in the art to make and utilize it."\(^{165}\)

The court also commented on 37 C.F.R. § 1.71(b), with which both the patent examiner and the Board stated that the specification failed to comply. 37 C.F.R. § 1.71(b) read at the time of Gay, as it does now, as follows:

The specification must set forth the precise invention for which a patent is solicited, in such manner as to distinguish it from other inventions and from what is old. It must describe completely a specific embodiment of the process, machine, manufacture, composition of matter or improvement invented, and must explain the mode of operation or principle whenever applicable. The best mode contemplated by the inventor of carrying out his invention must be set forth.\(^{166}\)

The court distinguished the requirement of 37 C.F.R. § 1.71(b) from the statutory requirement of 35 U.S.C. § 112, as follows:

One final point remains to be discussed—the Patent Office requirement based on Rule 71(b) that a “specific embodiment” of appellant’s invention be described in the specification. No direct statutory basis exists for this requirement other than portion [A] of section 112, which it appears to implement . . . . The word “specific” is a somewhat indefinite term in that it involves a matter of degree—the question, How specific?, is not answered. Obviously, it is not necessary that an application be more specific than is required by section 112, portion [A]. Not every last detail is to be described.

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\(^{164}\) Id. at 772.
\(^{165}\) Id.
\(^{166}\) 37 C.F.R. § 1.71(b) (2004) (emphasis added).
else patent specifications would turn into production specifications, which they were never intended to be.\textsuperscript{167}

The court held, with respect to the claimed device:

[T]he disclosure in the specification is such that undue experimentation would not be necessary for one skilled in the art and that this disclosure would be sufficient to enable him to make and use the instant invention; and . . . that in the instant case appellant’s disclosure in his specification, taken with his disclosure in the drawing, amounts to a disclosure of a specific embodiment of his invention.\textsuperscript{168}

Therefore, just as the court in \textit{Engineering Development Laboratories} relied on equivalence to embodiments identified in a specification to support amended claim language,\textsuperscript{169} the court in \textit{Gay} found that description of a “mode of operation or principle” of a specific embodiment in the patent disclosure supported enablement of claimed subject matter.

In \textit{In re Rainer}, the court held that claims directed to a process for cross-linking polyethylene were not entitled to the filing date of an earlier-filed application. Like \textit{Prutton}, the basis for the court’s holding was that, although all of the materials recited in the claims were listed in the earlier-filed application, there was no disclosure in the earlier specification to guide selection of those materials and thereby arrive at the claimed invention.\textsuperscript{170} The court in \textit{Rainer} distinguished the requirement of Rule \textit{71(b)} that the specification “set forth the precise invention” from the literal language of 35 U.S.C. § 112:

Where, however, the process claims are directed to the use of specific materials in the process and the specification discloses nothing to guide such a person in making the selection of such specific materials from the rather extensive catalog of materials recited, we think the spirit if not the actual provisions of section 112 are not met. Certainly, the specification here does not “set forth the precise invention for which a patent is solicited,” as required by Rule \textit{71(b)}.\textsuperscript{171}

Therefore, whereas the court in \textit{Gay} considered Rule \textit{71(b)} not to exceed the literal requirement of the first paragraph of 35 U.S.C. § 112, of enabling the claimed invention, the court in \textit{Rainer} suggested that the literal language of Rule \textit{71(b)},

\textsuperscript{167} \textit{Gay}, 309 F.2d at 774 (emphasis added).
\textsuperscript{168} \textit{Id}.
\textsuperscript{169} \textit{See supra Part II.B.2.}
\textsuperscript{170} \textit{In re Rainer}, 347 F.2d 574, 577 (C.C.P.A. 1965). The court stated that:

“True, one may, by blind, unguided selection of the claimed materials from the some 53 listed materials, ultimately arrive at the claimed invention, but there is nothing disclosed in the specification by which the skilled person in this art will be guided in making these particular selections in his efforts to practice the invention.”

\textit{Id}.
\textsuperscript{171} \textit{Id}. (emphasis added).
requiring the specification to “set forth the precise invention,” may exceed the literal meaning of 35 U.S.C. § 112.

The Court of Customs and Patent Appeals in *In re Ruschig*\(^{172}\) affirmed a decision by the Board rejecting a claim (claim 13) directed to a specific compound, N- (p-chlorobenzensulfonyl)-N'-propylurea.\(^{173}\) Claim 13 originally was suggested by a patent examiner for the purpose of an interference proceeding that later was dissolved by the examiner on his own motion.\(^{174}\) In the interim, divisional applications were filed by the parties to the interference that included, in one of the divisional applications, claims 3 and 7, specifying the same compound as that in claim 13 of the earlier-filed application.\(^{175}\) Patentability of the subject matter of claims 3 and 7 in the divisional application was contingent upon successful reliance on the earlier filing date.\(^{176}\) The Board held that the claims in the divisional application were not patentable because the specified compound was not disclosed in the patent application.\(^{177}\)

On appeal, the court stated the issue to be as follows:

The sole issue on this appeal is whether claim 13 [of the parent application] is supported by the disclosure of appellants' application, a question which had not been raised in this case at the time of the prior appeal [reversing a rejection of twelve claims of the same application based on prior art].\(^{178}\)

The court held that the parent application did not explicitly disclose the claimed compound, nor did it provide sufficient guidance to lead one skilled in the art to the claimed compound.\(^{179}\) Specifically, as stated by the court:

But looking at the problem, as we must, from the standpoint of one with no foreknowledge of the specific compound, it is our considered opinion that the board was correct in saying:

Not having been specifically named or mentioned in any manner, one is left to selection from the myriads of possibilities encompassed by the broad disclosure, with no guide indicating or directing that this particular selection should be made rather than any of the many others which could also be made.\(^{180}\)

Appellants argued that the written description of the class of compounds that embraced the specific compound of claim 13 was sufficient because it would enable

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\(^{172}\) *In re Ruschig*, 379 F.2d 990 (C.C.P.A. 1967).
\(^{173}\) *Id.* at 991.
\(^{174}\) *Id.*
\(^{175}\) *Id.*
\(^{176}\) *Id.*
\(^{177}\) *Id.*
\(^{178}\) *Id.*
\(^{179}\) *Id.* at 995.
\(^{180}\) *Id.*
one skilled in the art to make the claimed compound.\textsuperscript{181} The court argued, in response, that the question was not whether one motivated to make the specific compound would be enabled by the specification to do so, but whether appellants had, in fact, invented the specific compound claimed:

We find the argument unpersuasive for two reasons. First, it presumes some motivation for wanting to make the compound in preference to others. While we have no doubt a person so motivated would be enabled by the specification to make it, this is beside the point for the question is not whether he would be so enabled but whether the specification discloses the compound to him, specifically, as something appellants actually invented. We think it does not.\textsuperscript{182}

The basis for stating that the compound of claim 13 was not “something appellants actually invented” was the court’s finding that the specification failed to provide sufficient description to enable one skilled in the art to select the compound from the “myriads” of possibilities of the broad disclosure.\textsuperscript{183} The court stated, in other words, that identification of each of the variables from which selection is to be made is not sufficient, without guidance, to support any particular combination of those variables:

It is an old custom in the woods to mark trails by making blaze marks on the trees. It is no help in finding a trail or in finding one’s way through the woods where the trails have disappeared—or have not yet been made, which is more like the case here—to be confronted simply by a large number of unmarked trees. Appellants are pointing to trees. We are looking for blaze marks which single out particular trees. We see none.\textsuperscript{184}

Although the specification disclosed a class that included the specific compound, the court found that there was insufficient guidance in the specification to lead one skilled in the art from the class to the specific compound claimed. Therefore, the “invention” found lacking by the court was not an invention that the broad disclosure failed to embrace, but, instead, a selection not conveyed to one skilled in the art. As stated by the court:

Second, we doubt that the rejection is truly based on section 112, at least on the parts relied on by appellants. If based on section 112, it is on the requirement thereof that “The specification shall contain a written description \textit{of the invention} ***”. We have a specification which describes appellants’ invention. The issue here is in no wise a question of its compliance with § 112, it is a question of \textit{fact} \textit{Is the compound of claim 13 described therein?} Does the specification convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that

\textsuperscript{181} Id.
\textsuperscript{182} Id.
\textsuperscript{183} Id.
\textsuperscript{184} Id. at 994–95.
appellants invented that specific compound? Having considered the specification in the light that has been shed on it by all the arguments pro and con, we conclude that it does not.185

The court in Ruschig, therefore, resolved the discrepancy between Gay and Rainer by holding that a specification lacking adequate guidance to convey to those skilled in the art that “appellants invented” the claimed invention did not provide a “written description of the invention,” as required by 35 U.S.C. § 112.

After Ruschig, a distinction between an “enablement requirement” and a “description requirement” within the first paragraph of 35 U.S.C. § 112 was explicitly recognized. For example, as stated in In re Dileone, the court stated how the “enablement” requirement might be met without satisfying the “written description requirement”:

For greater clarity on this point, consider the case where the specification discussed 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 first paragraph of § 112 requires both description and enablement.186

In In re Smythe, the Court of Customs and Patent Appeals characterized a Board decision as being “narrowed” to a “description requirement” of the first paragraph of 35 U.S.C. § 112.187 The court relied on Ruschig to pose the issue to be decided as whether the appellants “invented” the claimed subject matter.188 The court found that, although the specification and original claims taught that the “segmentizing medium” is “air or other gas which is inert to the liquid,” it would “naturally occur” to one skilled in the art to employ an “inert fluid,” as later claimed, regardless of whether the fluid was a liquid or a gas.189 Upon the facts of the case,

185 Id.
186 In re Dileone, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971).
187 In re Smythe, 480 F.2d 1376, 1382 (C.C.P.A. 1973). The court reasoned that:
The solicitor states that the “Board’s rationale makes it clear that it regarded 35 U.S.C. § 112, paragraph 1 as the proper statutory basis of its rejection,” and particularly argues that appellants fail to describe their invention in their specification.2
2. The board may have also treated the rejection of these claims under § 112 under the “enablement” section of the first paragraph, but the solicitor has narrowed the rejection by his argument to the “description” requirement.

Id.
188 Id. The court further noted:
The question which must be answered is whether the application originally filed in the Patent Office clearly conveyed in any way to those skilled in the art, to whom it is addressed, the information that appellants invented the analysis system with an inert fluid as the segmentizing medium. If it did, then appellants have made a written description of their invention within the meaning of the first paragraph of 35 U.S.C. § 112.

Id. (citations omitted).
189 Id. at 1383. The court held that:
the court concluded that "applicants invented a sample analyzer with an inert fluid segmentizing medium." 190

The court in Smythe distinguished the patent application from cases where one skilled in the art would not necessarily predict performance of a general class in view of selected species or subcombinations disclosed; where there is such unpredictability, one skilled in the art would not have been "found to have been placed in possession of a genus." 191 The alternative to permitting introduction of broad language "that would naturally occur to one skilled in the art," according to the court, would cause an extreme burden on applicants and the public:

The alternative places upon patent applicants, the Patent Office, and the public the undue burden of listing, in the case of applicants, reading and examining, in the case of the Patent Office, and printing and storing, in the case of the public, descriptions of the very many structural or functional equivalents of disclosed elements or steps which are already stored in the minds of those skilled in the arts, ready for instant recall upon reading the descriptions of specific elements or steps. 192

The Court of Customs and Patent Appeals in In re Wertheim, stated that "[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him . . . ." 193 Thereafter, "possession by the inventor" was invoked as the threshold in several cases decided under the "written description requirement." For example, the court in In re Blaser relied on Wertheim to state that the function of the written description requirement is to "ensure that the applicant had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him." 194

We believe that the use of an inert fluid broadly in this invention would naturally occur to one skilled in the art reading the description of the use of air or other gas as a segmentizing medium to separate the liquid samples. While fluid is a broader term, encompassing liquids, as noted by the solicitor, the specification clearly conveys to one skilled in the art that in this invention the characteristics of a fluid are what make the segmentizing medium work in this invention.

Id. 196

190 Id. at 1384 ("Likewise, we find in the facts here a description of the use and function of the segmentizing medium which would convey to one skilled in the sample-analysis art the knowledge that applicants invented a sample analyzer with an inert fluid segmentizing medium.").

191 Id. at 1383. The court stated:

This is not a case where there is any unpredictability such that appellants' description of air or other inert gas would not convey to one skilled in the art knowledge that appellants invented an analysis system with the fluid segmentizing medium. In other cases, particularly but not necessarily, chemical cases, where there is unpredictability in the performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus or combination claimed at a later date in the prosecution of a patent application.

Id. (citations omitted).

192 Id. at 1384.


194 In re Blaser, 556 F.2d 534, 537 (C.C.P.A. 1977) (citations omitted).
Similarly, the Court of Customs and Patent Appeals in *In re Driscoll* heard an appeal by appellants from a decision by the Board that a claim directed to a chemical compound was not supported in “full, clear, and exact terms,” as is required by the first paragraph of 35 U.S.C. § 112. The question was whether the appealed claim was entitled to the filing date of an earlier application, thereby antedating an intervening prior art reference. The earlier application included a “Markush group” of fourteen constituents, one of which was the support required to entitle the appellant to the earlier filing date. The court held that one skilled in the art would recognize that, as of the earlier filing date, appellant had “possession” of the invention claimed because “one skilled in the art would recognize it as such from the earlier filed application.” The *Driscoll* court based public policy for the holding on a quotation from *Engineering Development Laboratories v. Radio Corp. of America*, in which the court employed equivalence as the test for support of claim language:

“If, when [applicants] yield any part of what they originally believed to be their due, they substitute a new ‘invention,’ only two courses will be open to them: they must at the outset either prophetically divine what the art contains, or they must lay down a barrage of claims, starting with the widest and proceeding by the successive incorporation of more and more detail, until all combinations have been exhausted which can by any possibility succeed. The first is an impossible task; the second is a custom already more honored in the breach than in the observance, and its extension would only increase that surfeit of verbiage which has for long been the curse of patent practice, and has done much to discredit it. It is impossible to imagine any public purpose which it could serve.”

