



AN ENZO WHITE PAPER: A NEW JUDICIAL STANDARD FOR A  
BIOTECHNOLOGY “WRITTEN DESCRIPTION” UNDER 35 U.S.C. §  
112, ¶ 1

HAROLD C. WEGNER

Abstract

The April 2, 2002, Federal Circuit opinion in *Enzo Biochem, Inc. v. Gen-Probe Inc.*, may have the greatest potential impact on a multidimensional basis of any decision from that court in recent years. Far more important than whatever disruption takes place domestically—which may be fixed through Congressional or further judicial action—one must look to the foreign impact of the *Enzo* opinion. This decision threatens to undermine the patent basis for American protection of biotechnology inventions abroad, once the case is understood and embodied in the several foreign patent laws. Problems with *Enzo* are not limited to biotechnology. What’s good for the biotechnology goose is good for the e-commerce gander. Fundamentally, we must address whether the pro-patent philosophy of *Chakrabarty* is to be maintained, with all the ramifications for not only existing patent rights but also for what will happen to the rights of Americans and others in foreign systems and what will happen for the new technologies of the future.

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AN *ENZO* WHITE PAPER:  
A NEW JUDICIAL STANDARD FOR A BIOTECHNOLOGY  
“WRITTEN DESCRIPTION” UNDER 35 U.S.C. § 112, ¶ 1\*

HAROLD C. WEGNER\*\*

I. OVERVIEW

The April 2, 2002 Federal Circuit opinion in *Enzo*<sup>1</sup> may have the greatest potential impact on a multidimensional basis of any decision from that court in recent years. This is a bold statement when one considers the significant impact of its *en banc* decisions of the past two years dealing with patent scope. Very important—but overshadowed by broader concerns—is the potential disruption of a wide scope of current patent rights that have been keyed to an understanding of patent law that goes back many years. There are two more important implications of the *Enzo* opinion.

Macroscopically, far more important than whatever disruption takes place domestically—which may be fixed through Congressional or further judicial action—one must look to the foreign impact of the *Enzo* opinion: It threatens to undermine the patent basis for American protection of biotechnology inventions abroad, once the case is understood and embodied in the several foreign patent laws.

A special new law is created for biotechnology. But, there is only one patent law for *all* technologies. *Enzo* creep that transfers principles of the case to other technologies provides the potential to undermine both currently evolving areas such as e-commerce but also the “new light bulb” of the future.

Beyond biotechnology, the creation of a new judicial framework for understanding the “written description” requirement does violence to the traditional statutory scheme. The quid pro quo of the patent system is not to provide claims as “technical descriptions of the disclosed inventions . . . .”<sup>2</sup> As part of the organization of the 1952 Patent Act, the late Giles Sutherland Rich and his colleagues judicially redrafted the disclosure requirements in 1970.<sup>3</sup> For a decade, the previous standard of “new matter” coexisted with the “written description” requirement.<sup>4</sup>

Difficulties in claiming certain types of inventions in words have always been a problem, one that did not start and will not end with biotechnology inventions.<sup>5</sup>

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<sup>1</sup> *Enzo Biochem, Inc. v. Gen-Probe Inc.*, No. 01-1230, 2002 WL 487156 (Fed. Cir. April 2, 2002) (Lourie, Dyk, Prost, JJ.; opinion by Lourie, J.; dissent by Dyk, J.).

<sup>2</sup> *In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985); *see also infra* Part II (The Statutory Scheme).

<sup>3</sup> DONALD S. CHISUM ET AL., PRINCIPLES OF PATENT LAW 21 (2d ed. 2001).

<sup>4</sup> *Id.*

<sup>5</sup> *See infra* Part III (Inventions with Less Than a Word Picture).

The special problems for biotechnology issues are then addressed.<sup>6</sup> The international patent community and its adoption of the American practice is next considered. Indeed, an entire treaty system was built around the U.S. system as embodied in the Budapest Treaty.<sup>7</sup>

Problems with *Enzo* are not limited to biotechnology. What's good for the biotechnology goose is good for the e-commerce gander.<sup>8</sup>

Fundamentally, we must address whether the pro-patent philosophy of *Chakrabarty*<sup>9</sup> is to be maintained,<sup>10</sup> with all the ramifications for not only existing patent rights but also for what will happen to the rights of Americans and others in foreign systems and what will happen for the new technologies of the future.<sup>11</sup>

## II. THE STATUTORY SCHEME

### A. Section 112 of the 1952 Patent Act

Dating back to the nineteenth century there have been several different but related statutory requirements for defining and supporting an invention. By the end of the nineteenth century, a claim was required to define the scope of an invention. The only portion of the specification that relates to the definition of the invention is the claims which "define the scope of protection afforded by the patent. . . . [C]laims are not technical descriptions of the disclosed inventions but are legal documents like the descriptions of land by metes and bounds in a deed which define the area conveyed but do not describe the land."<sup>12</sup>

The sole *objective* statutory disclosure requirement of the American patent law is one for "enablement" which is found in the first part of 35 USC § 112, ¶ 1, that "[t]he specification shall contain a written description of the invention . . . to enable any person skilled in the art . . . to make and use the [invention]. . . ."<sup>13</sup> There is no second objective disclosure requirement in 35 U.S.C. § 112.

<sup>6</sup> See *infra* Part IV (The Biotechnology Deposit Issues).

<sup>7</sup> *Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure*, April 28, 1977, 32 U.S.T. 1241, T.I.A.S. No. 9768; see also *infra* Part V (Argoudelis: Cornerstone for Global Protection).

<sup>8</sup> See *infra* Part VI (Brake on New Technologies: Et Tu E-Commerce?).

<sup>9</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>10</sup> *Id.*; *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 122 S.Ct. 593, 598 (2001).

<sup>11</sup> See *infra* Part VII (Conclusion).

<sup>12</sup> *In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985). The statutory requirement for precision in claim drafting is codified as 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." 35 U.S.C. § 112 (2000).

<sup>13</sup> The entire wording of this section includes modifiers for enablement as well as the independent and distinct subjective "best mode contemplated" requirement. The matters omitted from the quotation are highlighted and lettering is used to separate the objective and subjective requirements: "The specification shall contain a written description of the invention [(a)], 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 [(b)] shall set forth the best mode contemplated by the inventor of carrying out his invention."

It is beyond question that an original claim is a part of the specification as filed: As explained in *Myers*, “an unamended original claim . . . by elementary principles of patent law [is] to be considered as a part of the original disclosure.”<sup>14</sup> This principle is carried forward in *Anderson*,<sup>15</sup> and underscored in *Rasmussen*.<sup>16</sup>

The statutory scheme operates quite well, standing alone, insofar as an *original* claim is concerned without a separate “written description” interpretation of § 112. Because an original claim *is* a part of the original specification, an original claim *by definition* should be considered supported by the specification.<sup>17</sup>

But, what happens if the applicant amends his application to provide a claim that is not a part of the original disclosure? Again, their system took care of this by barring a new definition lacking antecedent basis by making a “new matter” rejection under 35 U.S.C. § 132.<sup>18</sup>

The usual method for adding new matter is not through an amendment to the specification but through the filing of a continuing application.<sup>19</sup> The claim in the continuing application is measured against the disclosure in the earlier application: If it would have been “new matter” to introduce the claim of the continuing application in the earlier application, then priority was denied.

