The Use of Examples in Patent Applications

By Bratislav Stanković

> For although education may furnish, and, as it were engraft upon a limited understanding of rules borrowed from other minds, yet the power of employing these rules correctly must belong to the pupil himself; and no rule which we can prescribe to him with this purpose is, in the absence or deficiency of this gift of nature, secure from misuse. A physician therefore, a judge or a statesman, may have in his head many admirable pathological, juridical, or political rules, in a degree that may enable him to be a profound teacher in his particular science, and yet in the application of these rules he may very possibly blunder-either because he is wanting in natural judgment (though not in understanding) and, whilst he can comprehend the general in abstracto, cannot distinguish whether a particular case in concreto ought to rank under the former; or because his faculty of judgment has not been sufficiently exercised by example and real practice. Indeed, the grand and only use of examples is to sharpen the judgment.[1]

Examples are useful in clarifying, reinforcing, or personalizing ideas. People typically learn by examples and often seek examples to help clarify a concept.[2] In patent applications, well integrated use of examples in the specification can be an effective way of communicating and illustrating a prototype for a class, a point, concept, or procedure of the invention. The number of examples given in a specification may affect the issue of how broadly the inventor may claim his or her invention.

Patent applications do not always contain examples. Some practitioners frequently use examples when drafting patent applications; for others, providing examples in support of the disclosure is unheard of. The use of examples is particularly practiced in the area of biotechnological and chemical inventions.[3]

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The history and the evolution of the rationale behind the unwritten requirement for the use of examples in patent applications are highlighted here. Seminal cases are used to identify reference points for determining when an examiner would typically require the applicant to provide examples of the invention and when might a patent be held invalid for want of examples. When should the patent attorney advise the client to go back to the drawing board or to the lab and conduct a few experiments, generating examples that will support the claimed invention?

Legal Framework

Inventors will obtain a patent from the US Patent and Trademark Office (PTO) if their invention is useful, novel, nonobvious, sufficiently described, and enabled in the patent application.[4] An applicant for a patent must "particularly point out and distinctly claim" the invention.[5] Three separate requirements under 35 U.S.C. § 112 exist: the specification needs to (*1*) contain a written description of the invention, (*2*) enable the invention through description of the manner and process for making and using it, and (*3*) set forth the best mode contemplated by the inventor of carrying out the invention. These patentability requirements have evolved unique properties in different technological areas.[6] Use of illustrative examples in the specification can help meet some or all of these requirements, teaching one skilled in the art how to make and use the invention as broadly as it is claimed.[7] However, interpretation of a patent claim is not limited to the examples that are described in the specification; rather, the scope of the patented invention is defined by the words in the claims that are supported by the specification.[8]

The US patent system matured in parallel with the industrial technologies. The first US patent that used an example to illustrate a claimed invention was issued in 1839. An example was used to illustrate the teachings of the invention[9] in a patent for a method of constructing flues of stoves. The ensuing increase in emphasis on technical disclosure, which occurred in the late 18th century, was manifested in the increasingly stringent requirement that the patent applicants describe their inventions clearly and completely. Toward the end of the 20th century, the increased complexity of inventions

in the fields of biotechnology and chemistry created a problem of unpredictability of disclosures in patent applications. This resulted in increased demand by the PTO for disclosure of specific, working examples. In many instances, the question became whether a specification that set forth a single or a limited number of examples could enable broad claims when the subject matter concerns biological materials or chemical reactions, which are generally considered to be unpredictable.[10] Recognizing that on this issue the examiners in this area did not appear to practice uniformly, in 1982 the PTO Board of Appeals dealt for the first time with the issue of need for examples in patent applications.[11] Since then, decisions by both the PTO Board of Appeals and the US Court of Appeals for the Federal Circuit (CAFC) have attempted to clarify when working examples are required to satisfy the requirements of 35 U.S.C. § 112,¶ 1.[12]