In *Vas-Cath, Inc. v. Mahurkar*, the CAFC addressed whether a claim to priority under 35 U.S.C. § 120 to an earlier design application should have been denied...
because the drawings did not provide an adequate “written description” of the claimed invention as required by the first paragraph of 35 U.S.C. § 112.\textsuperscript{200} The court recounted a history of the written description requirement that began by reciting the third section of the Patent Act of 1793, stating that the patent applicant must “deliver a written description of his invention . . . .”\textsuperscript{201} Objects that were set forth in \textit{Evans} under the Patent Act of 1793 were, according to the \textit{Vas-Cath} court, a “historical” explanation for “written description” and “definiteness” requirements under the first and second paragraphs of 35 U.S.C. § 112, respectively.\textsuperscript{202} The court then recited a “second, policy-based rationale for the inclusion in section 112 of both the first paragraph ‘written description’ and the second paragraph ‘definiteness’ requirement . . . .”\textsuperscript{203}

“[T]here is a subtle relationship between the policies underlying the description and definiteness requirements, as the two standards, while complementary, approach a similar problem from different directions. Adequate description of the invention guards against the inventor’s overreaching by insisting that he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation. The definiteness requirement shapes the future conduct of persons other than the inventor, by insisting that they receive notice of the scope of the patented device.”\textsuperscript{204}

As discussed, the court in \textit{Evans} required a specification to provide a description that would prevent the inventor from “practicing upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is . . . .”\textsuperscript{205} The basis for the concern at that time was whether an inventor, who had improved upon the prior art, was entitled to a patent on the improved device as a whole, or only on the portion of the device that represented the improvement.\textsuperscript{206} Further, even at the time of \textit{Evans}, the principle of an invention could embrace later improvements, as set forth in Section 2 of the Patent Act of 1793, separately from the “written description” requirement of Section 3 of that Act.\textsuperscript{207} The court in \textit{Vas-Cath} acknowledged that preventing an inventor from overreaching was a “second,

\textsuperscript{200} Vas-Cath Inc. v. Mahurkar, 935 F.2d 1555, 1559 (Fed. Cir. 1991).
\textsuperscript{201} \textit{Id.} at 1561 (quoting Evans v. Eaton, 20 U.S. 356, 430 (1822)).
\textsuperscript{202} \textit{Vas-Cath}, 935 F.2d at 1560-61.
\textsuperscript{203} \textit{Id.} at 1561.
\textsuperscript{204} \textit{Id.} (quoting Rengo Co. v. Molins Mach. Co., 657 F.2d 535 (3d Cir. 1981, cert. denied, 102 S.Ct. 600 (1981)).
\textsuperscript{206} \textit{Id.} at 434-35. The court reasoned that:

The specification must describe the invention “in such full, clear, and distinct terms, as to distinguish the same from all other things before known.” How can that be a sufficient specification of an improvement in the machine, which does not distinguish what the improvement is, nor state in what it consists, nor for how far the invention extends? . . . we do not say that the party is bound to describe the old machine, but we are of opinion that he ought to describe what his own improvement is, and to limit his patent to such improvement.

\textit{Id.}

\textsuperscript{207} \textit{See supra} Part II.B.1.
policy-based rationale,” distinct from the object of Evans, of “taking from the inventor the means of practicing upon the credulity or fears of other persons by pretending that his invention is more than it really is . . . .” 208 Therefore, the “second, policy-based rationale,” requiring a written description of the invention to prevent an inventor from “overreaching” by requiring that “he recount his invention in such detail that his future claims can be determined to be encompassed within his original creation,” 209 was new: it did not originate in the Patent Act of 1793, at least in view of the objects of the Act as explained in Evans and recited in Vas-Cath.

In Lockwood v. American Airlines, the CAFC affirmed a district court decision that two of three intervening applications failed to maintain continuity of disclosure, thereby denying entitlement to a necessary earlier filing date. 210 Judge Lourie stated that entitlement to a filing date “does not extend to subject matter which is not disclosed, but would be obvious over what is expressly disclosed.” 211 The court stated that a demonstration that one is “in possession” of the invention is satisfied by providing a description of the invention, not that which would make the invention obvious, 212 and that a written description demonstrates possession of the invention by “words, structures, figures, diagrams, formulas, etc., that fully set forth the claimed invention.” 213

The court then went on to state that, although the invention need not be described in exact terms, the description must be equivalent to the claimed subject matter: “[A]lthough the exact terms need not be used in haec verba . . . the specification must contain an equivalent description of the claimed subject matter. A description which renders obvious the invention for which an earlier filing date is sought is not sufficient.” 214

Therefore, as in Engineering Development Laboratories, 215 which was decided in 1946, prior to the Patent Act of 1952, adequate support in Lockwood was a literal description in a specification equivalent to claimed subject matter. Further, as was also true in earlier cases, the court in Lockwood held that speculation “as to modifications that the inventor might have envisioned” was not enough: the invention must be described:

It is not sufficient for purposes of the written description requirement of §112 that the disclosure, when combined with the knowledge in the art,

208 Vas-Cath, 935 F.2d at 1561.
209 Id.
211 Id. at 1571–72.
212 Id. at 1572. The court stated:
The question is not whether a claimed invention is an obvious variant of that which is disclosed in a specification. Rather, a prior application itself must describe an invention, and do so in sufficient detail that one skilled in the art can clearly conclude that the inventor invented the claimed invention as of the filing date sought . . . . One shows that one is ‘in possession’ of the invention by describing the invention, with all its claimed limitations, not that which makes it obvious.

Id. (citations omitted).
213 Id.
214 Id. (citations omitted).
would lead one to speculate as to modifications that the inventor might have envisioned, but failed to disclose. Each application in the chain must describe the claimed features.\textsuperscript{216}

In summary, under Lockwood and its legal precedents, an adequate written description must enable one skilled in the art to understand, from the literal teaching or its equivalent, the scope of the claimed invention.

2. Development of the Written Description Requirement as Applied to Biotechnology

In \textit{In re Fisher}, the Court of Customs and Patent Appeals affirmed a rejection by the Board for insufficient disclosure under the first paragraph of 35 U.S.C. § 112.\textsuperscript{217} The court held that, despite failure to provide a structural description of porcine adrenocorticotropic hormones ("ACTH"), porcine (hog)-extracts disclosed in the parent application provided adequate support under the first paragraph of 35 U.S.C. § 112 for rejected claim \textsuperscript{4}218 because they inherently included the sequence recited in the claim.\textsuperscript{219} On the other hand, the court held that the claimed hormone, which was not limited to that of any particular animal, could not be broadened beyond the thirty-nine amino acid sequence of hog-pituitary extracts because there was no demonstration that the structure of ACTH's of other animals would be the same and the specification would not enable one skilled in the art to "make or obtain" ACTHs

\textsuperscript{216} \textit{Lockwood}, 107 F.3d at 1572.
\textsuperscript{217} \textit{In re Fisher}, 427 F.2d 833, 840 (C.C.P.A. 1970).
\textsuperscript{218} \textit{Id.} at 837. As recited in \textit{Fisher}, Claim 4 reads as follows:

4. An adrenocorticotropic hormone preparation containing at least 1 International Unit of ACTH per milligram and containing no more than 0.08 units of vasopressin and no more than 0.05 units of oxytocin per International Unit of ACTH, and being further characterized as containing as the active component of [a?] polypeptide of at least 24 amino acids having the following sequence from the N terminus of the molecule: Serine, Tyrosine, Serine, Methionine, Glutamic Acid, Histidine, Phenylalanine, Arginine, Tryptophan, Glycine, Lysine, Proline, Valine, Glycine, Lysine, Lysine, Arginine, Arginine, Proline, Proline, Valine, Lysine, Valine, Tyrosine, Proline.

\textit{Id.} at 835.
\textsuperscript{219} \textit{Id.} at 836. The court set out that:

The examiner took the position that \ldots the parent contained insufficient disclosure to support claim 4 in the manner required by the first paragraph of 35 U.S.C. § 112. The board affirmed this rejection for two reasons. First, since the parent application lacked any structural description of the ACTH extracts therein disclosed, the Board concluded that it could not be determined whether those products would meet the terms of claim 4, which recites a specific sequence of the first 24 amino acids. Appellant contended that the parent application inherently disclosed products meeting the terms of claim 4, even though appellant did not know the chemical structure of those products when the parent application was filed. Appellant cited several cases in support of the proposition that inherent disclosure is sufficient under 35 U.S.C. § 112 \ldots. We agree with appellant that this finding was erroneous \ldots. The hog-extracted products disclosed in appellant's parent application must therefore have had the recited sequence.

\textit{Id.}
having other amino acid sequences. Therefore, in view of Fisher, a specification meets the requirement of the first paragraph of 35 U.S.C. § 112, and there is no need to provide literal support for a claimed sequence of amino acids where the sequence is inherent in a product otherwise adequately described. Further, a finding that a specification fails to support a claim beyond the literal or inherent description within the specification may be based on lack of enablement of one skilled in the art to "make or obtain" the product as broadly claimed.

The CAFC in Amgen v. Chugai Pharmaceutical Co. held that a generic claim, covering all possible DNA sequences that will encode any polypeptide having an amino acid sequence "sufficiently duplicative of [erythropoietin (EPO)] to possess the property of increasing production of red blood cells," was invalid under the enablement requirement of 35 U.S.C. § 112. The court approved of reliance by the district court on the portion of the decision in Fisher holding that a claim directed to a polypeptide having at least twenty-four amino acids of a sequence, without more, was inadequately supported under the enablement requirement of 35 U.S.C. § 112 by a specification that disclosed only a thirty-nine amino acid product.

With respect to the EPO gene, the CAFC in Amgen stated that the disclosure in Amgen's patent was not sufficient to enable the scope of DNA sequences claimed:

Moreover, it is not necessary that a patent applicant test all the embodiments of his invention . . .: what is necessary is that he provide a disclosure sufficient to enable one skilled in the art to carry out the invention commensurate with the scope of his claims. For DNA sequences, that means disclosing how to make and use enough sequences to justify grant of the claims sought. Amgen has not done that here. . . . What is relevant depends on the facts, and the facts here are that Amgen has not
enabled the preparation of DNA sequences to support its all-encompassing claims.

... .

It is not sufficient having made the gene and a handful of analogues whose activity has not been clearly ascertained, to claim all possible genetic sequences that have EPO-like activity. Under the circumstances, we find no error in the court's conclusion that the generic DNA sequence claims are invalid under Section 112.223

The court in Amgen, therefore, found that claims directed to DNA sequences were invalid for failure to meet the enablement requirement of 35 U.S.C. § 112.

The court also held that, under 35 U.S.C. § 102(g),224 conception of a gene, in the absence of a written description that is sufficient to distinguish it from other materials and a method to obtain it, does not occur until reduction to practice and that reduction to practice is defined as isolation of the gene:

Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it. It is not sufficient to define it solely by its principal biological property, e.g., encoding human erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identity of any material with that biological property. We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method of obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.225

Therefore, the court in Amgen did not require a written description that listed all nucleic acid sequences to demonstrate conception of the invention under 35 U.S.C. § 102(g). Rather, as in Fisher with respect to providing sufficient disclosure of a claimed polypeptide under the first paragraph of 35 U.S.C. § 112, only isolation of the claimed product was required in the absence of an explicit claimed structure.

Fiers v. Revel was an appeal from a decision by the Board in a three-way interference between parties Fiers, Revel and Sugano.226 The party Fiers argued

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223 Id. (citations omitted).
224 In analyzing the point, the court noted that under § 102(g):
   A person is entitled to a patent unless—(g) before the applicant's invention thereof the invention was made . . . by another who had not abandoned, suppressed, or concealed it. In determining priority of invention there shall be considered not only the respective dates of conception and reduction to practice of the invention, but also the reasonable diligence of one who was first to conceive and last to reduce to practice, from a time prior to conception by the other.

Id. at 1205.
225 Id. at 1206 (emphasis added).
226 984 F.2d 1164, 1167 (Fed. Cir. 1993).
that an enabling method for obtaining a DNA sequence was essentially the same as proving conception of the DNA.\textsuperscript{227} The court explained, in response to Fiers' argument, that a method of preparation may be employed as support for conception of a DNA sequence when the DNA is claimed by the method, i.e., as a product-by-process claim:

Our statement in \textit{Amgen} that conception may occur, \textit{inter alia}, when one is able to define a chemical by its method of preparation requires that the DNA be claimed by its method of preparation. We recognized that, in addition to being claimable by structure or physical properties, a chemical material can be claimed by means of a process. A product-by-process claim normally is an after-the-fact definition, used after one has obtained a material by a particular process. Before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process.\textsuperscript{228}

The court's reasoning in \textit{Fiers} arguably extends beyond that of \textit{Amgen} in that, in \textit{Amgen}, the method provided for obtaining the EPO gene was characterized as "uncertain."\textsuperscript{229} In contrast to \textit{Amgen}, there was evidence in the form of affidavits that one of ordinary skill in the art would have been able to isolate β-1F DNA based on the protocol proposed by Fiers without undue experimentation.\textsuperscript{230} The court in \textit{Fiers}, however, partitioned conception of DNA from any question of enablement related to its isolation, regardless of certainty: "Fiers has devoted a considerable portion of his briefs to arguing that his method was enabling. The issue here, however, is conception of the DNA of the count, not enablement. Enablement concerns teaching one of ordinary skill in the art how to practice the claimed invention."\textsuperscript{231} With respect to Fiers' argument for priority of invention, the court

\textsuperscript{227} \textit{Id.} at 1168. The court stated that:

[Appellant] Fiers suggests that the standard for proving conception of a DNA by its method of preparation is essentially the same as that for proving that the method is enabling. Fiers thus urges us to conclude that since his method was enabling for the DNA of the count, he conceived it in the United States when Gilbert and Sharp entered the country with the knowledge of, and detailed notes concerning, Fiers' process for obtaining it.

\textit{Id.} at 1169.

\textsuperscript{228} \textit{Id.} at 1169.

\textsuperscript{229} \textit{Amgen}, 927 F.2d at 1207. The \textit{Amgen} court stated:

As expert testimony from both sides indicated, success in cloning the EPO gene was not assured until the gene was in fact isolated and its sequence known. Based on the uncertainties of the method and lack of information concerning the amino acid sequence of the EPO protein, the trial court was correct in concluding that neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved . . .

\textit{Id.}

\textsuperscript{230} \textit{Id.} at 1168 ("Specifically, the Board determined that Fiers' disclosure of a method for isolating the DNA of the count, along with expert testimony that his method would have enabled one of ordinary skill in the art to produce that DNA . . . ").

\textsuperscript{231} \textit{Id.} at 1169.
stated that, when a substance was claimed "per se," conception required a "structure, name, formula, or definitive chemical or physical properties."\(^{232}\)

The CAFC also denied entitlement to an earlier-filed Israeli application to Revel, who was the second party in the three-way interference of Fiers.\(^{233}\) The court stated that Revel's method was not proven to be enabling\(^ {234}\) and that for Revel to claim priority to an earlier filing date, the earlier application needed to have described the DNA "itself."\(^ {235}\) The court succinctly stated the Board's conclusion as follows: "Relying on Amgen, the Board concluded that the Israeli application was not enabling since Revel had not conceived the DNA of the count and "[logically, one cannot . . . enable an invention that has not been conceived."\(^ {236}\) The court then paraphrased its explanation in Amgen, stating that a method for obtaining claimed DNA, without more, is inadequate as a conception of the DNA and, therefore, enablement need not be considered:

As we stated in Amgen and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA. If a conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties, as we have held, then a description also requires that degree of specificity. To paraphrase the Board, one cannot describe what one has not conceived.\(^ {237}\)

Revel asserted that, "since the language of the count refers to a DNA and not to a specific sequence, the specification need not describe the sequence of the DNA in order to satisfy the written description requirement."\(^ {238}\) The court disagreed and affirmed the Board's reasoning that, although "what is needed to meet the description requirement will necessarily vary depending on the nature of the invention claimed," there must be a demonstration to one skilled in the art that the inventor had possession of the claimed invention.\(^ {239}\) The court found that a count, or claim, that covers all DNAs that code for a specific protein is analogous to a single means claim and, therefore, does not comply with the first paragraph of 35 U.S.C. § 112:

Because the count at issue purports to cover all DNAs that code for 6-IF, it is also analogous to a single means claim, which has been held not to

\(^{232}\) Id. ("Conception of a substance claimed per se without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties.").

