Insulin, Interferon, and EPO:
A Decade of Written Description in Biotechnology Patents

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Measured by word count, the ratio of statutory language to the volume of judicial opinions and legal commentary must near its peak in the application of the written description requirement to patents in the life sciences. Why have such few words — "the specification shall contain a written description of the invention," by comparison to which even the terse statutory provision concerning obviousness appears prolix — spawned so much writing?

Many academic and practice-oriented papers have ably reviewed the pertinent cases. While providing what is hoped to be a useful review of the leading cases, the primary intent of this paper is to present the author's working hypothesis of some organizing principles for these issues. One is that the earlier opinions in this field can be understood as responses to the unique problems associated with attempts to claim known human genes (although the Federal Circuit has not agreed with this characterization). Another is that the well-developed, but largely obsolete, treatment of "functional" claiming in 19th century and early 20th century cases provide a useful and important framework to give content to this doctrine and guide its application in cases where it is alleged to apply.

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STATUTORY PROVISIONS AND CASE LAW DEVELOPMENT

The current provision concerning written description, from the Patent Act of 1952, is familiar enough:

> 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.

35 U.S.C. § 112 ¶ 1. Any modern patent lawyer would also be reasonably comfortable with the corresponding portions of this provision's immediate predecessor, enacted in 1870:

> Before any inventor or discover 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 . . . .

35 U.S.C. § 33 (R.S. § 4888). Going further back, these provisions can be traced back to the Patent Act of 1790:

> The grantee. . . [shall] deliver to the Secretary of State a specification in writing, containing a description. . . which specification shall be so particular. . . 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. . . 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.

2 Stat. 109 (1790). Three years later, the phrase "written description" entered the statute in place of "specification."[2]

In the 1822, the Supreme Court explained that this provision imposed two requirements, one immediately recognizable as enablement, and a second (in a time before patents had claims) that most closely corresponds to today's definiteness requirement:

> The specification, then, has two objects: one is to make known the manner of constructing the machine (if the invention is a machine), so as to enable artizans to make and use it, and thus to give the public the full benefit of the discovery after the expiration of the patent. . . .
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> The other object of the specification is, to put the public in possession of what the party claimed 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. It is, therefore, for the purpose of warning an innocent purchaser, or other person using a machine, of his infringement of the patent; and at the same time of taking from the inventor the means of practising upon the credulity or the fears of other persons, by pretending that his invention is more than what it really is, or different from its ostensible objects, that the patentee is required to distinguish his invention in his specification. Nothing can be more direct than the very words of the act. The specification must describe the invention "in such full, clear, and distinct terms, as to distinguish the same from all other things before known.

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[2] 2 Stat. 318, 321 (1793). For a fuller discussion of the history of these provisions, *see* Thomas L. Irving, et al., "The Significant Federal Circuit Cases Interpreting Section 112," 41 Am. U.L. Rev. 621, 624-27 (1992).

Evans v. Eaton, 20 U.S. (7 Wheat.) 356, 433-34, 5 L. Ed. 472, 491-92 (1822). The notice function was rendered largely irrelevant by the requirement of the Patent Act of 1870 that patents contain claims,[3] and the written description provision was for many years interpreted as an embodiment of enablement.[4]

In 1967, the Court of Customs and Patent Appeals suggested that Section 112 embodied a "written description" requirement that was distinct from enablement. *In re Ruschig*, 379 F.2d 990, 154 USPQ 118 (CCPA 1967), involved a picture claim to a chemical entity (the oral diabetes drug Diabinese (chlorpropamide/Pfizer)) added by amendment after the application was filed and said by the applicants to find support in an original claim to a genus embracing it. The court's classic discussion of the specification's failure to identify the species within the genus noted that the specification provided no guide to selection of the particular chemical entity:

> 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 might single out particular trees. We see none.

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[3] *See* Janice M. Mueller, "The Evolving Application of the Written Description Requirement to Biotechnological Inventions," 13 Berkeley Tech. L.J. 615, 620 (1998).

[4] *See* Laurence H. Petty, "The Recline and Fall of Mechanical Genus Claim Scope Under 'Written Description' in the Sofa Case," 80 J. Pat & Trademark Off. Soc'y 469, 470 (1998); David Kelly, "The Federal Circuit Transforms the Written Description Requirement Into a Biotech-Specific Hurdle to Obtaining Patent Protection For Biotechnology Patents," 13 Alb. L.J. Sci. & Tech., 249, 256-57 (2002).

