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Journal of the Patent and Trademark Office Society

April, 2003

85 J. Pat. & Trademark Off. Soc'y 275

LENGTH: 5666 words

ARTICLE: "Do-Over!" -- The Federal Circuit Takes a Second Look at Enzo v. Gen-Probe

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TEXT:

[*275] When my young niece fails at a challenging task or game, she often shouts "Do-over!" and gets a second chance to try. The Court of Appeals for the Federal Circuit has not been so forgiving to biotechnology patentees in recent years, and has invalidated a steady stream of patents for failing to meet the requirements of the first paragraph of *35 U.S.C. § 112.* n1 However, one plaintiff-appellant recently got a "do-over" from the Court that could ease the prosecution and enforcement of claims to early-stage biotechnology.

On July 15, 2002, a three-judge panel consisting of Judges Lourie, Dyk, and Prost granted a rehearing of the appeal that the panel had decided earlier in the year, reversed their decision and remanded to the District Court to resolve disputed issues of fact regarding resolution of the written description requirement of the first paragraph of *35 U.S.C. § 112* ("WDR"). n2 The earlier decision had affirmed summary judgment of **[*276]** invalidity of claims 1-6 of Enzo's U.S. Pat. No. 4,900,659 ("the '659 patent") for failure of the specification to meet the WDR. n3 The patent claims a method of detecting *Neisseria gonorrhoeae* by using DNA probes that selectively hybridize to *N. gonorrhoeae* in the presence of a related species of bacteria, *Neisseria meningitidis*. The invention was claimed both in terms of the ability of the probes to selectively hybridize to known reference strains of *N.* gonorrhoeae in the presence of known strains of *N. meningitidis*, and in dependent claims, by reference to three *N. gonorrhoeae* DNA inserts in plasmids deposited in the American Type Culture Collection (ATCC). Both the gonorrhoeae and meningitidis strains and the probe inserts were identified by ATCC reference numbers in claim 1, and in claims 4 and 6, respectively, and in the specification.

This is conventional practice when an applicant seeks to meet the requirements of § 112 by depositing a sample of biological material that is the invention, or is required to make it, in a public depository. n4 Such deposits are usually made in accord with the provisions of the "Budapest Treaty" that governs the deposit of microorganisms for patent purposes. n5 Upon issuance of the patent, restrictions on the deposited samples are withdrawn, and the depository will make the samples available to all requesters. Thus, such deposits effectively make the materials that they embody a part of the patent specification. However, the '659 patent did not provide the DNA sequences of either the bacterial strains identified in claim 1 or the probes identified in claims 4 and 6.

The first panel to consider Enzo's appeal issued a decision in April 2002 that rocked biotechnology patent law. The decision held that reference to a deposited biological material in the patent specification could not be relied upon in any way to meet the WDR. n6 The panel also disregarded the hybridization conditions and characteristics recited in claim 1 as the type of "functional definition" that did not contribute to the requirements of the WDR as set forth in *Regents of the University of* **[*277]** *California v. Eli Lilly & Co.* ("*Lilly*"). n7 In *Lilly*, the panel held that a description of a DNA sequence using functional language could not *per se* meet the WDR, even when coupled with an arguably enabling disclosure of how to make and use the DNA sequence. n8 The *Lilly* panel identified in the WDR a requirement that patent specifications must obtain a "precise definition" of claimed biological materials, if not by structural formulae, then by other non-functional properties that were not clearly articulated by the court. n9 The patentees in *Lilly* had not isolated the claimed DNA, thus leaving unresolved questions both for applicants or patentees who had isolated a biological material, but did not know the structure, as well as for applicants or patentees who had claimed biological material structurally, but who had not actually obtained a sample.

