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After the Fire and Rain, Lilly Still Stands.

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AFTER THE FIRE AND RAIN, *LILLY* STILL STANDS.

Enzo Biochem, Inc. v. Gen-Probe, Inc., 296 F.3d 1316 (Fed. Cir. 2002).

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I. INTRODUCTION

As biotechnological[1] inventions have progressed, inventors have increasingly sought patent protection to try to recoup some of the costs of their research. Along with the increase in the number of biotech patents issued, the number of infringement cases, and the assertion of patent invalidity as a defense to infringement have increased.[2] With more and more frequency, accused infringers are challenging biotechnological patents on the issue of sufficiency of the written description requirement.[3] This is precisely what happened in *Enzo Biochem, Inc. v. Gen-Probe, Inc.*[4]

In *Enzo*, the Federal Circuit confronted the issue of whether biological material deposited in a public access bank[5] and referenced in a patent application with regards to a described function could fulfill the written description requirement in 35 U.S.C. § 112.[6] The Federal Circuit previously required biological inventors to disclose the sequence of the DNA material in the specification.[7] In *Enzo*, however, the court held the deposit of the DNA material in the biological material bank combined with the functional description and reference to the sample in the description of

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[1] Biotechnological can also be referred to as biotech.

[2] Patent infringement is governed by 35 U.S.C. § 271, which provides, "[e]xcept as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent." 35 U.S.C.A. § 271(a) (West 2000).

[3] The written description requirement is set forth at 35 U.S.C. § 112 ¶ 1. It reads, "[t]he specification shall contain a written description of the invention." 35 U.S.C.A. § 112 (West 2000).

[4] 296 F.3d 1316 (Fed. Cir. 2002).

[5] Inventors originally deposited biological material in a publicly accessible bank to help fulfill the enablement requirement. *Enzo*, 296 F.3d at 1325. Enablement is another statutory requirement in 35 U.S.C. § 112, which requires the inventor to disclose in the specification enough information to enable the public to make and use the invention. *Id.*

[6] *See supra* n. 3 and accompanying text.

[7] *Enzo*, 296 F.3d at 1325.

the invention was sufficient to meet the written description requirement.[8]

The decision handed down by the Federal Circuit in *Enzo* was a misleading decision, which commentators have incorrectly read as relaxing the very strict written description requirement.[9] In actuality, the court correctly worded the opinion as a factual exception to the rule solidified in *Regents of the University of California v. Eli Lilly & Co.*, which required a biological invention consisting of DNA to disclose the exact sequence of the DNA to meet the written description requirement.[10] By doing so, the Federal Circuit has shown that it has some flexibility in regards to fulfillment of the written description requirement but generally, the rule set out in *Lilly* will stand. A biotech patent challenged on written description sufficiency will still have to disclose the sequence of the claimed DNA in order to be valid.

This note will argue that the court deliberately worded the opinion as a fact based exception to *Lilly*, which resulted in a return to the requirement of disclosure of the DNA sequence for inventions claiming DNA. Section II will provide a brief history of the written description requirement and *Lilly*. Section II will also establish the background of *Enzo*, its procedural history, and the court's rationale. Section III will argue that the historical importance of the written description requirement; historical treatment of precedent in this area; the actual language of the opinion; and the changes in technology will cause the court to restrict the holding in *Enzo* to its facts. Finally, Section IV will conclude.

II. BACKGROUND

A thorough understanding of the written description requirement necessitates an examination of several precedents. First, federal statutes and their amendments began to form the outline for the written description requirement in a patent application. Second, the Court of Customs and Patent Appeals revived the written description requirement for priority issues in *In re Ruschig*,[11] and the Supreme Court's decision in *Lilly* further expanded the written description requirement as an avenue for patent invalidity. Finally, *Enzo* represents the Federal Circuit's attempt to reconcile the written description requirement of the patent application with current gene mapping technology.

A. *The Historical Development of the Written Description Requirement*

In order to qualify for patent protection, the patent application must

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[8] *Id.* (holding "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").

[9] The Federal Circuit held that a deposit of biological material could help satisfy the written description requirement. *Id.* at 1330.

[10] 119 F.3d 1559, 1567 (Fed. Cir. 1997) (holding that a written description for DNA was invalid unless it disclosed the sequence of the DNA being claimed).