Id. at 994-95. While this opinion is generally cited as the first articulation of a distinct written description requirement separate from enablement, *see, e.g.*, *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1561, 19 USPQ2d 1111 (Fed. Cir. 1991), the court's treatment of the issue was far from explicit:

> Appellants refer to 35 U.S.C. § 112 as the presumed basis for this rejection and emphasize language therein about *enabling* one skilled in the art to *make* the invention, arguing therefrom that one skilled in the art would be enabled by the specification to make chlorpropamide. 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. Second, we doubt that the rejection is truly based on section 112, at least on the parts relied on by the appellants. If based on section 112, it is on the requirement thereof that "The specification shall contain a written description *of the invention* . . . . We have a specification which describes appellants' invention. The issue here is in no wise a question of its compliance with section 112, it is a question of *fact: 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 appellants invented that specific compound?

Id. at 995-96. The author's search of available contemporaneous literature failed to turn-up any academic or practitioner commentary on the *Ruschig* decision, suggesting that it was not recognized at the time as creating a new standard.[5]

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[5] The author would appreciate any contrary information known to the reader.

For most of its existence, the written description has been understood more as a formal requirement of the specification than as a substantive limit on patentability or the format of patent claims. Indeed, the first paragraph of Section 112 says nothing about the claims, which are the topic of the remaining five paragraphs of this section, most importantly (for our purposes) the requirement of definiteness in paragraph 2 of Section 112. For a time, the written description requirement was strictly applied to demand "explicit disclosure" of claimed subject matter.[6] Subsequently, the explicit disclosure requirement was liberalized, with the CCPA making clear that *in ipsis verbis* description was not required.[7]

In the 1991 *Vas-Cath* decision,[8] the Federal Circuit — responding to the district court's comment that "it is not so easy to tell what the law of the Federal Circuit is" — undertook to "review the case law development of the 'written description' requirement with a view to improving the situation." 935 F.2d at 1560. Following this review, the Federal Circuit stated that a "fairly uniform standard" for written description had been maintained throughout its cases, which it alternately stated as a requirement that the specification "must clearly allow persons of ordinary skill in the art to recognize that" the applicant had invented what is claimed, or that the specification "reasonably conveys

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6 *See, e.g., In re Ahlbrecht*, 435 F.2d 908, 911, 168 USPQ 293 (CCPA 1971).

7 *See e.g., In re Smith*, 458 F.2d 1389, 178 USPQ 620 (CCPA 1972); *In re Herschler*, 591 F.2d 693, 701, 200 USPQ 711 (CCPA 1979).

8 *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 19 USPQ2d 1111 (Fed. Cir. 1991).

to the artisan that the inventor had possession at the time of the later claimed subject matter." *Id.* at 1563.

The Federal Circuit and CCPA have recognized that the applicant's "possession" of the invention could be conveyed in a number of ways, such as by descriptive means such as words, structures, figures, diagrams, and formulas that set forth the claimed invention,[9] describing the invention in the specification in the same terms as the claims,[10] and by using functional language to describe the claimed invention.[11] In 1996, the Federal Circuit made clear that no particular form of disclosure was required, so long as possession of the claimed subject matter was reasonably conveyed.[12]

WRITTEN DESCRIPTION MEETS BIOTECHNOLOGY

No particular form of disclosure — that is — until the Federal Circuit began encountering cases involving claims directed to known human genes. From a patent policy standpoint, these cases presented real problems. It was well-known, of course, that every protein is coded for by a corresponding gene. It was also generally

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9 *See Lockwood v. American Airlines, Inc*. 107 F.3d 1565, 1572, 41 USPQ2d 1961 (Fed. Cir. 1997).

10 *See, e.g. In re Bowen*, 492 F.2d 859, 864, 181 USPQ 48 (CCPA 1974); *In re Gardner*, 475 F.2d 1389, 1391, 177 USPQ 396 (CCPA 1973).

11 *See, e.g., In re Swinhart*, 439 F.2d 210, 212, 169 USPQ 266 (CCPA 1971); *In re Hallman*, 655 F.2d 212, 215, 210 USPQ 609 (CCPA 1981); *In re Echerd*, 471 F.2d 632, 635, 176 USPQ 321 (CCPA 1973).

12 *In re Alton*, 76 F.3d 1168, 1172, 37 USPQ2d 1578 (Fed. Cir. 1996).

known how to go about isolating the gene for a given protein, although the effort in any individual case could be daunting and not certain to succeed.

Against this background, at what stage of research does an "inventor" become entitled to a patent, and what is the contribution to the public? At one extreme, it is clear enough that an arm-chair inventor with a basic understanding of biology gives nothing to the public by simply naming a gene (or the cDNA) for a protein that is already known to exist. At the other, the public is clearly enriched by the first researcher who identifies or isolates such a gene, makes and sequences a cDNA, solves any problems of expression, recovers the desired protein from transformed bacteria, files a fully elaborated patent application, and publishes the results. Between these extremes, however, the answer is not clear. How much work is required before a patent to a gene or cDNA is justified?