In patent applications, working examples typically correspond to work actually performed; the examples may describe experimental results, tests that have been conducted, and results that have been achieved. Additionally allowed is the use of prophetic examples and simulated or predicted test results.[13] The use of examples that are a combination of actual experiments is also allowed.[14] Not every example disclosed needs to be operative, nor does it have to give every detail of a necessary procedure to be followed; certain details may be left to the judgment of the skilled worker.[15] No formulae exist for determining the number of examples necessary to satisfy the disclosure requirement. Rather, the necessity for examples as part of the disclosure depends on the claims' breadth and on the degree of predictability in the pertinent art. The broader the claim and the less predictable the technological area (*e.g.*, chemistry or biotechnology as opposed to the more predictable mechanics or electronics), the greater the disclosure must be.[16] The need for examples increases in unusual instances when the disclosed device is of such nature that it cannot be tested by any known scientific principles. Then it is incumbent on the applicant to demonstrate the workability and utility of the device.[17] For example, 19 examples were not enough to support a claim "embracing many thousands of chemical compounds."[18] When a specification contained detailed analysis of preparation of the product, but none of the examples (powders created) satisfied the claim limitations, the patent was found to be invalid.[19] In another case, when patentability was predicated upon a catalytic phenomenon, the disclosure was necessarily limited to the single example that was disclosed in the specification.[20] Such a disclosure was deemed to be unsupportive of the broad terminology of the claims.[21]

If the mode of operation can be readily understood and conforms to the known laws of physics and chemistry, operativeness is not questioned and no further evidence is required.[22] This paramount principle holds true even when the disclosed invention can be practiced only on the moon. Indeed, the PTO Board of Appeals held that the gravity differences between the earth and the moon cannot be viewed as significant, when man was aware of them, and when known engineering principles could be applied and used in establishing an operative system on the moon.[23] Back on earth, to claim a genus, representative examples, together with a statement applicable to the genus as a whole, are ordinarily deemed sufficient, so long as a skilled artisan could be using the invention without undue experimentation.[24]

Problems related to the standards for use of examples in patent applications arise due to the heterogeneity of patent law in different jurisdictions. Certain countries issue patents for a "process only"; other countries do not. For process-only applications, inclusion of specific working examples frequently determines patent protection.[25] An applicant filing in multiple countries should be aware of possible obstacles to his patent application.

Use of Examples to Enable an Invention

Providing specific, working examples in a patent application facilitates, if not ensures, enablement of an invention.[26] Patent draftsmen are not loath to provide actual or constructive examples, with details, concerning what they wish to claim.[27] This is true particularly in applications involving unpredictable and undeveloped art.[28] However, compliance with the enablement requirement of 35 U.S.C. § 112 does not turn on whether an example is disclosed.[29] Even in the unpredictable arts, there is no mandatory need for any number of specific working examples in order to comply with the enablement requirement of 35 U.S.C. § 112.[30] The specification need not contain an example, if the invention is otherwise disclosed in such manner that a skilled artisan would be able to practice the invention without an undue amount of experimentation.[31]

The number and variety of examples are irrelevant if the disclosure is enabling.[32] There is no legal requirement that all of the examples in the patent specification actually be reduced to practice before the filing of the application; it is only required that the specification contain a disclosure that enables those skilled in the art to practice the invention.[33] If an invention pertains to art involving mechanical or electrical elements, disclosure, by a single example, of a way to make and use the claimed invention, can enable a broad claim.[34] In cases involving unpredictable factors, such as most chemical reactions and biological activity, greater disclosure

is required.[35] In such cases, the scope of enablement varies inversely with the degree of unpredictability of the factors involved.[36] To determine satisfaction of the enablement requirement, courts analyze the nature and the predictability of the art and examine the disclosure through a field-specific lens. Presence of working examples facilitates the satisfaction of the enablement requirement. An applicant cannot broadly claim an invention if only part of that invention is enabled. In deciding patentability of inventions, the use of examples has played a significant part.[37]