\(^{233}\) Id. at 1171.

\(^{234}\) Id. ("Revel's application does not even demonstrate that the disclosed method actually leads to the DNA, and thus that he had possession of the invention, since it only discloses a clone that might be used to obtain mRNA coding for 6-IF.").

\(^{235}\) Id. at 1170–71 ("An adequate written description of DNA requires more than a mere statement that it is a part of the invention and reference to a potential method for isolating it: what is required is a description of the DNA itself. Revel's specification does not do that.").

\(^{236}\) Id. at 1170.

\(^{237}\) Id. at 1171.

\(^{238}\) Id. at 1170.

\(^{239}\) Id. ("On reconsideration, the Board correctly set forth the legal standard for sufficiency of description: the specification of Revel's Israeli application must reasonably convey [to the artisan that the inventor had possession at the time of the . . . claimed subject matter." (citations omitted)).
comply with the first paragraph of §112. ... Claiming all DNA's [sic] that achieve a result without defining what means will do so is not in compliance with the description requirement; it is an attempt to preempt the future before it has arrived.240

The court declined to decide whether Revel’s prior application was enabling.241

The third party, Sugano, won the interference.242 Sugano was the first to not only describe a method for obtaining a DNA that coded for B-IF, but to provide a complete and correct nucleotide sequence, thereby meeting the enablement and written description requirements, respectively. 243

Therefore, the courts in both Amgen and Fiers required actual reduction to practice in order to demonstrate conception. However, in both cases, the requirement for actual reduction to practice rested on lack of certainty of enablement of the disclosed method.244 In Amgen, certainty would be established by isolation of the gene.245 In Fiers, the court, in explaining Amgen, also appeared to rely on certainty and, thus, enablement, to demonstrate conception by stating that, “[b]efore reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of that substance, can at most constitute a conception of the substance claimed as a process.”246 In other words, the court implied that conception of a claimed substance would hinge on the success of the process described for obtaining it. Therefore, despite the statement in Fiers specifically partitioning sufficiency of a written description (to demonstrate conception) from enablement, the court, by relying on actual reduction to practice, was consistent with the court in Amgen, which found actual reduction to practice and inherency to be a substitute for physical description of a composition, such as DNA.247

The CAFC in The Regents of the University of California v. Eli Lilly and Co. held that claims directed to cDNA sequences other than those found in rats were

240 Id. at 1171.
241 Id. at 1171 n.12 (“In light of our disposition of the written description question, we do not address whether Revel’s Israeli application satisfies the enablement requirement.”).
242 Id. at 1172.
243 Id. The court stated:

We conclude that Sugano is entitled to rely on his disclosure as enabling since it sets forth a detailed teaching of a method for obtaining a DNA coding for B-IF . . . . We also conclude that Sugano’s application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for B-IF and thus “convey[s] with reasonable clarity to those skilled in the art that, as of the filing date sought, [Sugano] was in possession of the [DNA coding for B-IF].”

Id. (citations omitted).

244 See generally Amgen v. Chugai Pharm. Co. 927 F.2d 1200 (Fed. Cir. 1991); Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993).
245 Amgen, 927 F.2d at 1206. The court held:

We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method for obtaining it, conception has not been achieved until reduction to practice has occurred, i.e., until after the gene has been isolated.

Id.

246 Fiers, 984 F.2d at 1169.
247 Amgen, 927 F.2d at 1206.
invalid for failure to comply with the written description requirement of the first paragraph of 35 U.S.C. § 112. However, with respect to each of the claims, the analysis employed by the court included considerations of enablement. For example, U.S. Patent No. 4,652,525 ("the '525 patent"), one of two patents at issue, included a claim (claim 5) directed to human insulin cDNA. A constructive example (Example 6) of the specification of the '525 patent provided a general method for obtaining human cDNA, which was actually employed to isolate rat cDNA, and provided the amino acid sequences of human insulin A and B chains. The court stated that providing an amino acid sequence is not an adequate description of a specific cDNA sequence due to redundancy of the genetic code. The court also stated that, absent the cDNA sequence, a general method (e.g., the method employed by Example 6) did not meet the written description requirement of the first paragraph of 35 U.S.C. § 112 in support of a claim directed to human insulin cDNA:

This example [Example 6] provides only a general method for obtaining human cDNA (it incorporates by reference the method used to obtain the rat cDNA) along with the amino acid sequences of human insulin A and B chains. Whether or not it provides an enabling disclosure, it does not provide a written description of the cDNA encoding human insulin, which is necessary to provide a written description of the subject matter of claim 5.

The CAFC held that a "written description of the cDNA encoding human insulin" was not provided. This holding was premised on the fact that, "whether or not" the specification was enabling, a "general method" for isolating the human cDNA and the corresponding human amino acid sequences was insufficient to

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248 Regents of the Univ. of Cal. v. Eli Lilly and Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997).
249 Id. at 1567.
250 The other patent at issue was U.S. Patent No. 4,431,740 (issued Feb. 14, 1984).
251 The claims of the '525 patent are as follows:
1. A recombinant plasmid replicable in procaryotic host containing within its nucleotide sequence a subsequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin.
2. A recombinant procaryotic microorganism modified to contain a nucleotide sequence having the structure of the reverse transcript of an mRNA of a vertebrate, which mRNA encodes insulin.
3. The bacterium Escherichia coli which has been modified to contain a nucleotide sequence having the structure of and transcribed from the rat gene for insulin.
4. A microorganism according to claim 2 wherein the vertebrate is a mammal.
5. A microorganism according to claim 2 wherein the vertebrate is a human.
6. A plasmid according to claim 1 comprising a plasmid containing at least one genetic determinant of col E1.
7. A microorganism according to claim 2 comprising a strain of Escherichia coli.
252 See Regents of The Univ. of Cal., 119 F.3d at 1567 ("The patent describes a method of obtaining this [human insulin encoding] cDNA by means of a constructive example, Example 6.").
253 Id. ("We had previously held that a claim to a specific DNA is not made obvious by mere knowledge of a desired protein sequence and methods for generating the DNA that encodes that protein." (citations omitted)).
254 Id.
255 Id.
support the specific claimed subject matter of cDNA encoding those amino acid sequences. In other words, the written description did not permit one skilled in the art to comprehend, on the basis of the general teachings, the specific human cDNA sequences encoding human insulin A and B chains.

Claims 1, 2, 4, 6 and 7, which were directed generically to cDNA encoding vertebrate or mammalian cDNA, also were held to be invalid for failure to meet the written description requirement of 35 U.S.C. § 112. The basis for the court's opinion was that the specification, which adequately described only one species (rat) of a genus (vertebrate or mammalian), did not meet the written description requirement with respect to the generic claims. The CAFC stated that, nevertheless, a genus of cDNAs could be adequately supported by providing a "representative number of cDNAs," thereby linking sufficiency of the written description with enablement:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of the genus under § 112, ¶1, by showing the enablement of a representative number of species within the genus.

The clear implication of the court was that the specification might have met the written description requirement other than by providing nucleotide sequences, even though, in the case of the '525 patent, the written description requirement had not been met:

We will not speculate in what other ways a broad genus of genetic material may be properly described, but it is clear to us, as it was to the district court, that the claimed genera of vertebrate and mammal cDNA are not described by the general language of the '525 patent's written description supported only by the specific nucleotide sequence of rat insulin.

Therefore, even in Lilly, despite clear statements that the written description requirement was distinct from the enablement requirement and that the decision was based entirely on failure to meet the written description requirement, the court employed reasoning associated with enablement and did not rule out alternatives to providing exact claimed structures.

In Enzo Biochem, Inc. v. Gen-Probe, the CAFC, on rehearing, vacated its own prior decision and reversed a district court decision.
granting summary judgment invalidating claims 1 through 6 of U.S. Patent No. 4,900,659 ("the '659 patent"), for failure to meet the written description requirement under the first paragraph of 35 U.S.C. § 112. The claims at issue were directed to nucleic acid probes that selectively hybridize to nucleic acid sequences of *Neisseria gonorrhoeae* relative to *Neisseria meningitidis*. Claims 1 through 4 of the '659 patent were directed to compositions and made reference to deposits at the American Type Culture Collection ("ATCC"). Claims 5 and 6 were directed to assays for detection of *N. gonorrhoeae* using the composition of claim 1 or a variant of that composition.

In vacating their previous decision and reversing the decision of the district court, the CAFC adopted guidelines issued by the USPTO, which stated, in part, that a specification can meet the written description requirement of 35 U.S.C. § 112 by including a "disclosure of sufficiently detailed, relevant identifying characteristics... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics." However, prior to applying the standard adopted from the USPTO's Guidelines, the court first considered, as an issue of first impression, "whether reference to a deposit of a nucleotide sequence may adequately describe that sequence... ." The court held that, considering the "history of biological deposits for patent purposes, the goals of patent law, and the practical difficulties of describing unique biological materials in a written description," reference to a "deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form," did satisfy the written description requirement under the first paragraph of 35 U.S.C. § 112. The court relied on rules promulgated by the USPTO stating that a deposit is not necessary when "it is known and readily available to the public or can be made or isolated without undue experimentation," to thereby allow deposited claimed subject matter as an alternative where the invention "cannot reasonably be enabled by a description in written form in the specification... ." Further, the court stated that the written description requirement is met by what a person skilled in the art can obtain from the deposit:

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262 *Enzo Biochem, Inc. v. Gen Probe Inc.*, 285 F.3d 1013 (Fed. Cir. 2002) (hereinafter *Enzo I*).
263 *Enzo II*, 323 F.3d at 960.
264 *Id.* at 961–62.
265 *Id.* at 962.
266 *Id.* at 964.
267 *Id.* at 965 ("Whether reference to a deposit of a nucleotide sequence may adequately describe that sequence is an issue of first impression in this court.").
268 *Id.*
269 *Enzo II*, 323 F.3d at 965. The court held as follows:
[W]e hold 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.
270 *Id.* (quoting 37 C.F.R. § 1.802(b) (2001)).
271 *Id.* ("Inventions that cannot reasonably be enabled by a description in written form in the specification, but that otherwise meet the requirements for patent protection, may be described in surrogate form by a deposit that is incorporated by reference into the specification.").
A person of skill in the art, reading the accession numbers in the patent specification, can obtain the claimed sequences from the ATCC depository by following the appropriate techniques to excise the nucleotide sequences from the deposited organisms containing those sequences . . . . The sequences are thus accessible from the disclosure in the specification . . . . We therefore agree with Enzo that reference in the specification to deposits of nucleotide sequences describe those sequences sufficiently to the public for purposes of meeting the written description requirement.272

Even claims 4 and 6 of the '659 patent, which were not limited to the deposited sequences, but also included “subsequences” (which were defined in the specification as having “greater than about twelve nucleotides”),273 did not necessarily fail the written description requirement of 35 U.S.C. § 112. According to the court, adequacy of the written description as applied to claims 4 and 6 was to be determined by “whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants, and mixtures sufficient to demonstrate possession of the generic scope of the claims.”274

The court concluded with a statement of public policy behind the written description requirement of 35 U.S.C. § 112 that is consistent with the historical quid pro quo of enabling the public to make and use the claimed invention in exchange for a limited period of exclusivity.275 As stated by the court in Enzo II:

For biological inventions, for which providing a description in written form is not practicable, one may nevertheless comply with the written description requirement by publicly depositing the biological material, as we have held today. That compliance is grounded on the fact of the deposit and the accession number in the specification, not because a reduction to practice has occurred. Such description is the quid pro quo of the patent system: the

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272 Id. at 965–66.
273 Id. at 966. With respect to claims 4 and 6, the court observed that:
Claim 4 is directed to nucleotide sequences that are selected from the group of three deposited sequences, discrete nucleotide subsequences thereof . . . . Claim 6 is also similarly directed to three deposited sequences and subsequences . . . . The specification defines a subsequence nonspecifically as a nucleotide sequence "greater than about 12 nucleotides."

Id.

274 Id. Specifically, the court stated:
On the other hand, because the deposited sequences [of claims 4 and 6] are described by virtue of a reference to their having been deposited, it may well be that various subsequences, mutations, and mixtures of those sequences are also described to one of skill in the art . . . . On remand, the court should determine whether a person of skill in the art would glean from the written description, including information obtainable from the deposits of the claimed sequences, subsequences, mutated variants, and mixtures sufficient to demonstrate possession of the generic scope of the claims.

Id.

275 Id. at 970.
The public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.\textsuperscript{276}

The order granting the petition for rehearing issued the same day as Enzo II and included three concurring and two dissenting opinions.\textsuperscript{277} Judge Lourie, who wrote the majority opinion reversing the decision by the district court, concurred with Judge Newman in the decision not to rehear the case en banc.\textsuperscript{278} He stated that the plain language of the first paragraph set forth both a written description requirement and an enablement requirement, and he supported this grammatical interpretation with a historical interpretation of the statute supporting the existence of a written description requirement prior to imposition of a requirement for claims:

The statute states that the invention must be described. That is basic patent law, the \textit{quid pro quo} for the grant of a patent. Judge Rader notes that historically the written description requirement served a purpose when claims were not required. While that may be correct, when the statute began requiring claims, it was not amended to delete the requirement: note the comma between the description requirement and the enablement provision, and the "and" that follows the comma. Judge Rich, whom Judge Rader cites, was in fact one of the earliest interpreters of the statute as having separate enablement and written description requirements.\textsuperscript{279}

\textsuperscript{276} \textit{Id.} (emphasis added). Interestingly, the distinction in this passage between reduction to practice and deposit makes sense only in the context of enablement. As was discussed in \textit{Amgen}, reduction to practice was for providing both a physical description and an enabling method:

We hold that when an inventor is unable to envision the detailed constitution of a gene so as to distinguish it from other materials, as well as a method of obtaining it, conception has not been achieved until reduction to practice has occurred; i.e., until after the gene has been isolated.