This problem was squarely presented in the first two leading cases that shape the application of the written description requirement to biotechnology patents. In *Amgen, Inc. v. Chugai Pharmaceutical Co.*, 927 F.2d 1200, 18 USPQ2d 1016 (Fed. Cir. 1991), the issue arose in an infringement suit as an attack on validity under 35 U.S.C. § 102(g) based on alleged prior invention. Although written description was not at issue, the court's analysis of when conception occurs for § 102(g) purposes, and its holding that conception in this case did not occur until a reduction to practice, have had a significant effect on subsequent cases applying the written description requirement of § 112.

In *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), the written description was squarely presented in an appeal from an interference, the issue being whether one of the parties was entitled to claim priority to a foreign application. The court also addressed another party's contention that it was entitled to priority based on prior conception in the U.S. under §102(g).

***Amgen v. Chugai*: what is necessary for conception of a gene?**

A representative claim at issue in *Amgen v. Chugai*, was an Amgen claim to a "purified and isolated DNA sequence consisting essentially of a DNA sequence encoding human erythropoietin." 927 F.2d at 1204. Amgen's inventor, Dr. Lin, reduced to practice in September 1983. The defendants contended that Amgen's claims were anticipated under § 102(g) by the prior invention of their scientist Dr. Fritsch, who in 1981 conceived of a probing strategy using two sets of fully degenerate cDNA probes of two different regions of the erythropoietin ("EPO") gene to screen a gDNA library, and was diligent until a reduction to practice in 1984. Indeed, Dr. Fritsch's strategy had resulted in the successful identification and isolation of the human EPO gene.

As the Federal Circuit's analysis makes clear, the controlling question is who was the first inventor of the claimed subject matter, which was the isolated and purified DNA sequence encoding EPO. Approaching the case as involving simultaneous conception and reduction to practice, the court found that neither scientist had conceived the claimed subject matter until the gene was actually in hand:

> A gene is a chemical compound, albeit a complex one, and it is well established in our law that conception of

> a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it. 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 erythropoietin, because an alleged conception having no more specificity than that is simply a wish to know the identify of any material with that biological property.

Id. at 1206 (citation omitted).

Clearly, neither Amgen's Dr. Lin nor Genetics Institute's Dr. Fritsch were mere armchair scientists. Dr. Fritsch was first to conceive the successful technique to isolate the human EPO gene, and Dr. Lin was first to actually isolate it. While not making explicit reference to the problem of claiming known human genes, the Federal Circuit did note as "important" the fact that the gene at issue was already known. *Id.* ("It is important to recognize that neither Fritsch or Lin invented EPO or the EPO gene.").

Fiers v. Revel: one cannot describe that which has not been conceived

The Federal Circuit next faced the problem of claiming known human genes in *Fiers v. Revel*, 984 F.2d 1164, 25 USPQ2d 1601 (Fed. Cir. 1993), which unlike *Amgen v. Chugai* expressly concerned application of the written description requirement. This case involved a three-way interference among Fiers, Revel, and Sugano relating to

DNA that codes for human fibroblast beta-interferon.[13] The single count in the interference read: "A DNA which consists essentially of a DNA which codes for a human fibroblast interferon-beta polypeptide." *Id.* at 1166.

To establish priority of invention, Revel sought the benefit of a foreign application that disclosed a method of isolating a fragment of DNA coding for beta-interferon as well as a method for isolating messenger RNA coding for beta interferon. The foreign application did not disclose a complete DNA sequence coding for beta-interferon, but Revel argued that since the count was drawn to "a DNA" and not a specific sequence, the specification need not describe a sequence to satisfy the written description requirement.

The PTO Board of Patent Appeals and Interferences held that the description in Revel's foreign application failed to support the count, and the Federal Circuit affirmed, stating that "an adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself." *Id.* at 1171. The court stated that "bare reference to a DNA with a statement that it can be obtained by reverse transcription is not a description; it does not indicate that Revel was in possession of the DNA." Although the court seemingly could have ended its analysis there, it reached back to the conception issue decided in *Amgen v. Chugai*, explaining that "if a

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[13] The assignees were Biogen (Fiers); Yeda Research & Dev. (Revel); and Juridical Foundation, Japanese Foundation for Cancer Research (Sugano). *Id.* at 1167 n.2.

conception of a DNA requires a precise definition, such as by structure, formula, chemical name, or physical properties . . . then a description also requires that degree of specificity." *Id.*

The court also reaffirmed *Amgen*'s holding concerning conception in rejecting Fiers' claim to priority under § 102(g) based on his alleged prior conception in the United States. Like Dr. Fritsch, the alleged prior inventor in *Amgen*, Fiers contended that his disclosure of a method for isolating the DNA of the count established conception of the count, given the expert testimony that this disclosure would enable one of ordinary skill in the art to make that DNA. *Id.* at 1168. Fiers sought to distinguish *Amgen* on the ground that his method could have been easily carried out by one of ordinary skill in the art, whereas the isolation method at issue in *Amgen* was attended by serious difficulties. The court rejected this argument, stating that *Amgen* had held that "irrespective of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility." *Id.* at 1169.