[11] 379 F.2d 990 (Cust. & Pat. App. 1967).

meet five separate requirements: (1) patentable subject matter;[12] (2) utility;[13] (3) novelty;[14] (4) nonobviousness;[15] and (5) specification.[16] The specification requirement includes three sub-requirements: (1) enablement;[17] (2) written description;[18] and (3) best mode.[19] This note will focus on the written description requirement codified at 35 U.S.C. § 112.[20]

Since its inception in the Patent Act of 1793, the wording of the written description requirement has essentially stayed the same although its function has greatly changed.[21] When originally introduced, the written description requirement's function was to define the limits of the invention.[22] When the Patent Act of 1870 introduced claims[23] into the specification[24] with the purpose of having them define the limits of the claimed invention, the exact function of the written description requirement became uncertain.[25] Even though the new act still maintained the written description language, it was unclear at that time what function the written description requirement would serve.[26]

In 1967, the Court of Customs and Patent Appeals[27] decided *In re Ruschig*[28] and gave the written description requirement its first real function since the statutory amendments.[29] In that case, the issue was whether the original specification described the amended claim, so that it could have the benefit of the original filing date.[30] The court found the enablement

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[12] 35 U.S.C.A. § 101 (West 2000) (stating "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title").
[13] *Id.*
[14] 35 U.S.C.A. § 102 (West 2000 & Supp. 2005).
[15] 35 U.S.C.A. § 103 (West 2000 & Supp. 2005).
[16] 35 U.S.C.A. § 112.
[17] *See supra* n. 5 and accompanying text.
[18] *See supra* n. 3 and accompanying text.
[19] The best mode requirement states that the specification "set forth the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C.A. § 112 ¶ 1.
[20] *See supra* n. 3 and accompanying text.
[21] *See Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1561-64 (Fed. Cir. 1991) (stating the Patent Act of 1793 required the applicant to "deliver a written description of his invention"). The modern Act requires "[t]he specification shall contain a written description of the invention." 35 U.S.C.A. § 112 ¶ 1.
[22] *Vas-Cath*, 935 F.2d at 1561.
[23] *See United Carbon Co. v. Binney & Smith Co.*, 317 U.S. 228, 232 (1942) (stating that claims set the boundaries for the patent rights of the claimed invention).
[24] The specification is the part of the patent document, which incorporates the description of the invention and the claims. Roger E. Schechter & John R. Thomas, *Intellectual Property: The Law of Copyrights, Patents and Trademarks* 394 (West 2003). When looking to the written description requirement, the courts usually refer to the specification as the pertinent document but limit the inquiry to the description and not the claims. *Id.* at 397.
[25] *Vas-Cath*, 935 F.2d at 1563.
[26] *Id.*
[27] This was the predecessor court to the United States Court of Appeals for the Federal Circuit. Martin J. Adelman, Randall R. Rader, John R. Thomas & Harold C. Wegner, *Cases and Material on Patent Law* 16 (2d ed., West 2003).
[28] *In re Ruschig*, 379 F.2d 990.
[29] *See supra* nn. 21-26 and accompanying text.
[30] 35 U.S.C.A. § 119 (West 2000 & Supp. 2005) (allows an inventor to add claims to a patent application already in process as long as the new claims fall within the scope of the invention as described in the original application).

requirement[31] was satisfied, but the original specification did not adequately describe the newly claimed invention.[32] The court held that in order for the amended claim to receive the benefit of the original filing date, the scope of the amended claim had to be within the written description of the original application.[33] Because the original specification failed to describe the compound by its structure and could have been one of several different compounds,[34] the court found the initial disclosure was inadequate as to the amended claim.[35] The court wanted to be sure that the inventor was in possession of the amended claim at the time of the original filing.[36] Otherwise, the inventor would get the advantage of the earlier filing date for something he had not even invented at that time. Although the court stated it was not sure whether priority of an invention was an issue under § 112,[37] the decisions that followed firmly grounded inventive priority decisions[38] on the written description requirement in §112.[39]

B. *The Further Revival of the Written Description Requirement in Biotech Inventions through* Lilly

Even though the Court of Customs and Patent Appeals in *In re Ruschig* revived the written description requirement specifically for priority issues,[40] the Federal Circuit did not limit its use to that function.[41] The Federal Circuit expanded the use of the written description requirement beyond the priority context by establishing it as another avenue upon which courts could find patents or their claims to be invalid.[42] The Federal Circuit especially placed emphasis on the written description requirement in this new context in the chemical and biotechnology sectors after the court realized, through *In re Ruschig*, that specifications for biological and chemical inventions could enable without adequately disclosing the invention[43] to one skilled in the art,[44] giving inventors the ability to claim

