The patent system is meant to protect technology—actual machines, devices, and new chemical compositions—rather than pure concepts. Without patents, enterprises that do not make the research and development investment needed to invent new medicines could directly copy the drug and challenge the innovator’s price, making it unfeasible for the innovator to generate funds to invest in discovering new medicines. Hence, the whole patenting process should not be prohibitive for companies but also should not accept loose principles allowing discrepancy to standards against consumers’ protection in order to allow companies to have undue profits. Biotechnology and chemistry inventions should have the same high written description standard injecting some reasonableness into the written description requirement in these regards. The main aim of the analysis is to investigate the existence of discrepancies in the standards between chemical and biotechnology patenting. The discrepancies between chemical and biotechnology patenting must be diminished in order to avoid double standards and so establishing predictability adding to the inventive prospects of firms.

**Keywords:** Chemical patenting, biotechnology patents, written description, best mode requirement

A patent is enormously powerful because it protects novel and non-obvious ideas and not just the expression of those ideas. 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 and in return for this period of exclusive use, the inventor fully discloses his invention to the public. The *quid pro quo* of the patent system requires that the public must receive significant disclosure in exchange for being excluded from practicing the invention for a limited period of time. Government patents granted under statutory standards make it possible for pharmaceutical companies to invest the $800 million needed to bring a drug to market. Statutory patentability requirements have to be satisfied for issuing a patent, and these requirements apply to all utility patents in every field of invention. The area of chemical practice has developed, resulting in a set of patentability standards and requirements that are distinctive to chemical inventions. On the other hand, the development of biotechnology patents is fairly young. The decisive case that gave birth to the field of biotechnology patent law was *Diamond v Chakrabarty* where the United States Supreme Court held that Congress meant for “anything under the sun” to be patented as long as it was useful and so a man-made strain of bacteria was patentable subject matter. Technically, DNA and protein sequences are complex chemical molecules, which means for patentability, these sequences should fall within the higher scrutiny standards that apply to chemical compound claims? Aim of the analysis is the investigation of the existence of discrepancies in the standards between chemical and biotechnology patenting.

**Utility and Obviousness in Chemical and Biotechnology Patents**

For a subject to be patent eligible, it has to be new and useful, and be encompassed within one of four expansive categories of invention. Among the statutory requirements that must be satisfied for issuing a patent are: utility, novelty, non-obviousness, and written description. The main focus of inquiry lies on whether the claimed invention has practical utility. The utility of an invention, in concert with its novelty and non-obviousness, merits the reward of patent protection. While the requirements for patentability are applicable to all areas of utility.
patents, the field of chemical practice has developed distinct standards. In fact, differences arise as to how the test of usefulness is to be applied to chemical processes. Utility presents a question of fact and an assumed inventive act is not legally cognizable unless the inventor conceived of the exact utility of the claimed invention. The fundamental quid pro quo underlying the patent monopoly requires that the invention be useful in its currently available form.

The USPTO rejected patent applications unless the specification undoubtedly established the utility of the claimed invention. The Court of Customs and Patent Appeals (CCPA) would find the utility requirement satisfied for any process that produces an intended result and “is not ‘detrimental to the public interest.’” In fact, the inventor must have in his possession knowledge of the boundaries of the utility of the invention. The patentee must fully disclose his invention specifying the precise utility of his invention so that the public can benefit from it. A specific attribute or utility of the invention must be shown and the utility requirement cannot be satisfied if the invention is valuable as an intermediate for making a final product with an unknown utility. In re Brana, the court typically analysed the utility of the invention of a patent application as part of a 35 U.S.C. § 112 1 analysis and it said that if a patent claim fails to meet the utility requirement because it is not valuable or operational, then it also fails to meet how-to-use aspect of the enablement requirement.