Thus while *Amgen* held under §102(g) that the putative inventor of a purified and isolated DNA sequence had not conceived of that subject matter by positing its existence and describing a method of obtaining it, *Fiers* held that such acts were also inadequate to satisfy the written description requirement for such a DNA sequence under § 112. And on the issue of what is necessary for conception under §102(g), *Fiers*

seemingly held that the need for a reduction to practice was virtually absolute when a DNA sequence was claimed *per se* (and not as a product-by-process).

Regents v. Eli Lilly: lack of written description as grounds of invalidity

While *Amgen v. Chugai* and *Fiers v. Revel* both presented the issue of claiming known human genes in the context of conception and priority disputes, *i.e.*, which party wins the race to claim an isolated human gene or cDNA, the next case faced the issue in the context of a validity challenge divorced from conception or priority. In *Regents of the University of California v. Eli Lilly & Co.*, 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997), the issue was recombinant production of insulin. Claims of the University's patents were directed to recombinant plasmids containing the reverse transcript of the mRNA for vertebrate insulin, mammalian insulin, and human insulin. *Id.* at 1563.

The specification of the University's patents contained more about the gene for insulin than Revel's foreign application contained about the gene for beta interferon. Here, the specification described the actual isolation of the cDNA of rat insulin, the procedure for isolating the cDNA of human insulin, and the amino acid sequences of both chains of human insulin. *Id.* at 1566-67. The district court, after a trial, found the claims invalid for lack of written description, and the Federal Circuit affirmed, holding that regardless of whether the specification enabled the isolation of the cDNA for human insulin, it did not describe it:

> 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 name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA's structural or physical characteristics; in other words, it thus does not describe human insulin cDNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes, as the Examples does, does not necessarily describe the cDNA itself.

Id. at 1567.

Although the court did not expressly refer to the problem of when an applicant will be permitted to claim a known human gene, its further discussion suggests an acute awareness of this issue. The court first noted that a specification that only renders a claim obvious is not sufficient to satisfy the written description requirement. *Id.* (citing *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961 (Fed. Cir. 1997)). It next pointed out that knowledge of a desired protein sequence and methods of generating DNA that encodes that protein do not necessarily render obvious a specific DNA sequence for that protein. *Id.* (citing *In re Deuel*, 51 F.3d 1552, 1558, 34 USPQ2d 1210 (Fed. Cir. 1995)). Thus, said the court, since knowledge of an amino acid sequence does not render obvious a specific DNA sequence, and a description that fails even to render a claim obvious surely does not describe it, the disclosure of an amino acid sequence does not provide adequate written description support for a claim to a DNA sequence. *Id.*

These points having been decided, the University's attempt to dominate the gene for human insulin by contending that its description of rat insulin supported generic claims to mammalian insulin and vertebrate insulin was clearly doomed. *Id.* at 1568.

Summing up *Amgen*, *Fiers*, and *Lilly*

What was the state of the written description in biotechnology patents after the *Lilly* decision in July 1997? In combination, *Amgen*, *Fiers*, and *Lilly* held that one cannot adequately conceive of or describe a gene by stating its name, describing the protein the gene encodes, or reciting a method by which the gene may be isolated. Several points were made clear by these cases:

1. In a priority contest involving claims to a known human gene, the winner will be the first to have actually isolated the gene at issue.

2. A human gene cannot be described by simply naming it by reference to its corresponding protein, since this only a statement of what one would like to have and not a meaningful description of the gene itself.

3. One cannot circumvent principles 1 and 2 by artful use of generic claims having minimal species support.

More fundamentally, since it is known that every protein is coded for by a corresponding gene, the mere act of writing down the name of a gene by reference to its protein is not an invention and gives nothing to the public. Such a description does not distinguish the would-be inventor's state of knowledge from the general knowledge of the ordinarily skilled biologist (or patent lawyer), who would also know that the gene

encoding for the particular protein in question exists and what its function is. The portion of the Federal Circuit's decision in *Fiers* addressing the issue of conception shows that the court clearly recognized this problem:

> The difficulty that would arise if we were to hold that a conception occurs when one has only the idea of a compound, defining it by its hoped-for function, is that would-be inventors would file patent applications before they could describe them. That is not consistent with the statute or the policy behind the statute, which is to promote disclosure of inventions, not of research plans.

984 F.2d at 1169. Similarly, a passage in *Lilly* also demonstrates the court's recognition of this issue. 119 F.3d at 1568 ("naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material").