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[31] *See supra* n. 5 and accompanying text.
[32] *In re Ruschig*, 379 F.2d at 996.
[33] *Id.* at 995.
[34] *Id.* at 992 (stating "The compound . . . is not named or identified by formula and it can find support only as choices made between the several variables involved. This is not regarded as adequate support for a specific compound never named or otherwise exemplified in the specification as filed.").
[35] *Id.*
[36] *Id.* at 996 (asking whether the specification conveys the information that the applicant actually invented the compound).
[37] *Id.* at 995 (stating that the original disclosure would enable someone skilled in the art to make the newly claimed invention, but the original disclosure failed to describe the compound, which would make this a written description question if it was actually an issue under § 112).
[38] Cases disputing whether amended claims can relate back to the original filing date under 35 U.S.C. § 119 are generally called *priority disputes*.
[39] *See e.g. Vas-Cath*, 935 F.2d at 1555 (holding that summary judgment was inappropriate because drawings could be used to satisfy the written description requirement to allow a subsequent claim to receive the benefit of the date of the earlier application).
[40] *Id.*
[41] *See e.g. Lilly*, 119 F.3d 1559 (Fed. Cir. 1997) (holding that the original specification failed to meet the written description requirement for one of the original claims and that claim was therefore invalid).
[42] *Id.*
[43] *In Re Ruschig*, 379 F.2d at 990; *see also Lilly*, 119 F.3d at 1567 (stating that the original specification may have provided an adequate disclosure, but "it does not provide a written description of the cDNA

and monopolize something they never really invented. The Federal Circuit's concern for over breadth of claims led to a very stringent written description requirement, which the court handed down in *University of California v. Eli Lilly*.[45]

In *Lilly*, the University of California's research led to the isolation and cloning of rat cDNA[46] for insulin.[47] Further testing revealed the use of non-human insulin had some success in humans.[48] In addition, it was well known in the industry that insulin proteins were very similar among very diverse species.[49] With the above knowledge, in 1977 the University applied for a patent for the recombinant DNA technology for insulin.[50] The initial claim for the patent was a very broad claim encompassing all prokaryotic organisms and then the claims subsequently narrowed to mammalian organisms and then to humans.[51] Although the insulin gene in humans had not been isolated at the time, the University described the amino acid sequence for the human insulin protein[52] and a method for obtaining and cloning the insulin gene sequence.[53] Eventually, Lilly separately obtained the technology for isolating the human insulin gene, isolated it, copied it, and used it to treat patients with diabetes.[54] The University of California then filed suit against Lilly for infringement of its patent.[55]

When the court looked at the patent in question, it found that there was no adequate written description of the claims Lilly was allegedly infringing.[56] Specifically, the court held that an adequate description of the human insulin gene required "a precise definition, such as by structure, formula, chemical name, or physical properties."[57] Since the University had

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encoding human insulin, which is necessary to provide a written description in the subject matter of [the] claim").

[44] The court looks at inquiries into patent validity through the eyes of one skilled in the art. 35 U.S.C. § 112. To determine the level of ordinary skill in the art, the court will look to the following factors: "(1) the education level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which inventions are made; (5) sophistication of the technology; and (6) education level of active workers in the field." *Envtl. Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696 (Fed. Cir. 1983).

[45] *Lilly*, 119 F.3d at 1559.

[46] cDNA is complimentary DNA which is a strong cloned copy of weaker messenger RNA which is used to encode proteins. *Velander v. Garner*, 348 F.3d 1359 (Fed Cir. 2003). The cDNA is then placed into a bacterial host which will then manufacture the desired protein (in *Lilly*, the scientists were producing insulin). *In re O'Farrell*, 853 F.2d 894, 898 (Fed. Cir. 1988).

[47] *Lilly*, 119 F.3d at 1562. The significance of human versus mammalian insulin was that some people had exhibited severe reactions to the non-human insulin. *Id.* Human insulin was much less likely to cause these reactions, so there was a ready market for whoever isolated the human insulin gene. *Id.*

[48] *Id.*

[49] *Id.*

[50] *Id.* at 1559.