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<sup>14</sup> *In re Myers*, 410 F.2d 420, 427 (C.C.P.A. 1969).

<sup>15</sup> *In re Anderson*, 471 F.2d 1237, 1238-39 (C.C.P.A. 1973) (citing MPEP §§ 706.03(n), 608.01(1)); see also *In re Myers*, 410 F.2d at 427 (“Claim 1 . . . is an unamended original claim in this application and therefore, by elementary principles of patent law, [is] to be considered as a part of the original disclosure[.]”); *In re Oswald*, 83 F.2d 827 (C.C.P.A. 1936).

The Manual of Patent Examining Procedure follows *Anderson*: “Original claims form part of the original disclosure and provide their own written description. As such, an application that contains at least one claim, but does not contain anything which can be construed as a written description of such claim(s), would be unusual.” Manual of Patent Examining Procedure (MPEP) 601.01(d), at 600-12 (8th ed. 2001) (citation omitted) [hereinafter MPEP].

<sup>16</sup> *In re Rasmussen*, 650 F.2d 1212, 1214 n.5 (C.C.P.A. 1981) (“An original claim is part of the disclosure at the time of filing.”); see also *In re Anderson*, 471 F.2d at 1238.

<sup>17</sup> On occasion, applicants would unsymmetrically draft their patent applications to have a definition of their invention only in the claims portion of the specification. In such a case, the examiner was authorized to require an amendment to the specification to copy the definition from the claims and place the same disclosure in the body of the specification.

Under the procedures set forth in the MPEP, an “objection” is made against the applicant who fails to provide the redundant definition of the claimed invention in the body of the specification. MPEP, *supra* note 15, § 608.01(o), at 600-78. Thus, where the only basis for a new claim is an original claim, under M.P.E.P. § 608.01(o), “the specification should be objected to for failing to provide proper antecedent basis for the terminology of the claims. *Id.*; cf. *In re Marzocchi*, 394 F.2d 571 (C.C.P.A. 1968). Then, responsive to this *objection*, the applicant is free to add the definition from the original claim into the specification. *Ex parte Porter*, 25 U.S.P.Q.2d (BNA) 1144, 1147 n.1a (B.P.A.I. 1992).

What the United States *should* do is simply follow some foreign patent system models that have the claims at the *beginning* of the specification; then, there would be no need for such redundancy.

<sup>18</sup> 35 U.S.C. § 132 (2000) (“No amendment shall introduce new matter into the disclosure of the invention.”).

<sup>19</sup> There is no point in considering the various labels such as “continuation” or “continuation-in-part,” because neither has a statutory basis or any other relevance to the issue at hand. Rather, the question is simply one of a statutory priority right under 35 U.S.C. § 120. Hence, to avoid unnecessary confusion, reference is made instead to a “continuing application” that is generic to both.

### *B. The 1970 Judicial “Written Description” Requirement*

The late Giles Sutherland Rich credited his then-Law Clerk, Ron Havleka, with the judicial fabrication of a tripartite set of requirements in 35 U.S.C. § 112, ¶ 1.<sup>20</sup> Instead of that paragraph being home merely to the objective enablement and subjective best mode requirements, the court invented the “written description” requirement that it calved from the clumsy wording of the enablement requirement.

The primary motivation of the court in creating the “written description” requirement was to deal with priority for continuing applications. This came out of the opinion of Judge Rich that Chapter 12 of the patent law did not provide a basis for substantive denial of rights, which necessarily meant that “new matter” could not be considered for determination of priority.<sup>21</sup>

While inclusion of “new matter” in this chapter may have been a manifestation of the clumsy nature of the patent law codification, it did not mean that “new matter” or other traditional grounds of rejection housed in that chapter were suddenly to be thrown out.

In 1980 in *Sasse*, the predecessor court judicially threw out a statutory bar under this chapter on the ground that the chapter is procedural in nature.<sup>22</sup> Years later, *Sasse* was dismissed in *McGrew*.<sup>23</sup>

With the “written description” requirement being set through case law as finding a statutory home under 35 U.S.C. § 112, ¶ 1, now the court had a neat statutory scheme to deny priority where a claim would have been “new matter” if added to the parent.<sup>24</sup> While that test had stood the test of time dating back to the nineteenth century, suddenly the court could say that the claimed invention lacked a “written description” in the parent. Since 35 U.S.C. § 120 requires compliance with 35 U.S.C. § 112, ¶ 1, everything now fell into a neat statutory scheme.<sup>25</sup>

<sup>20</sup> See CHISUM, *supra* note 3, at 21.

<sup>21</sup> 35 U.S.C. §§ 131-35 (2000) (Chapter 12, Examination of Application, has five sections: § 131, Examination of Application; § 132, Notice of rejection; § 133, Time for Prosecuting Application; § 134, Appeal to the Board of Patent Appeals and Interferences; and § 135, Interferences.).

<sup>22</sup> *In re Sasse*, 629 F.2d 675, 680 (C.C.P.A. 1980) (Rich, J.).

[W]e do not agree that a substantive bar is raised by [35 USC] § 135(b) in an *ex parte* context. The Commentary on the New Patent Act by P. J. Federico is in accord in stating, “[t]he sections just mentioned, 131 to 135, deal with procedure in the Patent Office, of which only a small part is reflected in the statute. This statement complements our decision in *In re McKellin*, where § 135(a) was also found to be procedural in nature.

*Id.* (citations omitted).

<sup>23</sup> *In re McGrew*, 120 F.3d 1236, 1239 (Fed. Cir. 1997) (“The Board did not err in refusing to follow *Sasse* as ‘precedent’ because the aspect of that case relied on, being dictum, is not ‘precedent’ which we must follow.”).

<sup>24</sup> The perception of a need for a separate “written description” requirement evolved in the late 1960s. See *In re Borkowski*, 422 F.2d 904 (C.C.P.A. 1970); *In re Wakefield*, 422 F.2d 897 (C.C.P.A. 1970).

<sup>25</sup> Priority is granted for “[a]n application for patent for an invention disclosed in the manner provided by the first paragraph of section 112 of this title in [the] application previously filed in the United States.” 35 U.S.C. § 120 (2000).

### C. “New Matter” versus “Written Description”

#### 1. Continuation of “New Matter”

The Patent Office continued to adhere to the “new matter” basis for denying a new or amended claim; it also embraced the “written description” requirement. Now, instead of rejecting claims on the basis of “new matter” alone, two identical rejections were often made under both statutory requirements. Typically, a new claim was “rejected under 35 U.S.C. § 112 and § 132 as directed to ‘new matter.’”<sup>26</sup> Never in this period of coexistence was there any serious thought given to this ground of rejection being applicable to an *original* claim: It is impossible for something that is a part of the original application, i.e., an original claim, to be new matter vis-à-vis the original application.