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 that the other statutory patentability requirements are satisfied. While DNA exists in biological organisms, it is technically a chemical compound and as a result, should be subject to the patentability requirements that exist for chemical practice. According to Utility Examination Guidelines, the utility requirement of 35 U.S.C. § 101 is satisfied when a specific, substantial, and credible utility is disclosed. Therefore, DNA is a chemical compound and should be evaluated as such. While 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, the highly similar proteins encoded by these DNA sequences in fact exert opposite or varied effects on the cells in which they are present. Consequently, allowing a patent to be issued 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 which means a contradiction between precedent that have been established for chemical practice. Several examples exist of proteins and their encoding DNA sequences that share a high degree of homology yet serve different functions. It could be argued that first, the guidelines allow utility to be inferred based on likeness to compounds with known use and second, when a DNA or protein is analogous to a known compound, the USPTO ascribes the same function to the new invention in contradiction to chemical practice. While biotechnology is a subset of chemical practice meaning the application of the same standards, it could be said that there is a tendency to be more elastic regarding biotechnology patenting in relation to traditional interpretation considering chemical patents.

A frequent issue of patent litigation is whether or not the invention disclosed in a patent application is ‘obvious’. The key consideration taken into account in chemical practice is the amount of structural match between the claimed and prior art compounds. All obviousness analyses begin with an evaluation of three factors that were set forth in Graham v John Deere Co. The 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 non-obviousness of the subject matter is determined. 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. In re Lambooy, the biological effect of the small difference in structure was a compound with an effect opposite to that of the compound known in the art which means that this difference has to be a prime example of how to overcome prima facie obviousness. The prior art disclosure of a broad genus does not unavoidably render obvious a specific compound within the genus. The scope and content of the prior art, the level of ordinary skill in the art at the time of the invention, objective evidence of non-obviousness, and differences between the prior art and the claimed invention are facts examined in order to find out the non-obviousness.
If the written description of the patent that includes the generic claim does not indicate that the particular compound as ‘typical’ or ‘preferred,’ the court may hold that application for the particular compound is not obvious in the light of the art because the art has not distinctively taught the applicant’s invention. In *Amgen Inc v Chugai Pharmaceutical Co Ltd*, the court held that even if a high degree of sequence resemblance exists, obvious-to-try does not create a case of obviousness if motivation is absent and there is no likelihood of success if tried, which means that the standards for obviousness for DNA sequence claims may be consistent with the standards created by *Dillon* for chemical practice. In fact, disclosure of a protein sequence does not make the DNA sequence encoding that protein obvious because (over 10 x e36) different DNA sequences that could encode for the protein which means 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.

### Written Description

Under current US law, three disclosure doctrines are presently recognized as emanating from the first paragraph of 35 U.S.C. § 112— written description, enablement, and best mode. The written description requirement purports to determine whether the written description in a patent disclosure ‘reasonably conveys(s) to one of skill in the art that the inventor possessed’ the claimed subject matter. In order to comply with the written description requirement, a patent has to describe an invention in adequate detail that one skilled in the art could undoubtedly conclude that the inventor had possession of the claimed subject matter. Chemical inventions need a greater degree of description and examples of the invention in order to make certain that the inventor understands and possesses all that he claims as his invention. It could be argued that the portrayal of the structure in a generic chemical claim may be adequate to permit one skilled in the art to picture, which species particularly fall within or outside of the claim. Moreover, the extent of disclosure required is dependent on the specific case showing that the inventor has a conception of his invention. Conception of an invention cannot be defined in terms of functional utility alone and so an adequate description of how to obtain or make the invention must exist. There is a need to consider whether the scope of the claimed invention is matching with the scope of description of the invention in the specification. The court interprets and confines the claims only to be as broad as what is described in the specification.