The complexities inherent in biotechnology patents are illustrated through the famous *Amgen* erythropoietin (EPO) case, where deficiency in the number of examples precluded patentability of this invention.[38] The applicant claimed all possible DNA sequences that would encode for the protein and all of its analogs, while only describing how to make a few of those. The purpose of such a claim was to prevent a subsequent party from subtly changing the DNA or amino acid sequence in an attempt to invent around the disclosed invention. That turned out to be a fatal mistake, as the patent was found to be too broad and did not enable one skilled in the art the ability to practice the full scope of the invention.[39] Similarly, broad claims to a method for producing any desired mammalian peptide in any plant cell were rejected when the applicant's specification gave only a single working example of how to practice the method.[40] That single example was found not to enable a biotechnician of ordinary skill to produce any type of mammalian protein in any type of plant cell, as claimed.[41] Claims were found invalid for lack of enablement when a significant amount of experimentation is needed to secure stable insertion of a heterologous gene into a monocot plant cell.[42] The absence of experimental data was evidence for lack of enablement for an invention claiming the insertion of an insect-resistant gene into a plant cell.[43] Additionally, an application that showed working examples in tobacco did not enable the method in other plant species, including a closely related tomato species.[44] Since the specification taught that transformation of other plant species was not predictable, the claim was not allowed under 35 U.S.C. § 112.[45]

When the claims were broadly drafted to encompass the application of antisense technology in a wide range of organisms, but the specification disclosed working examples for controlling the expression of only three genes in a single bacterium, the application could not broadly enable the use of antisense technology in all organisms.[46] The breadth of enablement in the patent specification was not commensurate in scope with the claims, as the quantity of experimentation required to practice antisense in cells other than *E. coli* would have been undue.[47] When a patent application claimed processes for producing live, nonpathogenic vaccines against any pathogenic RNA virus and for using these vaccines to protect all living organisms against that RNA virus, and yet the specification gave only a single working example, it was deemed insufficient experimental or documentary evidence to support utility or enablement.[48] The single example and the general description only invited experimentation to determine whether other vaccines having *in vivo* immunoprotective activity could be constructed for other RNA viruses.[49] Similarly, claims involving preparation of vectors for yeast transformations generally were not enabled by a specification that disclosed the making of a vector replicable in only one yeast species, *Saccharomyces cerevisiae*.[50] Indeed, the term yeast as used in the claims included a number of diverse fungi that are quite different, morphologically and biochemically, from *S. cerevisiae*. The rejection used the standard language indicating that a single embodiment may provide broad enablement in cases involving predictable factors, such as mechanical or electrical elements, whereas in cases involving unpredictable factors, including most chemical reactions and physiological activity, more is required.[51] Inadequacy of the disclosed experimental data precluded patentability of the biological invention.

A litany of examples in a patent application does not automatically guarantee enablement. Even the inclusion of examples in the written description of a patent on nucleic acid tests was insufficient to enable a broadly claimed method for nucleic acid diagnostic assays.[52] When the disclosed examples are simply an invitation to perform extensive experimentation to practice the suggested method, they are insufficient to enable the invention.[53] In an unpredictable technology such as chemistry, examples that are very similar to each other do not suffice to enable a broadly claimed invention.[54]

Examples and Undue Experimentation

A specification need not contain a working example if the invention is otherwise disclosed in such a manner that one skilled in the art will be able to practice it without an undue amount of experimentation.[55] Absence of a working example, as such, is not the ultimate test.[56] The lack of a working example is in itself insufficient ground for rejection of a claim.[57] Moreover, an applicant is not required to disclose a test using every species covered by a claim.[58] Requiring such a detailed and complete disclosure would require a patent application with thousands of examples, forcing an inventor to carry out a prohibitive number of actual experiments.[59] That would discourage inventors from

filing patent applications in unpredictable areas since the patent claims would be limited and easily avoided. The proper question is whether, given the disclosure as a whole, including operative examples and given the unpredictability of the art, a skilled artisan must engage in undue experimentation to determine which species would work.[60]

The oft-cited *Wands* decision sets forth eight factors that a court should consider in determining whether a disclosure is enabling or undue experimentation is required to practice the claimed invention.[61] One of these factors is *the presence or absence of working examples* (emphasis supplied). As the *Wands* factors are illustrative, not mandatory, the court is required to consider only those factors that are relevant to the facts of each case.[62]

The unpredictability of a particular art area may alone provide a reasonable doubt as to the accuracy of a broad statement made in support of the enablement of a claim. In the unpredictable arts, although an inventor may understand the theory behind an invention, the inventor may not know or understand the subtle variations that practically enable the invention.