#### 2. Eliminating “New Matter” as Redundant

By 1981, the Court decided that it was happy with the statutory framework of substituting “written description” for “new matter” and saw no need for both grounds. In *Rasmussen* the court simply abolished “new matter” as a separate ground of rejection.<sup>27</sup>

#### 3. Original Claims Per Se Support Themselves

The PTO through the early 1990’s continued to correctly understand the law of “new matter” as being carried forward *sub nom* “written description.” In the *Porter* case, claims 2 and 3 on appeal were *original* claims that had been finally rejected by the Primary Examiner as lacking a proper “written description” of the invention.<sup>28</sup> Reversing the Primary Examiner, the Board stated that “[s]ince original claims constitute part of the original disclosure . . . , the . . . rejection of claims 2 and 3 under 35 U.S.C. § 112, ¶ 1, as lacking descriptive support is clear legal error.”<sup>29</sup>

Repudiating this line of reasoning, the panel majority in *Enzo* states:

Enzo’s claims do not meet the written description requirement simply because they are *in ipsius verbis* supported by the specification. Even if a claim is supported by the specification, the language of the claim must describe the invention so that one skilled in the art can recognize what is claimed. The appearance of the words of the claim in the specification or as an original claim does not necessarily satisfy that requirement. . . . If a purported description of an invention does not meet the requirements of the statute, the fact that it appears as an original claim or in the specification

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<sup>26</sup> MPEP, *supra* note 15, § 2163.06, at 2100-172.

<sup>27</sup> *In re Rasmussen*, 650 F.2d 1212 (C.C.P.A. 1981).

<sup>28</sup> *Ex parte Porter*, 25 U.S.P.Q.2d (BNA) 1144 (B.P.A.I. 1992).

<sup>29</sup> *Id.* (citing *In re Anderson*, 471 F.2d 1237 (C.C.P.A. 1973)).

does not save it. A claim does not become more descriptive by its repetition, or its longevity.

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The written description requirement is the most basic requirement of the patent law—to *adequately identify what one has invented*. It is true that knowledge of one skilled in the art is relevant to meeting that requirement, as it is to enablement. An invention may be properly enabled even if some experimentation is required to practice it, provided that experimentation is not undue. However, *to require the public to go to a public depository and perform experiments to identify an invention is not consistent with the statutory requirement to describe one's invention in the specification*.<sup>30</sup>

It is probably less onerous “to go to a public depository” than it is to try to identify the nature of some products defined in product-by-process form. The contrasting view of Circuit Judge Dyk is worth noting:

On the face of it, a specification that describes the invention by reference to a deposit of a sample of the invention in a recognized depository is an ideal way of satisfying the written description requirement. The primary purpose of the statutory written description requirement is to provide notice to competitors and the public of the scope of the patent claims. The Supreme Court has stated that

The object of the statute is to require the patentee to describe his invention so that others may construct and use it after the expiration of the patent and “to inform the public during the life of the patent of the limits of the monopoly asserted, so that it may be known which features may be safely used or manufactured without a license and which may not.”

*Schriber-Schroth Co. v. Cleveland Trust Co.*, 305 U.S. 47, 57 (1938) (quoting *Permutit Co v. Graver Corp.*, 284 U.S. 52, 60 (1931)). [The Court of Customs and Patent Appeals] stated that “the ‘essential goal’ of the description of the invention requirement is to clearly convey the information that an applicant has invented the subject matter which is claimed.” *In re Barker*. A description by reference to the deposited sample provides a precise and unmistakably clear description of the invention that is accessible to the public.<sup>31</sup>

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<sup>30</sup> *Enzo*, 2002 WL 487156, at \*17-\*18, \*20-\*21 (citations omitted) (emphasis added).

<sup>31</sup> *Id.* at \*38 (Dyk, J., dissenting) (second citation omitted).



### III. INVENTIONS WITH LESS THAN A WORD PICTURE

#### A. *An Enabling Disclosure as the Quid Pro Quo*

The *quid pro quo* of the patent system is that in exchange for the grant of a patent the inventor provides the public with full possession of the means for carrying out the invention, not a neatly worded description of that invention. Thus, it is simply incorrect to state that insofar as it is implied that there is a word picture of the invention that “[t]he written description requirement reflects the *quid pro quo* of our patent system, in which an inventor is only entitled to claim subject matter that is adequately described to the public.”<sup>32</sup>

There are numerous situations where the applicant is unable to provide a word picture, yet the patent system thrives in those areas. If there is a problem in a claim form presenting difficulties in determination of the scope of protection, the legislature or the courts can readily devise ways of avoiding the problem. For example, it is difficult to understand the nature of a product where it is defined as a product-by-process. But, the court system saw this difficulty and created a claim construction rule in the *Badische Anilin* case to limit infringement to products made by the same process, even to the point of excluding from infringement the *identical* product made by a different process.<sup>33</sup>

#### B. *Examination Difficulties*

It is a total non sequitur to pose examination problems as a reason for a “written description” of the invention. There are far more extreme examples where it is *impossible* to examine an application at the time of filing with the information at hand in the file wrapper. For example, it is perfectly proper to incorporate by reference essential elements from a secret document unavailable to the examiner.<sup>34</sup>

##### 1. *Statutory Presumptions*

The false issue is from time to time raised that somehow a patent examiner will have undue difficulty because he cannot determine the precise nature of the product. It has now been over fifty years since Harvey Edelblute’s introduction of the deposit system for patent protection. There has never been any significant criticism of this

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<sup>32</sup> *Id.* at \*15 (majority opinion).

<sup>33</sup> *Cochrane v. Badische Anilin & Soda Fabrik*, 111 U.S. 293, 310 (1884); *accord* *Atl. Thermoplastics Co., Inc. v. Faytex Corp.*, 974 F.2d 1299, 1300 (Rader, J., concurring in the denial of rehearing in banc) (explaining conflict with earlier panel opinion in *Scripps Clinic & Research Foundation v. Genentech, Inc.*, 927 F.2d 1565 (Fed. Cir. 1991)); *see also* *Gen. Elec. Co. v. Wabash Appliance Corp.*, 304 U.S. 364, 374 n.17 (1938) (Reed, J.); *Purdue Research Found. v. Watson*, 122 U.S.P.Q. 445 (D.D.C. 1958), *aff’d*, 265 F.2d 107 (D.C. Cir. 1959); Jon S. Saxe and Julian S. Levitt, *Product-by-Process Claims and Their Current Status in Chemical Patent Office Practice*, 42 J. PAT. OFF. SOC’Y 528, 559 (1960).

<sup>34</sup> *In re Hawkins*, 486 F.2d 569, 574-75 (C.C.P.A. 1973) (allowing incorporation of essential material was incorporated by reference from a secret, foreign patent application).

system and, indeed, to the contrary, it has been endorsed and globally spread through the Budapest Treaty.