[51] *Id.* at 1563.

[52] Even though the University had isolated the human insulin protein, redundancy in the genetic code prevented them from disclosing the exact sequence of the gene that encoded for human insulin without isolating the gene itself. *Id.*

[53] *Id.*

[54] *Id.*

[55] *Id.* at 1562.

[56] *Id.* at 1568.

[57] *Id.* at 1566.

not isolated the gene, they did not have and could not get the DNA sequence for the gene.[58] Because the University described the process for obtaining the DNA in question and not the sequence of the DNA itself, the court held the disclosure was not sufficient to meet the written description requirement.[59]

C. *Facts of* Enzo Biochem, Inc. v. Gen-Probe, Inc.

Enzo Biochem was the assignee[60] of a patent for the ability of a DNA probe to preferentially hybridize with Neisseria Gonorrhoeae over Neisseria Meningitidis.[61] Since N. gonorrhoeae and N. meningitidis have about 93% homology,[62] doctors were getting back false positive results for tests for gonorrhea because the test probes were actually detecting N. meningitidis.[63] With this new probe, the accuracy of the test results was greatly improved.[64]

The patent in question described the invention as "a composition of matter specific for [N.] gonorrhoeae . . . which hybridizes to chromosomal DNA of [N.] gonorrhoeae" over the chromosomal DNA of N. meningitidis at a ratio greater than about five.[65] Additional claims go on to describe the complimentary strands to which the DNA probe will preferentially bind (the target sequence), how the inventors discovered the binding rate, and how that rate was calculated. In the specification, Enzo Biochem made reference to the fact that it had deposited the specifically claimed nucleotide sequences in a publicly accessible DNA bank.[66]

D. *Procedural History of* Enzo

Enzo Biochem believed that Gen-Probe was infringing on its patent, so it brought an action against Gen-Probe for patent infringement.[67] Gen-Probe moved for summary judgment, claiming the patent was invalid for failure to meet the written description requirement.[68] Guided by *Lilly*, the United States District Court for the Southern District of New York found that the written description requirement was lacking because the

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[58] *Id.* at 1563.
[59] *Id.* at 1568.
[60] An assignee of a patent is a person or entity to whom the inventor has signed over his patent rights. 35 U.S.C.A § 152 (West 2000). This is common in employer/employee relationships.
[61] A DNA probe is a small piece of DNA with a known sequence, which is used to target a complimentary sequence on a large strand of DNA, which the researcher is trying to isolate. *Enzo*, 296 F.3d at 1321.
[62] Homology is the similarity between two strands of DNA. *Id.* Here the two strands were 93% homologous, which means that 93% of their sequences were the same. *Id.* This made it tough for researchers to find a probe that would target one but not the other and led to a lot of incorrect test results. *Id.*
[63] *Id.*
[64] *Enzo*, 296 F.3d at 1320-21.
[65] *Id.* at 1321.
[66] *See supra* n. 5 and accompanying text.
[67] Patent infringement is governed by 35 U.S.C.A. § 271.
[68] *See supra* n. 3 and accompanying text.

specification did not state the structure of the DNA probe.[69] The United States Court of Appeals for the Federal Circuit affirmed the lower court's decision also relying on the reasoning of *Lilly*.[70] Enzo Biochem petitioned for a rehearing to determine the issue of whether a deposit could help fulfill the written description requirement. The Federal Circuit granted the rehearing and the same three judges that heard the initial appeal reversed their earlier decision holding that the facts surrounding and including the deposit in this case could satisfy the written description requirement.[71] The court denied a motion to rehear the case en banc.[72]

E. *On Rehearing, the Court's Rationale in* Enzo

Reviewing its own earlier decision, the court seemed to loosen the restriction of its earlier decision in *Lilly* by stating that not all functional descriptions of genetic material will fail to meet the written description requirement.[73] The court looked to the United States Patent and Trademark Office ("PTO") guidelines, which had addressed this issue to a certain extent and used them as guidance.[74] According to the PTO guidelines, a functional description of a nucleic acid probe would be sufficient if the specification could link that function to a structure which is sufficiently known or which the specification discloses.[75]

Next, the court considered whether the deposit would link the functional description to a structure that is sufficiently known or disclosed. The court held that:

> [R]eference 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,

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[69] *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 2001 U.S. Dist. LEXIS 23791 (S.D.N.Y. Apr. 4, 2001), *rev'd in part on other grounds*, 323 F.3d 956 (Fed. Cir. 2002).