In the chemical arts, an overly broad claim to an improved immunoassay method using catalysts generally was not allowed, when the specification disclosed a single example in which the catalyst is an enzyme.[63] The nature of the catalyst enzyme was critical to the claimed method and the specification incorporated by reference a patent disclosing a wide variety of non-enzymatic catalysts. It turned out that, because the enzyme and non-enzyme catalysts were so divergent, it was not unreasonable to require a reasonable number of examples in support of the broad claim.[64]

Overly broad or generic claims to biologicals, unsupported by working examples, are not allowed. One working example involving a single mature protein was insufficient for broadly claiming a yeast expression vehicle and a protein expression method.[65] The rationale is sound: Such a broad claim would be open to embodiments in which genes are inserted in positions other than that those demonstrated by the working example, thus a skilled artisan would not be able to determine the scope of practice of the claimed invention.[66] Similarly, when an invention claims the application of an unpredictable technology in the early stages of development, an enabling description in the specification must provide a specific and useful teaching, including actual or constructive detailed examples. A specification describing the production of a recombinant protein with no leader sequence, without describing in any detail whatsoever how to make it, was determined to be insufficient.[67] Not every aspect of a generic claim needs to have been carried out by an inventor or exemplified in the specification; nonetheless, reasonable detail must be provided in order to enable the invention.[68] In absence of reproducible working examples, a claim to a generic class of hybrid vaccines was rejected as being based on an insufficiently enabling disclosure.[69] The PTO Board of Appeals held that experiments in genetic engineering produce, at best, unpredictable results.

Broad claims to genes and transformed cells are not allowed when there is no correlation between the narrow disclosure in the specification and the broad scope of protection sought. Thus, the disclosure of only two working examples in a broadly claimed genetic engineering application was deemed insufficient.[70] In support of generic claims in unpredictable art areas, there must be sufficient disclosure (*e.g.*, through illustrative examples) to teach how to make and how to use the invention as broadly as claimed.

Difficult questions arise when examples are disclosed, but certain experimental details are omitted. When an example in a patent application was based on an *in situ* hybridization experiment involving RNase, but the inventor failed to disclose the RNase treatment in the specification, the patent was invalidated.[71] Although it turned out that the inventor may have eventually concluded that RNase was not necessary in all cases for practicing the invention, it was unclear what the inventor's state of mind was at the time of the filing. Because inventors typically use patent examples that are representative of their work, the omission of any reference to RNase in the example might seem purposeful and could have misled others to believe that RNase treatment was not desirable in the application.[72]

Technical or factual errors in the examples do not automatically constitute irreversible errors. Experimentation that is otherwise reasonable is not rendered unreasonable merely because there is a technical or factual error in the specification's examples, provided the error is easily detectable by one of ordinary skill in the art.[73] Further, one needs to look at the disclosed examples in a laboratory setting.[74] A patent is considered to be a starting point; indeed, a patent discloses basic information by which one could practice the invention in a laboratory setting.[75]

Use of Examples to Meet the Best Mode Requirement

In the Patent Act of 1952, § 112 broadened the best mode provision to cover all kinds of inventions, not just machines.[76] To meet the best mode requirement, the written description part of the specification must disclose the best way known to the inventor for practicing the invention. This is usually done by disclosing examples of the invention.[77]

Specific, working examples are often included in patent specifications because examples can be the best method of teaching how to make and use the invention. These examples need not necessarily be based on actual experiments; prophetic examples that are described in the specification in present tense may suffice.[78] Moreover, the results shown may be of actual experimental tests that are further modified to reflect the most effective intended formulation.[79]

The standard of art (un) predictability is again applied. In a patent application describing a relatively simple mechanical invention, the best mode requirement did not dictate the inclusion of a working example to comply with the enablement requirement. The disclosure, lacking a working example, was found in compliance with the requirements of section § 112.[80]

The absence of a specific working example is not necessarily evidence that the best mode has not been disclosed; nor is the presence of example evidence that it has.[81] An inventor may represent his contemplated best mode by a preferred range of conditions or a group of reactants; alternatively, the contemplated best mode may be presented by a working example that employs unitary values of each variable involved.[82]

Examples and the Issue of Correlation

The concept of "correlation" in patent applications relates to an aspect of the presence of working examples in the disclosure, in support of the claims of the biological invention. Used in the context of a claimed method, correlation refers to the relationship between *in vivo* and *in vitro* model assays (typically assays with animal model systems) disclosed in the application.[83] An *in vitro* animal model example in the specification may constitute a working example, if it correlates with a disclosed *in vivo* method of the claimed method invention. Patentability is not allowed when the *in vitro* data do not support *in vivo* applications; the examples in the application are not deemed to constitute working examples.[84]