The PTO's written description guidelines and *Enzo Biochem v. Gen-Probe*

In an attempt to provide guidance in the wake of these cases, the Patent and Trademark Office released its Written Description Guidelines in January 2001. At the outset, the Guidelines state that the purpose of the written description analysis is to confirm that applicant had possession of what is claimed.[14] In describing what may suffice to establish possession, the Guidelines note that actual reduction to practice is one of a number of ways to show possession of the invention and is appropriate when a

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[14] 66 Fed. Reg. 1099, 1100 (2001).

definition by function is insufficient to define the composition (as in *Amgen v. Chugai* and *Eli Lilly*).[15]

On the issue of whether a full sequence must be set forth, the Guidelines are careful to note that describing the complete DNA sequence of a claimed DNA is only one method of satisfying the written description requirement, and that there is no *per se* rule requiring disclosure of the complete DNA sequence or limiting DNA claims to only the sequence disclosed. Other methods include describing an actual reduction to practice of the claimed invention, depiction of the invention in detailed drawings or in structural chemical formulas which permit a person skilled in the art to clearly recognize that the applicant had possession of the claimed invention, and any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention.[16] With respect to describing identifying characteristics of the claimed invention, the Guidelines clarify previous biotech cases discussing functional language by stating that identifying characteristics can be functional characteristics coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics.[17]

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15 *See id.* at 1101.

16 *See id*. at 1104.

17 *See id.* at 1106.

The Guidelines also distinguish between "predictable" and "unpredictable" technologies by noting that where the knowledge and level of skill in the art is high, a written description question should not be raised for original claims even if the specification discloses only a method of making the invention and the function of the invention.[18] In contrast, for inventions in emerging and unpredictable technologies, or for inventions characterized by factors not reasonably predictable which are known to one of ordinary skill in the art, more evidence is required to show possession. In such emerging and unpredictable, the Guidelines state that disclosure of only a method of making the invention and the function may not be sufficient to support a product claim.[19]

The PTO's Guidelines were put to the test in the next key biotech written description case, *Enzo Biochem, Inc. v. Gen-Probe Inc.*, which has produced two published panel decisions and several unpublished opinions concurring with and dissenting from the court's decision not to rehear the case *en banc*.[20]

Unlike the facts of *Amgen v. Chugai*, *Fiers*, and *Lilly*, the patent at issue in *Enzo* was not directed to genes or sequences encoding proteins. Rather, the claims were directed to nucleic acid probes that selectively hybridized to the DNA of the bacteria that

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[18] *See id*.

[19] *See id*.

[20] *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002), *vacating* 285 F.3d 1013, 62 USPQ2d 1289 (Fed. Cir. 2002). The concurring and dissenting opinions may be found at 63 USPQ2d 1618-33. In the interest of disclosure, it is noted that the author and his firm represent Enzo in this case.

causes gonorrhea. For example, claim 1 was directed to "A composition of matter that is specific for *Neisseria gonorrhoeae* comprising at least one nucleotide sequence for which the ratio of the amount of said sequence which hybridizes to chromosomal DNA of *Neisseria meningitidis i*s greater than about five, said ratio being obtained by a method comprising the following steps . . . ." The steps that followed provided the technique to measure the claimed ratio and recited strains of *N. gonorrhoeae* and *N. meningitidis* that had been deposited at the ATCC and were to be used in making the measurement. Claim 4 was directed to three deposited probes (identified by the ATCC accession numbers) and variations thereof.

The district court, relying on *Amgen v. Chugai*, *Fiers*, and *Lilly*, found all claims invalid on summary judgment for lack of written description, holding that the descriptions were purely functional and that the probes deposited at the ATCC did not supplement the contents of the specification. The Federal Circuit reversed. While the court did not agree with the proposition that *Lilly* and *Fiers* were limited to the unique problem of claims directed to human genes, it appeared to temper their holdings by stating that not all functional descriptions of "genetic material" failed to meet the written description requirement. 296 F.3d at 1324. The court referred to the PTO's Written Description Guidelines on this point, holding that the written description requirement can be satisfied if disclosed functional characteristics are coupled with a known or disclosed correlation between function and structure. *Id.* at 1324-25. Accordingly, the court held that the written description requirement would be met if the characteristic of preferential binding to *N. gonorrhoeae* over *N. meningitidis* was coupled with a correlation to a

known or disclosed structure. The court further held that a specification's 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, constitutes an written description of the deposited material. *Id.* at 1325-26.

EPO again: *Amgen v. Hoechst Marion Roussel*

Like the *Amgen v. Chugai* case decided in 1991, the most recent Federal Circuit biotechnology written description case also involves Dr. Lin's patents concerning recombinant EPO. In *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 65 USPQ2d 1385 (Fed. Cir. 2003), the claims at issue included several directed to cells containing DNA encoding EPO and cells containing DNA sequences that control transcription of DNA encoding EPO. The defendants contended that these claims were, *inter alia*, invalid for lack of written description under *Lilly* and *Enzo*.

