Patentability of Chemical and Biotechnology Inventions: A Discrepancy in Standards

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The United States Constitution sets forth provisions that promote the progress of science and useful arts. Industrious parties heed the call to create and to have their inventions patented. Once an invention is patented, the inventor alone reaps the benefits of his creation and has the right to exclude others from using his invention. In return for this period of exclusive use, the inventor fully discloses his invention to the public.

Today, obtaining patent rights is essential to the viability of corporate America, and arguably, of the national economy. This is especially true for the pharmaceutical industry, where companies invest hundreds of
millions of dollars in drug discovery. In order to ensure a return on their investments in drug discovery and development, pharmaceutical companies guard their patent rights for the full duration of the patent’s life and often seek extensions on that life. The pharmaceutical-company patentees dread the expiration of a patent term, which can, and often does, adversely affect Wall Street’s valuation of the company.

Pharmaceutical companies have patented a large number of therapeutic chemical and biological compounds. Statutory patentability requirements must be satisfied in order for a patent to issue, and these requirements apply to all utility patents in every field of invention. However, over the last century the area of chemical practice has developed, resulting in a set of patentability standards and requirements that are unique to chemical inventions. These standards surpass the level of review prescribed by statute and result in higher scrutiny by the United States Patent and Trademark Office (“PTO”) and the courts for these types of inventions.

6. Steven C. Tighle et al., Comment: U.S. Major Pharmaceuticals, Patents and Cost Effective Research Spending, Merrill Lynch Report, 4 (Mar. 27, 2002). It is estimated that in 1990, the average cost to bring a pharmaceutical product to market was $500 million. Id. Today, the cost is believed to be $800 million. Id. “Since a pharmaceutical company’s products all eventually go off patent, production of new, innovative drugs and therefore new patents is essential in order for the company to continue growing.” Id. at 2.

7. See Chisum supra note 2 at 833. Three reasons exist to seek an extension of a patent’s duration: delayed responses from the PTO, greater than three year pendency, and interferences, secrecy orders, and appeals. Id. However, of significance to pharmaceutical companies, the Hatch-Waxman Act allows patent term extensions in certain circumstances caused by regulatory delays in drug approval by the Food and Drug Administration. Id. at 1210.

8. See Tighle, supra note 6, at 2. “[T]he number of granted patents indicates the level of innovation taking place in the company, and can be considered one potential indicator of the company’s success in developing new drugs.” Id. at 2.


Patent references are of particular interest for technology analysis because they offer a measure of patent importance and a method of identifying links among patents. Citation analysis was performed on the set of all U.S. patents that cover new chemical entities (NCEs) claimed as pharmaceuticals and issued during the years 1993 through late 1997. Merck & Co. heads the list, with 577 patents or almost 5% of the total. Hoechst Marion Roussel is second with 499 patents or about 4% of the total. Eli Lilly is third with 337 patents or about 3% of all patents.


12. Chisum, supra note 2, at ch. 2. Before a patent can be granted, patent applications are submitted to the PTO for review to determine if the statutory patentability requirements have been satisfied. Id. Patent law is governed exclusively by federal law. Id. The Court of Appeals for the Federal Circuit (“Federal Circuit”) has federal question jurisdiction over matters concerning patents. Id. Decisions made by the PTO can be appealed directly to the Federal Circuit. Id. Teachings in patent
In contrast to the field of chemical practice, the development of therapeutic biological compounds in the pharmaceutical industry, termed biotechnology, is fairly young.\(^\text{13}\) As a result, the Court of Appeals for the Federal Circuit ("Federal Circuit") and the United States Supreme Court have heard few cases interpreting the patentability requirements for biotechnology inventions.\(^\text{14}\)

Within the area of biotechnology, a number of patents pertain to deoxyribonucleic acid ("DNA")\(^\text{15}\) and protein sequences.\(^\text{16}\) Scholars and scientists who fear ethical repercussions resulting from the patenting of genetic material that exists in living beings assail these patents and find them to be controversial.\(^\text{17}\)

Technically, DNA and protein sequences\(^\text{18}\) are complex chemical molecules.\(^\text{19}\) Thus, for patentability, these sequences should fall within the higher scrutiny standards that apply to chemical compound inventions.\(^\text{20}\)

However, an examination of issued patents suggests that the PTO is not holding patents on DNA and protein sequences to the same rigorous standards as chemical compound claims.\(^\text{21}\) The Federal Circuit rulings also display an inconsistency with chemical practice.\(^\text{22}\) One concern that arises...
is that while the PTO is issuing patents for DNA and protein sequence claims, it is not clear whether these patents will survive judicial scrutiny.\textsuperscript{23} If the patents are not invalidated, a discrepancy will result between chemical practice and biotechnology practice at the PTO and in the courts.\textsuperscript{24} If the patents are invalidated, a discrepancy will exist between PTO practice and the standards followed by the court.\textsuperscript{25} Neither result is desirable.

The Overview section of this Note will present the standards of review that exist for chemical patents and biotechnology patents, and will highlight perceived differences between the two standards. The Analysis section will discuss the implications of these disparities, the questions that the Federal Circuit has yet to address, and the unresolved concerns in the present patent system.

Finally, this Note proposes that biotechnology practice, a subset of chemical practice, should be held to the same standards as chemical practice. Otherwise, the United States patent system will suffer, becoming the subject of increased litigation. The discrepancies in patentability between biotechnology and chemical inventions need to be corrected and avoided to lend credibility and predictability to this subset of chemical practice. Failure to correct these problems will negatively impact pharmaceutical research and development as well as technological advancement.

I. OVERVIEW

Among the statutory requirements that must be satisfied in order for a patent to issue, four provisions are key: utility,\textsuperscript{26} novelty,\textsuperscript{27} nonobviousness,\textsuperscript{28} and written description.\textsuperscript{29} These provisions are the subject of dispute in both the PTO and the courts.

\textsuperscript{23} See infra notes 33-58, 66-77.
\textsuperscript{24} Compare notes 113-21 with 131-46.
\textsuperscript{25} Compare notes 33-58 with 66-77.
\textsuperscript{27} 35 U.S.C. § 102. The statutory requirement of novelty will not be discussed in this Note.
II. UTILITY

A. Chemical Practice

Although the requirements for patentability are applicable to all areas of utility patents, the field of chemical practice has developed distinct standards. In Brenner v. Manson, the Supreme Court addressed the issue of chemical invention utility and was required to determine whether or not the patent applicant had demonstrated that his invention was useful. The Court stated that, in contrast to utility patents in other fields of technology, “it is not remarkable that differences arise as to how the test of usefulness is to be applied to chemical processes.” Thus, distinct utility requirements developed for chemical practice.

Prior to the Brenner case, the trend in chemical patent jurisprudence was that the PTO rejected patent applications unless the specification clearly established the utility of the claimed invention. In contrast, the Court of Customs and Patent Appeals (“CCPA”) took the position that.


31. This Note focuses on chemical practice in the sense of chemical compounds that are used for pharmaceutical purposes only. Different requirements have been established as to the patentability requirements for pharmaceutical and non-pharmaceutical chemical compounds. ROSENSTOCK, supra note 11, at 2-20.3 to 2-21. The focus of this Note is the comparison of chemical claims to DNA and protein sequence claims in the context of pharmaceuticals.