There is merit in applying the principle of correlation, because, for a given compound or process assayed, the *in vitro* test results do not always correlate with the *in vivo* outcomes. At the same time, there is difficulty in applying a rigid standard to non-linear, biological compounds, methods and processes. The PTO examiner must weigh the evidence and decide whether a skilled artisan would accept the *in vitro* model as reasonably correlating to the condition. Thus, establishment of the level of correlation becomes a factual determination. Rigorous or exact correlation between *in vitro* test results and *in vivo* test results is not required.[85]

Conclusion

The US Patent and Trademark Office does not have a requirement for experimental evidence to demonstrate the utility or function of any invention. However, there are instances when the use of specific (working) examples might be the easiest or the only method to adequately describe an invention. The technological field will dictate the relative importance of inclusion of examples in a patent application. There is a correlation between the need for examples and the unpredictability, complexity, and increase in the breadth of the invention, which is particularly obvious in respect to meeting the 35 U.S.C. § 112, ¶ 1 requirements.

As the unpredictable arts mature and become more predictable, the pendulum might start to swing in the other direction. The CAFC recently stated that a sequence need not appear in a patent specification to support a DNA-based invention, provided that the state of the scientific knowledge includes such structural information.[86] While the PTO Board of Patent Appeals and Interferences had opined that neither party's specification satisfied the patent statutes' written description requirement as it relates to a sequence-based biological invention, the CAFC concluded that the PTO Board had erred in its application of the written description law.[87]

The overlapping technological interfaces between the predictable and the unpredictable arts blur the line delineating the need for use of examples in patent applications. Nanotechnology epitomizes this quandary. Patents in the newly created nanotechnology class encompass both living and non-living inventions in the atomic, molecular, or macromolecular levels. It is unclear what standards the courts will apply when facing questions on the need for providing examples for nanotechnology inventions. The existing principles of (un)predictability in the art appear to currently influence the PTO.[88]

The above-referenced examples (no pun intended) highlight the development of the requirement for working examples. A driving force in the evolution of this requirement appears to have been the progression of the biotechnological and chemical inventions to a point where they were no longer unpredictable because the specifications would enable overly broad claims. The CAFC's solution was to increase the level of scrutiny and to use the disclosure of examples as a tool to invalidate overly broad claims for want of specific, working examples.[89] The very nature of chemical compounds, nucleic acids, proteins, and physiological processes makes claiming all possible aspects of the invention nearly impossible, which reduces the patent protection and opens the door to a second party's misappropriating some aspects of the discovery. It is

possible that many of the earlier issued biotechnology patents will not withstand the current levels of scrutiny.[90] There is a reason for caution when attempting to draft broad chemical and biological claims. Certainly, there is an increased need for use of specific, working examples in patent applications, particularly in the technological areas of biology and chemistry. Until the unpredictable arts become more predictable, practitioners should take note.