The *Enzo I* panel left the former group of applicants or patentees in a much worse position than it left the second group. The panel held that disclosure of actual reduction to practice taken alone, or with a deposit made in accord with PTO requirements, could not meet the WDR without something more. n10 While noting the mention of binding affinity in the PTO's WDR Guidelines, the panel also tossed the comparative hybridizations of claim 1 into the useless "functional" bin, since the hybridization was not recited to occur between defined structures. n11 Even though the patent statutes have never been read to require actual reduction to practice (you can draw a hammer that will work), n12 the second group of patentees/applicants could feel pretty secure -- disclosing structure, they only had to meet the enablement and utility requirements. Enablement is usually not a problem for claims of reasonable scope, even in biotechnology (you can synthesize or clone **[*278]** anything). Despite the heightened PTO utility requirements, a utility need not be novel or even reduced to practice (you can guess if you guess right), and only one utility is required to be disclosed. n13

This dichotomy is exacerbated by the fact that the first group of applicants/patentees is much larger than the second. While structure has always been relatively easy to derive in the pharmaceutical arts (the classic "methyl-ethyl-isopropyl" Markush group), it is much harder both to obtain an initial structure of a biological material, such as a gene or a protein, and then to genericize it, so as to obtain claims of reasonable scope. While techniques are progressing that can generate genuses of genes and proteins from databases once a single reference sequence has been identified, computational gene amplification and high throughput screening techniques did not exist until relatively recently in the history of biotechnology. Thus, while there is a large group of biotechnol-

ogy applicants/patentees who disclose "actual possession" of biological materials they claim, without much, or any, structural information, there are relatively few who have lots of structural information, actual or hypothetical, without actual possession. n14

The *Enzo I* panel's effective requirement for structural claiming, even when the patent recited the deposit number of the reference sequence, or probe, clouded the validity of thousands of biotechnology patents which explicitly or implicitly relied upon deposited materials to meet any of the requirements of § 112. n15 Such patents include not only those that claim DNA or polypeptides encoded thereby, but also patents claiming antibodies that are the foundation of widely used diagnostic assays. Despite the panel's implied exception of antibodies from the "precise definition" requirement, much less is known about the nature of antibody antigen/receptor binding than is known about the type of binding that occurs when two complementary strains of DNA hybridize.

[*279] While the Federal Circuit declined, over dissent, to rehear the *Enzo* appeal *en banc*, the first panel granted rehearing and reversed its holding that reference to deposited biological materials cannot contribute to the ability of the specification to meet the WDR. n16 The *Enzo II* panel recognized that a properly identified deposit functions as a description "in surrogate form" of a claimed invention, and can help satisfy the WDR. n17 The panel also cited with approval the hybridization example in the PTO WDR Synopsis, which could bode well for *Enzo* upon remand. n18 This finding also necessitated reversing the earlier holding affirming the invalidity of claim 1, which recited deposited reference sequences used to identify the claimed probes. n19 Unfortunately, the panel did not do so on the basis that the ability of a probe to hybridize to a reference sequence is a chemical property of the probe. Rather, the panel continued to refer to hybridization as a "functional ability" of the claimed probes, and cited the PTO WDR Guidelines with approval, again noting that antibodies could be described using functional characteristics, at least in part. n20

However, because claim 1 was generic to the three deposited probes, and claims 4 and 6, which recited the deposited probes, also claimed subsequences, mutants and/or variants of the deposited probes, the panel remanded the appeal to the district court, to resolve the issue of whether or not the claims, in fact, meet the WDR. The district court was not simply instructed to consider the deposits and hybridization disclosure, but also to evaluate the generic claim in view of the *Lilly* decision. n21 The panel also suggested that claim 1 might well be broader than the enabling disclosure. n22

The panel also strongly rejected Enzo's contention that the specification met the written description requirement because it literally supported the claim language (*in ipsis verbis*). The panel affirmed its holding in *Lilly* that the existence of a WDR in § 112 that is not simply a part of the enablement requirement leads to the conclusion that "an adequate written description of genetic material requires a precise definition, such as by structure, formula, chemical **[*280]** name or physical properties, not a mere wish or plan for obtaining the claimed chemical invention." n23

The continued viability of the *Lilly* "precise definition" test, coupled with the rejection by the panel of a limited role of the WDR in testing priority, could well lead the district court to reject all of the claims for failure to meet the WDR, despite the contributions of the deposit and hybridization disclosures. At least in part, this fact fueled the spirited exchange between the Judges who would have reheard the case *en banc* and reversed *Lilly*, led by Judge Rader, and the *Enzo II* panel, led by Judge Lourie, who appear to believe that

the "precise description" requirement of *Lilly* is necessary to save biotechnology inventors from themselves. n24 The arguments on both sides are set forth in the commentary which accompanied the order granting the petition for rehearing, but denying rehearing *en banc*. n25 Judge Lourie, the author of the decision of the *Enzo II* panel, authored an opinion concurring in the decision not to rehear *en banc* in which Judge Newman joined. Judges Newman and Dyk also concurred separately in the decision, while Judges Rader and Linn each filed dissenting opinions in which the other, and Judge Gajarsa joined.