32. See supra note 11.

33. Brenner v. Manson, 383 U.S. 519 (1966). In this case, applicant had filed for a patent for a steroidal compound. Id. at 520. The examiner rejected the application because it failed to disclose utility. Id. at 521. The examiner did not accept applicant’s argument that the compound in question had utility based on the fact that it was similar to a compound that was being tested for anti-tumor effects. Id. at 521-22. The Patent Board of Appeals affirmed the rejection, stating, “it is our view that the statutory requirement of usefulness of a product cannot be presumed merely because it happens to be closely related to another compound which is known to be useful.” Id. at 522.

34. Id. at 530.

35. Id. at 534.

Whatever weight is attached to the value of encouraging disclosure and of inhibiting secrecy, we believe a more compelling consideration is that a process patent in the chemical field, which has not been developed and pointed to the degree of specific utility, creates a monopoly of knowledge which should be granted only if clearly commanded by the statute. Until the process claim has been reduced to production of a product shown to be useful, the metes and bounds of that monopoly are not capable of precise delineation.

36. Id. at 529-30.

37. CHISUM, supra note 2, at 25 n.94. The CCPA was the predecessor of the Federal Circuit that exists today. Id. The Federal Circuit has subject-matter jurisdiction over matters pertaining to patents. 28 U.S.C. § 1295 (2001).
the utility requirement is satisfied if it is “sufficient that a process produces the result intended and is not ‘detrimental to the public interest.’” According to the approach taken by the CCPA, almost every patent application would satisfy the utility requirement.

In \textit{Brenner}, the Supreme Court held that to satisfy the utility requirement, the inventor must have in his possession knowledge of the boundaries of the utility of the invention. According to the Court, the reason for requiring this level of definitiveness in the utility of the invention is that otherwise, patentees would be granted the right to exclude others from using the claimed invention even in areas that are not of legitimate use or exclusive to the patentee.

In the patent process, an inventor receives the right to exclude others from practicing the patented invention. In return for this right, the patentee must fully disclose his invention so that the public can benefit from it. If the patentee does not specify the precise utility of his invention and is nonetheless granted a patent, the patent would preclude others from developing applications and uses for the invention in other fields. This result ultimately is detrimental to society because science and the arts would not be developed to their fullest extents. The Supreme Court sought to prevent this potential chilling effect on the advancement of the inventive process. In addition, the Court set forth the standard that chemical compounds must satisfy for the utility requirement and the rationale underlying this requirement.

39. \textit{Id.} at 530. The CCPA would find the utility requirement satisfied for any process that produces an intended result and “is not ‘detrimental to the public interest.’” \textit{Id.}
40. \textit{Id.} at 534.
41. \textit{Id.} at 534.
42. \textit{Id.}
43. \textit{Id.}
44. \textit{Id.}
45. \textit{Id.}
46. \textit{Id.} at 533-34.
47. \textit{Id.} at 534-35. “Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” \textit{Id.} Today, the utility requirement is not often the focus of review at the PTO or in the courts. \textit{In re Brana}, 51 F.3d 1560, 1564 (Fed. Cir. 1995). As exemplified in \textit{In re Brana}, the court typically analyzes the utility of the invention of a patent application as part of a 35 U.S.C. § 112 ¶ 1 analysis:

The requirement that an invention have utility is found in 35 U.S.C. § 101: “Whoever invents . . . any new and useful . . . composition of matter . . . may obtain a patent therefor . . .” (emphasis added). It is also implicit in § 112 ¶ 1, which reads: 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
In the case In re Kirk, the CCPA further described how to satisfy the utility requirement.\(^48\) First, the court made it clear that the assertion of utility in a patent application required more than a broad statement that the invention is useful.\(^49\) Also, reemphasizing the holding in Brenner,\(^50\) the court held that a specific attribute or utility of the invention must be shown, and that it is not up to the court or public to attempt to ascertain that usefulness.\(^51\) Next, the court held that the utility requirement cannot be satisfied if the invention is useful as an intermediate for making a final product with an unknown utility.\(^52\) Finally, the court clearly stated that a chemical compound cannot acquire utility based solely on its structural forth the best mode contemplated by the inventor of carrying out his invention. 

\(^48\) 376 F.2d 936 (C.C.P.A. 1967).
\(^49\) Id. at 941 ("It seems to us that the nebulous expressions ‘biological activity’ or ‘biological properties’ appearing in the specification convey no more explicit indication of the usefulness of the compounds and how to use them than did the equally obscure expression ‘useful for “technical and pharmaceutical purposes . . . .”’").
\(^50\) See supra notes 35, 40.
\(^51\) In re Kirk, 376 F.2d at 942.
\(^52\) Id. at 945.

We find absolutely no warrant for the proposition that although Congress intended that no patent be granted on a chemical compound whose sole “utility” consists of its potential role as an object of use-testing, a different set of rules was meant to apply to the process which yielded the unpatentable product. That proposition seems to us little more than an attempt to evade the impact of the rules which concededly govern patentability of the product itself. (quoting Brenner v. Manson, 383 U.S. 519, 535 (1966)) (emphasis omitted).

[The practical utility of the compound, or compounds, produced from a chemical "intermediate", the "starting material" in such a process, is an essential element in establishing patentability of that intermediate. It seems clear that, if a process for producing a product of only conjectural use is not itself "useful" within 101, it cannot be said that the starting materials for such a process—i.e., the presently claimed intermediates—are "useful." It is not enough that the specification disclose that the intermediate exists and that it "works," reacts, or can be used to produce some intended product of no known use.

\(^{1075}\)
similarity to a compound or class of compounds that has a known utility. Thus, a chemical that structurally resembles a compound of known utility fails to share the same function as the known compound. Thus, a patent application must specifically describe the utility of the chemical invention. Utility cannot be inferred from vague statements of “utility”, the compound’s use as an intermediate to produce a final product with unknown function, or from structural similarity to a compound of unknown function.

B. Biotechnology Practice

In contrast to chemical practice, the field of biotechnology is a more recent development. The United States Supreme Court essentially created the field in 1980 with *Diamond v. Chakrabarty*. The Court concluded that Congress’ intent when it recodified the Patent Act in 1952 was for “statutory subject matter to ‘include anything under the sun that is made by man.’” The Court made clear that non-naturally occurring discoveries and inventions are patentable, while previously unknown but natural compositions of matter that are discovered are not patentable.

Following the reasoning set forth by the Court, a DNA sequence or gene taken out of its natural context in a living cell could be patentable subject matter because it is not in its naturally occurring state, provided

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53. *Id.* at 942. “It cannot be presumed that a steroid chemical compound is ‘useful’ under 101, or that one of skill in the art will know ‘how to use’ it, simply because the compound is closely related only in a structural sense to other steroid compounds known to be useful.” *Id.*
54. *Id.* (“Appellants’ arguments fail to recognize that many steroid compounds may possess no activity whatsoever.”).
55. *Id.*
56. *Id.* at 941-42.
57. *Id.* at 945.
58. *Id.* at 945-46.
60. 447 U.S. 303.
61. *Id.* at 309 (citing S. Rep. No. 1979, at 5 (1954)). The Court also reiterated that “[t]he laws of nature, physical phenomena, and abstract ideas have been held not patentable.” *Id.*
62. *Id.* at 309-10
63. *Id.* The DNA is in a state made by man, outside of its natural context. *Id.*
that the other statutory patentability requirements are satisfied. However, this simple application of the Chakraberty ruling to DNA sequences and genes is only the beginning of the analysis: Although DNA exists in biological organisms, it is technically a chemical compound and thus, should be subject to the patentability requirements that exist for chemical practice.