Any problems where the examiner cannot determine the exact structure of a product are no different than in other areas. For example, consider the situation where a product is defined only by reference to its process of manufacture. There, the Patent examiner has no ability to analyze the product and determine whether it is novel and, if novel, whether it is sufficiently different to be free from obviousness. Such a case is simply handled by placing the burden of the patent applicant “to prove that the prior art products do not necessarily or inherently possess the characteristics of his claimed product.”<sup>35</sup>

## 2. *Amendments to the Specification*

Often, it becomes possible to better identify the nature of a biotechnology material as time goes on. This is the norm in biotechnology: The goal is to quickly file for an invention to nail down patent rights, but then as time goes on the better identification of the biotechnology material is given to the authorities. This is specifically recognized in the Budapest Treaty: “Where, in connection with the deposit of a microorganism, the scientific description and/or taxonomic designation of the microorganism was/were not indicated, the depositor may later indicate or, where already indicated, may amend such description and/or designation.”<sup>36</sup>

The examiner who feels that disclosure incorporated-by-reference should be embodied directly in the specification does have one remedy: He may make a requirement for the applicant to physically introduce the secret material into the file wrapper or even into the specification by amendment.

### *C. False Statutory Home for Clarity in Claiming*

The idea that the *claims* should provide a written description of the invention is without foundation in the statute or the case law. It is sufficient that they precisely define the scope of protection. As explained in *Vamco*, “claims are not technical descriptions of the disclosed inventions.”<sup>37</sup>

Thus, it is entirely the function of the claims to define the *scope of protection* that is being sought. Imagine a deed to a piece of real property that defines the exact perimeters of the lot but says nothing about whether square in the center of that lot there is a beautiful home, a stream, a factory or whatever. Does this make the deed defective? Obviously not. In the case of patent claims, they “are legal documents like the descriptions of land by metes and bounds in a deed which define the area conveyed but do not describe the land.”<sup>38</sup>

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<sup>35</sup> *In re Thorpe*, 777 F.2d 695 (Fed. Cir. 1985) (quoting *In re Fitzgerald*, 619 F.2d 67, 70 (C.C.P.A. 1980)); *In re Best*, 562 F.2d 1252, 1255 (C.C.P.A. 1977).

<sup>36</sup> Budapest Treaty, Rule 8.1(a), *Later Indication or Amendment of the Scientific Description and/or Proposed Taxonomic Designation*.

<sup>37</sup> *In re Vamco Mach. & Tool, Inc.*, 752 F.2d 1564, 1577 n.5 (Fed. Cir. 1985).

<sup>38</sup> *Id.*

To be sure, fuzzy claiming may present a problem, but it is one of clarity that has nothing to do with the “written description” problem.<sup>39</sup>

#### *D. Unsupported Embodiments Within a Genus*

Broad claims may in some instances be unwarranted because there is inadequate teaching of how to make and use *some* of the varied embodiments. Where there is a problem, the statutory home is the enablement requirement of 35 U.S.C. § 112, ¶ 1.

Contemporaneously with the refinements of *Wakefield*<sup>40</sup> and *Borkowski*,<sup>41</sup> the court also recognized in *Fisher*<sup>42</sup> that claims of the *Enzo* variety should not be granted. Fisher presented an *Endo*-like lack of representative support for a broadly claimed medicinal invention with limited enablement, certainly insufficient to suggest possession of the full scope of the subject matter of the claims. Affirming a rejection under 35 U.S.C. 112, ¶ 1 under the enablement requirement, the court said:

It is apparent that . . . an inventor [with such a broad claim] should be allowed to dominate the future patentable inventions of others where those inventions were based in some way on his teachings. Such improvements, while unobvious from his teachings, are will within his contribution, since the improvement was made possible by his work. It is equally apparent, however, that he must not be permitted to achieve this dominance by claims which are insufficiently supported and hence not in compliance with the first paragraph of 35 U.S.C. § 112. That paragraph requires that the scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.<sup>43</sup>

Judge Gajarsa also provides an understanding of the scope of enablement rejection following the same rationale as *Fisher*. He explains that “[t]he enablement requirement of § 112 demands that the patent specification enable those skilled in the art to make and use the full scope of the claimed invention without undue experimentation.”<sup>44</sup> Quoting also from *Fisher*, he notes that:

The enablement requirement ensures that the public knowledge is enriched by the patent specification to a degree at least commensurate with the scope of the claims. The scope of the claims must be less than or equal to the scope of the enablement. The scope of enablement, in turn, is that which is

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<sup>39</sup> The statutory home for a rejection, here, is 35 USC § 112, ¶ 2, that has nothing to do with the “written description” issue.

<sup>40</sup> *In re Wakefield*, 422 F.2d 897 (C.C.P.A. 1970).

<sup>41</sup> *In re Borkowski*, 422 F.2d 904 (C.C.P.A. 1970).

<sup>42</sup> *In re Fisher*, 427 F.2d 833 (C.C.P.A. 1970).

<sup>43</sup> *Id.* at 839.

<sup>44</sup> *Nat'l Recovery Techs., Inc. v. Magnetic Separation Sys., Inc.*, 166 F.3d 1190, 1195 (Fed. Cir. 1999) (internal quotation marks omitted) (quoting *Genentech, Inc. v. Novo Nordisk A/S*, 108 F.3d 1361, 1365 (Fed. Cir. 1997) (quoting *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993)) and citing *In re Vaec*, 947 F.2d 488, 495 (Fed. Cir. 1991)).

disclosed in the specification plus the scope of what would be known to one of ordinary skill in the art without undue experimentation.<sup>45</sup>

While there may very well be problems with the scope of enablement in the facts of the *Enzo* case, particularly when one looks to the broader claims that are not limited to any specific American Type Culture Collection (“ATCC”) deposit,<sup>46</sup> the remedy lies in the *Fisher* line of cases.<sup>47</sup>

#### IV. THE BIOTECHNOLOGY DEPOSIT ISSUES

##### A. *The Ad Hoc Domestic Creation of the Practice*

More than fifty years ago the late Harvey Edelblute, one of the more brilliant and creative patent counsel of the era, was faced with an economically important microorganism that could brew tetracycline but which could not be described in words. On an ad hoc basis, he created the system of incorporation-by-reference of microorganism deposits to meet the disclosure requirements of 35 USC § 112, ¶ 1, which were “codified” a generation later in *Argoudelis*.<sup>48</sup> The practice up to *Argoudelis* was the subject of a discussion at a Cold Spring Harbor experts’ conference a little more than ten years ago:

The *Argoudelis* case utilized a deposit with the [Northern Regional Research Laboratory of the U.S. Department of Agriculture, the] NRRL, as had been the custom since the practice developed on an ad hoc basis roughly twenty years earlier. The practice may be attributed to the late Harvey Edelblute, a brilliant corporate staff attorney with American Cyanamid Co., who faced the problem of claiming an invention that produced a tetracycline family drug by “brewing” a certain species of *Streptomyces*. Edelblute recognized that there was no way that mere words could teach a worker skilled in the art how to make a tetracycline drug from his client’s *Streptomyces*, short of having a sample of the very *Streptomyces*. From his scientists, Edelblute learned that the U.S. Department of Agriculture, through its Northern Regional Research Laboratory in Peoria, Illinois, maintained samples of microorganisms, assigning “NRRL” numbers and providing samples to members of the public. It was Edelblute who crafted

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<sup>45</sup> *Nat’l Recovery Techs.*, 166 F.3d at 1195-96. The quotation continues with a citation of *In re Goodman*, 11 F.3d 1046, 1050 (Fed. Cir. 1993), for the proposition that “the specification must teach those of skill in the art how to make and how to use the invention as broadly as it is claimed,” which cites to *Vaeck*, 947 F.2d at 496. Also quoted is *In re Fisher*, 427 F.2d at 839, for the proposition that “[t]he scope of the claims must bear a reasonable correlation to the scope of enablement provided by the specification to persons of ordinary skill in the art.”