The Federal Circuit began its analysis by quoting *Vas-Cath* for the purpose of the written description requirement:

> The purpose of the written description requirement is to prevent an applicant from later asserting that he invented that which he did not; the applicant for a patent is therefore required to "recount his invention in such detail that his future claims can be determined to be encompassed within his original creation."

314 F.3d at 1330. It explained that *Lilly* held that "the adequate description of claimed DNA requires a precise definition of the DNA sequence itself — not merely a recitation of its function or a reference to a potential method of isolating it. *Id.* at 1332. It further explained that *Enzo* clarified *Lilly* in that a functional description does not necessarily fail

to satisfy the written description requirement, but could suffice it the function is correlated with a known structure. *Id.*

> The Federal Circuit then distinguished both *Lilly* and *Enzo*:
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> > Both *Eli Lilly* and *Enzo Biochem* are inapposite to this case because the claim terms at issue here are not new or unknown biological materials that ordinarily skilled artisans would easily miscomprehend. Instead, the claims of Amgen's patents refer to types of cells that can be used to produce recombinant human EPO. Thus, [defendant] can only challenge the adequacy of disclosure or the vertebrate or mammalian host cell — not the human DNA itself. This difference alone sufficiently distinguishes *Eli Lilly* . . . . Indeed, the district court's reasoned conclusion that the specification's description of producing the claimed EPO in two species of vertebrate or mammalian cells adequately supports claims covering EPO made using the genus vertebrate or mammalian cells, renders *Eli Lilly* listless in this case.

Id. (footnote omitted).

WHAT'S NEXT?

While the Federal Circuit continues to clarify the application of the written description requirement to biotechnology patents, issues and difficulties remain. The three seminal cases, *Amgen v. Chugai*, *Fiers*, and *Lilly*, all applied the law to the problem of claiming known genes. *Enzo* is the only case squarely applying these precedents to a patent that is not directed to genes. *Amgen v. Hoechst* sheds light on the types of patents to which these principles do not apply, but provides no guidance on their application to cases where they do apply.

An obvious question is the application of the *Fiers*, *Lilly*, and *Enzo* line of cases to patents outside the field of biotechnology. As this paper was being prepared, they were applied in *University of Rochester v. G.D. Searle & Co.*, 2003 WL 759719, Civil Action No. 00-61611 (W.D.N.Y. March 5, 2003), in which the University asserted its U.S. Patent 6,048,850 against Pfizer and Pharmacia's Cox-2 inhibitor Celebrex. Among the claims of this patent were:

> 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.
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> 3. The method of claim 1 in which the activity of PGHS-1 is not inhibited.
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> 4. The method of claim 3 in which the compound is a non-steroid anti-inflammatory drug.
>
> 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 pre-determined- 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 pre-determined 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.

According to the district court, the specification of the patent did not disclose any compound that actually worked in the claimed method of treatment.

The parties cross-moved for summary judgment on the issue of written description. The court framed the issue as "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." Slip op. at 7 (footnote omitted). Relying on *Fiers*, *Lilly*, and *Enzo*, the court granted defendants' motion for summary judgment that the claims were invalid for lack of written description:

> 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.

Slip op. at 12.[21] The court also expressly held that *Fiers*, *Lilly*, and *Enzo* were not limited to "claims directed to nucleic acid sequences." *Id.* at 14. The extent to which these

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[21] The court also ruled on summary judgment that the claims were invalid for lack of enablement. *Id.* at 25-32.

precedents will be applied to other chemical cases remains open, as does their potential application beyond the chemical arts.[22]

The five separate opinions concurring with and dissenting from the Federal Circuit's decision not to rehear the *Enzo* case *en banc* also demonstrate a hitherto unknown dialog among members of the court over basic written description doctrine. Dissenting from the court's denial of rehearing *en banc*, Judge Rader (joined by Judges Gajarsa and Linn) characterized *Lilly* as a departure from 30 years of precedent in erroneously elevating the written description requirement from its proper place, solely as a mechanism to police priority, to a new substantive requirement of patentability that eclipses the statutory standard of enablement. *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 63 USPQ2d 1618, 1625-26 (Fed. Cir. 2002) (Rader, J., dissenting). Also dissenting from denial of *en banc* rehearing, Judge Linn (joined by Judges Rader and Gajarsa) wrote that in cases where priority is not at issue, as is the case with original claims or claims that find *in ipsis verbis* support in the specification, the sole focus on compliance with the written description requirement is enablement. *Id.* at 1631-32 (Linn, J., dissenting). And Judge Dyk, who was a member of the panel and concurred in the Court's decision not to rehear the case *en banc*, wrote that the concurring and dissenting opinions raised interesting and important questions, including about the correctness of *Lilly*, that "may someday warrant the court's *en banc* attention." *Id.* at 1622 (Dyk, J., concurring).