In 2001, the PTO set forth new examination procedure guidelines for patent applications for inventions involving DNA sequences and isolated genes. The guidelines state that the utility requirement of 35 U.S.C. § 101 is satisfied when a specific, substantial, and credible utility is disclosed.

In certain respects, the guidelines appear to concede that DNA is a chemical compound and should be evaluated as such. However, the guidelines contradict chemical practice in several ways. First, the guidelines state:

[W]hen a patent application claiming a nucleic acid asserts a specific, substantial, and credible utility, and bases the assertion upon homology to existing nucleic acids or proteins having an accepted established utility, the asserted utility must be accepted by

64. See MERGES, supra note 10.
65. See supra note 13.
66. See supra notes 18-19.
67. See supra notes 33-58 and accompanying text.
69. Id. at 1094. The guidelines also make clear that, “[i]f a patent application discloses only nucleic acid molecular structure for a newly discovered gene . . . the claimed invention is not patentable. But when the inventor also discloses how to use the purified gene isolated from its natural state, the application satisfies the ‘utility’ requirement.” Id. at 1093. Nucleic acid is the chemical building blocks of which DNA is composed. See generally ALBERTS, supra note 15, ch. 2.

When patents for genes are treated the same as for other chemicals, progress is promoted because the original inventor has the possibility to recoup research costs, because others are motivated to invent around the original patent, and because a new chemical is made available as a basis for future research. Other inventors who develop new and nonobvious methods of using the patented compound have the opportunity to patent those methods.

Id.

A DNA sequence—i.e., the sequence of the base pairs making up a DNA molecule—is simply one of the properties of a DNA molecule. Like any descriptive property, a DNA sequence itself is not patentable . . . [A]n isolated and purified DNA molecule may meet the statutory utility requirement if, e.g., it can be used to produce a useful protein or it hybridizes near and serves as a marker for a disease gene. Therefore, a DNA molecule is not per se unpatentable for lack of utility.

Id. “A DNA sequence is not patentable because a sequence is merely descriptive information about a molecule.” Id. at 1095.
the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion.71 (emphasis added).

This statement directly contradicts chemical practice, which holds that because even structurally-similar chemical compounds can have unpredictably-different properties, no utility can be claimed on the basis of similarity to a compound of known function.72 Indeed, there are numerous examples of DNA sequences that display a high degree of homology and even identity in certain regions or domains of the gene; however, the highly similar proteins encoded by these DNA sequences in fact exert opposite or varied effects on the cells in which they are present.73

Next, the guidelines contradictorily state, “[w]hen a class of proteins is defined such that the members share a specific, substantial, and credible utility, the reasonable assignment of a new protein to the class of sufficiently conserved proteins would impute the same specific, substantial, and credible utility to the assigned protein.”74 As already stated, numerous examples exist of proteins and their encoding DNA sequences that share a high degree of homology yet serve different functions.75 Allowing a patent to issue on a DNA or protein sequence where the only utility is based upon homology to known sequences runs the hazard of ascribing a function to a protein that is in fact opposite to its true function.76 Also, it runs the hazard of contradicting the rules and precedent that have been established for chemical practice.77

71. Id. at 1096. Loosely, homology means similarity.
72. See supra notes 33, 53.
73. B. Matiba et al., The CD95 System and the Death of a Lymphocyte, 9(1) SEMINARS IN IMMUNOLOGY 59-68 (Feb. 1997). For example, a naturally-occurring mutation (change) in the CD95 protein’s DNA sequence causes the protein to have a completely opposite effect on the cell from the effect the normal CD95 has. Id. As another example, the proteins involved in controlling programmed cell death include a number of proteins that are nearly identical for most of the proteins’ regions yet vary in other regions, resulting in proteins that exert opposite effects on the cell. Q.L. Deveraux & J.C. Reed, IAP Family Proteins- Suppressors of Apoptosis, 13 GENES AND DEVELOPMENT 239-52 (1999).
75. See supra note 73.
76. Id.
77. See supra notes 33-58 and accompanying text. The guidelines contradict established chemical practice. Id.
III. NONOBSVIOUSNESS

A. Chemical Practice

A frequent issue of patent litigation is whether or not the invention disclosed in a patent application is “obvious”\textsuperscript{79}: If the claimed invention would have been evident to someone with ordinary skill in the art or if the

\textsuperscript{78} 35 U.S.C. § 103 reads: Conditions for patentability; non-obvious subject matter:
(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

(b)(1) Notwithstanding subsection (a), and upon timely election by the applicant for patent to proceed under this subsection, a biotechnological process using or resulting in a composition of matter that is novel under section 102 and nonobvious under subsection (a) of this section shall be considered nonobvious if—
(A) claims to the process and the composition of matter are contained in either the same application for patent or in separate applications having the same effective filing date; and
(B) the composition of matter, and the process at the time it was invented, were owned by the same person or subject to an obligation of assignment to the same person.

(2) A patent issued on a process under paragraph (1)—
(A) shall also contain the claims to the composition of matter used in or made by that process, or
(B) shall, if such composition of matter is claimed in another patent, be set to expire on the same date as such other patent, notwithstanding section 154.

(3) For purposes of paragraph (1), the term "biotechnological process" means—
(A) a process of genetically altering or otherwise inducing a single- or multi- celled organism to—
   (i) express an exogenous nucleotide sequence,
   (ii) inhibit, eliminate, augment, or alter expression of an endogenous nucleotide sequence, or
   (iii) express a specific physiological characteristic not naturally associated with said organism;
   (B) cell fusion procedures yielding a cell line that expresses a specific protein, such as a monoclonal antibody; and
   (C) a method of using a product produced by a process defined by subparagraph (A) or
       (B), or a combination of subparagraphs (A) and (B).

(c) Subject matter developed by another person, which qualifies as prior art only under one or more of subsections (e), (f), and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.


\textsuperscript{79} See CHISUM, supra note 2, ch. 5. Obviousness is frequently the largest hurdle to overcome in attaining a patent. \textit{Id}. In addition, when a patent is asserted against an alleged infringer in court, the infringer invariably challenges the validity of the patent, often as being obvious. \textit{Id}.
The key consideration taken into account in chemical practice is the amount of structural similarity between the claimed and prior art compounds. As set forth in In re Dillon, a showing of such similarity, in combination with motivation from the art to make the compound, gives rise to a \textit{prima facie} case of obviousness that the applicant must rebut. Several cases have suggested that structural similarity alone may give rise to a \textit{prima facie} case, such as when the state of knowledge in the field provides motivation for making the modification of the prior art to create the invention. However, this result can only be consistent with Dillon if


[T]he scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined.

Id. In addition to these three factors, the court also reviews secondary considerations. Graham, 383 U.S. at 17-18 and ROSENSTOCK, supra note 11, at 8-7 to 8-8. The secondary considerations, not limited to chemical practice, that may overcome a \textit{prima facie} case of obviousness include: long felt need for the invention, commercial success of the invention, initial expressions of disbelief by experts, copying by an infringer, near simultaneous invention by others, initial skepticism by experts, initial praise by experts, prior failure by others. Id.