<sup>46</sup> See *Ajinomoto Co. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345 (Fed. Cir. 2000), *cert. denied*, 121 S. Ct. 1957 (2001) (explaining how the deposit of biological material may help satisfy the enablement requirement); see also 37 C.F.R. § 1.803(a)(2) (authorizing American Type Culture Collection (ATCC) as a suitable depository).

<sup>47</sup> For purposes of this paper, the specific facts of the case have not been dealt with. It should be noted, however, that some of the claims are specifically limited to biotechnology deposits.

<sup>48</sup> *In re Argoudelis*, 434 F.2d 1390 (C.C.P.A. 1970).

the incorporation-by-reference of the *Streptomyces* into the patent application, simply by making a specific reference to the NRRL number in the patent application. Thus, when the patent was granted, any person would be able to gain a sample of the *Streptomyces* from the NRRL, and through this incorporated-by-reference sample, practice the invention. . . .

The Edelblute practice became an international norm as parallel, foreign filings were made by American Cyanamid. The dean of the Japanese patent profession, Shoji Matsui, coordinated the filing, prosecution and successful enforcement of the Japanese counterpart patents, creating on an ad hoc basis a framework in Japan for the patenting of biotechnology inventions based upon NNRL deposits.<sup>49</sup>

The *Argoudelis* practice is summarized in *Lundak*:

35 U.S.C. § 112 states that the specification must contain a “written description” which must “enable” the practice of the invention by others. The examination for patentability proceeds solely on the basis of the written description. . . . Although a sample is not a written description, *Feldman* established that the availability of a sample to the public after the patent has issued will meet the enablement requirement. On point is *In re Hawkins*, 486 F.2d 569, 574 (C.C.P.A. 1973), wherein the court observed that:

In *Argoudelis*, we rejected the board’s proposition that [35 U.S.C. § 111] requires that the specification must be enabling as filed. We again reject it. . . . [T]he function of section 112 in ensuring complete public disclosure is only violated if the disclosure is not complete at the time it is made public, i.e., at the issue date.<sup>50</sup>

In *Amgen v. Chugai* there is a further recapitulation of the practice:

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<sup>49</sup> Wegner, *Biotechnology Patent Issues at the Patent Office*, BANBURY RESEARCH CONFERENCE: INTELLECTUAL PROPERTY AND BIOTECHNOLOGY, Cold Spring Harbor, Long Island, New York, October 10-13, 1991 (citing *Argoudelis*, 434 F.2d at 1392-93; *Feldman v. Aunstrup*, 517 F.2d 1351 (C.C.P.A. 1975); Albert P. Halluin, *Patenting the Results of Genetic Engineering: An Overview*, Banbury Report 10: Patenting of Life Forms, 67, 68 (1982)).

This conference was led by Nobel Laureate James Watson and featured the then-future (1993) Nobel Laureate Kary B. Mullis. The interesting evolution of his invention of polymerase chain reaction that was explained in greater detail at the Banbury Research Conference is summarized by Emily Yoffe, *Is Kary Mullis God?*, ESQUIRE, Vol. 122, No. 1 (July 1, 1994), available at 1994 WL 13263352.

A significant representation from both science and the law were present, including the late S. Leslie Misrock, Dennis Allegetti, and Mullis’ counsel, Albert P. Halluin, then Vice-President of Cetus Corporation who had also participated and helped create the first Banbury Research Conference dealing with biotechnology ten years previously.

From the Federal appellate judiciary the members present included the Hon. Pauline Newman, the Hon. Alan D. Lourie, and the late Hon. Giles Sutherland Rich.

<sup>50</sup> *In re Lundak*, 773 F.2d 1216, 1223 (Fed. Cir. 1985) (citations omitted) (second omission in original).

For many years, it has been customary for patent applicants to place microorganism samples in a public depository when such a sample is necessary to carry out a claimed invention. This practice arose out of the development of antibiotics, when microorganisms obtained from soil samples uniquely synthesized antibiotics which could not be readily prepared chemically or otherwise. *In re Argoudelis*. Such a deposit has been considered adequate to satisfy the enablement requirement of 35 U.S.C. § 112, when a written description alone would not place the invention in the hands of the public and physical possession of a unique biological material is required. *See, e.g., In re Wands* (“Where an invention depends on the use of living materials ... it may be impossible to enable the public to make the invention (*i.e.*, to obtain these living materials) solely by means of written disclosure.”); *In re Lundak* (“When an invention relates to a new biological material, the material may not be reproducible even when detailed procedures and a complete taxonomic description are included in the specification.”); *see generally* Hampar, *Patenting of Recombinant DNA Technology: The Deposit Requirement*, 67 J. Pat. & Trademark Off. Soc’y 569, 607 (1985) (“The deposit requirement is a nonstatutory mechanism for ensuring compliance with the ‘enabling’ provision under 35 U.S.C. § 112.”).<sup>51</sup>

As explained more recently in *Ajinomoto*, “[t]he deposit of biological organisms for public availability satisfies the enablement requirement for materials that are not amenable to written description or that constitute unique biological materials which can not be duplicated.”<sup>52</sup>

### *B. Codification of Harvey Edelblute’s Practice*

Faced with the need of the American biotechnology community to secure *Argoudelis*-like protection globally, lengthy efforts to internationally codify the practice were greeted with success through global adoption of the Budapest Treaty.<sup>53</sup> By 1989,

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<sup>51</sup> *Amgen, Inc. v. Chugai Pharm. Co.*, 927 F.2d 1200, 1210 (Fed. Cir. 1991) (Lourie, J.) (citations omitted).

<sup>52</sup> *Ajinomoto Co., Inc. v. Archer-Daniels-Midland Co.*, 228 F.3d 1338, 1345-46 (Fed. Cir. 2000) (Newman, J.).