[70] *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 285 F.3d 1013 (Fed. Cir. 2002), *vacated*, 296 F.3d 1316 (Fed. Cir. 2002). In order to encourage greater efficiency and more uniform decisions in several areas of law, Congress established the United States Court of Appeals for the Federal Circuit in 1982. This court hears all appeals from federal district courts on issues relating to certain subjects, patent law is one of them. *The U.S. Court of Appeals for the Federal Circuit: "An Act To establish a United States Court of Appeals for the Federal Circuit, to establish a United States Claims Court, and for other purposes."*, http://air.fjc.gov/history/landmark/22a_frm.html (accessed Sept. 9, 2005).

[71] *Enzo*, 296 F.3d at 1320.

[72] *Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 42 Fed. Appx. 439 (Fed. Cir. 2002). Within the opinion denying the en banc petition arose a disagreement amongst the justices of the Federal Circuit. *Id.* The majority opinion espoused the view that the written description requirement was grounded in the history of patent law and was here to stay while the dissent argued that the written description requirement should be limited to issues of priority and should never have been elevated to the position it holds today over the validity of patents. *Id.*

[73] *Enzo*, 296 F.3d at 1324.

[74] *Id.*

[75] *See* 66 Fed. Reg. 1099, 1106 (Jan. 5, 2001) (stating that the specification meets the written description requirement 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").

> constitutes an adequate description of the deposited material sufficient to comply with the written description requirement . . . .[76]

Specifically, even though the structures were not stated within the specification, "those structures may not have been reasonably obtainable and in any event were not known to Enzo [Biochem] when it filed its application in 1986."[77] As a result, the court allowed Enzo Biochem to satisfy the written description requirement based on the disclosure of the target DNA strands and the deposited probe material because the technology at the time Enzo Biochem filed its patent was such that it would take an enormous amount of time for Enzo Biochem to have sequenced the DNA probes it was claiming.[78] The court laid out some very specific guidelines to satisfy its fact based exception to *Lilly*: (1) the deposit had to be in a facility which was publicly accessible; (2) the specification had to reference the deposited material; and (3) a description must not have been available in written form (i.e., technology would not allow for a written description of the invention).[79]

III. ANALYSIS

This note will establish that the restrictive wording used by the court in its holding in *Enzo* is correct because (1) the written description requirement is separate from the enablement requirement and needs to remain as such; (2) *Enzo* is factually distinguishable from the precedent set in *Lilly*; and (3) there are important societal reasons to have a more stringent written description requirement in the area of biotechnology.

A. *Written Description v. Enablement*

From the time of the Patent Act of 1793, the legislature has recognized there is a need for a written description requirement for patents.[80] Even though the function of the written description requirement has changed over time, the statutory language requiring it has not.[81] Even though there is currently a split amongst the judges of the Federal Circuit regarding the purpose and scope of the written description requirement,[82] it has remained through several amendments to the Patent Act, and due to its increasing importance in patent law, it appears it is here to stay.[83]

Looking first to the wording of 35 U.S.C. § 112, "[t]he specification

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[76] *Enzo*, 296 F.3d at 1325.
[77] *Id.* at 1326.
[78] *Id.*
[79] *Id.*
[80] For the historical development of the written description requirement, *see supra* § II (A).
[81] For the historical development and the revival of the written description in biotech inventions, *see supra* §§ II (A)-(B).
[82] *See supra* n. 71 and accompanying text; *Enzo*, 296 F.3d at 1320.
[83] For the historical development and the revival of the written description in biotech inventions, *see supra* §§ II (A)-(B).

shall contain a written description of the invention, and of the manner and process of making and using it . . . ," the statute clearly states there is a written description requirement.[84] In addition, looking at the syntax of the statute, the placement of the comma after the word *invention*, and the use of the word *and* after the comma would also tend to show there is a separate written description requirement.[85] Not requiring a separate written description would make the first part of the statute superfluous, which is against the canons of statutory construction.[86] Specifically, not reading a separate written description requirement into the statute would in essence require removal of the comma and the word *and* from the statute entirely. Interpreting the statute in light of the canons of construction necessitates a reading of both a written description requirement and an enablement requirement.