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[22] *Cf.* Harold Wegner, "An Enzo White Paper: A New Judicial Standard for Biotechnology 'Written Description' under 35 U.S.C. § 112, ¶ 1," 1 J. Marshall Rev. Intell. Prop. L. 254, 269-71 (2002) (discussing potential for inhibition of new technologies by creation of a heightened patentability requirements).

Also of interest is the extent to which the prohibition against "functional" description or claiming will be extended outside biotechnology, and the content of that doctrine in cases where it is argued to apply. The written description requirement of 35 U.S.C. §112 ¶ 1 is, of course, a requirement of the specification, not a requirement of the claims. In the cases discussed above, the Federal Circuit has indeed phrased its analysis in terms of the adequacy of the specification, but the concept of "functionality" it has applied in this context is very similar to the old law against functional claiming. Few practitioners now living have ever confronted this doctrine, but a review of older cases shows that it was a persistent feature of U.S. patent law for well over 100 years.

For example, the Supreme Court relied on this doctrine and the predecessor of § 112 to hold in *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 14 L. Ed. 601 (1853), that Samuel Morse could not generally claim the function of using electromagnetism to print letters at a distance based on his specification's description of the telegraph:

> The Act of Congress above recited requires that the invention shall be so described, that a person skilled in the science to which it appertains, or with which it is most nearly connected, shall be able to construct the improvement from the description given by the inventor.
>
> Now, in this case, there is no description but one, of a process by which signs or letters may be printed at a distance. And yet he claims the exclusive right to any other mode and any other process, although not described by him, by which the end can be accomplished, if electro-magnetism is used as the motive power. That is to say, he claims a patent for an effect produced by the use of electro-magnetism distinct from the process or machinery necessary to produce it. The words of the Act of Congress

> above quoted show that no patent can lawfully issue upon such a claim.

Id. at 120.

Seventy five years later, the Supreme Court relied on *O'Reilly v. Morse* to reach the same result in *Holland Furniture Co. v. Perkins Glue Co.*, 277 U.S. 245 (1928), in which the patentee had invented a new starch-based glue that overcame the need to use large amounts of water. His new, low-moisture glue worked with wood veneers, which previously required animal glues. *Id.* at 247-49. The claims at issue—broadly drawn to all starch-based glues that functioned like animal glue—were described by the Court as covering "a starch glue which, combined with about three parts or less by weight of water, will have substantially the properties as animal glue." *Id.* at 250.

The Court invalidated these claims under 35 U.S.C. § 33 (quoted above), the predecessor of 35 U.S.C. § 112, holding that discovery of a particular starch glue that functioned like animal glue did not support claims to all starch glues that so functioned:

> [A]n inventor may not describe a particular starch glue which will perform the function of an animal glue and then claim all starch glues which gave those functions, or even all starch glues made with three parts water and alkali, since starch glues may be made with three parts water and alkali that do not have those properties. . . One attempting to use or avoid the use of Perkins' discovery as so claimed and described functionally could do so only after elaborate experimentation.

Id. at 256-57 (citations omitted).

Ten years later, the Supreme Court applied the doctrine to invalidate claims directed to improved electric light bulbs. *General Electric Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 37 USPQ 466 (1938). A representative claim at issue in that case read as follows:

> A filament for electric incandescent lamps or other devices, composed substantially of tungsten and made up mainly of a number of comparatively large grains of such size and contour as to prevent substantial sagging and offsetting during a normal or commercially useful life for such a lamp or other device.

Id. at 368. The Court assumed that the claim was novel and unobvious. *Id.* ("We need not inquire whether Pacz exhibited invention, or whether his product was anticipated.). Turning to the predecessor of § 112 (35 U.S.C. § 33), the Court also assumed that the claim was enabled. *Id.* ("We may assume that Pacz has sufficiently informed those skilled in the art how to make and use his filament."). But, explained the Court:

> The statute has another command. . . . Patents, whether basic or for improvements, must comply accurately and precisely with the statutory requirements as to claims of invention or discovery. The limits of a patent must be known for the protection of the patentee, the encouragement of the inventive genius of others and the assurance that the subject of the patent will be dedicated ultimately to the public. The statute seeks to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their rights.

Id. at 368.

The section of the statute to which the Supreme Court was referring was the requirement that the applicant "shall particularly point out and distinctly claim the part, improvement, or combination which he claims as his invention or discovery," the

forerunner to the definiteness requirement of 35 U.S.C. § 112 ¶ 2 ("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."). The Court's statement of the problem undoubtedly related to definiteness, and has been cited in modern cases for this proposition. *See, e.g., Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581, 37 USPQ2d 1365 (Fed. Cir. 1996) ("As courts have recognized since the requirement that one's invention be distinctly claimed became part of the patent law in 1870, the primary purpose is 'to guard against unreasonable advantages to the patentee and disadvantages to others arising from uncertainty as to their [respective] rights.'").