<sup>53</sup> *Guide to the Deposit of Microorganisms under the Budapest Treaty*, at <http://www.wipo.int/about-ip/en/budapest/guide> (last visited April 24, 2002). As explained by the treaty organization responsible for administration of the Budapest Treaty:

A fundamental requirement of patent law is that the details of an invention must be fully disclosed to the public. For disclosure to be adequate, an invention must be described in sufficient detail to permit a person skilled in the art to repeat the effect of the invention: in other words, the disclosure should enable the average expert with access to the appropriate facilities to reproduce the invention for himself. Disclosure is normally achieved by means of a written description supplemented where necessary by drawings. However, inventions involving the use of new microorganisms . . . present problems of disclosure in that repeatability often cannot be ensured by means of a written description alone. . . . [Difficulties in reproducing the invention from the text alone] led to the industrial property offices in an increasing number of countries either requiring or recommending that the written disclosure of an invention involving the use of a

the treaty had been ratified and the PTO codified the practice through formal rulemaking.

As part of that rulemaking, the *Argoudelis* practice of incorporation-by-reference of a biotechnology deposit was codified through a rule stating that “[w]here an invention is [to] a biological material, the [specification] may include reference to a deposit of such biological material.”<sup>54</sup> It is made explicitly plain that the purpose of the deposit is to meet the disclosure requirements of 35 U.S.C. § 112, ¶ 1: “Biological material need not be deposited unless access to such material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. § 112.”<sup>55</sup> It is clear that “[i]f a deposit is necessary” then making a deposit in accordance with the regulations *shall* be accepted: Thus, it is expressly stated that “[the deposit] *shall* be acceptable if made in accordance with these regulations.”<sup>56</sup> In the Deposit Rules package, the PTO highlights this point by placing in the “Summary” the statement that “[w]here an invention *is* or relies on a biological material which cannot be described in writing alone, and access to the biological material is necessary to satisfy the statutory requirements for patentability under 35 U.S.C. 112, these rules prescribe the procedures and conditions for making a deposit that *will* satisfy these requirements.”<sup>57</sup> Underscoring the point, it is reiterated that

Every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. Where the invention involves a biological material and words alone cannot sufficiently describe how to make and use the invention in a reproducible or repeatable manner, access to the biological material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. § 112.<sup>58</sup>

It is further stated with specific reference to the relevant rule that: “[37 CFR] § 1.802(b)] prescribes that biological material need not be deposited unless access to the material is necessary to satisfy 35 U.S.C. §112. If a deposit is necessary, it shall be acceptable if made in accordance with these regulations. . . .”<sup>59</sup>

In its sectional analysis, the PTO explains Rule 802(b) as follows: “This section permits a deposit of a biological material to be referenced in a patent application where an invention is, or relies on, a biological material. . . . [B]iological material need not be deposited unless access to such material is necessary for the satisfaction of the

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new microorganism be supplemented by the deposit of the microorganism in a recognized culture collection. The culture collection would then make the microorganism available to the public at the appropriate point in the patenting procedure.

*Id.*

<sup>54</sup> 37 CFR § 1.802(a).

<sup>55</sup> 37 CFR § 1.802(b).

<sup>56</sup> 37 CFR § 1.802(b) (emphasis added).

<sup>57</sup> *Deposit of Biological Materials for Patent Purposes*, 54 Fed. Reg. 34864-01 (1989) (final rulemaking, effective January 1, 1990) (emphasis added) [hereinafter Deposit Rules].

<sup>58</sup> *Id.* (Supplementary Information).

<sup>59</sup> *Id.*

statutory requirements for patentability under 35 U.S.C. § 112 and that access is not otherwise available in the absence of a deposit.”<sup>60</sup>

It is also useful to understand the rulemaking that codified the *Argoudelis* practice in terms of the customs of the domestic industry of the day. In the 1980’s, leading up to the implementation of Rule 802, it was the common practice of the domestic biotechnology industry to identify living inventions solely or principally by an incorporation-by-reference to a deposit, often at the ATCC, that became the norm by that time, largely replacing what had been Edelblute’s Peoria depository, the NRRL. Thus, a typical claim of that era is: “The *E. coli* ATCC 39052 strain.”<sup>61</sup> In the context of a plant patent, the cross-reference was approved in the *Solomons and Scammell* case:

Initially we note that each of the applications contains a written description of the here claimed subject matter:

“\* \* \* Fusarium graminearum Schwabe deposited with  
Commonwealth Mycological Institute and assigned the numer I.M.I.  
145425 \* \* \*”

We consider such a “deposit” to adequately describe the invention here claimed (35 USC 112/162). Our position in this regard appears congruent with the requirements of 35 USC 112 for an adequate disclosure pertaining to microorganisms.<sup>62</sup>

Also contemporaneous with the codification of the *Argoudelis* practice through the new rule, the PTO’s Board of Patent Appeals and Interferences stated that:

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<sup>60</sup> *Id.* at 34874-75.

<sup>61</sup> U.S. Patent No. 4,666,837 (issued May 19, 1987). This patent names as counsel the author of the *Enzo* opinion, as is the case for U.S. Patent No. 4,506,017 (issued Mar. 19, 1985) (Claim 1: “*Pasteurella haemolytica* having all of the identifying characteristics of ATCC 31612.”); U.S. Patent No. 4,559,306 (issued 1985) (Claim 1: “A biologically pure culture of *Pasteurella multocida* bacterial having all of the identifying characteristics of ATCC No. 31610.”); U.S. Patent No. 4,694,069 (issued Sept. 15, 1987) (Claim 1: “A biologically pure culture of *Kibdelosporangium aridum largum* which has the identifying characteristics of ATCC 39922. . . .”); U.S. Patent No. 4,672,036 (issued June 9, 1987) (Claim 1: “A biologically pure culture of the microorganism *Kibdelosporangium aridum* Shearer gen. nov., sp. nov. ATCC 39323 or an active mutant thereof, said microorganism and mutant being capable of producing AAD 216A, AAD 216B or AAD 216C in recoverable quantity upon cultivation in aqueous nutrient medium containing assimilable sources of nitrogen and carbon.”); U.S. Patent No. 4,791,064 (issued Dec. 13, 1988) (Claim 1: “Plasmid pSO408, which is naturally present in *N. orientalis* strain NRRL 2452, isolated from such strain, or a functional mutant or genetically engineered derivative thereof wherein said mutant or derivative possesses sufficient amount of the replicon of pSO408 to permit stable autonomous replication.”); U.S. Patent No. 4,293,545 (issued Oct. 6, 1981) (Claim 1: “A modified live *Pasteurella multocida* vaccine capable of inducing immunity in bovine, porcine and ovine animal species without serious side effects comprising a vaccinal amount of modified live *Pasteurella multocida* bacteria prepared by chemical modification of virulent *Pasteurella multocida* strain ATCC No. 31609 with an acridinium salt, and a carrier therefor.”); U.S. Patent No. 4,385,122 (issued May 24, 1983) (Claim 1: “A biologically pure culture of the microorganism *Streptosporangium fragile* Shearer sp. nov. ATCC 31519, said culture being capable of producing fragilomycin A in recoverable quantity upon cultivation in an aqueous nutrient medium containing assimilable sources of nitrogen and carbon.”).