Put simply, the debate within the Federal Circuit is between the Judges who want to return the WDR to its role in settling priority disputes, and the Judges who want the WDR to ensure that the specification demonstrates that the inventors had "adequate possession" of the invention -- to do something more than simply teach the interested public how to make and use the invention. Even a disclosure of actual reduction to practice (e.g., of actual possession), is not, *per se*, sufficient for this group. n26 The specification must also permit the art to "visualize or recognize the identity of the subject matter of the claim." n27

In his opinion, Judge Lourie argued that, not only does § 112 contain a WDR that is separate from enablement, but that the evolution of the WDR beyond its use in resolving support issues regarding priority, **[*281]** to impart a precise description requirement to the specification, is an appropriate interpretation of the statute. Judge Lourie believes that this evaluation of the WDR is necessary because of the fairly recent perception that patents are stronger, and thus, "claims are being asserted to cover what was not reasonably described in the patent." n28 Judge Lourie noted that this is also why "more doctrine of equivalents issues are in the courts." n29 In a rather conclusory statement, Judge Lourie argued that "a written description issue should not arise unless a patentee seeks to have his claims interpreted to include subject matter that he has not adequately disclosed in his patent. [In recent cases,] the losing patents (or applications) involved did not adequately disclose what was claimed." n30 He reiterated that "showing possession is not necessarily equivalent to providing a written description [of the full scope of the claim]," and that enablement alone does not equate to an adequate description. n31

Judge Rader responded with a blunt and well-researched dissent, including an appendix synopsis of 37 pre- and post-Lilly decisions in which the CCPA and Federal Circuit had applied the WDR ("WD") solely in the context of resolving support issues in priority disputes. His opening line: "The tortuous path of this case shows the perils of ignoring the statute and over thirty years of consistent written description case law," set the stage for his characterization of *Lilly* and *Enzo I* as aberrant decisions: "Because the [WDR] as created and applied for thirty years *does not apply to this case*, I would grant *en banc* review and correct the rest of this court's misapplication of the description requirement." n32 In terms of statutory interpretation, Judge Rader quoted from the United States' brief as *amicus curiae*, which took the position that the written description required by § 112 is only that which would permit others to make and use the invention. n33 Judge Rader went on to cite the recent decision in *J.E.M. AG Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, in which the Supreme Court noted that "a breeder must describe the plant [in the patent] with sufficient specificity to enable others to 'make and use' the invention after the patent term **[*282]** expires." n34 Judge Rader noted that the Supreme Court in *Festo* mentioned a description requirement separate from the enablement requirement, but did not otherwise endorse the *Lilly* and *Enzo* tests. n35 He argued that the CCPA carved a WDR from the § 112 enablement requirement to support rejections based on the introduction of new matter into the claims as opposed to

the remainder of the disclosure. n36 Citing *In re Wertheim*. n37 Judge Rader concluded that "WD was a new matter doctrine, a priority policeman... WD, the equivalent of the statutory new matter doctrine, simply has no application to claims without priority problems." n38

Judge Rader then summarized *Lilly*, as "not [testing] a later claim amendment against the specification for priority, but [rather asserting] a new free-standing disclosure requirement [the "precise definition" test] in place of the statutory standard of enablement." n39 Judge Rader went so far as to assert that a lack of enablement rejection would have been appropriate under the *Wands* test for enablement, since *inter alia*, "the patent's prophetic disclosure of human insulin cDNA hardly enabled its production as claimed." n40 He concluded that "WD had never been a free-standing substitute for enablement." n41