These three cases (*O'Reilly*, *Holland Furniture*, and *General Electric*) show that the problems with "functional" descriptions and claims can be overbreadth (what we would now call nonenablement) or lack of notice (what we would now call indefiniteness). But *General Electric* also suggests that another problem with such claiming can be failure to distinguish the claimed invention from the prior art, or the knowledge of the alleged inventor from those who went before him:

> Pacz did not adequately set out "what he claims to be new." The tungsten filament "made up mainly of a number of comparatively large grains," differentiates the claimed invention from tungsten drawn into a single crystal and from Coolidge's fine-grained thoriated filament, but serves aptly to describe the product of earlier manufacture, with its large regular grains subject to offsetting. . . . The failure of the patentee to make claim to a distinct improvement is made clear by comparison of the language of the claims under consideration with descriptions of offset difficulties recognized by earlier inventors. [304 U.S. 369-70]

In its classic formulation of the problem of functional claiming, the Supreme Court explained in *General Electric* that the issue arises when the applicant uses "conveniently functional" language at the "exact point of novelty":

> The claim uses indeterminate adjectives which describe the function of the grains to the exclusion of any structural definition, and thus falls within the condemnation of the doctrine that a patentee may not broaden his product claims by describing the product in terms of function. Claim 25 vividly illustrates the vice of a description in terms of function. "As a description of the invention it is insufficient and if allowed would extend the monopoly beyond the invention." [citing *Holland Furniture*] The Court of Appeals for the Ninth Circuit relied no the fact that the description in the claims is not 'wholly' functional. 80 F.2d 958, 963. But the vice of a functional claim exists not only when a claim is "wholly" functional, if that is ever true, but also when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty.
>
> A limited use of terms of effect or result, which accurately define the essential qualities of a product to one of skill in the art, may in some instances be permissible and even desirable, but a characteristic essential to novelty may not be distinguished from the old art solely by its tendency to remedy the problems in the art met by the patent.

304 U.S. 371-72. Is there any similarity to the problem the Federal Circuit confronted 50 years later when it faced claims to a known human gene that had not yet been isolated?

> A definition by function . . . is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. Accordingly, naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material.

Lilly, 119 F.3d at 1568 (citations omitted).

From the Supreme Court's discussion, we see that a primary vice of "functional" claiming is the opportunity to turn a statement of a problem into a claim to the solution when that solution has not been found. It is claiming the gene for a known protein without having that gene in hand, thereby failing to distinguish the "inventor's" knowledge from that of the art and failing to give the public something it does not already have. It is claiming "a steroid that lessens inflammation" without distinguishing that steroid from others or putting it in possession of the public. *Cf. Enzo*, 296 F.3d at 1329. It is, in the words of the Federal Circuit, "an attempt to preempt the future before it has arrived." *Fiers*, 984 F.2d at 1171.

How can one recognize patents that have this vice? As known by practitioners of the era in which allegations of "functionality" were featured in dozens if not hundreds of reported decisions, the task is not easy:

> It has been perfectly well settled ever since the time of *Corning v. Borden* [56 U.S. (15 How.) 252, 14 L. Ed. 683 (1853)] that a function is not patentable, but to determine whether a claim is so far functional in character as to be invalid is a constantly recurring problem. It is never a question of the rule itself, but whether the claim comes under the rule.

William Macomber, The Fixed Law of Patents § 426 at 385 (1909). However, the ancient texts offer some guidance:

> Two attributes of an invention are wanting in an effect. In the first place, it is the end and not the means. It is that changed condition of affairs which constitutes the satisfaction of a human want. Although produced by an invented means, it is not the fruit of inventive skill, but has existed, at least in intellectual contemplation, ever since the want which it supplies arose. As the antithesis of this want, it is perceptible to every person to whom the want itself

> becomes apparent, and none can claim the merit of its sole discovery, or assert a superior title to its benefits.

1 Robinson on Patents § 148 at 213 (1890) (citation omitted). Or, as stated by the Federal Circuit: "A definition by function . . . is only a definition of a useful result rather than a definition of what achieves that result." *Lilly*, 119 F.3d at 1568.

CONCLUSION

More than forty years after it grappled with light-bulb filament technology in *The Incandescent Lamp Patent*, 159 U.S. 465 (1895), the Supreme Court was still dealing with claims to filaments in the *General Electric* case. More than fifty years after the Court invalidated Samuel Morse's broad "functional" claims to the use of electromagnetism to write letters at distance, a leading treatise stated that applying the rule to particular claims was "a constantly recurring problem." Macomber, *supra*. With only ten years of appellate development of the written description's requirement to biotechnology patents, is it any surprise that issues remain? Computerized legal research may speed the task of finding cases, but it does nothing to speed the development of the law. As said by Judge Rich, "The life of a patent solicitor has always been a hard one." *Ruschig*, 379 F.2d at 993.