\textit{Amgen v. Chugai Pharm. Co.}, 927 F.2d 1200, 1206 (Fed. Cir. 1991). In neither \textit{Amgen} nor \textit{Enzo II} was there a physical description of the product. However, in \textit{Amgen}, reduction to practice ensured that the method described was enabling: "before reduction to practice, conception only of a process for making a substance, without a conception of a structural or equivalent definition of a substance, can at most constitute a conception of the substance claimed as a process." \textit{Fiers v. Revel}, 984 F.2d 1164, 1165 (C.A.F.C. 1993) (emphasis added). In \textit{Enzo II}, lack of an enabling description in the specification was presumed: "inventions that cannot be enabled by a description in written form in the specification, but that otherwise meet requirements for patent protection, may be described in surrogate form by a deposit that is incorporated by reference into the specification." \textit{Enzo II}, 323 F.3d at 965. Therefore, while \textit{Amgen} required reduction to practice to ensure that the method provided was enabling, in \textit{Enzo II} a publicly accessible deposit was a substitute for lack of an enabling written description. It should be noted, however, that the court in \textit{Fiers} stated that conception also can occur in the absence of reference to a process: "conception of a substance claimed \textit{per se} without reference to a process requires conception of its structure, name, formula, or definitive chemical or physical properties." \textit{Fiers}, 984 F.2d at 1169.

\textsuperscript{277} \textit{Enzo Biochem, Inc. v. Gen-Probe Inc.}, 323 F.3d 970 (Fed. Cir. 2002) (non-precedential opinion) [hereinafter \textit{Enzo IIA}.]

\textsuperscript{278} \textit{Id.} at 971.

\textsuperscript{279} \textit{Id.} (Lourie, J., concurring) (citations omitted) As discussed in Part II.A, \textit{supra}, prior to a specific requirement that the application particularly point out and distinctly claim the invention, the relevant patent statute did, in fact, require a written description of the invention, separate and
Judge Lourie disagreed with Judge Rader who, in a dissenting opinion (discussed infra), argued that the written description in the first paragraph, until Enzo II, was limited to establishing priority of invention. He also disagreed with the proposition that claims finding literal support in the specification, by definition, meet with the written description requirement and employed an example set forth in DiLeone to distinguish enablement from the written description requirement on the basis that the breadth of enablement of a disclosure may exceed the breadth of the invention disclosed. Moreover, Judge Lourie asserted his belief that an elevated interest in patent protection and a consequent effort to broaden claim coverage beyond literal support in a patent application is the impetus behind renewed focus on the written description requirement:

It is said that applying the written description requirement outside of the priority context was novel until several years ago. Maybe so, maybe not; certainly such a holding was not precluded by statute or precedent. New interpretations of old statutes in light of new fact situations occur all the time. I believe these issues have arisen in recent years for the same reason that more doctrine of equivalents issues are in the courts viz., because perceptions that patents are stronger tempt patent owners to try to

apart from a requirement that the applicant enable the invention. Upon statutory recognition of claims in the Patent Act of 1836, the language of the statute was changed so that sufficiency of written description was "as to" enable one skilled in the art to make and use the invention. With respect to § 112, ¶ 1 of the Patent Act of 1952, Judge Markey provided a grammatical construction in his dissent in In re Barker, which is different from Judge Lourie's in that it supports the proposition that enablement is the measure by which satisfaction of the "written description requirement" is met:

Section 112, first paragraph, is a simple sentence, with a comma after "it," making the phrase "in such full *** the same" a modifier of both objects of the verb "contain." All before that comma prescribes what shall be described. The phrase following the comma prescribes how and for whom it shall be described.


280 Enzo III, 323 F.3d at 972 (Lourie, J., concurring). In his concurrence, Judge Lourie noted:

Moreover, the dissenters would limit the requirement, to the extent that they credit the written description portion of the statute as being a separate requirement at all, to priority issues. The statute does not say "a written description of the invention for purposes of policing priority."

Id.

281 Id. In discussing the dissenting opinion, Judge Lourie commented:

I believe that the dissenters miss the point in seeing this case as involving an original claim or in ysis verbis issue. There is no question that an original claim is part of the specification . . . . It is incorrect that the mere appearance of vague claim language in an original claim or as part of the specification necessarily satisfies the written description requirement or shows possession of a generic invention.

Id.

282 Id. at 975. In his concurrence, Judge Lourie noted:

Some commentators have had difficulty in understanding how one may have enabled an invention, but not described it. The believe they must coincide. As an example of how the written description and enablement provisions differ in chemistry, however, one may readily have enabled the making of an invention, but still not have described it . . . .

Id. (citations omitted).
assert their patents beyond the original intentions of the inventors and
their attorney. That is why the issues are being raised and that is why we
have to decide them. Claims are now being asserted to cover what was not
reasonably described in the patent.283

Judge Newman, in a separate concurring opinion, reiterated Judge Lourie’s
opinion that the written description requirement has never been limited to
antedating prior art or establishing priority.284 She also stated that deposit of
biological material to meet the written description requirement, was “a special case”
that does not change the statutory requirement for a written description.285

Judge Rader, in his dissent, firmly stated that, until Judge Rich’s opinion in
Ruschig, there was no written description requirement apart from enablement, and
that the new “written description” (“WD”) doctrine created in Ruschig extended no
further than “policing priority”:

In 1967, in In re Ruschig, this court’s predecessor created for the first
time a new WD doctrine to enforce priority. In the context of a new claim
added “[a]bout a year after the present application was filed,” the Ruschig
court sought to determine “whether [the new] claim 13 is supported by the
disclosure of appellants’ application.” Rather than use § 132, however, Ruschig
assigned the role of policing priority to § 112 . . . . To deal with new
matter in the claims, the court calved a new WD doctrine out of the § 112
enablement requirement.

. . . .

In any event, the WD doctrine, at its inception, had a very clear
function—preventing new matter from creeping into claim amendments.286

Judge Rader then recited language employed by Judge Rich, correlating satisfaction
of the written description requirement with a demonstration in the specification that
the claimed invention was in the possession of the inventor at the time of filing, as
the means for policing priority:

In resolving this question, Judge Rich stated again the purpose of
WD: “The function of the description requirement is to ensure that

283 Id. at 971–72.
284 Id. at 975 (Newman, J., concurring). Judge Newman concurred by stating:
The theory of the dissent that a description of the invention is not needed in order
to support the claims, but serves only to antedate prior art or establish priority in
an interference, is a dramatic innovation in the theory and practice of patents. It
has never been the sole purpose of the description requirement, and negates not
only the logic but the history of patent practice.

Id.
285 Id. (“And the special case of the biological deposit is a method of complying with the
statutory requirements, as the panel now confirms: this expedient implements the statute for the
special subject matter, but does not change it.”).
286 Enzo III, 323 F.3d at 977–78 (Rader, J., dissenting) (citations omitted).
the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him.” In sum, the WD was a new matter doctrine, a priority policeman.\textsuperscript{287}

Judge Rader’s dissent summarized the written description requirement as “the equivalent of the statutory new matter doctrine,” further stating that the doctrine “simply has no application to claims without priority problems.”\textsuperscript{288} He presented an appendix that “will briefly explicate all written description cases from its creation in 1967 in the Court of Customs and Patent Appeals to the present.”\textsuperscript{289} Judge Rader stated that the “appendix shows that only two cases, this ENZO case and the 1997 LILLY case have purported to apply the doctrine outside its purpose and function.”\textsuperscript{290} According to Judge Rader, the CAFC in \textit{Lilly} extended the written description requirement beyond priority to a “free-standing disclosure requirement” substituting for enablement: “In sum, the \textit{Lilly} opinion does not test a later claim amendment against the specification for priority, but asserts a new free-standing disclosure requirement in place of the statutory standard of enablement.”\textsuperscript{291} In essence, according to Judge Rader, the “free-standing written description requirement” established by the \textit{Lilly} opinion was far more exacting than that of enablement and, in effect, eliminated enablement as a means for “demarking the boundary between pioneer inventions and patentable improvements”:

Replacement of enablement doctrines with an ill-defined general disclosure doctrine of WD imperils the integrity of the patent system. Enablement, arguably the most important patent doctrine after obviousness, has many important applications. Beyond mere adequacy of disclosure, it serves as the line of demarcation between the visionary theorist (adds nothing to the useful arts) and the visionary pioneer (contributes to the useful arts), and also serves to limit claim scope thus demarking the boundary between pioneer inventions and patentable improvements. The WD possession test cannot perform these functions.\textsuperscript{292}

As an indication of the breadth of opinion that existed within the CAFC, at least at the time of \textit{Lilly}, Judge Linn, in his dissenting opinion, with whom Judges Rader and Gajarsa joined, stated that the sufficiency of a written description is measured in terms of enablement and that “possession of the invention” is not relevant:

\textsuperscript{287} \textit{Id.} at 978 (quoting \textit{In re Wertheim}, 541 F.2d 257, 262 (C.C.P.A. 1976).
\textsuperscript{288} \textit{Id.} at 979 (stating that the “WD, the equivalent of the statutory new matter doctrine, simply has no application to claims without priority problems”).
\textsuperscript{289} \textit{Id.} at 976 n.1.
\textsuperscript{290} \textit{Id.}
\textsuperscript{291} \textit{Id.} at 980.
\textsuperscript{292} \textit{Id.} at 982 (citations omitted).
Satisfaction of the "possession of the invention" test simply is not relevant.293

Patent validity in view of the written description requirement of the first paragraph of 35 U.S.C. § 112, was again at issue in Amgen, Inc. v. Hoechst Marion Roussel, Inc.294 The technology on which the patent was based included expression of human erythropoietin ("EPO") by transfection of exogenous DNA into a host cell, such as a Chinese hamster ovary ("CHO") cell.295 Transkaryotic Therapies, Inc. ("TKT"), a co-defendant with Hoechst Marion Roussel, Inc., employed a method wherein an endogenous EPO gene in a human cell was activated by transfection of non-coding DNA into the chromosome of the cell.296 The claims that Amgen was asserting against TKT did not include a limitation that the EPO was encoded by DNA that was exogenous to the host cell.297 Despite the fact that all of the examples employed non-native DNA to encode EPO, and that TKT's method of activating unexpressed, endogenous DNA was not taught, the CAFC held that the specification supported claims that were broad enough to include TKT's human EPO product.298

The CAFC distinguished an earlier case relied upon by TKT, Gentry Gallery, Inc. v. Berkline Corp.299 on the basis that, unlike Gentry, where the claimed invention was broader than the invention disclosed, Amgen's claimed invention, a non-naturally occurring human EPO composition, was not broadened by embracing a product made by a method that differed from the method disclosed in the patent specification.300

Separately, TKT stated that claim limitations that included "non-naturally occurring," "vertebrate cells," and "mammalian cells" excluded expression of human EPO in human cells.301 TKT argued that a variation in language between the specification and a 1993 application to which priority was claimed indicated an intentional exclusion from the specification of expressing human DNA in human host

293 Id. at 988 (Linn, J., dissenting) (citations omitted).
294 See Amgen, Inc. v. Hoechst Marion Roussel, Inc., 314 F. 3d 1313 (Fed. Cir. 2003).
295 Id. at 1321.
296 Id. at 1325.
297 Id. ("None of the asserted claims contain either an 'exogenous DNA' or 'endogenous DNA' limitation.").
298 Id. at 1334 ("In light of the evidentiary record and TKT's inability to persuade us that precedent requires a contrary result, we hold that the district court's finding that Amgen satisfied the written description requirement is not clearly erroneous.").
300 Hoechst, 314 F. 3d 1313, 1333. In distinguishing Hoechst from Gentry, the court noted: The undisclosed element leading to the Gentry court's holding of invalidity for lack of an adequate description was a location for the controls other than on the console—leading to a different and undescribed product ... . Amgen's invention is not the location of the control sequences and EPO DNA in relation to the cell, but rather the production of human EPO using those sequences. Thus, the undisclosed element TKT urges invalidates Amgen's product claims is a different method (endogenous activation) of making the claimed compositions. But, as the district court noted, under our precedent the patentee need only describe the invention as claimed, and need not describe an unclaimed method of making the claimed product.
301 Id. (citations omitted).
The CAFC concluded that there was no such intent and that these terms should be "construed... in a manner consistent with their plain meaning." The court, in essence, relied on what it considered to be a "fair reading" of the specification.

TKT also asserted that Amgen "failed to sufficiently describe the use of all vertebrate and mammalian cells." The CAFC affirmed the holding by the district court that the specification adequately described use within the broad classifications and attributed support for the district court holding to expert testimony which stated that, although there "might be 'minor differences' in applying the method of the disclosed examples (utilizing CHO and COS-1 (monkey) cells)... those of ordinary skill could 'easily' figure out those differences in methodology." The CAFC held that Lilly and Enzo II were "inapposite to this case because the claimed terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend."

Accordingly, adequacy of written description in Hoechst was based on a "fair reading" of the specification to embrace expression of human DNA in human cells, without limitation to method as applied to composition claims, and without regard to "minor differences" that could be "easily" figured out by one of ordinary skill in the art with respect to claims generically embracing "mammalian" and "vertebrate" cells exemplified only by CHO and COS-1 cells. Therefore, adequacy of the written description was measured by enablement of one skilled in the art reading the specification to comprehend claim scope (despite a source of a claimed product different from that of the specification).

Judge Clevenger, in his dissent, stated that the majority improperly distinguished Lilly by relying on the fact that the DNA sequences employed in Amgen's claims were not novel. According to the dissent, Lilly stood for two

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302 Id.
303 Id. at 1328. The court stated:
"As a result, we are satisfied that the terms "non-naturally occurring," "vertebrate" and "mammalian" should be construed as they were by the district court, in a manner consistent with their plain meaning. Accordingly, we reject TKT's attempt to limit the scope of the asserted claims under an unduly constricted reading of the specification.

Id.
304 Id. ("Moreover, the specification can fairly be read to, if not expressly, disclose the use of human DNA in human host cells in culture ... ").
305 Id. at 1331.
306 Id. With respect to the decision by the district court, the CAFC observed that:
"[T]he court weighed the testimony and found that the evidence showed that the descriptions adequately described to those of ordinary skill in the art in 1984 the use of the broad class of available mammalian and vertebrate cells to produce the claimed high levels of human EPO in culture... In so doing, the court credited in particular the testimony of Amgen's expert, Dr. Harvey Lodish, who testified, among other things, that there might be 'minor differences' in applying the method of the disclosed examples (utilizing CHO and COS-1 (monkey) cells) to any vertebrate or mammalian cells, but that those of ordinary skill could 'easily' figure out those differences in methodology. (citations omitted).

Id.
307 Id. at 1332.
308 Id. at 1361.
broader principles of the written description requirement: “that *in haec verba* description of broadly described generic subject matter may not suffice to describe the subject matter of that particular claim, and that disclosure of a species may not suffice to describe a genus . . . .” Judge Clevenger also stated that the failure of *Gentry* to recite location of control means was similar to the failure of Amgen’s claims to recite the limitation that the DNA was “exogenous.” Judge Clevenger cautioned that failure to limit claims to embodiments explicit to the specification would make analysis under 35 U.S.C. § 112 more difficult: “But the absence of such limitations must weigh heavily in the section 112 inquiry, else we hold that claims become more resistant to written description challenges the more broadly drafted they are.”