81. In re Jones, 958 F.2d 347, 349 (Fed. Cir. 1992). “The question of ‘structural similarity’ in chemical patent cases has generated a body of patent law unto itself.” Id. (citation omitted).


[S]tructural similarity between claimed and prior art subject matter, proved by combining references or otherwise, where the prior art gives reason or motivation to make the claimed compositions, creates a \textit{prima facie} case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that \textit{prima facie} case.

Id. In In re Papesch, the court stated a reminder that the structure of the compound is only one characteristic of the compound and although this characteristic must be taken into account, it is not the exclusive consideration in the matter of obviousness. 315 F.2d 381, 391 (C.C.P.A. 1963).

[A] formula is not a compound and while it may serve in a claim to \textit{identify} what is being patented, as the metes and bounds of a deed identify a plot of land, the \textit{thing} that is patented is not the formula but the compound identified by it. And the patentability of the thing does not depend on the similarity of its formula to that of another compound but of the similarity if the former compound to the latter.

Id.

83. See, e.g., In re Merck & Co., 800 F.2d 1091, 1096 (Fed. Cir. 1986) (discussing the theory of biososterism, “where the substitution of one atom or group of atoms for another atom or group of atoms having a similar size, shape and electron density provides molecules having the same biological activity.”). The court in \textit{Merck} also quoted the \textit{Payne} decision, stating, “structural similarity, alone, may be sufficient to give rise to an expectation that compounds similar in structure will have similar properties.” Id. at 1096 (citing In re Payne, 606 F.2d 303, 313 (C.C.P.A. 1979). This holding is consistent with \textit{Merck} since biososterism was also a consideration in \textit{Payne}.
the state of knowledge in the field does in fact provide the motivation of likelihood of success that, in addition to the structural similarity, satisfies the Dillon requirements for prima facie obviousness.84

The prima facie case of obviousness can be overcome in several ways, including demonstration of unobvious85 or unexpected properties.86 For example, in In re Lambooy, the Board of Appeals of the PTO held the applicant’s invention to be obvious in light of the prior art since, inter alia, the chemical structure of the applicant’s compound was highly related to that of a known compound.87 However, the Federal Circuit reversed the board’s decision, holding that the biological effect of the small difference in structure was a compound with an effect opposite of that of than the compound known in the art.88 The court found this difference to be a prime example of how to overcome prima facie obviousness.89

Another consideration taken into account when determining if a claimed compound is prima facie obvious is how generic or specific the

84. See In re Dillon, supra note 82, at 692.
85. In re Papesch, 315 F.2d at 386-87. “If that which appears, at first blush, to be obvious though new is shown by evidence not to be obvious, then the evidence prevails over surmise or unsupported contention and a rejection based on obviousness must fall.” Id.
86. In re Albrecht, 514 F.2d 1389, 1396 (C.C.P.A. 1975). Appellants’ affidavit evidence, we note, shows that the additional advantageous activity disclosed for the claimed compounds, namely antiviral activity, is not in fact possessed by the prior art analog. That a claimed novel compound possesses a certain advantageous activity which is not in fact possessed by a prior art compound is itself evidence of the nonobviousness of the subject matter as a whole . . . . [A] newly discovered activity of a claimed novel compound which bears no material relationship to the activity disclosed for the prior art analogs is further evidence, not to be ignored, of the nonobviousness of the claimed invention.
87. In re Lambooy, 300 F.2d 950, 954 (C.C.P.A. 1962). The chemical structure of applicant’s compound contained two ethyl side groups where the compound known in the art, riboflavin, contained methyl groups. Id. at 952. An ethyl group consists of two fully saturated carbons while a methyl group consists of one. Id.
88. Id. at 955.
89. Id.

There is no evidence in the record which would lead one skilled in this art to expect that the differences in molecular structure between riboflavin and appellant’s compound would cause this difference in properties. The former compound is a vitamin, the latter an antivitamin; the former is a metabolite, the latter an antimetabolite; the former acts to promote the well-being of the animal, the latter acts to its detriment. We find it difficult to conceive of a better example of a difference in kind than is presented in this case and we also find in view of this record that this difference was unexpected and unobvious.
prior art is in teaching the applicant’s invention. In chemical patents, a claim may disclose a generic structure that can optionally be substituted by any one of a number of possible chemical groups. When the number of positions for substituents on the generic structure is large and the number of possible chemical groups that can be substituents is also large, the number of chemical compounds embraced by such a generic claim is enormous or infinite. An applicant may claim as his invention a specific compound that falls within the scope of another patent’s generic claim. If the written description of the patent that includes the generic claim does not teach that specific compound as “typical” or “preferred,” the court may hold that the application for the specific compound is not obvious in light of the art because the art has not specifically taught the applicant’s invention.

90. See ROSENSTOCK, supra note 11, at 8-27.

[W]here a genus or generic formula has a relatively small number of variables, that is, substituents, then a prima facie case of obviousness can be made out. One the other hand, where the genus or generic formula disclosed in the prior art has a relatively large number of substituents that can be made, a showing of obviousness is not so readily accomplished.

Id.

91. In re Baird, 16 F.3d 380 (Fed. Cir. 1994); Jones, 958 F.2d 347.

92. Baird, 16 F.3d at 382. “In the instant case, the generic diphenol formula disclosed in Knapp contains a large number of variables, and we estimate that it encompasses more than 100 million different diphenols . . . .” Id.

93. Id. at 382-83.

While the Knapp formula [prior art] unquestionably encompasses bisphenol A [applicant’s compound] when specific variables are chosen, there is nothing in the disclosure of Knapp suggesting that one should select such variables. Indeed, Knapp appears to teach away from the selection of bisphenol A by focusing on more complex diphenols . . . . [F]ifteen typical diphenols are recited. None of them, or any of the other preferred phenols recited above, is or suggests bisphenol A.

Id.

94. Id. See also Jones, 958 F.2d at 350.

[T]hough Richter [prior art] discloses the potentially infinite genus of “substituted ammonium salts” of dicamba, and lists several such salts, the salt claimed here [applicant’s compound] is not specifically disclosed. Nor, as we have explained above, is the claimed salt sufficiently similar in structure to those specifically disclosed in Richter as to render it prima facie obvious.
B. Biotechnology Practice

With regard to DNA sequence claims, the consideration of structural similarity in making a case for obviousness arose in *Amgen, Inc. v. Chugai Pharmaceutical Co., Ltd.* The court rejected the defendant’s allegation that the plaintiff’s claimed invention was obvious. The defendant alleged that it was obvious to try to clone the human DNA sequence at issue because the human DNA sequence possessed a high degree of similarity to the monkey DNA sequence. The Federal Circuit held that, even if a high degree of sequence similarity exists, obvious-to-try does not create a case of obviousness if motivation is absent and there is no likelihood of success if tried. Thus, it appears that the standards for obviousness for DNA sequence claims may be consistent with the standards created by *Dillon* for chemical practice.