<sup>62</sup> *Ex Parte Solomons*, 201 U.S.P.Q. (BNA) 42, 43 (B.P.A.I. 1978).



In relevant part, 35 USC § 112, first paragraph, requires the specification of a patent application to contain a written description of the invention so as to enable any person skilled in the art to which it pertains to make and use the claimed invention. In most patent cases, written words are adequate to satisfy this requirement. However, in patent cases where biological material plays an integral, necessary role in the claimed subject matter, written words may not suffice to provide an enabled description of the invention. In these cases, a practice has evolved in which the enablement requirement of 35 U.S.C. §112, first paragraph, may be complied with by applicant depositing a viable sample of the biological material involved in the claimed invention in a recognized depository. In this manner, the public will be in a position to make and use that invention when a patent is granted as required by this section of the statute upon obtention of a viable sample of deposited material from the depository.<sup>63</sup>

*C. No Case Law on the “Written Description”, Per Se*

All of the biotechnology deposit case law related to the issue of a “written description” of the manner of making or using an invention and not to a “written description,” per se, in the sense of a word picture to *identify* the invention. This is entirely understandable from the case law which evolved under the plain wording of the statute that there is no separate “written description” requirement or, even after the *Borkowski* era, that the “written description” requirement relates only to new matter.<sup>64</sup> But, quite clearly, deposits were routinely incorporated by reference is a primary and sometimes sole means to identify a deposit.<sup>65</sup>

V. *ARGOUEDELIS*—CORNERSTONE FOR GLOBAL PROTECTION

Vital to the American biotechnology industry is the necessity of gaining global patent rights for their innovations: If patents are lost for the rest of the world, clearly, the industry is disastrously impacted. But, the entire *Argoudelis* practice and its global basis stems from the American example. To the extent that the United States is now to repudiate *Argoudelis*, there is nothing to stand in the way of such a highly negative example spreading throughout the world. If *Argoudelis* is a humpty-dumpty that falls globally, it may never be put back together again: It is one thing for the American biotech industry to go to a sympathetic Congress to restore the necessary practice of *Argoudelis*; it is yet another thing to imagine doing so in the various global legislatures which may be less sympathetic to securing a pro-patent environment that may be locally seen as primarily benefiting Americans—and Japanese and Germans.

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<sup>63</sup> *Ex Parte* Hildebrand, 15 U.S.P.Q.2d (BNA) 1662, 1662-63 (B.P.A.I. 1990).

<sup>64</sup> *In re* Borkowski, 422 F.2d 904 (C.C.P.A. 1970).

<sup>65</sup> Indeed, earlier in this paper there are quotations from claims in eight separate patents from the 1980's that were procured by the author of the *Enzo* opinion where the sole or a primary means to identify the product were by a specific incorporation-by-reference *in the claim itself* of an ATCC biotechnology deposit.

## VI. BRAKE ON NEW TECHNOLOGIES: ET TU E-COMMERCE?

A. *A Special Law for Biotechnology*

Until the previous decade, there had never been any thought given to suppression of a new technology by placing a special statutory test to deny patenting. To the contrary, a highlight of judicial precedent in the latter part of the twentieth century was the strong signal of the Supreme Court that new technologies are patent-eligible, both in biotechnology for life forms in *Chakrabarty*<sup>66</sup> and in software in *Diehr*.<sup>67</sup>

The dissent in *Enzo* correctly notes that the majority creates a special requirement for a “written description” unique to biotechnology. The majority “impos[es] a unique written description requirement in the field of biotechnology, [which] is open to serious question.”<sup>68</sup>

New technologies frequently pose problems for both the examiners and the public to adapt to rapidly evolving new technologies. This is hardly a reason to shut the door on their patentability. To the contrary, a new technology needs to be fostered, despite problems such as search and examination difficulties. If it's biotechnology today, will the court tomorrow impose new statutory proscriptions on e-commerce? On the next new technology to come along?

Essentially no damage was done to the patent regime by the *Borkowski* era creation of a “written description” separate requirement as long as it was limited to being synonymous with “new matter.” A series of panel opinions in the past decade have created a new law for biotechnology by its expansion of the “written description” requirement to apply to *original* claims. In *Enzo* itself, the author of these earlier opinions cites these opinions as basis for the new practice:

We have . . . previously considered the written description requirement as applied to certain biotechnology patents, in which a gene material has only been defined by a statement of function or result and have held that such a statement did not adequately describe the claimed invention. In *Eli Lilly*, we concluded that a claim to a microorganism containing a human insulin cDNA was not adequately described by a statement that the invention included human insulin cDNA. The recitation of the term human insulin cDNA conveyed no distinguishing information about the identity of the claimed DNA sequence, such as its relevant structural or physical characteristics. We stated that an adequate written description of genetic material “requires a precise definition, such as by structure, formula, chemical name, or physical properties,’ not a mere wish or plan for obtaining the claimed chemical invention.” The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter

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<sup>66</sup> *Diamond v. Chakrabarty*, 447 U.S. 303 (1980).

<sup>67</sup> *Diamond v. Diehr*, 450 U.S. 175 (1981).

<sup>68</sup> *Enzo Biochem, Inc. v. Gen-Probe Inc.*, No. 01-1230, 2002 WL 487156, at \*33 (Fed. Cir. April 2, 2002) (Dyk, J., dissenting).

of the claim. A description of what the genetic material does, rather than of what it is, does not suffice.<sup>69</sup>

### *B. No Case is Made for a Special Rule*

More than fifty years have passed since Harvey Edelblute took his *Streptomyces* strain to Peoria. A generation has elapsed since the triumph of the American government to gain enactment of the Budapest Treaty. More than a decade has passed since the domestic rulemaking codification of Budapest as satisfying the requirements of 35 U.S.C. § 112, ¶ 1. Biotechnology has thrived. Careful examination of the majority opinion in *Enzo* shows no special need for the judicial legislation embodied in that case and the earlier cases from the previous decade.

#### *1. Quid Pro Quo to the Public*

The *Enzo* majority without citation of authority boldly states that “[t]he written description requirement reflects the *quid pro quo* of our patent system, in which an inventor is only entitled to claim subject matter that is *adequately described* to the public.”<sup>70</sup> As discussed earlier in this paper, this has never a key point of the law. There is no more ambiguity about the nature of a product pinpointed to a specific biotechnology deposit than by a more general product-by-process description. In either case, the reader of the patent will not know, absent a lot of work, precisely what the structure of the product may be.

Judicial safeguards to protect the public are readily made. For example, in the area of the very indefinite product-by-process language where it is often impossible to tell precisely what product is made, it would be unfair to permit a patentee to sue parties who have made a product by a different method which may or may not be the same or equivalent. Therefore, dating back to the nineteenth century, the Supreme Court has held that third parties need not figure out the nature of the final product: As long as they make their product by a *different* method, then they will be free from a finding of infringement *even if it later turns out that the identical product is produced by this different method*.