As discussed above, the permissible breadth of Amgen’s claims was limited by the specification as understood by the skilled artisan. However, the concern expressed by Judge Clevenger regarding the potential limitless breadth of claims could have been allayed by more explicitly basing satisfaction of the first paragraph of 35 U.S.C. § 112 on whether one skilled in the art would understand, in view of the specification as written, that the scope of the invention included a recombinant method expressing endogenous DNA, as well as the exogenous embodiments particularly described. In other words, did the written description of the invention “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”? The controversy regarding interpretation of the written description requirement of 35 U.S.C. § 112 that began in *Enzo II* continued in *Moba v. Diamond Automation Inc.* The majority opinion of *Moba* held that a claim broad enough to encompass a machine that lifted eggs from a conveyer was not necessarily invalid for failure to meet the written description requirement of the first paragraph of 35 U.S.C. § 112, despite the fact that the embodiment of the claimed invention in the specification did not lift eggs directly from a moving conveyer, but rather caused them to be stopped.

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309 Id. (Clevenger, J., dissenting). Judge Clevenger stated: *Eli Lilly* articulated two principles of the written description requirement: that *in haec verba* description of broadly described generic subject matter may not suffice to describe the subject matter of that particular claim, and that disclosure of a species may not suffice to describe a genus. The district court followed neither of these principles here, and the majority, dismissing *Eli Lilly* on the grounds that no undisclosed DNA molecule appears in this case, verges on confining *Eli Lilly* to its facts.

310 Id. In discussing *Gentry*, Judge Clevenger noted: Nor am I convinced that the district court’s approach was faithful to *Gentry* Gallery . . . . Because the specification failed to disclose any location for the controls other than on the console, those claims that lacked such limitations were invalid under § 112, ¶ 1 . . . . The question here is similar: whether the claims fail the written description requirement for lack of “exogenous DNA” limitations, because the specification discloses only the exogenous DNA technology that was state of the art in 1984.

311 Id.

312 Id. at 1332.


prior to lifting. In particular, the term "holding station" in the relevant claim (claim 24) of U.S. Patent No. 4,519,505, was interpreted by the court to mean only that the eggs were controlled; there was no requirement by the claim that the eggs be held in a stationary position prior to lifting.

In explaining the Moba court's holding that the specification met the written description requirement of the first paragraph of 35 U.S.C. § 112, the court repeated the familiar wording of the test for compliance: the specification must convey to one skilled in the art, as of the filing date, that the "inventor possessed the invention." The court identified two applications of the first paragraph of 35 U.S.C. § 112: Ruschig, which "inaugurated use of § 112 to prevent the addition of new matter to claims," and Lilly, which "invoked the written description requirement in a case without priority issues." Lilly, Enzo II and Hoechst were all cited for the proposition that the disclosure need not take any particular form, so long as possession by the inventor is demonstrated. The CAFC in Moba concluded that, "accordingly," the jury finding in the lower court with respect to the written

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315 Id. at 1321. The court stated:

FPS's [Food Processing Systems[Moba's] contention that the '505 patent does not adequately disclose lifting eggs from a moving conveyor merely revives its non-infringement argument in the cloak of a validity challenge. As noted, the jury found that one of skill in the art would discern possession of the invention at the time of filing, a finding supported by substantial record evidence. Therefore, the trial court correctly determined that claim 24 is not invalid for lack of adequate written description.

316 Id. at 1315. The court discussed the construction of claim 24 of the '505 patent:

The district court correctly construed the "holding station" of claim 24 of the '505 patent as "a first location in space to which an egg is moved and at which an egg may maintain position until the egg is lifted simultaneously with an egg at a 'spaced-apart location.' Nonetheless FPS argues that the district court's construction requires that an egg cease motion before the lift to the overhead conveyor. The claims simply do not require a specific temporal limitation associated with the term holding . . . ." Moreover, the ordinary meaning of "to hold" is "to keep in position, guide, control, or manage." This meaning also imposes no requirement that an object remain stationary.

317 Id. at 1320 ("The test for compliance with § 112 has always required sufficient information in the original disclosure to show that the inventor possessed the invention at the time of the original filing." (citations omitted)).

318 Id. at 1319 ("Federal Circuit case law reflects two applications of 35 U.S.C. § 112, ¶ 1. First, in 1967, this court's predecessor inaugurated use of § 112 to prevent the addition of new matter to claims." (citations omitted)).

319 Id. at 1320 ("The second application of the written description requirement is reflected in Regents of University of California v. Eli Lilly & Co. There, this court invoked the written description requirement in a case without priority issues." (citations omitted)).

320 Moba, 325 F.3d at 1321. In discussing Lilly, Enzo II and Hoechst identified by the court as "Amgen"), the court noted:

In Enzo and Amgen, the record showed that the specification that taught one of skill in the art to make and use an invention also convinced that artisan that the inventor possessed the invention. Similarly, in this case, the Lilly disclosure rule does not require a particular form of disclosure because one of skill could determine from the specification that the inventor possessed the invention at the time of filing.
description requirement of the first paragraph of 35 U.S.C. § 112 was supported by "substantial evidence."321

In his concurring opinion, Judge Rader admonished that CAFC case law expanding the "written description" requirement beyond a means of "priority protection" made "no sense."322 According to Judge Rader, a disclosure that enables a person skilled in the art to make and use the invention shows "possession of that invention" under the first paragraph of 35 U.S.C. § 112.323 He criticized the "new" disclosure requirement of Lilly as lacking a basis in statute or case law:

In 1997, this court inexplicably wrote a new disclosure requirement, found nowhere in title 35, and attributed that new requirement to the written description doctrine. This new disclosure doctrine, applied so far only to biotechnology cases, requires a nucleotide-by-nucleotide recitation of the structure of a biotechnological invention. Ironically, this court could have reached the same result in Lilly without making a new disclosure rule. Under the statute's enablement rule, this court would have also determined that the invention was not sufficiently disclosed. Instead, this court presumed to create another doctrine for sufficiency of disclosure. Although characterized as a written description doctrine, the Lilly rule cannot in fact trace its origin to the statute or any prior case.324

321 Id. The court discussed the juries findings:
Accordingly, substantial evidence supports the jury's finding that the '505 patent is not invalid for lack of an adequate written description. The '505 patent specification describes every element of claim 24 in sufficient detail so that one of ordinary skill in the art would recognize that the inventor possessed the invention at the time of filing. Id.

322 Id. at 1322–23 (Rader, J., concurring). Judge Rader stated:
Specifically this court—contrary to the statute and its own thirty-year body of case law—applies the written description doctrine beyond the purpose for which the doctrine was created, namely priority protection. By making written description a free-standing disclosure doctrine, this court produces numerous unintended and deleterious consequences.

Under Federal Circuit case law, FPS [Food Processing Systems/Moba] asked this jury to decide that the patent's disclosure can enable a skilled artisan to make and practice the invention, but still not inform that same artisan that the inventor was in possession of the invention. Puzzling . . . The Lilly doctrine simply makes no sense in this context. In fact, outside its proper context of policing priority, it never makes sense but compounds the confusion, increases the chances for error, and augments the expense of the trial process. Id.

323 Id. at 1323. Judge Rader explained:
The language of § 112, ¶ 1, indicates that a patent will contain an adequate description if it provides enough information to enable a person skilled in the art to make and use the invention. Any disclosure that enables one to make and use the invention also, by definition, also shows that the inventor was in possession of that full invention. Consequently, the erroneous written description requirement of [the] Lilly case lacks both a statutory and a logical foundation. Id.

324 Id. at 1324 (citations omitted).
Hoechst and Enzo II were interpreted by Judge Rader as a “decline” of the “Lilly rule” because they explicitly recognized that not all “functional descriptions of genetic material necessarily [fail] as a matter of law to meet the written description requirement,” and that “deposited material satisfies the Lilly standard if it meets the enablement standard.” Judge Rader concluded that, nevertheless, the doctrines of “written description” and “enablement” remain and overlap, suggesting that this will be the basis for future confusion:

With some understanding of the difficulties and redundancy of the Lilly rule, the Federal Circuit has begun to convert it into the enablement doctrine with a different label. Unfortunately that leaves trial courts in the fix that the trial court faced in this case—presenting the jury two disclosure doctrines with apparently overlapping requirements. After all, to enable is to show possession, and to show possession is to enable.

In Judge Bryson’s concurring opinion, he stated that he did not “believe that Lilly constituted a departure from prior law when it applied a written description requirement in a non-priority context.” Specifically, he contested Judge Rader’s interpretation of Ruschig as imposing a distinct written description requirement only for the purpose of establishing priority. Judge Bryson then raised the prospect that recent case law, including Lilly, has misinterpreted 35 U.S.C. § 112 since Ruschig, and that this is the real question to be taken up en banc.

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325 Id. at 1326. Judge Rader discussed the Lilly rule:
Fortunately, the viability of the Lilly rule is on the decline. After Enzo, this court recognized “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, rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” Amgen, 314 F.3d at 1332, 1361 (dissent: “[T]he majority verges on confirming Eli Lilly to its facts.

In this case, as in Enzo, the court explained that the written description requirement is satisfied when “one of skill in the art would discern possession of the invention at the time of filing.” Indeed, the Enzo court struggled to distinguish the so-called written description requirement from enablement. In reversing its original decision that deposits of biological material do not satisfy the written description requirement, the Enzo panel cited cases that found that such deposits satisfy the enablement requirement. In other words, because Lilly did in fact compel the result of the original Enzo panel, the court on reconsideration had to concede that deposited material satisfies the Lilly standard if it meets the enablement standard.

Id.

326 Moba, 325 F.3d at 1326 (Rader, J., concurring).
327 Id. at 1327 (Bryson, J., concurring).
328 Id. In contesting Judge Rader’s opinion, Judge Bryson noted:
The problem, as I see it, is that if it is correct to read section 112 as containing a separate written description requirement, it is difficult to find a principled basis for restricting that requirement to cases involving priority disputes. There is no language in section 112 that would support such a restriction.

Id.
Perhaps the entire line of cases stemming from Ruschig is wrong, and perhaps we should at some point address that question en banc. I take no position on that issue at this juncture. I think it is worth pointing out, however, that the real question raised by Judge Rader's statutory analysis is not whether Lilly was an unwarranted departure from the Ruschig line of cases, but whether that entire line of cases is based on a fundamentally flawed construction of 35 U.S.C. § 112, paragraph 1.329


The question of whether a patent specification enables one skilled in the art either to select a claimed invention from broad teachings, to comprehend the scope of an invention as broadly claimed from specific embodiments taught, or to understand an invention as claimed to be equivalent to the language of the specification, predates the Patent Act of 1952. Even after 1952, such inquiries have been interpreted variously under 35 U.S.C. §§ 112 and 132, or without any statutory basis.

Ruschig was not the first case under the Patent Act of 1952 to assess sufficiency of support for claim scope, regardless of reliance on the first paragraph of 35 U.S.C. § 112. The facts in Ruschig are similar to those in prior cases, including Prutton, discussed above, wherein, as in Ruschig, the court held that claims to a specific compound are not supported by a general description of a class of compounds.330 Prutton was decided in 1956, well before Ruschig, and did not make specific reference to 35 U.S.C. § 112. However, Rainer, which also was decided prior to Ruschig and, also like Ruschig, addressed support for claims directed to use of particular materials in light of a broad disclosure, does make reference to 35 U.S.C. § 112.331

Contrary to Judge Rader's assertion,332 sufficiency of a written description was addressed separately, or at least distinguished from enablement, in cases decided after Ruschig and before Lilly and Enzo II, without reference to priority. The court in In re Robins,333 which was not listed in Judge Rader's appendix in Enzo III of "written description cases," for example, addressed inclusion of representative examples to specifically support generic language as an issue distinct from priority and dealing with the first paragraph of 35 U.S.C. § 112:

Mention of representative compounds encompassed by generic claim language clearly is not required by § 112 or any other provision of the statute. But, where no explicit description of a generic invention is to be found in the specification (which is not the case here) mention of

329 Id. at 1328.
330 See generally Prutton v. Fuller, 230 F.2d 459 (C.C.P.A. 1956); supra Part II.C.1 (discussing Prutton).
331 In re Rainer, 347 F.2d 574, 575 (C.C.P.A. 1965) ("As a basic proposition we note that section 112 necessarily requires us to determine what 'the invention' is and Patent Office Rule 71(b) requires us to go further and determine the 'precise invention' for which the patent is solicited."); see also supra Part II.C.1 (discussing Rainer).
332 See supra Part II.C.2.
representative compounds *may provide an implicit description upon which to base generic claim language* . . . . It also has been one way of teaching how to make and/or use the claimed invention, thus satisfying that aspect of § 112.\(^{334}\)

Judge Rich, for the court in *Robins*, held that the specification of the patent application met the requirements of the first paragraph of 35 U.S.C. § 112, including “a statement of appellants’ invention, which is as broad as appellants’ broadest claims” and “sufficiency of the specification to satisfy the ‘best mode’ requirement of § 112 and to enable one skilled in the art to practice appellants’ process as broadly as it is claimed.”\(^{335}\) There is no discussion in *Robins* whether the claims were amended after filing to include the language at issue.