Next, the Federal Circuit has addressed the issue of generic claims in the field of biotechnology. Specifically, the court has held that, due to the degeneracy of the genetic code, disclosure of a protein sequence does not make the DNA sequence encoding that protein obvious. In *In re Bell*, the court found that the prior art disclosure of a protein sequence suggested over $10^{35}$ different DNA sequences that could encode for the protein. The applicant claimed as his invention a few of those...
sequences; those that actually encode the human protein IGF.\textsuperscript{104} The court held that although the prior art suggested an enormous number of DNA sequences that could code for the protein, including the applicant’s sequences, the art provided no teaching to suggest which of the vast number of sequences encoded the human protein.\textsuperscript{105} Thus, the applicant’s invention was not obvious over the prior art because the art did not teach or suggest that the sequences claimed by the applicant would encode the human protein.\textsuperscript{106} The Federal Circuit reiterated this view in \textit{In re Deuel}.\textsuperscript{107}

Also, the court held that the existence of a general technique for isolating DNA sequences when a protein sequence is known does not render the DNA sequence obvious because knowledge of the protein sequence, coupled with the general method, still does not suggest the selection of specific DNA sequences.\textsuperscript{108} In the absence of such a suggestion, the \textit{prima facie} case of obviousness is not made.\textsuperscript{109}

Although the courts have yet to address a number of issues pertaining to obviousness, the few teachings that do exist suggest consistency with the field of chemical practice.\textsuperscript{110}

\textsuperscript{104} \textit{Id.}
\textsuperscript{105} \textit{Id.}
\textsuperscript{106} \textit{Id.}
\textsuperscript{107} \textit{In re Deuel, 51 F.3d at 1558-59.}
\textsuperscript{108} \textit{Id.}
\textsuperscript{109} \textit{Id.}
\textsuperscript{110} \textit{See supra notes 81-94.}
IV. WRITTEN DESCRIPTION

A. Chemical Practice

“To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that ‘the inventor invented the claimed invention.’”112 Because of the unpredictability of the properties of seemingly-related compounds, this standard is heightened in chemical cases.113 Therefore, chemical inventions require a greater degree of description and examples of the invention in order to ensure that the inventor understands and possesses all that he claims as his invention.114 However, the Federal Circuit has also recognized that generic claims can be allowed in chemical practice: The description of the structure in a generic chemical claim may be sufficient to allow one skilled in the art to envision which species specifically fall within or outside of the claim.115

111. 35 U.S.C. § 112 ¶ 1 contains three requirements that must be satisfied in order to obtain a patent: written description, enablement, and best mode. The courts have recognized that each is a distinct, separate requirement. In re Ruschig, 379 F.2d 990 (C.C.P.A. 1967). This Note focuses exclusively on the written description requirement of § 112 ¶ 1 and does not discuss the enablement or best mode requirements. For a discussion of these two requirements, see CHISUM supra note 2, ch. 3. 35 U.S.C. § 112 ¶ 1 reads: Specification:

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.


112. Regents of the University of California v. Eli Lilly and Co., 119 F.3d 1559, 1566 (Fed. Cir. 1997) (quoting Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572 (Fed. Cir. 1997)). Stated another way, to comply with the written description requirement, an applicant must “‘describ[e] the invention, with all its claimed limitations, not that which makes it obvious,’ and by using ‘such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention.’” Id. (quoting Lockwood, 107 F.3d at 1572).

113. In re Smythe, 480 F.2d 1376, 1383 (C.C.P.A. 1973). “In other cases, particularly but not necessarily, chemical cases, where there is unpredictability (citation omitted) in performance of certain species or subcombinations other than those specifically enumerated, one skilled in the art may be found not to have been placed in possession of a genus . . . .” Id.

114. Id. at n.3. “[I]t is the predictability or the unpredictability of the elements, be they chemical or mechanical, which is determinative . . . .” Id.

115. Regents of the University of California, 119 F.3d at 1568.

In claims involving chemical materials, generic formulae usually indicate with specificity what the generic claims encompass. One skilled in the art can distinguish such a formula from others and can identify many of the species that the claims encompass. Accordingly, such a formula is normally an adequate description of the claimed genus.

Id.
The degree of disclosure required is dependent on the particular case.\textsuperscript{116}

Inherent in the written description requirement is the requirement that the inventor has a conception of his invention.\textsuperscript{117} However, conception of the structure alone cannot satisfy the written description requirement: A sufficient description of how to obtain or make the invention must also exist.\textsuperscript{118} Furthermore, conception of an invention cannot be defined in terms of functional utility alone.\textsuperscript{119}

Cases dealing with the written description requirement in chemical practice also consider whether the scope of the claimed invention is commensurate with the scope of description of the invention in the specification.\textsuperscript{120} Even if the specification enables one of skill in the art to practice a broader scope than what the specification teaches, the court interprets and limits the claims only to be as broad as what is described in the specification.\textsuperscript{121}

\textbf{B. Biotechnology Practice}

Initially, with respect to the written description requirement, biotechnology practice appeared to be consistent with chemical practice.\textsuperscript{122} The Federal Circuit in \textit{Fiers v. Revel} made it clear that the rules from chemical practice governed determinations of whether a patent applicant satisfied the written description requirement for claims pertaining to DNA.\textsuperscript{123} Specifically, the DNA itself, not a method for isolating or using

\begin{itemize}
  \item \textsuperscript{116} See supra note 112.
  \item \textsuperscript{117} Fiers v. Revel, 984 F.2d 1164, 1168 (Fed. Cir. 1993) (quoting Amgen, Inc., 927 F.2d at 1206). “Conception does not occur unless one has a mental picture of the structure of the chemical, or is able to define it by its method of preparation, its physical or chemical properties, or whatever characteristics sufficiently distinguish it.” \textit{Id.}
  \item \textsuperscript{118} Amgen, Inc., 927 F.2d at 1206. “[C]onception of a chemical compound requires that the inventor be able to define it so as to distinguish it from other materials, and to describe how to obtain it.” \textit{Id.}; Oka v. Youssefyeh, 849 F.2d 581, 583 (Fed. Cir. 1988). “Conception requires (1) the idea of the structure of the chemical compound and (2) possession of an operative method of making it.” \textit{Id.}
  \item \textsuperscript{119} See infra note 123.
  \item \textsuperscript{120} Rosenstock, supra note 11, at 9-6. The PTO rejects patent applications for lack of written description when “the claim or claims have encompassed more elements, compositions, utilities, and the like than those recited in the specification.” \textit{Id.}
  \item \textsuperscript{121} In re D Leone, 436 F.2d 1404, 1405 n.1 (C.C.P.A. 1971). “For greater clarity on this point, consider the case where the specification discusses only compound A and contains no broadening language of any kind. This might very well enable one skilled in the art to make and use compounds B and C; yet the class consisting of A, B and C has not been described.” \textit{Id.}; In re Ahlbrecht, 435 F.2d 908, 911 (C.C.P.A. 1971) (“In the present case, there are no negative statements that esters with two methylenes are not within what is regarded as the invention, but rather here esters wherein n is 2 were never described in explicit terms at all.”).
  \item \textsuperscript{122} See supra notes 112-21.
  \item \textsuperscript{123} Fiers v. Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993). “We thus determined that, irrespective
the DNA, must be described and the inventor must make it clear that he has possession of the DNA that is claimed.\textsuperscript{124} The court held that the appellee had satisfied the written description requirement because, in contrast to the appellants, he actually described the DNA of the invention by providing the complete nucleotide sequence of the DNA.\textsuperscript{125}