#### *2. False Burdens on the Examiner*

The majority complains that use of a deposit makes examination difficult. But, again using product-by-process claims as an example, applicants are further discouraged from use of the product-by-process form by the judicial doctrines that place a very heavy burden on the patent applicant to *prove* that his product is both different and unobvious versus prior art structures, even if made by a different method.

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<sup>69</sup> *Id.* at \*11 (majority opinion).

<sup>70</sup> *Id.* at \*6 (emphasis added).

### 3. *Broad Claims That Are Not Enabled*

The majority makes a false point by stressing the breadth of claim 1 and other claims that are not restricted to a deposit number. Certainly, there *are* problems that may arise where there is a limited scope of enablement. But, there is a statutory scheme already in place to deal with this problem.

### C. *Playing by the Rules of Practice (in Patent Cases)*

The *Enzo* majority is dismissive of the ad hoc practice, stating that the court is free to disregard published guidelines such as in the Manual of Patent Examining Procedure (“MPEP”);<sup>71</sup> it ignores the court’s own precedent that patent applicants have a right to rely upon the procedures set forth in the MPEP.<sup>72</sup> Much more serious is the fact that beyond such guidance an entire global framework was built upon this ad hoc practice into the Budapest Treaty. Furthermore, the practice in the MPEP and the Budapest Treaty was codified in the form of formal rules that have been in force since 1990.

## VII. CONCLUSION

While the damage wrought by *Enzo* may be minimized for domestic biotechnology through appropriate Congressional action, it often takes many years to correct what seems to be so obvious a problem, and when Congress does act, the numerous competing interests far too often create a muddled compromise that often creates more problems than there had been before.

### A. *Teaching Foreign Governments How to Kill Biotech*

Where *Enzo* will do its greatest damage in the short range will be in the international patent arena where even developed countries take a serious look at whatever major policy changes are made, particularly in the high technology areas where American intellectual property protection is seen as a boon to its expansion. If something is good for America in this area, it may well be adopted in *developed* countries. *A fortiori*, if a *developing* country wants to put the brakes on the local patent system, to gum up the works to make it impossible for American biotechnology concerns to gain the broad protection they need overseas to share the immense costs of development of the new generation of biotechnology products, what better sand in the

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<sup>71</sup> *Id.* at \*5 (“[T]he Guidelines [for Examination of Patent Applications Under the ‘Written Description’ Requirement], like the MPEP, are not binding on this court.”) (citing *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1180 n.10 (Fed. Cir. 1995) (noting that the MPEP is not binding on this court but is “entitled to judicial notice as an official interpretation of statutes or regulations as long as it is not in conflict therewith”)).

<sup>72</sup> But, it is well settled that the MPEP may be relied upon by patent applicants where there is no conflicting statutory standard. *See Ethicon v. Quigg*, 849 F.2d 1422, 1425 (Fed. Cir. 1988) (following *In re Kaghan*, 387 F.2d 398, 401 (C.C.P.A. 1967)).

gears is possible than a statutory *Enzo* adoption in local law. On what basis can the U.S. Trade Representative use the TRIPs to attack an onerous provision in a developing nation's law that is taken straight from Madison Place?

### B. *The Future of the Next New Technology*

The genius of the American patent system has been its flexible accommodation of any "new manufactures"<sup>73</sup> that come along. Blessed by the positive imprimatur of *Chakrabarty* and *Diehr*, and the continued green light to patent-eligibility expressed in the most recent term in the *J.E.M.* reaffirmation of *Chakrabarty*, the Supreme Court has signaled Wall Street and the developers of new technologies that the patent water is fine. Jump in the pool. Develop your new technologies. Certainly, every new technology has difficulties for claiming and examination and understanding by the public. Indeed, there have been impressive patent litigations in the past generation that have drawn great attention to problems in our system. So, too, have we seen problems in the area of e-commerce and business patents. But, macroscopically looking at the picture, nobody can seriously argue that American society would be better off *without* a strong and healthy development of these new technologies.

To judicially legislate difficult, if not impossible, barriers to the evolution of new technologies today creates a negative precedent for the next "better light bulb" to come down the pike in the coming years.

### C. *Chakrabarty: The Ongoing Message from the Court*

The philosophy of an open door to patentability of new manufactures in *Chakrabarty* should be sustained and fueled, as it was so recently by the Federal Circuit in *AT&T* in the context of patent-eligibility: "[T]his court \* \* \* has struggled to make our understanding of the scope of [35 U.S.C.] § 101 responsive to the needs of the modern world."<sup>74</sup> Even more powerfully and in its current term, the Supreme Court has underscored the continued vitality of *Chakrabarty* in the *J.E.M.* case:

As this Court recognized over 20 years ago in *Chakrabarty*, the language of § 101 is extremely broad. "In choosing such expansive terms as 'manufacture' and 'composition of matter,' modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given

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<sup>73</sup> "New manufactures" represents the terminology from the English parent patent statutes and was presented by the author in various writings in the 1970's that were considered in the *Bergy* case. *In re Bergy*, 596 F.2d 952, 974 n.10 (C.C.P.A. 1979), *aff'd sub nom. Diamond v. Chakrabarty*, 447 U.S. 303 (1980) ("See Wegner, *The Patentability of 'New Manufactures' The Living Invention, 'New Manufactures' Encouragement of Pioneer Research*, 1978 Patent Law Conference Coursebook (BNA) 253-62.) (Mr. Wegner has extensively researched the question while a fellow at the Max Planck Institute for Foreign and International Patent, Copyright, and Competition Law, Munich, Germany. See Wegner, *Patent Protection for Novel Microorganisms Useful for the Preparation of Known Products*, 5 Int'l Rev.Indus.Prop. & Copyright L. 285 (1974); Wegner, *Patenting Nature's Secrets Microorganisms*, 7 Int'l Rev.Indus.Prop. & Copyright L. 235 (1976).").

<sup>74</sup> *AT&T Corp. v. Excel Communications, Inc.*, 172 F.3d 1352, 1356 (Fed. Cir. 1999) (Plager, J.) (citing *Diamond v. Diehr*, 450 U.S. 175 (1981)).

wide scope.” This Court thus concluded in *Chakrabarty* that living things were patentable under § 101, and held that a manmade micro-organism fell within the scope of the statute. As Congress recognized, “the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions.”<sup>75</sup>

In *Chakrabarty*, the Court also rejected the argument that Congress must expressly authorize protection for new patentable subject matter:

It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is “the province and duty of the judicial department to say what the law is.” *Marbury v. Madison*. Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in Construing the language Congress has employed. . . . The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting “the Progress of Science and the useful Arts” with all that means for the social and economic benefits envisioned by Jefferson.<sup>76</sup>

Whither goes the court? Is the *Chakrabarty* philosophy that was followed almost immediate for computer software in *Diehr* and a generation later in *J.E.M.* to be followed? What lessons are we to provide the rest of the world on the protection of new technologies through local patent systems?

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<sup>75</sup> *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 122 S. Ct. 593, 598 (2001).

<sup>76</sup> *Diamond v. Chakrabarty*, 447 U.S. 303, 315 (1980).