The Court of Customs and Patent Appeals in *DiLeone*\(^{336}\) cited *Robins*, and, like *Robins*, was an appeal from a decision by the Board. According to the court in *DiLeone*, “[t]he sole issue is whether the specification satisfies the description requirement of the first paragraph of 35 U.S.C. § 112, with respect to claims of the breadth sought here.”\(^{337}\) The enablement and description requirements were explicitly partitioned by the court.\(^{338}\) The court in *DiLeone* cited *Ahlbrecht* as a specific example of a case wherein the description requirement of 35 U.S.C. § 112 was not satisfied with respect to a class of compounds, despite the fact that the same class was enabled.\(^{339}\) Although *Ahlbrecht* was a “priority” case cited by Judge Rader in his dissent in *Enzo III*, the court in *DiLeone* did not refer to priority when it relied on *Robins* and *Ahlbrecht* to state that an invention may be enabled but not described.\(^{340}\) To the contrary, the court in *DiLeone* explicitly stated that the claim language at issue “appeared in the originally filed claims.”\(^{341}\)

Further, and also contrary to Judge Rader’s concurring opinion in *Moba*, the written description requirement as set forth by the CAFC in *Lilly* was not new, but instead followed legal precedent. For example, the *Lilly* court cited *Fiers* in support of its statement that, even in the case of cDNA, an adequate written description “requires a precise definition, such as by structure, formula, chemical name or physical properties.”\(^{342}\) Both the *Lilly* and *Enzo II* courts, as in many earlier cases,
relied upon, or drew parallels with enablement considerations in their determinations of satisfaction of the written description requirement. The court in *Lilly* stated that a genus claim, even of genetic material, may be adequately supported by a written description that does not list every species; sufficiency of the written description may be achieved by means "analogous to enablement of a genus under the first paragraph of 35 U.S.C. § 112 by showing the enablement of a representative number of species within the genus."\(^3\)\(^4\) Similarly, and as noted by Judge Rader, the holding by the *Enzo II* court that public availability of a deposit of genetic material is sufficient to meet the written description requirement, at least implicitly suggests a connection between the written description requirement and enablement by one skilled in the art.\(^3\)\(^4\)

### III. Rochester Revisited

As discussed above, the CAFC in *Rochester II*\(^3\)\(^4\) affirmed a lower court decision\(^3\)\(^4\) holding that claims directed to a method of inhibiting prostaglandin H synthase-2 ("PGHS-2," or "COX-2") activity in a human host by administering a non-steroidal compound which selectively inhibits PGHS-2 gene product were invalid for failure to meet the written description requirement under the first paragraph of 35 U.S.C. § 112.\(^3\)\(^4\) The CAFC did not reach a decision with respect to the lower courts' holding that the same claims also were invalid for lack of enablement under 35 U.S.C. § 112.\(^3\)\(^4\)

As had many cases since *Ruschig*, the analysis by the CAFC stemmed from the premise that the first paragraph of 35 U.S.C. § 112 includes a "written description requirement," an "enablement requirement," and a "best mode requirement."\(^3\)\(^4\) The

An adequate written description of a DNA, such as the cDNA of the recombinant plasmids and microorganisms of the '525 patent, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. *Fiers v. Revel*, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

*Id.*

\(^3\)\(^4\) *Id.* at 1569. The court noted that:

A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to the members of the genus, which features constitute a substantial portion of the genus. This is analogous to enablement of a genus under § 112, ¶ 1, by showing the enablement of a representative number of species within the genus.

*Id.*

\(^3\)\(^1\) *Moba v. Diamond Automation*, 325 F.3d 1306, 1326 (Fed. Cir. 2003) (Rader, J., concurring) ("In other words, because *Lilly* did in fact compel the result of the original *Enzo* panel, the court on reconsideration had to concede that deposited material satisfies the *Lilly* standard if it meets the enablement requirement.").

\(^3\)\(^4\) *Rochester II*, 358 F.3d 916 (Fed. Cir. 2004).


\(^3\)\(^7\) *Rochester II*, 358 F.3d at 930.

\(^3\)\(^8\) *Id.* at 929–30 ("In view of our affirmance of the district court's decision on the written description ground, we consider the enablement issue to be moot and will not discuss it further.").

\(^3\)\(^9\) *Id.* at 921.
CAFC employed the example of DiLeone, discussed above, to state that “an invention may be enabled even though it has not been described” and that, conversely, a “specification can likewise describe an invention without enabling the practice of the full breadth of its claims.”

The CAFC also recited the holding in Rusehig that, despite broad enablement by the specification, the specific compound claimed was not taught by the specification.

Extrapolating the logic of Rusehig, the CAFC quoted Enzo II and stated that, while claimed subject matter need not be described in haec verba, the written description requirement “must still be met in some way so as to ‘describe the claimed invention so that one skilled in the art can recognize what is claimed.’”

Using an analogy, the CAFC stated that use of the word “automobile,” as that label would be interpreted in the nineteenth century, would not describe a “newly invented automobile,” without further including in the description components of the claimed invention:

Similarly, for example, in the nineteenth century, use of the word “automobile” would not have sufficed to describe a newly invented automobile: an inventor would need to describe what an automobile is, viz., a chassis, an engine, seats, wheels on axles, etc. Thus, generalized language may not suffice if it does not convey the detailed identity of an invention. In this case, there is no language here, generalized or otherwise, that describes compounds that achieve the claimed effect.

By this statement, the CAFC, in effect, imposed a categorical requirement of physical identity without specifying what or how much identity is required. In particular, using the CAFC’s analogy, no explanation is provided for determining the limits of “viz.” and “etc.” Further, the CAFC appears to overlook that subject matter is defined by how it is claimed, regardless of whether the combination of, for example, a chassis, an engine, seats, and wheels on axles reads on what is commonly known as an automobile or some other device, such as a golf cart, a crane, or a locomotive. The CAFC also does not address the fact that a single well-recognized device, such as an automobile, can be defined in different ways which may not overlap. For example, one skilled in the art may recognize an automobile defined by the combined features...

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351 Id. at 922. When looking to In re Rusehig, the court stated:
In reaching its decision, the court observed that the claimed compound was not described in the specification and would not "convey clearly to those skilled in the art, to whom it is addressed, in any way, the information that appellants invented that specific compound".... It did not teach the specific compound.
Id. (citations omitted).
352 Id. at 923. The Rochester II court, however, quoted only the latter portion of the sentence. The complete sentence from Enzo II specifies that, even where the language of claims is supported, the specification, "to the extent possible," must describe the claimed invention so that one skilled in art can recognize what is claimed. Enzo II, 323 F.3d 956, 968 (Fed. Cir. 2002) ("Even if a claim is supported by the specification, the language of the specification, to the extent possible, must describe the claimed invention so that one skilled in the art can recognize what is claimed." (emphasis added)).
353 Rochester II, 358 F.3d at 923.
of a steering wheel, a windshield, a transmission, and a speedometer, as opposed to the features cited in the analogy.

The CAFC relied on Jepson v. Coleman\(^5\) to state that, even prior to Rusehig, "our predecessor court explicitly rejected the notion that an enabling disclosure necessarily satisfies the written description requirement."\(^3\) However, Jepson was directed to sufficiency of a specification to entitle a senior party in an interference to make claims, and nowhere mentions 35 U.S.C. § 112.\(^3\) A quotation taken from Jepson by the Rochester II court, requiring that the "application necessarily" disclose the particular device,\(^3\) refers to the issue in Rusehig and other cases before and after Rusehig, wherein the specification was found not to adequately direct one skilled in the art to select a specific claimed embodiment from broad teachings of the disclosure.\(^5\)

In re Moore and In re Sus were also cited by the CAFC in Rochester II to support the position that a written description requirement was recognized before Rusehig.\(^5\) In Moore, the claims were broader than the invention as taught in the specification.\(^6\) The court in Moore, in fact, referred to enablement in conjunction with establishing what one would understand to be appellant's invention.\(^5\) Similarly, Sus related to breadth of the invention, as claimed, given teachings that only specific embodiments would be suitable for a particular purpose.\(^5\)

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\(^6\) Rochester II, 358 F.3d at 923.
\(^7\) See generally Jepson v. Coleman, 314 F.2d 533 (C.C.P.A. 1963).
\(^8\) Rochester II, 358 F.3d at 923 ("It is not a question whether one skilled in the art might be able to construct the patentee's device from the teachings of the disclosure of the application. Rather, it is a question whether the application necessarily discloses that particular device." (quoting Jepson v. Coleman, 314 F.2d at 536)).
\(^9\) Jepson, 314 F.2d at 536. The court stated:

Unquestionably appellees in their specification accurately and concisely disclose each and every feature of their preferred embodiment and in the so-called 'critical paragraph' herein quoted, they negatively disclose a different blanket than described as their preferred embodiment. That different blanket may or may not have all the features of appellant's device [as claimed]. Certainly it could, but is that sufficient to satisfy the law on this subject? We think not.

Id.

\(^5\) Rochester II, 358 F.3d at 923.
\(^6\) In re Moore, 155 F.2d 379, 382 (C.C.P.A. 1946) ("We are of the opinion that claims 2 and 3 are broader than the disclosure in appellant's application and that they were properly rejected for that reason.").

\(^7\) Id. The court noted that:

[Appellant's application is limited, as stated by the Primary Examiner and as hereinbefore noted, to so-called "fumigants," and there is nothing in the application to indicate that appellant's composition would kill insects when applied in either solid or liquid form. On the contrary, appellant states in his application that his alleged "invention in its broadest aspect" is concerned with the discovery that all members of the generic class of monosubstituted acetonitriles which have a boiling point below 200 [degrees] C. are useful as fumigants."

Id.

\(^8\) In re Sus, 306 F.2d 494, 504 (C.C.P.A. 1962). The court reasoned:

Thus, it seems to us that one skilled in this art would not be taught by the written description of the invention in the specification that any "aryl or substituted aryl radical" would be suitable for the purposes of the invention but
Moore, at least peripherally considered enablement in conjunction with sufficiency of disclosure.\textsuperscript{363}

In neither Jepson, Moore nor Sus was a statutory minimum requirement for written description set forth that was distinct from that of enabling one skilled in the art to understand how to make and use the invention. To the contrary, all of these cases addressed sufficiency of the written description of a specification from the perspective of enabling one skilled in the art to select the claimed invention.\textsuperscript{364} Moreover, as discussed supra, where adequate support for a claimed invention was at issue, there are other cases predating Ruschig that did not rely on a distinct statutory requirement for a written description that was separate from enablement under 35 U.S.C. § 112; some relied on Rule 71(b)\textsuperscript{365} or did not explicitly rely on any statute or rule.\textsuperscript{366} Prior to Ruschig, sufficiency of written description was not considered to be a statutory requirement separate from enablement.

The Rochester II court provided further historical support for a separate written description requirement by reciting the Supreme Court case of Evans\textsuperscript{367} which was decided under the Patent Act of 1793. According to the Rochester II court, although the patent statute has changed “extensively” since 1822, it was “not very different in its articulation of the written description requirement.”\textsuperscript{368} As discussed above, contrary to the statement by Judge Lourie in Rochester II, the language of the Patent Act of 1952 is very different than that of the Patent Act of 1793, if for no other reason than because of changes that were made with respect to requirements of the written description.

The Rochester II court also interpreted the earlier cases of Fiers, Lilly, and Enzo II, which the University of Rochester attempted to distinguish as being limited to DNA-based inventions.\textsuperscript{369} Although the court acknowledged that these cases all related to genetic material, it refused to so limit application of the statute under these cases.\textsuperscript{370} The CAFC then recited guidelines adopted in Enzo II regarding satisfaction of the written description:

\begin{itemize}
  \item rather that only certain aryl radicals and certain specifically substituted aryl radicals would be suitable for such purposes.
\end{itemize}

\textit{Id.}\textsuperscript{363} Id. at n.7 (“We question also whether all ‘aryl and substituted aryl radicals’ would produce light-sensitive aromatic azides insoluble in water but soluble in organic solvents as is required by the invention disclosed in the specification.”).

\textsuperscript{364} Jepson v. Coleman, 314 F.2d 533, 536 (C.C.P.A. 1963); Moore, 155 F.2d at 382; Sus, 306 F.2d at 497.

\textsuperscript{365} See, e.g., \textit{In re Gay}, 309 F.2d 769 (C.C.P.A. 1962); \textit{In re Rainer}, 347 F.2d 574 (C.C.P.A. 1965).

\textsuperscript{366} See, e.g., Prutton v. Fuller, 230 F.2d 459 (C.C.P.A. 1956).


\textsuperscript{368} Rochester II, 358 F.3d 916, 925 (Fed. Cir. 2004) (“Although the patent statutes have been extensively revised since 1822, most notably in the addition of the requirement of claims, the language of the present statute is not very different in its articulation of the written description requirement.”).

\textsuperscript{369} Rochester II, 358 F.3d at 925 (“Rochester also argues that Fiers v. Revel, Lilly and Enzo are all distinguished because they were limited to DNA-based inventions.” (citation omitted)).

\textsuperscript{370} Id. (“We agree with Rochester that Fiers, Lilly and Enzo differ from this case in that they all related to genetic material whereas this case does not, but we find that distinction to be unhelpful to Rochester’s position. It is irrelevant; the statute applies to all types of inventions.”).
In *Enzo*, we explained that functional descriptions of genetic material can, in some cases, meet the written description requirement if those functional characteristics are “coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”

However, the CAFC recited only a portion of the written description guidelines recited in *Enzo II*. The portion of the written description guidelines quoted by *Enzo II* was not limited to functional characteristics coupled with correlation between function and structure as an alternative to a complete description of structure. The complete quote taken from *Enzo II* provides for additional alternatives:

In its Guidelines, the PTO has determined that the written description requirement can be met by “showing that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics . . . i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.”

Further, the analysis applied in *Enzo II* was not limited to nucleic acid sequences; it also included a determination of the functional characteristics of preferential binding of claimed antibodies in combination with the structural characteristics of known classes of antibody. As stated by the court in *Enzo II*:

For example, the PTO would find compliance with §112, ¶1, for a claim to an “isolated antibody capable of binding to an antigen X,” notwithstanding the functional definition of the antibody, in light of the “well defined structural characteristics for the five classes of antibody, the functional characteristics of antibody binding, and the fact that the antibody technology is well developed and mature.” . . . Thus, under the Guidelines, the written description requirement would be met for all of the claims of the ‘659 patent if the functional characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitides* were coupled with a disclosed correlation between that function and a structure that is sufficiently known or disclosed. We are persuaded by the Guidelines on this point and adopt the PTO’s applicable standard for determining compliance with the written description requirement.

The CAFC in *Rochester II* appeared to be much more restrictive in its application of the USPTO Guidelines than was the CAFC in *Enzo II*. Specifically, the *Rochester II* court employed an example of an application of the USPTO Guidelines wherein complementary strands of nucleic acids could easily be deduced from any given strand of DNA or RNA, and then stated that, in contrast, even providing three-dimensional structures of enzymes may not be sufficient:

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371 Id.
372 *Enzo II*, 323 F.3d 956, 964 (Fed. Cir. 2002).
373 Id. (citations omitted).
Given the sequence of a single strand of DNA or RNA, it may therefore have become a routine matter to envision the precise sequence of a “complementary” strand that will bind to it. Therefore, disclosure of a DNA sequence might support a claim to the complementary molecules that can hybridize to it.