In \textit{Regents of the University of California v. Eli Lilly}, the Federal Circuit held that disclosure and description of the DNA sequence from one vertebrate species, in combination with general methods for cloning DNA, was not a sufficient written description to allow a claim to all vertebrate DNAs that encode a particular protein of interest.\textsuperscript{126} This holding was consistent with \textit{Fiers}.\textsuperscript{127} In addition, the court found that the claim for vertebrate DNAs that encode for the protein of interest merely described a function of the DNA, not the DNA itself.\textsuperscript{128} Finally, the court specifically rejected a claim to the human DNA sequence that encoded for the protein because the human DNA was not described in the application and there was no way to distinguish this DNA from any other.\textsuperscript{129} The holdings in

\begin{itemize}
\item of the complexity or simplicity of the method of isolation employed, conception of a DNA, like conception of any chemical substance, requires a definition of that substance other than by its functional utility.” \textit{Id.}
\item \textsuperscript{124} \textit{Id.} at 1170-71.
\item An adequate written description of a DNA requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it; what is required is a description of the DNA itself. . . . [A] bare reference to a DNA with a statement that it can be obtained by reverse transcription [a technique] is not a description; it does not indicate that Revel [appellant] was in possession of the DNA. \textit{Id.}
\item \textsuperscript{125} \textit{Id.} at 1172.
\item “[S]ugano’s [appellee’s] application satisfies the written description requirement since it sets forth the complete and correct nucleotide sequence of a DNA coding for B-IF [protein of interest] and thus ‘conveys with reasonable clarity to those skilled in the art that . . . [Sugano] was in possession of the [DNA coding for B-IF].’” \textit{Id.}
\item \textsuperscript{126} \textit{Lilly}, 119 F.3d at 1569. “The claimed genera of vertebrate and mammal cDNA are not described by the general language of the 525 patent’s written description supported only by the specific nucleotide sequence of rat insulin [protein of interest].” \textit{Id.}
\item \textsuperscript{127} See supra note 124.
\item \textsuperscript{128} \textit{Lilly}, 119 F.3d at 1566. “An adequate written description of a DNA . . . ‘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.” \textit{Id.}
\item It is only a definition of a useful result rather than a definition of what achieves that result. Many such genes may achieve that result. The description requirement of the patent statute requires a description of an invention, not an indication of a result that one might achieve if one made that invention. \textit{Id.}
\item \textsuperscript{129} \textit{Id.} at 1568.
\item \textsuperscript{129} \textit{Id.} at 1567.
\item The name cDNA is not itself a written description of that DNA; it conveys no distinguishing information concerning its identity . . . it thus does not describe human insulin [protein of

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Fiers and Lilly are consistent with the written description requirements of chemical practice. ¹³⁰

Recently, in Enzo Biochem, Inc. v. Gen-Probe, Inc., the Federal Circuit appears to have broken away from the rules of chemical practice.¹³¹ In Enzo, the court held that the written description requirement could be satisfied by deposit¹³² of the biological material at a publicly-accessible depository.¹³³ Significantly, the court’s decision was directly in contradiction to the precedent set forth in Fiers and Lilly: As a result of the Enzo decision, DNA no longer needs to be described by its sequence or structural information or in a way that distinguishes the claimed DNA from other DNA that may perform the same function.¹³⁴ The court claimed to be applying the written description requirement guidelines that the PTO had recently published.¹³⁵ According to the guidelines, a functional description can be used to describe the invention, only if it is “coupled with a known or disclosed correlation between function and structure. . .”.¹³⁶ However, in Enzo, the court did not apply this standard; instead, the court held that a deposit alone could satisfy the written description requirement, even in the absence of structural data.¹³⁷

In addition, the PTO’s Manual for Patent Examination Procedure (“MPEP”) states that a deposit can substitute for a written description when words alone cannot sufficiently describe the invention.¹³⁸ However,
Enzo’s invention was a DNA sequence and until this case, the Federal Circuit had required the sequence of the DNA to be disclosed in order to satisfy the written description requirement.\textsuperscript{139} The Federal Circuit set forth no reason for breaking from precedent and why words alone could no longer describe DNA.\textsuperscript{140}

Another concern is the fact that the court’s new standard does not require that the inventor be in possession of or have a conception of his invention.\textsuperscript{141} In this case, the inventor knew that the deposited bacteria contained DNA that could perform a desired function.\textsuperscript{142} Rather than describe that DNA, the inventor described the function and deposited the bacteria containing the DNA.\textsuperscript{143} The court required no correlation between function and structure; instead, a deposit replaced disclosure of the structure.\textsuperscript{144} Thus, it is not clear that the inventor had the DNA in his possession: Enzo could not describe the sequence of the DNA, could not describe its structure, physical or chemical properties, or any functional property \textit{in combination with} a structural property.\textsuperscript{145} In other words, Enzo could not satisfy the written description requirement or possession stating “[a] deposit may be necessary . . . ‘where the invention involves a biological material and words alone cannot sufficiently describe how to make or use the invention . . . .’” Id.\textsuperscript{139} See supra notes 124, 128-29.

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requirement of the PTO guidelines and hence of section 112 paragraph 1, as established for chemical practice. 146

V. ANALYSIS

As discussed Part II.B, the utility requirement guidelines issued by the PTO contradict chemical practice in several ways. 147 First, the guidelines allow utility to be inferred based on similarity to compounds with known use and second, when a DNA or protein is similar to a known compound, the PTO will ascribe the same function to the new invention. 148

To date, the Federal Circuit has not heard a case addressing the utility requirement for a DNA or protein sequence. Thus, there is no guidance from the court on this issue. When a case does come before the Federal Circuit, it will be of interest to see if the court acknowledges that chemical practice is applicable or whether the court will try to set new precedent, in accord with the PTO Guidelines, for this area by distinguishing the chemical field.

The Federal Circuit has not yet decided on whether a claimed invention of a DNA sequence will be rejected as obvious if it is highly homologous (similar) or nearly identical to a sequence known in the art. That is, the court has not decided if similar DNA sequences are prima facie obvious. For example, the prior art may disclose the DNA sequence for a protein that is a key intermediate in an intracellular signaling pathway. The art only discloses a role for the protein in signaling. The applicant may have discovered the DNA sequence for a protein that is identical to the protein known in the art except for one amino acid difference due to the change of one nucleotide in the DNA. 149 Although this difference is slight and results in only a single amino acid change in the encoded protein, it causes the protein to inhibit signaling and thus behave in an opposite manner from the already-known protein.

146. Guidelines for Examination of Patent Application Under the 35 U.S.C. 112 ¶ 1, “Written Description” Requirement, 66 Fed. Reg. at 1106. The requirements for satisfying the possession requirement are very similar as those for satisfying the written description requirement:

   An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure . . . ."

Id. See also supra notes 112-21.
147. Compare supra notes 33-58 with 68-77.
148. See supra notes 71-76.
149. For a review of molecular biology, see ALBERTS, supra note 15.
Biotechnology is a subset of chemical practice, but it is not clear that the Federal Circuit will apply the same standards, although Amgen raises the hope that the same standard will apply. Applying the standards of Dillon, a *prima facie* case of obviousness is not made in the hypothetical presented in the preceding paragraph. Although there is a high degree of sequence structural similarity, the motivation to discover or try this invention is absent. The art only teaches a role in promoting intracellular signaling, not in inhibiting signaling. If the PTO erroneously rejected the application due to *prima facie* obviousness, on appeal, the result should be the same as in Lambooy, where the patentee overcame an obviousness rejection by a showing of unexpected results.