Notes

1. Immanuel Kant, "Of the Transcendental Faculty of Judgment in General," in Critique of Pure Reason (Cambridge University Press, 1999).
2. The Austrian philosopher Ludwig Wittgenstein maintained that sentences and concepts are pictures or images, an idea he arrived at by seeing a diagram of an accident. Also, query by example is a widely used method for querying a database.
3. Donald S. Chisum, Chisum on Patents, § 7.03[4][d][i], at 7-64 (2003).
4 Patent Act of 1952, 35 U.S.C. § 1-376 (1994 & Supp. II 1996).
5. *Id*.
6. "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention…." 35 U.S.C. § 112 (2004).
7. In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991).
8. *See* Specialty Composites v. Cabot Corp., 845 F.2d 981, 987 (Fed. Cir. 1988). In a typical PTO action rejection received under § 103, the PTO examiner views the person of ordinary skill in the art as a genius. "This person has anticipated every possible complex development, regardless of how many patents and publications it takes to combine to meet what is in the claims. Two pages later, under § 112, this person becomes a blithering idiot, unable to follow even step-by-step instructions of the examples in the patent application in order to practice the same invention that was obvious two pages earlier." *See* Franklin Pierce Law Center's Fifth Biennial Patent System Major Problems Conference, "Additional Major Problems," 36 *IDEA* 443, 462 (1996).
9. US Pat. No. 1,395 (issued Oct 31, 1839).
10. Chisum on Patents, § 7.03[4][d], at 7-63 (2002); *see also* Brian P. O'Shaughnessy, "The False Inventive Genus: Developing a New Approach for Analyzing the Sufficiency of Patent Disclosure within the Unpredictable Arts," 7 *Fordham Intell. Prop. Media & Ent. L.J.* 147, 155-56 (1996) (stating that "[L]iving materials such as microorganisms or cultured cells, and other aspects of biochemistry and genetic manipulation …are generally categorized as among the unpredictable arts").
11. Ex parte Jackson, 217 U.S.P.Q. (BNA) 804 (Bd. Pat. App. & Int'f 1982).
12. Astra Aktiebolag v. Andrx Pharm., 222 F. Supp. 2d 423 (S.D.N.Y. 2002), citing In re Strahilevitz, 668 F.2d 1229, 212 U.S.P.Q. 61 (C.C.P.A. 1982).
13. MPEP § 608.01(p) (2002); Atlas Powder Co. v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984).
14. Hoffmann-La Roche, Inc. v. Promega Corp., 323 F.3d 1354, 66 U.S.P.Q.2d (BNA) 1385 (Fed. Cir. 2003).
15. Farrington v. Mikeska, 155 F2d 412, 69 U.S.P.Q. (BNA) 509 (C.C.P.A. 1946).
16. Ex parte Sudilovsky, 21 U.S.P.Q.2d 1702, 1705 (Bd. Pat. App. & Int'f 1992), stating the principle that "[t]hough not controlling, the lack of working examples is…a factor to be considered in a case involving both physiological activity and an undeveloped art."; Smith v. Bousquet, 111 F.2d 157, 45 U.S.P.Q. (BNA) 347 (C.C.P.A. 1940), holding that "[i]n the experimental sciences of chemistry and biology this element of unpredictability frequently prevents a conception separated from actual experiment and test." *See also* In re Vaeck, 947 F.2d 488, 496, holding that when a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than the disclosure of an invention involving a "predictable" factor such as a mechanical or electrical element.
17. In re Perrigo, 48 F.2d 965, 9 U.S.P.Q. 152 (C.C.P.A. 1931).
18. In re Cavalitto, 282 F.2d 363, 127 U.S.P.Q. (BNA) 206 (C.C.P.A. 1960).
19. Bayer AG v. Sony Electronics, Inc., 229 F. Supp. 2d 332 (D. Del. 2002).
20. In re Grant, 304 F.2d 676, 134 U.S.P.Q. (BNA) 248 (C.C.P.A. 1962).
21. *Id*.
22. In re Gazave, 379 F.2d 973, 154 U.S.P.Q. (BNA) 92 (C.C.P.A. 1967).
23. Ex parte *McKay,* 200 U.S.P.Q. 324, 326 (PTO Bd. App. 1975). The disclosure was adequate to teach the artisan how to practice the invention, "leaving him, at most, with only a minimum of routine experimentation to cope with and which is not in derogation of 35 U.S.C. §112."
24. MPEP § 2164.02 (2002).
25. Akim F. Czmus, "Biotechnology Protection in Japan, the European Community, and the United States," 8 *Temp. Int'l & Comp. L.J.* 435 (1994).
26. David S. Wainwright, "Patenting Around Nuisance Prior Art," 81 *J. Pat. & Trademark Off. Soc'y* 221 (stating that "It can be difficult for one outside the art to know whether a specific item is enabling or not. However, suspicious items can include patent applications which disclose no real examples.").
27. Genentech, Inc. v. Novo Nordisk, 108 F.3d 1361, 42 U.S.P.Q.2d 1001 (Fed. Cir. 1997), *cert. denied*, 522 U.S. 963 (1997).
28. Matthew D. Kellan, "Making Sense Out Of Antisense: The Enablement Requirement In Biotechnology After *Enzo Biochem v. Calgene*," 76 *Ind. L.J.* 221, 230 (2001).
29. MPEP § 2164.02 (2004).