Looking to the history of the Patent Act itself, the legislature has had several opportunities to remove the written description requirement language from the statute but has chosen not to do so.[87] Specifically, when the legislature added the use of claims to the specifications, which took over the function of the written description requirement at that time, the legislature chose to leave in the language requiring a written description allowing it to develop a different function over time.[88] Because the legislature chose to leave the wording within the statute, the court must give meaning to the wording.[89]

Some would argue the function the written description requirement is now serving is that of enablement.[90] While in many instances, the same information from the specification will satisfy both requirements, there are times when an invention can be enabled but not disclosed.[91] This is especially true in the areas of biology and chemistry.[92]

> For example, a propyl or butyl compound may be made by a process analogous to a disclosed methyl compound, but, in the

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[84] 35 U.S.C.A. § 112 ¶ 1; *See Enzo Biochem, Inc. v. Gen-Probe, Inc.*, 42 Fed. Appx. at 440 (stating that reading the statute as to give effect to its language would require that the invention itself be described) (Lourie, J., concurring).

[85] *Enzo*, 42 Fed. Appx. at 440 ("note the comma between the description requirement and the enablement provision, and the 'and' that follows the comma") (Lourie, J., concurring).

[86] *TRW, Inc. v. Andrews*, 534 U.S. 19, 31 (2001) (stating "[i]t is 'a cardinal principle of statutory construction' that 'a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause, sentence, or word shall be superfluous, void, or insignificant'").

[87] For the historical development and the revival of the written description in biotech inventions, *see supra* §§ II (A)-(B).

[88] *Id.*

[89] *Id.*

[90] *Enzo*, 42 Fed. Appx. at 445-452 (Rader, J., dissenting).

[91] For a discussion of the further revival of the written descriptions in biotech inventions through *Lilly*, *see supra* § II(B).

[92] *See Enzo*, 42 Fed. Appx. at 443 (stating "[p]erhaps there is little difference in electrical and mechanical inventions between describing an invention and enabling one to make and use it, but that is not true of chemical and chemical-like inventions") (Lourie, J., concurring).

> absence of a statement that the propyl and butyl compounds are part of the invention, they have not been described and they are not entitled to a patent.[93]

Since it is possible to fulfill one but not the other, this would also lead to the conclusion that they are separate requirements that overlap, but not completely.[94] As such, the two requirements are just that: two requirements, each of which has to be fulfilled in order to meet the requirements under 35 U.S.C. § 112.

Finally, not reading a separate written description requirement into the wording of § 112 would allow the exact problem which the Federal Circuit in *Lilly* and *Enzo* was trying to prevent, the overreaching of claims.[95] By leaving the written description wording within the statute, Congress gave the courts an avenue by which they could help develop patent requirements which could keep up with the fast paced environment of technological progress. The courts have seen the hole that needed to be filled and have now used the written description requirement to plug that hole.

B. Enzo *v.* Lilly

In *Enzo*, some commentators see the supposed clash of the precedent set in *Lilly*. *Lilly* required a biotech invention to disclose the sequence of the claimed gene in order to satisfy the written description requirement.[96] *Enzo* allows the court to consider a deposit of biological material along with what is disclosed in the specification to meet the written description requirement.[97] While at first glance these two cases appeared to conflict, the factual difference in these two cases allowed the court to make a limited factual exception to the *Lilly* rule.

In *Lilly*, the University isolated the gene in rats that produced insulin and then tried to claim not only the gene in rats, but the gene in humans that produced insulin, which the University never actually isolated.[98] Basically, the University had a plan for isolating the human insulin gene, which the University was not even sure would be successful, and with that plan erroneously obtained a patent.[99] Without ever having isolated the gene, the University made it impossible for anyone to deduce the sequence of the gene from the patent.[100]