Judge Rader then specifically addressed the facts of the Enzo appeal, finding that the case presented no new matter or priority issues requiring application of the original WDR doctrine. He argued that remand on the WDR question was improper, since the only remaining issues were of enablement, not written description. n42 Judge Rader went on to explain why replacing enablement with the "aberrant form of WD" would be disruptive of the patent system, by permitting defendants to attack patents that meet the enablement requirement for failure to meet **[*283]** the new WDR. n43 He clearly believes that the enablement requirement is more than sufficient to "[serve] as the line of demarcation between the visionary theorist (adds nothing to the useful arts) and the visionary pioneer (contributes to the useful arts)." n44 In Judge Rader's view, *Lilly* imposed a new requirement for disclosure of a defined nucleotide sequence to support claims to DNA, and that this requirement both jeopardizes the validity of biotech claims issued pre-Lilly, and imposes an unfair burden on inventors who do not have the resources to meet the specific WDR prior to filing. n45

Judge Linn's dissenting opinion further emphasized what he also believes to be conflation of "two unrelated issues" -- possession of the invention as relevant to priority and putting the public in possession of the invention as required by the enablement requirement. n46 Judge Linn argued that possession of the invention "was not and should not be a test for sufficiency of disclosure, per se. It should have no place in and does not aid in the disposition of cases where the claims in question are part of the original disclosure. [Such claims] provide their own written description." n47

Thus, in late 2002, the legal battle lines are sharply drawn. One camp of Judges, led by Judge Rader, believes that the WDR is no more than a semantic test for the "right to use" the claim *language* in question. If the claim language is supported by the specification, the WDR is satisfied. Enablement is a separate issue that is to be resolved by application of the very fact- specific *Wands* factors. n48 The camp led by Judge Lourie expects a lot more from the WDR; along with the enablement requirement, it now imparts or denies the "right to claim" the *invention* at issue. That is nearly as equitable a mission as that assigned to the doctrine of equivalents.

However, contrary to Judge Rader's opinion, the elevated WDR of *Lilly* and *Enzo I* is not an absolute requirement for a complete recitation of structure or formulae in claims. Judge Lourie's discussion of claiming antibodies is an explicit recognition of this point. However, the **[*284]** new WDR *is* certainly something more than possession, which Judge Lourie has made clear is no safe harbor from the requirements of the WDR. The PTO, patent bar and their clients seemed to be able to live with the implicit "rules" of *Fiers* and *Amgen* that no disclosure of actual possession and no structure results in no valid claim to a biological material. n49 This just sounded like nonenablement. The *Lilly* rules

seemed to be that "one species does not support a generic DNA claim" (but two might) or that no disclosure of actual possession and functional claiming equals no valid claim. n50 Nonetheless, *Enzo II* remains troubling, even after the reversal of the first panel's position.

The WDR is evolving one fact situation at a time, and without *en banc* review, entire classes of patents will move in and out of its invalidity shadow. Two hypothetical fact patterns may serve to illustrate the uncertainties in the current WDR. In the first, an inventor isolates a new protein, factor X, from liver cells. The inventor knows nothing about the structure, or even the class of protein, such as an enzyme or a hormone, only that it is not an antibody. However, the protein binds to a receptor site on prostate cancer cells and blocks their division completely. If the inventor files at this point, the court is presented with actual possession and purely functional claiming. If the inventor deposits some of factor X, a step usually not taken with a pure chemical compound, the claim to "factor X" and its functional language could presumably be within the *Enzo* safe harbor. n51 If the inventor fails to deposit prior to issuance, the specification would not meet the WDR, the claims would be invalid, and a continuation-in-part fully characterizing factor X would not be entitled to the filing date of the parent, since the description of factor X in the parent would not meet the requirements of § 112. n52

In the second hypothetical case, an inventor uses computational chemistry to identify consensus sequences that are responsible for the enzymatic activity of a protein encoded by a series of related plant **[*285]** genes. The software developed by the inventor then "mixes and matches" the consensus sequences on the inert peptidyl framework to optimize the bioactivity of the enzyme, arriving at a genus of hypothetical high-activity enzymes, all defined by complete sequences. If the inventor files at this point, with adequate directions as to how to assemble the synthetic enzymes, he has produced a presumably enabling specification with complete structural data, but with no actual reduction to practice whatsoever. Is this an example of a specification that should fail the heightened WDR, or one that should meet the precise definition test of the new WDR? Do we need more than the *Wands* factors to evaluate the ability of the specification to place the invention in the hands of the public? Should this inventor, who never walked into a laboratory receive a patent, while the inventor of factor X be left with nothing but the satisfaction of curing cancer?