30. *Genentech*, 108 F.3d 1361, 42 U.S.P.Q.2d 1001.
31. In re Borkowski, 422 F.2d 904, 910, 164 U.S.P.Q. 642, 646 (C.C.P.A. 1970).
32. *Borkowski*, 422 F.2d at 910, 164 U.S.P.Q. at 646.
33. Corning Glass Works v. Sumitomo Elec. U.S.A. Inc., 671 F. Supp. 1369, 1391, 5 U.S.P.Q.2d 1545 (S.D.N.Y. 1987), *aff'd*, 868 F.2d 1251, 9 U.S.P.Q.2d 1962 (Fed. Cir. 1989).
34. Spectra-Physics v. Coherent, Inc., 827 F.2d at 1533 (Fed. Cir. 1987); *see also* Ex parte Hitzeman, 9 U.S.P.Q. 2d (BNA) 1821 (Bd. Pat. App. & Int'f 1987).
35. *Hitzeman,* 9 U.S.P.Q.2d (BNA) 1821; In re Vaeck, 947 F.2d 488.
36. In re Fisher, 427 F.2d at 833, 839, 166 U.S.P.Q. (BNA) 1, 19 (C.C.P.A. 1970).
37. *Id.*; Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362 (Fed. Cir. 1999); In re Goodman, 11 F.3d 1046, 29 U.S.P.Q. 2d (BNA) 2010 (Fed. Cir. 1993).
38. *Amgen,* 927 F.2d 1200.
39. *Id.* at 1213. Although "it is not necessary that a patent applicant test all the embodiments of his invention," an applicant must disclose "how to make and use enough sequences to justify grant of the claims sought."
40. In re Goodman, 11 F.3d 1046 (Fed. Cir. 1993).
41. *Id.* at 1050-1051 (discussing the field's unpredictability).
42. Plant Genetic Sys. v. Dekalb Genetics Corp., 175 F. Supp. 2d 246 (D. Conn. 2001).
43. Mycogen Plant Sci., Inc. v. Monsanto Co., 61 F. Supp. 2d 199 (D. Del. 1999).
44. Adang v. Kemp, 286 F.3d 1346, 62 U.S.P.Q. 2d (BNA) 1054 (2002).
45. *Id.*
46. *Enzo Biochem*, 188 F.3d 1362 (discussing how the enablement requirement requires a patent applicant to adequately disclose the invention so that others may practice it).
47. *Id.* at 1377.
48. In re Wright, 999 F.2d 1557, 1561-1563 (Fed. Cir. 1993). The court held that the claims were so broad that "they would encompass vaccines against AIDS viruses. Today it is clear that no one has yet, years after [Wright's] invention, developed a generally successful AIDS virus vaccine."
49. *Id.*
50. *Hitzeman*, 9 U.S.P.Q. 2d (BNA) 1821.
51. *Id.* The specification failed "to provide those having ordinary skill in the art reasonable assurance, as by adequate representative examples, that vectors and yeast transformants falling within the scope of the appealed claims can be prepared and used."
52. Gen-Probe, Inc. v. Vysis, Inc., No. 99-CV-2668 H (AJB), 2002 U.S. Dist. LEXIS 25020 (S.D. Cal. Aug. 2, 2002) (vacated and remanded on other grounds).
53. *Id.* at 70, 77-80.
54. Glaxo Wellcome, Inc. v. Eon Labs Mfg., Inc., No. 00 Civ. 9080 (LMM), 2002 U.S. Dist. LEXIS 14950 (S.D.N.Y. Aug. 13, 2002).
55. Ex parte Krenzer, 199 U.S.P.Q. 227, 229 (Bd. Pat. App. & Int'f 1978).
56. Shanks v. Scheffer, 204 U.S.P.Q. 781, 783 (Bd. Pat. Int'f. 1979).
57. In re Stephens, 529 F.2d 1343, 188 U.S.P.Q. 659 (C.C.P.A.1976).
58. In re Angstadt, 537 F.2d 498, 190 U.S.P.Q. 214 (C.C.P.A.1976); *see also* In re Marzocchi and Horton, 169 U.S.P.Q. 367 (C.C.P.A. 1971), discussing how many examples are needed to support a generic chemical claim.
59. *Id.* at 502-503 ("The examples, both operative and inoperative, are the best guidance this art permits, as far as we can conclude from the record").
60. *Id.* at 503.
61. In re Wands, 858 F.2d 731 (Fed. Cir. 1988).
62. Amgen Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213, 18 U.S.P.Q. 2d (BNA) 1016 (Fed. Cir. 1991).
63. Ex parte Sizto, 9 U.S.P.Q. 2d (BNA) 2081 (Bd. Pat. App. & Int'f 1988).
64. *Id.*
65. Ex parte Singh, 17 U.S.P.Q. 2d (BNA) 1714 (Bd. Pat. App. & Int'f 1990) (the claim was directed to a "DNA sequence encoding a lys arg C-terminal pre-pro peptide of yeast alpha factor gene operably connected in translation reading frame without intervening Glu (or Asp) Ala dipeptide repeats to a DNA sequence encoding a mature protein heterologous to the yeast strains.").
66. *Id.*
67. *Genentech*, 108 F.3d 1362.
68. *Id.* at 1366.
69. Ex parte Forman, 230 U.S.P.Q. (BNA) 546 (1986). The PTO Board held that it may, in fact, be impossible to present an exactly reproducible working example in cases of this type.
70. *Vaeck*, 947 F.2d 488, 496. The rejection relied, *inter alia*, on the relatively high degree of unpredictability in this particular art, on the heterogeneity of the bacterial host, and on the unpredictability of heterologous gene expression in cyanobacteria.
71. Regents of the Univ. of Cal. v. Oncor, Inc., 44 U.S.P.Q. 2d (BNA) 1321, No. C-95-3084-VRW, 1997 U.S. Dist. LEXIS 15068 (N.D. Cal. Aug. 19, 1997).
72. *Id.*
73. PPG Indus., Inc. v. Guardian Indus. Corp., 75 F.3d 1558, 1564, 37 U.S.P.Q. 2d 1618, 1624 (Fed. Cir. 1996).
74. Syntex (U.S.A.) Inc. v. Paragon Optical Inc., 7 U.S.P.Q. 2d (BNA) 1001, 1009 (D. Ariz. 1987).
75. *Id.*
76. *Chisum on Patents*, § 7.02[4], at 7-8.
77. Jon O. Nelson, "Patentability of Inventions and Grant of Patents," 35 *U.S. N.I.T.A.* § 112 (2003).
78. MPEP § 608.01(p) (2004); *see also* Atlas Powder Co., v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984).
79. Atlas Powder Co., v. E.I. du Pont de Nemours & Co., 750 F.2d 1569, 224 U.S.P.Q. 409 (Fed. Cir. 1984).
80. In re *Gay,* 309 F.2d 769, 135 U.S.P.Q. 311 (C.C.P.A. 1962).
81. In re Honn and Sims, 364 F.2d 454, 462, 150 U.S.P.Q. 652, 658 (C.C.P.A. 1966).