In addition, the Federal Circuit has declined to decide if the amino acid sequence of a protein is obvious if the DNA sequence is known. The standard set forth in Dillon does not apply because the DNA and protein sequences are not structurally similar because they are composed of different chemical subunits. Because the amino acids encoded by particular triplets of nucleotides are known, it seems obvious to expect success in determining the exact amino acid sequence encoded by a DNA sequence. The *prima facie* case of obviousness is made: Knowledge of the nucleotides can be used to deduce the exact amino acid sequence. However, proteins are sometimes changed by post-translational modification after they have been translated. For example, amino acids at one end of the protein may have to be removed before the protein can be functional. This modification is not reflected in the DNA sequence. Thus, if a claim for such a protein is rejected as *prima facie* obvious, this obviousness rejection should be overcome by showing the unexpected

150. *See supra* notes 96-99.
151. *Id.*
152. *See supra* notes 87-89.
153. *In re* Bell, 991 F.2d 781, 784 n.6 (Fed. Cir. 1993). The court notes: “We also express no opinion concerning the reverse proposition, that knowledge of the structure of a DNA, e.g., a cDNA, might make a protein obvious.” *Id.*
155. *In re* Bell, 991 F.2d at 783. “A *prima facie* case of obviousness is established when the teachings from the prior art itself would appear to have suggested the claimed subject matter to a person of ordinary skill in the art.” (quoting *In re* Rinehart, 531 F.2d 1048, 1051 (C.C.P.A. 1976)).
156. *See* THOMAS E. CREIGHTON, PROTEINS: STRUCTURES AND MOLECULAR PROPERTIES 78-99 (2d ed. 1993). A protein can be translated into a form that is inactive and nonfunctional. *Id.* To become functional, the protein must be modified after translation is completed (i.e., it must be post-translationally modified). *Id.* Different types of post-translational modifications can be performed. *Id.*
157. *Id.* at 79.
158. *Id.* at 78-99. Certain post-translational modifications can be predicted based upon knowledge of the sequence, while other modifications cannot be predicted from DNA sequence knowledge alone. *Id.*
result that the mature protein sequence cannot be discerned from
knowledge of the DNA sequence.\textsuperscript{159}

In \textit{Enzo}, the Federal Circuit declined to rule and instead remanded the
issue of whether claims to subsequences and mutations of the claimed
DNA sequences were valid.\textsuperscript{160} Since the inventor could not describe
the structure or sequence of the invention and instead deposited the sequences,
it is difficult to understand how the inventor can claim to be in possession
of subsequences and variants or even know if such sequences will perform
the claimed function.\textsuperscript{161} However, the court suggests that such claims will
be allowed under the new rules set forth in the case: Since deposit satisfies
the written description requirement of the sequences, the deposit may also
satisfy this requirement as to subsequences because they too have
technically been deposited.\textsuperscript{162}

Additional issues with regard to the written description requirement
exist. For example, DNA inventions often claim any DNA sequences that
are similar by a certain percentage to the disclosed sequence.\textsuperscript{163} However,
it is not clear that such claims are sufficiently described. What if the
patented prior art sequence is thirty nucleotides in length and a sequence
that is over 1,000 nucleotides in length has the requisite amount of
similarity in a region that is similar to the disclosed sequence of thirty
nucleotides? Would the court consider the sequence of over 1,000

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159. See supra notes 87-89 wherein a seemingly minor modification caused an unexpected result,
thereby overcoming an obviousness rejection.

160. \textit{Enzo}, 296 F.3d at 1326. Subsequences are parts or regions of the full length DNA of the
invention. \textit{Id.} Mutations are nucleotide differences from the original sequence. ALBERTS, supra note
15, at 242. There is no way to predict where these changes will occur. \textit{Id.} at 245.

161. \textit{Enzo}, 296 F.3d at 1326. “[T]here are at least hundreds of subsequences of the deposited
sequences, an unknown number of which might also meet the claimed hybridization ratio [function].”
\textit{Id.}

162. \textit{Id.} at 1326-27. “[B]ecause the deposited sequences are described by virtue of a reference to
their having been deposited, it may well be that various subsequences, mutations, and mixtures of
those sequences are also described to one of skill in the art.” \textit{Id.}

163. As an example, see U.S. Patent No. 6476206B1, claims 3, 15 (issued Nov. 5, 2002). Claim 3
reads: 3. A cDNA molecule which is at least 99% identical to the nucleotide sequence shown in SEQ
ID NO:1, wherein percent identity is determined using a Smith-Waterman homology search algorithm
using an affine gap search with a gap open penalty of 12 and a gap extension penalty of 1. Claim 15
reads: 15. A cDNA molecule which is at least 99% identical across its entire length to the nucleotide
sequence shown in SEQ ID NO:1, wherein percent identity is determined using a Smith-Waterman
homology search algorithm using an affine gap search with a gap open penalty of 12 and a gap
extension penalty of 1. Note that claim 15 contains the requirement that the percent-identity must
extend along the entire length of the DNA, while claim 3 does not contain such a requirement. In claim
15, the identity must exist along the length of the disclosed sequence (SEQ ID NO:1); however, the
other DNA molecule may be considerably longer than the DNA shown in SEQ ID NO:1 so that the
percent-identity could exist for only a small section of that second DNA’s length. Should the claimed,
patented sequence embrace this second sequence? It is not clear that the inventor ever conceived of
such a sequence.
nucleotides to fall within the claim and to be sufficiently described just because it happens to contain the thirty nucleotides of the invention? Would it fall within the claim even though the patentee never conceived of the idea of the sequence that is over 1,000 nucleotides? What if a protein encoded for by a DNA sequence with a high degree of similarity to a disclosed DNA sequence performs function opposite to the function of the protein encoded for by the disclosed and described sequence? Would such a sequence fall within the scope of the claims even though it arguably has not been described functionally and has not been conceived?

Further, the court has held that the scope of the claims cannot be broader than what the inventor describes as his invention in the specification.164 This is at least true for chemical practice. However, a claim to sequences with similarity to a known sequence may be enabled and one skilled in the art could isolate that sequence based on the enablement. It is unclear whether such a claim is adequately disclosed in the patent or that the inventor ever possessed or conceived of that particular sequence.165

The court in Enzo set a new standard, holding that a deposit of the invention satisfies the written description requirement.166 However, this deposit option originally arose for a different purpose: to satisfy the enablement requirement for complex biotechnology inventions that could not easily or adequately be enabled by words alone.167 Such acknowledgment of the complexities of biotechnological inventions seems reasonable for inventions such as cell lines and other inventions that are difficult to describe or teach how to make.168 These inventions do not fall within the area of chemical practice.169 However, DNA, although classified within the field of biotechnology, is in fact a chemical and thus chemical practice should apply to DNA inventions.170 In addition, the deposit option exists for inventions that are not adequately described or

164. See supra notes 120-21 and accompanying text.
165. See supra notes 111, 121 and accompanying text.
166. See supra note 133 and accompanying text.
167. See supra note 132.
168. See ROSENSTOCK, supra note 11, at 9-7.
169. See ROSENSTOCK, supra note 11, at 9-7.
170. See supra notes 18-19 and accompanying text.
enabled by words alone. 171 DNA is easily described by its sequence: The knowledge and ability to sequence DNA has existed since the 1970s. 172 In Fiers, the court required that the DNA at issue be described by its sequence before the written description requirement was satisfied. 173 The dates of invention in that case were 1979 and 1980. 174 It is not clear why the court did not require Enzo to sequence the DNA of the invention, because DNA sequencing methodology had been well established. 175

Finally, it is yet to be determined what effect the Enzo decision will have on the patenting of biotechnology inventions. 176 Will this holding change biotechnology practice? Will inventors now routinely deposit their materials, including sequences, deciding to forgo writing an adequate description of their invention with its chemical or structural properties?