Conversely, *Enzo* isolated a specific probe sequence in humans that

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[93] *Id.* at 444.
[94] For a discussion of the further revival of the written descriptions in biotech inventions through *Lilly*, *see supra* § II(B).
[95] For a discussion on the differences between *Enzo* and *Lilly* and why biotechnology needs more stringent requirements, *see infra* §§ III(B)-(C).
[96] For a discussion of *Lilly*, *see supra* nn. 46-59 and accompanying text.
[97] For a full discussion of *Enzo*, *see supra* §§ II(C)-(E).
[98] For a discussion of *Lilly*, *see supra* nn. 46-59 and accompanying text.
[99] *Id.*
[100] *Id.*

it used to target a specific site on the bacteria that caused gonorrhea.[101] So, at the time Enzo Biochem filed for a patent, it had not only isolated the specific sequence that it wanted to claim, but it had performed experiments on that specific sequence which disclosed its inherent usefulness at solving the doctor's false positive problem for gonorrhea tests.[102] Enzo Biochem limited its claims to that probe, disclosed the sequence to which that probe bound, and deposited the probe material in a DNA bank.[103] Even though Enzo Biochem did not specifically disclose the DNA sequence of the probe, by making the probe available to the public, it gave others the opportunity to obtain the sequence of the probe.

With the significant ongoing changes in biotechnology,[104] the *Lilly* court set a rule that would help prevent biotech inventors from overreaching their actual invention.[105] In essence, the court told the University that it could have protection for the rat insulin gene, but not for the human insulin gene, which it had not discovered.[106] If the University wanted protection for the human insulin gene, it needed to wait until it actually isolated the gene to get protection. Disclosing a plan for obtaining the gene was not sufficient to show the University had possession of the gene, which is one of the ways of determining written description.[107]

In *Enzo*, on the other hand, the Federal Circuit allowed courts to look at the deposited material to help determine whether the inventor was in possession of the invention and to help prevent the overreaching of claims seen in *Lilly*.[108] What the court did was lay out a factually specific holding in order to show that the preference is for the sequence to be disclosed, but that the court will allow exceptions to this rule when the facts call for such an exception.[109] The decision in *Enzo* shows the Federal Circuit's concern for the constant changing in technology in the biotech area and demonstrates that the court is willing to be flexible when necessary.[110] Do not, however, mistake the court's flexibility for a shift in the law. In the Federal Circuit, all opinions by three judge panels set precedent.[111] That said, it requires an

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[101] For a discussion of the facts of *Enzo*, *see supra* § II(C).
[102] *Id.*
[103] *Id.*
[104] Until recently, researchers believed that only 2% of DNA (the part that coded for proteins) was significant. W. Wayt Gibbs, *The Unseen Genome: Genes Among the Junk*, Scientific American 47, 47-53 (Nov. 2003). Recent discoveries have now shown that there are genes among the 98% junk DNA which act through RNA and "play major roles in the health and development of plants and animals." *Id.* at 48.
[105] For a discussion of rule in *Lilly*, *see supra* nn. 56-59 and accompanying text.
[106] *Id.*
[107] *Id.*
[108] *Enzo*, 42 Fed. Appx. at 442 (stating "the opinion refines the 'possession' test for circumstances such as these in which the inventors showed possession of a species of the invention by reference to a deposit, but may not have described what else within the scope of the claims they [were in] possession of") (Lourie, J., concurring).
[109] For a discussion of *Lilly*, *see supra* nn. 46-59 and accompanying text.
[110] *Id.*
[111] Adelman et al., *supra* n. 27, at 16.

en banc decision to overturn precedent set by a three judge panel.[112] The court had the opportunity to hear this case en banc and overturn *Lilly* but chose not to do so stating "although it was true that the written description requirement has been applied vigorously in some recent cases, [none] . . . of those cases were decided wrongly."[113] The refusal to hear the case en banc and the restrictive wording in the holding shows the court is willing to be flexible, but feels the need to keep the more stringent requirement as the precedent in order to ensure that biotechnological inventors are not overreaching the true breadth of their inventions.[114]

C. *Why Biotechnology Needs a More Stringent Written Description Requirement*

From the time of the Framers, the ability to receive a reward for an invention has been a well accepted idea.[115] This idea has developed into modern patent law, which grants an inventor a monopoly for a certain amount of time as a reward for disclosing his invention to the public.[116] The disclosure of an invention helps further more invention as people think of improvements or spin-offs of the patented technology.[117] In addition, the limited monopoly allows an inventor to recoup costs of developing his invention and gives him an avenue to raise funds through investors for future projects on which he will work.[118]