If factor X is an antibody, and the target is known, perhaps binding affinity language would meet the WDR. But what if it is a hormone, or a small molecule, or an "anti- inflammatory steroid," an example of inadequate description given by the panel? n53 And is it really the best use of the court's time to resolve endless fact situations on the basis of five words in the statute that provide no guidance whatsoever as to what they require, beyond some degree of correspondence between the specification and the claims? With the clearly articulated division of opinions within the court, the fate of any patent appealed from a WDR decision below will depend entirely on the panel that appellant draws. Whether or not the interested public all agree with the *Wands* requirements, they have proved to be a workable test for meeting the make-and-use requirement of § 112. It is time for the court to deliver *Lilly* and *Enzo (I)* to the doctrinal scrap heap where holdings like *Durden* n54 and *Druey* n55 ended up, and let the evolution of biotechnology patent law continue in a productive direction.

Legal Topics:

For related research and practice materials, see the following legal topics:

Civil ProcedureJudicial OfficersJudgesGeneral OverviewPatent LawClaims & SpecificationsClaim LanguageGeneral OverviewPatent LawDate of Invention & Priority-General Overview

FOOTNOTES:

n1 *35 U.S.C. § 112,* first paragraph: "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode...." This paragraph contains both a "written description requirement" and an "enablement requirement," and both can be used to invalidate or deny patent claims. *See, e.g., In re Goodman, 11 F.3d 1046 (1993)* (transgenic monocots not enabled by transgenic dicots); *Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999)* (antisense technology practiced in *Escherichia coli* does not enable practice in other organisms); *In re Vaeck, 947 F.2d 488 (Fed. Cir. 1991)* (expression of insecticidal proteins in all bacteria not enabled by expression in one species); *Amgen, Inc. v. Chugai Pharm. Co., Ltd., 927 F.2d 1200 (Fed. Cir. 1991)* (generic claim to EPO variants non-enabled); *Regents of the University of California v. Eli Lilly & Co., 119 F.3d 1559 (Fed. Cir. 1997)* (sequence of one cloned DNA sequence insufficient to describe genus) ("*Lilly*").

n2 *Enzo Biochem, Inc. v. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1618* (Fed. Cir., July 15, 2002)

n3 *Enzo Biochem, Inc, v. Gen-Probe Inc., 285 F.3d 1013, 62 USPQ2d 1289* (Fed. Cir., April 2, 2002) ("*Enzo I*").

n4 See 37 C.F.R. §§ 1.801-1.809 (2001).

n5 Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (Budapest, Hungary, April 28, 1977) and Regulations (January 31, 1981), WIPO pub. (1981). The treaty requires signatory countries to recognize a deposit with any International Depository Authority which has been approved by WIPO.

n6 *See, e.g., 285 F.3d at 1021-1022.* The panel stated that Enzo's showing of "'possession' of the invention [the deposits] does not contribute to its description in the patent specification." *Id. at 1021.*

n7 *119 F.3d 1559 (Fed. Cir. 1997).* The *Enzo I* panel stated that "hybridization from one DNA segment to another is just as much a functional definition as translation from a nucleic acid to a protein." *285 F.3d at 1018.*

n8 *Lilly, 119 F.3d at 1567-1568.*

n9 *Id. at 1568.* "A written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials."

n10 *285 F.3d at 1021* ("A showing of 'possession' is secondary to the *statutory mandate* that 'the specification shall contain a written description of the invention'").

n11 *285 F.3d at 1019. See* Guidelines for Examination of Patent Applications Under the *35 U.S.C. § 112,* P1, "Written Description" Requirement, *66 Fed. Reg. 1099* (Jan. 5, 2001), available at *http://www.uspto.gov*. A Synopsis of Application of Written Description Guidelines is available at the same website. The *Enzo I* panel found that "Enzo's claims do not meet that test [for a correlation of antibody binding with structure]. Enzo has not asserted that the claimed function is known to correlate to a specific structure..."

n12 *See, e.g., In re Robins, 429 F.2d 452 (CCPA 1970).*

n13 *See, e.g., In re Kamal, 398 F.2d 867 (CCPA 1968); In re Gottlieb, 328 F.2d 1016 (CCPA 1964); see* Utility Examination Guidelines, *66 Fed Reg. 1092* (Jan. 5, 2001).