VI. PROPOSAL

As the Federal Circuit stated in Amgen, “DNA is a chemical compound, albeit a complex one.” 177 I propose that courts follow the precedent set in the field of chemical practice since DNA is a chemical compound and until recently, the Federal Circuit had acknowledged this fact. 178 If the court follows chemical practice precedent, some patent holders risk invalidation if their patents were allowed under the PTO guidelines that contradict chemical practice. 179 However, this result is more favorable than the alternative, which is the creation of a new body of law for a subset of an established area of patent law. This alternative would create unpredictability in the fields of both chemistry and biotechnology: The classification of DNA as a chemical or biotechnology invention would become dispositive of the question of a patent’s validity. 180

171. See supra notes 167-68 and accompanying text.
172. See DARNELL, supra note 101, at 213-14.
173. See supra note 124 and accompanying text.
174. Fiers, 984 F.2d at 1167-68.
175. See supra note 172. The sequences were 850 or 1300 nucleotides in length. Enzo, 296 F.3d at 1326.
176. Compare notes 124 and 128 with note 133.
177. See supra note 19.
178. Compare notes 124 and 128 with note 133.
179. Compare notes 33-58 with notes 68-77.
180. If classified as a biotechnology invention, a statement that the sequence resembles a known sequence would satisfy the utility requirement and disclosure of only a functional property or deposit of the material would satisfy the written description requirement. If classified as a chemical invention, a higher level of scrutiny would apply. This standard would require proof of actual utility of the claimed invention to satisfy the utility requirement and disclosure of a chemical or structural property
The Federal Circuit has yet to hear a case that specifically deals with the utility requirement. The PTO recently set forth guidelines on how to satisfy this requirement. However, as discussed above, several of the provisions contradict established chemical practice. The risk currently exists that the court, although not bound by the PTO guidelines, will apply the guidelines exclusively and ignore the precedent set forth in Brenner. Also, the risk exists that the PTO has been issuing patents for DNA sequences that fail the patentability requirements set forth in Brenner yet satisfy the requirements in the guidelines. If such cases reach the Federal Circuit, since DNA is a chemical, the court should follow chemical practice and apply the precedent from Brenner. The court should not create a new field of practice for the biotechnology subset of chemical practice, even at the risk of invalidation of patents the PTO has allowed.

Next, the standards applied for obviousness appear to be consistent between chemical and biotechnology practice. However, the Federal Circuit has heard only a limited number of cases and, as discussed above, the court has yet to decide numerous issues. When these issues come before the court, the court should look to chemical practice to maintain consistency and predictability with an established area of patent law. Specifically, the court should first look to determine the degree of similarity between the prior art and the proposed invention and determine whether or not the art provides motivation to try the proposed invention.

Finally, while it appeared that the written description requirements between chemical and biotechnology practices were consistent, the recent Enzo decision has changed that appearance dramatically. The Enzo decision directly contradicts the standard and teaching from Fiers: that regardless of how complex or simple the DNA may be, its structure, not function, must be described. Also, the court in Enzo implied that a description of the invention’s function alone may satisfy the written to satisfy the written description requirement. See supra notes 33-58, 78-77, 113-21, 131-46.

181. See supra note 68.
182. See supra notes 71, 74 and accompanying text.
183. See supra notes 33-46 and accompanying text.
184. See supra note 19 and accompanying text.
185. See supra notes 33-46 and accompanying text.
186. See supra notes 33-58 and 68-77 and accompanying text.
187. See supra notes 81-109 and accompanying text.
188. See supra notes 112-109 and accompanying text.
189. Compare notes 112-29 with notes 131-33.
190. See supra note 124.
description requirement.\textsuperscript{192} This specifically contradicts \textit{Fiers} and \textit{Lilly}.\textsuperscript{193} Hence, the \textit{Enzo} dictum cannot be broadly applied or followed in future cases.

If the \textit{Enzo} decision becomes precedent, the Federal Circuit should narrow the rule from \textit{Enzo} and only allow a deposit to satisfy the written description requirement for biotechnology inventions that are not in fact chemical compounds. In other words, the court should not allow a deposit to satisfy the written description requirement for a DNA sequence.\textsuperscript{194}

\textbf{CONCLUSION}

The current patent standards that exist in the fields of chemical and biotechnology practice are inconsistent. The standards for the utility requirement vary between the two fields.\textsuperscript{195} Specifically, the PTO recently set forth new utility guidelines that appear to lower the utility requirement for biotechnological patent applications, while a heightened standard applies to chemical claims.\textsuperscript{196} The Federal Circuit has yet to hear a case resolving this issue.

The standards for review of obviousness appear to be consistent between chemical and biotechnology practices.\textsuperscript{197} However, the Federal Circuit has yet to hear a number of specific issues relating to obviousness with regard to DNA sequences. When these issues do come to the Federal Circuit, the court must continue to follow chemical practice precedent.

Finally, the Federal Circuit recently changed the written description requirements for biotechnology practice.\textsuperscript{198} The break from established practice is unsupported and is inconsistent with the new PTO guidelines for written description.\textsuperscript{199} This decision will likely impact and alter how companies pursue their patent strategies and file patent applications.\textsuperscript{200}

Today’s pharmaceutical companies spend hundreds of millions of dollars in the development of new drugs and therapies.\textsuperscript{201} The companies

\begin{enumerate}
\item 192. \textit{Enzo}, 296 F.3d at 1330. “It is not correct, however, that all functional descriptions of genetic material fail to meet the written description requirement.” \textit{Id}.
\item 193. \textit{See supra} notes 124, 128.
\item 194. \textit{See supra} note 138. The MPEP instructions specifically state that a deposit satisfies the written description requirement only when words alone cannot. \textit{Id}.
\item 195. \textit{Compare} notes 33-58 with 66-77.
\item 196. \textit{Id}.
\item 197. \textit{See supra} notes 81-109.
\item 198. \textit{See supra} notes 131-37, 139-45.
\item 199. \textit{See supra} notes 113-21, 138.
\item 200. \textit{See supra} note 180.
\item 201. \textit{See supra} note 6.
\end{enumerate}
need to ensure that their rights will be protected, otherwise, the incentives to invest in research are lost. The court must carefully consider how to proceed in the rapidly growing area of biotechnology, which is a subset of chemical practice, and set clear, predictable precedents that are consistent with chemical practice.

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