The same is not necessarily true in the chemical arts more generally. Even with the three-dimensional structures of enzymes such as COX-1 and COX-2 in hand, it may even now not be within the ordinary skill in the art to predict what compounds might bind to and inhibit them, let alone have been within the purview of one of ordinary skill in the art in the 1993—1995 period in which the applications that led to the ‘850 patent were filed. Rochester and its experts do not offer any persuasive evidence to the contrary.374

The University of Rochester also distinguished Fiers, Lilly, and Enzo II as being limited to composition of matter claims.375 The CAFC dismissed this as a semantic distinction and stated that, either by actual or constructive reduction to practice, the “specification must teach the invention by describing it.”376 The CAFC further stated that, absent identification in the patent specification of any compounds by the disclosed assays, the claimed methods of their use cannot be practiced.377 Lilly was relied upon by the CAFC to state that, without identification of compounds that selectively inhibit PGHS-2, the specification represents a “mere wish or plan for obtaining the claimed invention”:

As pointed out by the district court, however, the ‘850 patent does not disclose just “which ‘peptides, polynucleotides, and small organic molecules’ have the desired characteristic of selectively inhibiting PGHS-2.” Without such disclosure, the claimed methods cannot be said to have been described. As we held in Lilly, “an adequate written description of a DNA . . . ‘requires a precise definition, such as by structure, formula, chemical name, or physical properties,’ not a mere wish or plan for obtaining the claimed chemical invention.” For reasons stated above, that requirement applies just as well to non-DNA (or [non]-RNA) chemical inventions.378

However, as discussed above, the CAFC in Fiers, Lilly and Enzo II employed analyses that incorporated lack of certainty in methods for isolating a gene of interest or lack of knowledge of the amino acid sequence of the protein encoded by

374 Rochester II, 358 F.3d 916, 925 (Fed. Cir. 2004).
375 Id. at 926 (“Rochester also attempts to distinguish Fiers, Lilly, and Enzo by suggesting that the holdings in those cases were limited to composition of matter claims.”).
376 Id. (“We agree with the district court that that is ‘a semantic distinction without a difference’ . . . The specification must teach the invention by describing it.” (citations omitted)).
377 Id. at 927 (“It is undisputed that the ‘850 patent does not disclose any compounds that can be used in its claimed methods. The claimed methods thus cannot be practiced based on the patent’s specification, even considering the knowledge of one skilled in the art.”).
378 Id. (citations omitted).
the gene. Further, the CAFC in *Fiers* relied on *Amgen* for support in discussing the inadequacies of a description that represents merely a "wish . . . or a plan": "As we stated in *Amgen* and reaffirmed above, such a disclosure just represents a wish, or arguably a plan, for obtaining the DNA." The *Amgen* court, in turn, like *Fiers*, *Lilly* and *Enzo II* included enablement in its analysis: "Based on the uncertainties of the method and lack of information concerning the amino acid sequence of the EPO protein, the trial court was correct in concluding that neither party had an adequate conception of the DNA sequence until reduction to practice had been achieved . . . ." Therefore, in each of *Amgen*, *Fiers*, *Lilly*, and *Enzo II*, sufficiency of the description of the invention hinged, at least in part, on lack of predictability of the methods described to obtain the claimed genetic material, thus necessitating either identification of the nucleotide sequence or a publicly accessible deposit. Identification of a structure of a compound was required where the methods provided were not sufficiently certain to enable the skilled artisan to isolate or identify the claimed gene, or where a publicly accessible deposit had not been made.

The University of Rochester relied on *Union Oil Co. v. Atlantic Richfield Co.* [hereinafter *Unocal*] as legal precedent to support claims describing a composition by "desired characteristics" rather than "exact chemical components." The *Rochester II* court, in response, distinguished the facts of *Unocal* by stating that, unlike that case: "Rochester did not present any evidence that the ordinarily skilled artisan would be able to identify any compound based on its vague functional description as a 'non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product.'" Without questioning the discovery of the inventors or the ability of the assay to distinguish between PGHS-1 and PGHS-2 inhibitors, the *Rochester II* court further stated that, in the absence of novelty of any compounds identified by the assay, the claims of the '850 patent would not be novel. In *dicta*, therefore, the CAFC effectively barred patentability of the claimed therapeutic method unless compounds identified by the assays would not only selectively inhibit PGHS-2 activity, but be novel as well.

Two other cases, *In re Edwards* and *In re Herschler*, relied upon by the University of Rochester, also were distinguished by the CAFC as inapposite.

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379 See supra Part II.C.2 (discussing *Fiers*, *Lilly* and *Enzo II*).
382 *Union Oil Co. v. Atl. Richfield Co.*, 208 F.3d 989 (Fed. Cir. 2000).
383 *Rochester II*, 358 F.3d at 926.
384 Id. at 928.
385 Id. at 928 n.7. The court noted that:
   Indeed, if compounds that selectively inhibit activity of the PGHS-2 gene product had been known in the art, it is difficult to see how the claims of the '850 patent would have satisfied the novelty requirement of 35 U.S.C. § 102. After all, the novelty of those claims, if any, would appear to reside in the fact that COX-2-selective inhibitors were previously unknown. The issue of patentability under § 102, however, was not decided by the district court, and we do not address it further.
388 *Rochester II*, 358 F.3d at 928.
Specifically, the CAFC stated that, with respect to Edwards, the written description requirement for a claimed compound was satisfied by teaching a method to make the compound:

In Edwards, the court held that the written description requirement was satisfied by a specification that described a claimed compound by the process by which it is made, rather than by its structure, because the court found that Edward's application, “taken as a whole, reasonably leads persons skilled in the art to the [recited reactions] and, concomitantly, to the claimed compound.”\(^3\)

According to the Rochester II court, the specification provided by the University of Rochester provided no method for making “even a single non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product.”\(^3\)

However, the issue in Edwards was not, as described by the CAFC in Rochester II, whether “the written description requirement was satisfied by a specification that described a claimed compound by the process by which it is made, rather than by its structure . . . .”\(^3\) On the contrary, the CAFC accepted that a claimed compound can be described by the method of making it and that the “primary concern is whether the description requirement has been complied with, not the mode selected for compliance.”\(^3\) The issue in Edwards was whether, on facts of that case, a parent application complied with the “written description requirement.”\(^3\) The CAFC in Edwards found that, “on the facts of this case, an adequate description of the aforementioned reactions is, concomitantly, an adequate description of the claimed compound.”\(^3\)

As applied to the facts of Rochester II, the “mode selected for compliance” with the written description requirement under Edwards could have been the assay described in the University of Rochester’s ‘850 Patent. Under such an analysis, on the facts of Rochester II, an adequate description of the selective assay could have been found to reasonably lead a person skilled in the art to selective inhibitors and, “concomitantly,” to the claimed therapeutic method for their use.

With respect to Herschler, the Rochester II court stated that claims directed to concurrent topical administration of a steroidal agent and dimethyl sulfoxide (“DMSO”) were supported by a specification that included only one example of a

\(^{380}\) Id. (quoting In re Edwards, 568 F.2d 1349, 1354 (C.C.P.A. 1978)).

\(^{390}\) Id. at 928 (“In marked contrast to the Edwards application, the specification of the ‘850 patent contains no disclosure of any method for making even a single ‘non-steroidal compound that selectively inhibits activity of the PGHS-2 gene product.’”).

\(^{391}\) Id.

\(^{392}\) Edwards, 568 F.2d at 1352 (“As the board apparently recognized, the description in the parent is not intrinsically defective merely because appellants chose to describe their claimed compound by the process of making it: our primary concern is whether the description requirement has been complied with, not the mode selected for compliance.”).

\(^{393}\) Id. at 1351 (“In the context of the present case, this translates into whether the parent application provides adequate direction which reasonably leads persons skilled in the art to the later claimed compound . . . . By the very nature of this inquiry, each case turns on its own specific facts.” (citations omitted)).

\(^{394}\) Id. at 1352.
"physiologically active steroidal agent."\textsuperscript{395} The distinction from \textit{Herschler}, according to the \textit{Rochester II} court, was that many steroidal agents were known, unlike "non-steroidal compounds that selectively inhibit[] activity of the PGHS-2 gene product."\textsuperscript{396} Again, the \textit{Rochester II} court seemed to rely on the belief that patentability of the '850 patent claims resided in the novelty of compounds that selectively inhibit PGHS-2 activity: "As the court there [in \textit{Herschler}] noted, 'were this application drawn to novel 'steroidal agents,' a different question would be posed.' The novelty in that invention was the DMSO solvent, not the steroids."\textsuperscript{397}

In fact, the novelty in \textit{Herschler} was not of DMSO, but the use of DMSO \textit{in combination} with a steroidal agent.\textsuperscript{398} The issue in \textit{Herschler} was whether adequate support for a claim limitation directed to a class of compounds (e.g., steroids) was met by a specification that identified only one member of the class (glucocorticosteroids).\textsuperscript{399} The court concluded in the affirmative.\textsuperscript{400} Specifically, the court held that, with respect to the claimed method of enhancing penetration by use of steroids in combination with DMSO, identification of only one member of the class of steroids was, in fact, sufficient:

Steroids, when considered as drugs, have a broad scope of physiological activity. On the other hand, steroids, when considered as a class of compounds carried through a layer of skin by DMSO, appear on this record to be chemically quite similar. The diversity of exemplified materials "potentiated" by DMSO in the great-grandparent application, is \textit{much broader} than the diversity of steroid compounds shown contemporaneously in the art. In this instance, we conclude that one having ordinary skill in this art would have found the use of the subgenus of steroids to be apparent in the written description of the great-grandparent application.\textsuperscript{401}

As further stated by the court in \textit{Herschler}:

In sum, claims drawn to the \textit{use of known} chemical compounds in a manner auxiliary to the invention must have a corresponding written description only so specific as to lead one having ordinary skill in the art to that class of compounds. Occasionally, a functional recitation of those

\textsuperscript{395} \textit{Rochester II}, 358 F.3d at 928.
\textsuperscript{396} Id. ("Critically, however, there was no question in that case that, unlike 'non-steroidal compounds that selectively inhibit[] activity of the PGHS-2 gene product,' numerous physiologically active steroidal agents were known to those of ordinary skill in the art.").
\textsuperscript{397} Id. (quoting \textit{Herschler}, 591 F.2d at 701).
\textsuperscript{398} In re \textit{Herschler}, 591 F.2d 683, 695 (C.C.P.A. 1979) ("The appellant has found that DMSO enhances the penetration of a number of materials through skin tissue. In the application at hand, a mixture of DMSO and a 'physiologically active steroidal agent' is administered to skin (or a mucous membrane) with the result that the steroid penetrates the membrane.").
\textsuperscript{399} Id. at 696 ("We have carefully considered the great-grandparent case but the only disclosure relating to steroids . . . . is limited to glucocorticosteroids . . . ." (quoting Patent and Trademark Office Board of Appeals, No. 304,283)).
\textsuperscript{400} Id. at 701 ("The question is simple: does the array of information supplied by appellant in the great-grandparent application teach one having ordinary skill in this art that one of the class of steroids will operate in the claimed process. We conclude that it does.").
\textsuperscript{401} Id.
known compounds in the specification may be sufficient as that description.\textsuperscript{402}

Therefore, contrary to the position of the Rochester II court, patentability of the claimed method in Herschler did not rely upon novelty of DMSO as a compound, but rather in the therapeutic use of such compounds. Further, the court in Herschler, as in other cases decided prior to Rochester II, did not categorically dismiss functional definitions of compounds employed in a claimed method. The ‘850 patent provides a description of a class of compounds functionally identifiable, in the case of Rochester II by an assay, the enablement of which the court did not address.

After dismissing a plea by amici\textsuperscript{403} asserting that the “court’s decision will have a significant impact on the continuing viability of technology transfer programs at universities and on the equitable allocation of intellectual property rights between universities and the private sector,”\textsuperscript{404} the Rochester II court summarized the failure of the ‘850 patent as not providing “any guidance” to compounds suitable for use in the claimed methods:

\begin{quote}
In sum, because the ‘850 patent does not provide any guidance that would steer the skilled practitioner toward compounds that can be used to carry out the claimed methods—an essential element of every claim of that patent—and has not provided evidence that any such compounds were otherwise within the knowledge of a person of ordinary skill in the art at the relevant time, Rochester has failed to raise any question of material fact whether the named inventors disclosed the claimed invention.\textsuperscript{405}
\end{quote}

Contrary to the CAFC’s statement, the assay described in the ‘850 patent specification was the guidance to a skilled practitioner necessary to identify compounds that would be employed in the method claimed. There is no allegation by the court that the assay described would not, in fact, identify existing compounds that selectively inhibit PGHS-2 activity, nor that the amount of experimentation employing the assay to identify any such compounds would be undue, thereby rendering the specification non-enabling. There also is no allegation by the court that, if such a compound were identified, the disclosure would not provide an adequate written description for its use, as claimed by the ‘850 patent.\textsuperscript{406}

Instead, the CAFC concluded that, absent disclosure of a PGHS-2 (COX-2) selective compound, or “pre-existing awareness in the art of any compound having COX-2 selective activity,” the ‘850 patent clearly and convincingly proves its own invalidity:

\begin{quote}
\textsuperscript{402} Id. at 702
\textsuperscript{404} Rochester II, 358 F.3d 916, 929 (Fed. Cir. 2004).
\textsuperscript{405} Id.
\textsuperscript{406} This article does not address general discussions of “reach-through claims” such as are described in EPO, JPO & USPTO, TRILATERAL PROJECT B3b, MUTUAL UNDERSTANDING IN SEARCH AND EXAMINATION: REPORT ON COMPARATIVE STUDY ON BIOTECHNOLOGY PATENT PRACTICES (Nov. 2001), available at http://www.jpo.go.jp/torikumi_e/kokusai_e/tws/report/B3b_report_pdf/B3b_reachthrough_text.pdf (last visited May 19, 2005).
Although section 282 of the Patent Act places the burden of proof on the party seeking to invalidate a patent, it does not foreclose the possibility of that party demonstrating that the patent in suit proves its own invalidity, and as detailed in section I above, we conclude that the '850 patent clearly and convincingly does just that. The patent's claims all require a COX-2-selective compound, but no COX-2-selective compound is disclosed in the patent, and it is undisputed that there was no pre-existing awareness in the art of any compound having COX-2-selective activity.

IV. IMPLICATIONS

Judge Newman, in her dissent from the order by the CAFC denying a petition for rehearing and denying a petition for rehearing en banc the Rochester II decision, stated that she fully shared Judge Lourie's understanding of the law, and that "it is simply incorrect to say that there is not now and never has been a 'written description' requirement in the patent law." She concisely summarized "past decisions . . . offered to support the exotic proposition that it is not necessary for the inventor to describe the patented invention, but that enablement alone suffices under the statute," as "traditional issues of generic disclosures and specific examples, and questions of support and predictability for scientific concepts and their embodiments." However, the heart of the issue is not elimination of a requirement that the invention be described, but the gauge for measuring compliance with the requirement. The danger of a free-standing written description requirement is exemplified in Judge Rader's dissenting opinion. In his dissent, Judge Rader reasserted his position, first announced in his dissent in Enzo III, that the modern "written description" requirement was first established in 1967, and only to "police priority." According to Judge Rader, the CAFC in Lilly established, without legal basis, a new doctrine (the "Eli Lilly doctrine") that requires the specification to provide "adequate support" for the claims:

In simple terms, contrary to logic and the statute itself, Eli Lilly requires one part of the specification (the written description) to provide "adequate support" for another part of the specification (the claims). Neither Eli Lilly nor this case has explained either the legal basis for this new validity

407 Rochester II, 358 F.3d at 930 (citations omitted) (The relevant portion of 35 U.S.C. § 282 referenced is: "The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity.").
409 Id.
410 Id. at 1311 (Rader, J., dissenting).