n14 The group that has been treated as though it has lots of both possession and structure are the inventors of bioactive "small molecules," who can write traditional Markush-type claims covering large genuses of compounds based on a relatively small number of working examples.

n15 Including, as pointed out by H. C. Wegner, "An Enzo White Paper: A New Judicial Standard For a Biotechnology 'Written Description' Under *35 U.S.C. § 112,* P1," 1 *J. Marshall Rev. Intell. Prop.*, 254 (2002), patents prosecuted by Judge Lourie. As argued by Judge Rader in his commentary accompanying the Order on Petition for Rehearing accompanying *Enzo II* at page 13: "*Lilly* and now this case change the application of the WD test and 'up the ante' for disclosure -- a situation inventors might have addressed if they could have foreseen that this court would disrupt settled disclosure principles. At this point, those inventors have no way to change patents that comply with enablement disclosure, but not the stiffer demands of *Lilly*."

n16 *Enzo II. See* note 2, *supra*.

n17 *Id.* at 1326.

n18 *Id.* at 1324-1325. *See* note 11, *supra*.

n19 *Id.* at 1327.

n20 *Id.* at 1324-1325. *See* note 11, *supra*.

n21 *See* text accompanying notes 7-8, *supra*.

n22 *Enzo II* at 1327-1328.

n23 Id. at 1324.

n24 *Enzo Biochem, Inc. v. Gen-Probe Inc., 2002 U.S. App. LEXIS 14412 (Fed. Cir. 2002),* Opinions accompanying Order on Petition for Rehearing (July 15, 2002) (*Enzo II Order*). At page 7 of the slip opinion, Judge Lourie cited with approval an article by M. J. Stewart of Eli Lilly which stated that "the holding in *Lilly* actually avoided a disaster that would have crippled the biotechnology industry."

n25 *Id.*

n26 *Id.* at page 6 ("While 'possession' is a relevant factor in determining whether an invention is described, it is only a criterion for satisfying the statutory written description requirement. Showing possession is not necessarily equivalent to providing a written description").

n27 *Enzo I* at 1018.

n28 *Enzo II Order*, slip op. at 3.

n29 *Id.*

n30 *Id.* at 3-4.

n31 *Id.* at 6.

n32 *Enzo II Order* (Rader, dissenting) at 1-2.

n33 *Id.* at 2-3.

n34 *122 S. Ct. 593, 604 (2001).* The Supreme Court also recognized that the claimed seeds were described in part by reference to a deposit: "The description requirement for plants includes a deposit of biological material, for example, seeds, and mandates that such material be accessible to the public." *Id.*

n35 *122 S. Ct. 1831, 1840 (2002).*

n36 Citing *In re Ruschig, 379 F.2d 990 (CCPA 1967).*

n37 *541 F.2d 257 (CCPA 1976).*

n38 *Enzo II Order* (Rader, dissenting) slip op. at 6-7.

n39 *Id.* at 9.

n40 *Enzo II Order* (Rader, dissenting) slip op. at 9-10.

n41 *Id.* at 10.

n42 *Id.* at 11-12.

n43 *Id.* at 12-13.

n44 *Id.* at 13-14.

n45 *Id.* at 15.

n46 *Enzo II Order* (Linn, dissenting) slip op. at 3.

n47 *Id.* at 2.

n48 *In re Wands, 858 F.2d 731 (Fed. Cir. 1988).* These eight factors, used for determining whether or not the enablement requirement is met, include the nature of the invention, the breadth of the claims, the level of ordinary skill in the art, the level of predictability in the art and the existence of working examples. *See* also M.P.E.P. 2164.01(a) (8th ed. 2001).

n49 *Fiers v. Revel, 984 F.2d 1164 (Fed. Cir. 1993); Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200 (Fed. Cir. 1991).*

n50 *See* text accompanying note 9, *supra*.

n51 The American Type Culture Collection does not list "proteins" as materials it will accept for deposit (http://www.atcc.org).

n52 *35 U.S.C. § 120.*

n53 *Enzo II* at 1329.

n54 *In re Durden, 763 F.2d 1406 (Fed. Cir. 1985)* (patentability of process depends on inventiveness of process steps).

n55 *In re Druey, 319 F.2d 237 (CCPA 1963)* (patentable intermediate must have intrinsic utility).