Disclosure is central to the idea of patent protection. Without a sufficient disclosure, the public gains nothing. The Patent Act requires three forms of disclosure: (1) written description, (2) enablement, and (3) best mode.[119] While most inventions cannot be enabled without adequately being described, this is not so for many biotechnology inventions.[120] As such, the written description requirement is very important in the biotechnology industry because it helps prevent inventors from overreaching the true limits of their inventions.[121] Take *Lilly*, for instance, the University had isolated the rat gene that produced insulin and yet they claimed all mammalian insulin genes including those of humans.[122] While it is possible

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[112] *Id.*
[113] *Enzo*, 42 Fed. Appx. at 440 (stating "Taking the case en banc would therefore delay and hence frustrate the remand of the case solely for the purpose of revisiting written description law. That law is sound and does not need revision.") (Lourie, J., concurring).
[114] *Id.* at 441 (stating "[i]nterpretation of written description as this court has done furthers the goal of the law to have claims commensurate in scope with what has been disclosed to the public").
[115] U.S. Const. art. I, § 8, cl. 8 (stating that Congress should "promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries").
[116] Adelman et al., *supra* n. 27, at 26-38.
[117] *Id.*
[118] *Id.*
[119] For a discussion of the requirements, *see supra* nn. 12-20 and accompanying text.
[120] For a discussion of *Lilly*, *see supra* nn. 46-59 and accompanying text.
[121] *Id.*; *See also Enzo*, 42 Fed. Appx. at 441 (stating that "perceptions that patents are stronger tempt patent owners to try to assert their patents beyond the original intentions of the inventors") (Lourie, J., concurring).
[122] For a discussion of *Lilly*, *see supra* nn. 46-59 and accompanying text.

the process they disclosed for isolating the human insulin gene was enabling, allowing this process description to allow them to claim the human insulin gene would reward them for an invention they had not yet invented. It was at this point that the Federal Circuit solidified its earlier belief that there was a need for a more specific written description requirement for biotechnology by requiring the recitation of the sequence of the DNA when DNA is claimed.[123] By refusing to overrule *Lilly* in *Enzo*, the Federal Circuit made it clear that the problem of overreaching in biotech patent claims is very real; and at present, requiring the inventor to recite the sequence is the best way to prevent it.

In addition, the court has made all aware through *Enzo*, that exceptions will be made to the *Lilly* requirement as long as the facts show a sufficient disclosure was made without specifying the sequence.[124] It seems as long as the inventor would have been hard pressed to identify the sequence himself and others could derive the sequence if necessary that the court will consider the written description requirement satisfied.[125] However, the changes in sequencing technology will soon make the need for exceptions to *Lilly* unnecessary.[126] As of June 2003, scientists have now sequenced the entire human genome allowing researchers to go on websites and compare isolated proteins with possible corresponding genes.[127] This will greatly reduce time needed to find the gene which researchers would like to patent.[128] Also, the constantly improving techniques of sequencing has itself already dramatically improved the time necessary to determine the sequence of the gene an inventor may want to patent.[129] Looking at the special ability of biological inventors to enable overreaching claims and how the changes in technology are facilitating the use of the sequencing requirement set forth in *Lilly*, it is easy to see why the heightened written description requirement for biotechnology inventions is here to stay. Even though early commentators hailed *Enzo* as a lessening of the written description requirement on biotech inventions, a closer look reveals that the court purposely used restrictive language in its holding and refused to overrule *Lilly*, so the first line of defense for patent overreaching would remain intact.

IV. CONCLUSION

The court in *Enzo* has shown its willingness to carve out exceptions to the rule in *Lilly* when the public has received its end of the bargain, an adequate disclosure of the invention. In addition, the court, by carving out an exception to *Lilly* instead of overruling it, has made a statement that

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[123] *Id.*
[124] For a discussion on the rehearing of *Enzo*, *see supra* § II(E).
[125] *Id.*
[126] Ingrid Wickelgren, *The Gene Masters: how a new breed of scientific entrepreneurs raced for the biggest prize in biology*, 241-255 (1st ed., N.Y. Times Books 2002).
[127] *Id.*
[128] *Id.*
[129] *Id.*

biotechnology is different and because of its unique characteristics it needs to have a more stringent requirement. Because the written description requirement has an important role in the patent system, especially within biotechnological inventions, the court was correct in using restrictive wording in its holding in *Enzo* in order to show its flexibility but also its resolve in making biotech inventors truly show that they deserve patent protection for what they have claimed in their application.