Beginning in 1967, this court and its predecessor applied the written description language to achieve this vital purpose of the Patent Act—tying disclosure to the time of invention. In the words of Judge Rich, the first judge to use the description requirement to police priority, "[t]he function of the description requirement is to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him."

Id. (citations omitted).
Judge Rader did not deny the existence of a written description requirement, but restricted its proper application to determinations of priority.\textsuperscript{412} Regardless of its intended purpose, the question raised by Judge Rader of the standard for “adequate support” under the written description requirement remains.

A hypothetical relied upon in the majority opinion of Rochester II was employed by Judge Rader in his dissent in Rochester III to explain why extension of the written description requirement beyond policing priority is “both superfluous and dangerous.”\textsuperscript{413} As described by Judge Rader:

\begin{quote}
\textit{Rochester} refers to a situation where a patent can enable an invention that is not described by the specification. In the words of the opinion, “[s]uch can occur when enablement of a closely related invention A that is both described and enabled would similarly enable an invention B ifB were described.”\textsuperscript{414}
\end{quote}

As described in Section III.C.1, this hypothetical was also presented in DiLeone.\textsuperscript{415} Judge Rader asserted that such a hypothetical “rarely, if ever, happens.”\textsuperscript{416} In support of this position, he employed an analogy of an invention that “solves a problem that enables those of ordinary skill in the art to know how to make and use both a radio and a TV.”\textsuperscript{417} According to the hypothetical, the inventor describes only a radio but broadly claims an “electrical receiver.”\textsuperscript{418} Judge Rader raised two issues associated with this hypothetical. First, he contended that, if television truly were enabled, the inventor would have disclosed and claimed it, even if only in a separate application, and that for this “very practical reason, no case has ever presented the hypothetical.”\textsuperscript{419} Second, it was his position that, “if the radio inventor for some unfathomable reason does not grasp that he has enabled a TV and later asserts the

\begin{quote}
\textit{Id.} at 1307–08 (Rader, J., dissenting).
\textit{Id.} at 1311 (Rader, J., dissenting). In discussing the written description requirement, Judge Rader stated: “In fact, every application of the written description doctrine before \textit{Eli Lilly} in 1997 applied the written description doctrine for this important purpose and only for this important purpose.” \textit{Id.} The “important purpose” that Judge Rader referred to was “to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter \textit{later} claimed by him.” \textit{Id.} (quoting \textit{In re Wertheim}, 541 F.2d 257, 262 (C.C.P.A. 1976)).
\textit{Id.} at 1312.
\textit{Id.}
\textit{Id.}
\textit{See supra} Part II.C.1.
\textit{Rochester III}, 375 F.3d at 1312. Judge Rader stated:

\begin{quote}
In the first place, the hypothetical rarely, if ever, happens. No actual case presents the hypothetical. In both \textit{Eli Lilly} and \textit{Rochester}, for instance, the invention A (rat insulin in \textit{Eli Lilly}; an assay for Cox 1 and 2 in \textit{Rochester}) was enabled and described, but the invention B (human insulin in \textit{Eli Lilly}; a Cox 2 inhibitor in \textit{Rochester}) was not enabled.
\end{quote}
\textit{Id.}
radio patent against a TV maker," the "court would properly interpret the claim as limited to the radio." According to Judge Rader, "the Eli Lilly doctrine would instead invalidate the radio patent."

Leaving aside the issues of whether no case has ever presented the hypothetical, as alleged, and whether the written description requirement is limited to determinations of priority, there is a difference in application of the written description requirement between the "Eli Lilly doctrine" and Judge Rader's resolution of the hypothetical. The difference is that, while under the Eli Lilly doctrine, the patent would be invalidated for lack of written description of an "electrical receiver," Judge Rader would hold that the claim, properly interpreted, would be limited to the radio. This analysis, however, begs the question presented by Judge Rader of "adequate support." In other words, how much support is required for a claim to an "electrical receiver" so that it will properly encompass the embodiment of television? Without reference to enablement of one skilled in the art, whether sufficiency of written description is posed as an issue of priority or validity, a question of how much disclosure is sufficient to demonstrate to one skilled in the art that the inventor was in "possession" of the invention, or to "understand what is claimed and to recognize that the inventor invented what is claimed," remains. To simply answer that television must be described, as suggested by Judge Rader, would, in effect, reduce the specification to a claim, and make the presence of claims, as such, superfluous.

With respect to the occurrence of any case represented by the hypothetical, a case that closely, if not exactly, parallels the hypothetical is Smythe. In this case, claims reciting use of an "inert fluid immiscible with said liquid samples," was held by Judge Rich to meet the written description requirement of the first paragraph of 35 U.S.C. § 112 despite the fact that the specification and original claims taught only "air or other gas which is inert to the liquid." The solicitor rejected the claims under the written description requirement of the first paragraph of 35 U.S.C. § 112 on the basis that they were broader than the specification because "fluid" embraced both "liquid" and "gas." Judge Rich reversed the decision, stating: "We cannot agree with the broad proposition, apparent in the above quoted language, that in every case where the description of the invention in the specification is narrower than that in the claim there has been a failure to fulfill the description requirement in 35 U.S.C. § 112." The reasoning applied by Judge Rich stemmed from predictability in the art: "This is not a case where there is any unpredictability such

420 Id.
421 Id.
422 In re Smythe, 480 F.2d 1376, 1384 (C.C.P.A. 1973); see also supra Part II.C.1.
423 Smythe, 480 F.2d at 1378.
424 Id. at 1377.
425 Id. at 1382. The court set out that:

The solicitor, explaining the basis of this rejection on the facts of this case, takes the position that "where the description of the invention is narrower than the scope of protection sought by the claims [the claims may be rejected under Section 112, paragraph 1, even though the term "fluid" embraces both "liquid" and "gas"] and even though it "would not encompass undue experimentation to arrive at a satisfactory method and structure to employ liquid and gases other than air."

Id.
426 Id.
that appellants' description of air or other inert gas would not convey to one skilled in the art knowledge that appellants invented an analysis system with a fluid segmentizing medium." Judge Rich noted that the issue could have been addressed under the "enablement" portion of the first paragraph of 35 U.S.C. § 112: "[t]he board may have also treated the rejection of these claims under 35 U.S.C. § 112 under the 'enablement' section of the first paragraph, but the solicitor has narrowed the rejection by his argument to the 'description' requirement." 

Presumably, the patent in Smythe could successfully be enforced against embodiments employing a liquid as the "inert fluid." Therefore, regardless of whether a "written description requirement" is employed to police priority, as arguably would be the case in Smythe, there is precedent for embracing certain embodiments within broad terminology that is supported literally in the specification only by different embodiments. Judge Rich, in reversing the solicitor, held that one skilled in the art would understand from the specification the scope of the invention as later claimed, given the predictability in the art. Judge Rader, according to his analysis of the hypothetical of a claimed electrical receiver embodied by a radio, apparently would have limited enforcement of the claims in Smythe to the literal description of the specification, without consideration of enablement by one skilled in the art.

The analogy employed by Judge Rader is not limited to cases that predate Lilly. For example, Chiron Corp. v. Genentech Inc., which was decided in March 2004, prior to Judge Rader's dissent of July 2004, was directed to monoclonal antibodies that bind to human breast cancer antigen. The language of the claims of the issued patent appeared in one or more of four earlier applications to which the patent claimed priority. The district court, prior to trial, construed the claims of the patent to cover murine, chimeric, and humanized antibodies that bind to c-erbB-2 ("HER2") antigen. The first-filed application, although including all of the language of independent claims 1 and 19 of the issued patent, did not teach chimeric or humanized antibodies as possible embodiments. The subsequent

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427 Id. at 1383.
428 Id. at 1382 n.2.
429 Id. at 1383.
432 Id. at 1250–52. The claims at issue were directed to monoclonal antibodies that bind to a human breast cancer antigen, also known as c-erbB-2, or HER2. Id. at 1250. The antibodies are identified in claims 1 and 9 as "monoclonal antibody 454C11 which is produced by the hybridoma deposited with the American Type Culture Collection having Accession No. HB 8484," and "monoclonal antibody 520C9 which is produced by the hybridoma deposited with the American Type Culture having Accession No. HB 8656," respectively. Id. Claim 19 only identifies the monoclonal antibody as binding to human c-erbB-2 antigen. Id. Monoclonal antibody 454C11 and the hybridoma were disclosed in the first application filed in 1984. Id. at 1251. Monoclonal antibodies 454C11 and 520C9, along with their respective hybridomas were disclosed in a 1985 continuation-in-part (CIP) application. Id. A 1986 CIP includes these and additional murine antibodies and hybridomas. Id. All of the antibodies disclosed in the 1984, 1985 and 1986 applications were murine; none were chimeric or humanized. Id. The CIP that became the issued patent, U.S. Patent No. 6,054,561 (issued Apr. 25, 2000), was filed on June 7, 1995. Id.
433 Id. at 1252 ("Before trial, the district court broadly construed the claims of the '561 patent to embrace chimeric and humanized antibodies in addition to murine antibodies that bind HER2.").
434 Id. at 1251.
continuation-in-part ("CIP") applications preceding the specification of the issued patent made reference to monoclonal antibodies as not "limited as regards the source of the antibody or the manner in which it is made," but did not specifically identify chimeric or humanized antibodies as possible embodiments. The CAFC stated that, under In re Hogan, the first-filed application did not need to enable chimeric or humanized antibodies because such technology was not known at the time. The CIP applications preceding the issued patent, on the other hand, were held to be non-enabling because, by the time they were filed, chimeric and humanized antibody technology was in existence (although "nascent") and, therefore, the specification required disclosure and enablement of those embodiments.

Conversely, with respect to the first-filed application, the court stated that the issued patent could not claim priority to that application because, as interpreted by the district court, the issued patent claims were broad enough to embrace chimeric and humanized antibodies and this technology did not exist at the time of the first-filed application. Therefore, according to the CAFC, the inventors could not be in "possession" of the invention and, as a consequence, the specification failed to meet the written description requirement as applied to the issued claims. Therefore, the '561 patent was not entitled to the filing date of the first-filed application, despite the presence of the literal language of the claims in that first-filed application, and despite the fact that the first-filed application was held to be enabling under the first paragraph of 35 U.S.C. § 112.

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435 Id. at 1251–52.
436 In re Hogan, 559 F.2d 595 (C.C.P.A. 1977).
437 Chiron Corp., 363 F.3d at 1254 ("Because the first publication documenting the successful creation of chimeric antibodies occurred after the 1984 application, this sequence of events shows that this new technology arose after the filing date and thus was, by definition, outside the bounds of the enablement requirement." (citations omitted)).
438 Id. at 1256–57. The court noted:

Substantial evidence, however, supports the jury’s implicit finding that the technology was still nascent at the time of the 1986 application (as well as, of course, at the time of the 1985 application) and thus would have still required undue experimentation . . . . Accordingly, the record amply supports the jury’s conclusion that the 1985 and 1986 applications do not enable the claims of the '561 patent without undue experimentation.

Id.
439 Id. at 1255. The court stated:

Because chimeric antibody technology did not even exist at the time of the 1984 filing, the record conclusively supports that the Chiron scientists did not possess and disclose this technology in the February 1984 filing. Thus, the '561 patent cannot claim priority based on the 1984 application because it fails to comply with the written description requirement.

Id. (citations omitted).
440 Id. The court stated:

In this case, the Chiron scientists, by definition, could not have possession of, and disclose, the subject matter of chimeric antibodies that did not even exist at the time of the 1984 application. Thus, axiomatically, Chiron cannot satisfy the written description requirement for new matter appearing in the '561 patent, namely chimeric antibodies.

Id.
The generic term, “monoclonal antibody,” was limited in *Chiron* under a written description requirement to embodiments explicitly listed in the specification. The scope of “possession” precluded subsequent improvements in technology within the literal language of subsequently issued claims. According to Judge Rader’s reasoning in his dissent in *Rochester III*, a court would hold that any claims of the ’561 patent issuing from the first-filed application, as opposed to a continuation-in-part, also would be construed as not encompassing chimeric and humanized antibodies, because such technology did not exist at the time of filing the first-filed application. However, to do so effectively confines the scope of claims to the language of the specification or, in the alternative, causes any issued patent to fail to meet the written description requirement in the face of technological advancements since such claims would embrace embodiments that, by definition, could not be described in the specification.

V. CONCLUSION

There has always been a requirement under United States patent law that inventors provide a written description of their invention. The various Patent Acts since 1790, while including the phrase “a specification in writing containing a description” (Patent Act of 1790) or the phrase “written description” (Patent Acts of 1793, 1836 and 1952), have differed in the components of the requirement. Legal precedent recognizes the existence of the statutory written description requirement and analysis of representative case law strongly suggests that comprehension of the scope of the invention claimed by one skilled in the art underlies the requirement. The purposes are to notify the public as a warning against infringement and to put the public in possession of the invention as part of the quid pro quo of obtaining a limited term of exclusivity.

The concept of possession by the public extends back to cases decided under the Patent Act of 1793. The test for possession was enablement and understanding by one skilled in the art of the “principle” or “mode of operation” of the invention, given the language of the specification filed, to distinguish the invention from subject matter previously known and to define the exclusive rights of an inventor. These

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411 *Id.*

412 *Id.* at 1258.

Thus, the ’561 patent defined “monoclonal antibody” to include chimeric and humanized antibodies. Still only a portion of this updated meaning of ‘monoclonal antibody’ can claim priority to the earliest application. If required to engage in claim construction, therefore, this court would face a dilemma: Either construe the term according to the meaning of the earliest application but contrary to the explicit definition in the ’561 patent or construe the term according to the explicit definition in the ’561 patent but broader than the disclosure of the earliest application. Again, the latter alternative would run afoul of the prohibition against importing new matter into later patent documents. As noted, however, the record amply supports the jury’s verdict of invalidity without reaching this complex claim construction question.

*Id.*

guiding principles have proved remarkably adept at accommodating extraordinary advancements in technology for the last two-hundred years. So long as the written description of claimed subject matter was measured by enablement, in terms of comprehension by one skilled in the art, satisfaction of the statutory requirement could be gauged on a case-by-case basis that would permit a patent applicant to draft a specification meeting that bargain with the public which would entitle him to protection of claimed subject matter.

Severing the statutory requirement of providing a written description from enablement is likely to result in holdings that are difficult to reconcile. The decision by the court in Rochester, which foregoes any analysis of enablement, and Judge Rader's vigorous dissent, which imposes a written description requirement that would effectively limit claim scope to the literal language of the specification and bars enforcement against future improvements in technology, may well represent not only departures from legal precedent, but also the seeds of a new split in authority at the CAFC.