82. *Id*.
83. MPEP § 2164.02 (2002).
84. *Id*.; *see also* In re Brana, 51 F.3d 1560, 1566, 34 U.S.P.Q. 2d 1436, 1441 (Fed. Cir. 1995).
85. Cross v. Iizuka, 753 F.2d 1040, 1050, 224 U.S.P.Q. 739, 747 (Fed. Cir. 1985).
86. Capon v. Eshhar v. Dudas, U.S. Court of Appeals for the Federal Circuit, Case No. 03-1480, -1481, decided Aug. 12, 2005.
87. *Id*. (In the PTO Board's words "We are led by controlling precedent to understand that the full scope of novel chimeric DNA the parties claim is not described in their specifications under the 35 U.S.C. §112, first paragraph…in accordance with the plans, schemes, and examples thereof the parties disclose.").
88. Compare recently granted U.S. Pat. Nos. 6,708,160; 6,581,048; 6,281,503 (nanobiology patents that use examples) with U.S. Pat. Nos. 6,894,327; 6,891,227 (nanoelectronics patents that do not use examples).
89. Margaret Sampson, "The Evolution of the Enablement and Written Description Requirements under 35 U.S.C. § 112 in the Area of Biotechnology," 15 *Berkeley Tech. L.J.* 1233 (2000).
90. *Id*. at 1235.