In biotechnology inventions, an adequate written description of nucleic acids, such as, DNA or RNA, requires an accurate definition, including the pertinent ‘structure, formula, chemical name, or physical properties’ which means that a simple statement that a nucleic acid is part of the invention and ‘a reference to a potential method for isolating it,’ will not be adequate. Moreover, the Federal Circuit in *Fiers v Revel* specified that the rules from chemical practice governed determinations of whether a patent applicant satisfied the written description requirement for claims pertaining to DNA. Expressly, the DNA itself, not a method for isolating or using the DNA, has to be described and the inventor has to make it apparent that he has possession of the DNA that is claimed which means describing the DNA of the invention by providing the complete nucleotide sequence of the DNA. It has to be taken into account that disclosure and description of the DNA sequence from one vertebrate species, in combination with general methods for cloning DNA, is not an adequate written description to permit a claim to all vertebrate DNAs that encode a specific protein of interest. So, there is a need not to merely describe a function of the DNA, but the DNA itself which means that the human DNA has to be described in the application in order to distinguish this DNA from any other. In *Regents of the University of California v Eli Lilly*, the human DNA was not described in the application and there was no way to distinguish this DNA from any other. However, in *Enzo Biochem Inc v Gen-Probe Inc*, the court held that the written description requirement could be satisfied by deposit of the biological material at a publicly-accessible depository. It seems that 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 contradicting the precedent set forth in *Fiers and Lilly*: The court held that a deposit alone could satisfy the written description requirement, even in the absence of structural data in contradiction to the guidelines where it is stated that 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. . .” Can a deposit substitute for a written description when words alone cannot sufficiently describe the invention? The sequence of the DNA has to be disclosed in order to satisfy the written description requirement and the inventor to show that he has possession of the DNA that is claimed. The court’s new standard does not require that the inventor be in possession of or have a conception of his invention. Instead of describing that DNA, the inventor described the function and deposited the bacteria containing the DNA. It could be said that Enzo could not describe the sequence of the DNA, could not describe its structure, physical or chemical properties, or any functional property in combination with a structural property which means that Enzo could not satisfy the written description requirement or possession requirement of the USPTO guidelines and consequently of Section 112 paragraph 1, as established for chemical practice. Does patent law allow an inventor to patent an invention that has not yet been reduced to practice? Is it not essential, in today’s day and age, to require inventors to provide exact sequences of their DNA inventions in order not to create extra work? It seems that the Federal Circuit departs from Eli Lilly-based precedent by apparently granting more lenience toward biotechnology inventions described in functional terms. There is need to satisfy what someone skilled in the art would think is essential to the invention, rather than what the patentee thought was essential to the invention.

Do courts hurry up to award patents to companies before companies finish invention in order to secure the companies profits? Is there a danger in a possible premature award of a patent to a company, which does not hold complete knowledge of the performance of an invention? How an inventor can claim to be in possession of sub-sequences and variants or even know if such sequences will perform the claimed function when the inventor could not describe the structure or sequence of the invention? A patent’s written description has to focus on the factual state of knowledge in the applicable industry and on the predictability associated with the invention at issue. The applicant has to be in full possession of the claimed subject matter on the filing date so that the specification discloses the compound. Does a description that makes the claimed invention obvious satisfy the written description requirement? The patentee must in fact possess the inventive concept, and not simply something close to it.

Can the deposit show that the inventor is in possession and knowledge of the claimed invention and its performance in order to avoid bad consequences for the customers? The deposit option arose to satisfy the enablement requirement for complex biotechnology inventions that could not easily or effectively be enabled by words alone. Could the deposit option be used for complex biotechnology inventions that could not without doubt or satisfactorily be enabled by words alone? The author considers that deposit and written description should be used in tandem. For instance, for inventions such as cell lines and other inventions that are difficult to describe or teach how to make, deposit and the best possible written description should be used in tandem. As mentioned earlier, DNA is a chemical and as a consequence chemical practice should apply to DNA inventions. It could be said that the PTO new utility guidelines appear to lower the utility requirement for biotechnological patent applications, while a heightened standard applies to chemical claims. Biotechnology is a subset of chemical practice, which means that there is a need to set clear, predictable precedents that are consistent with chemical practice.

Is it not necessary to provide exact chemical formulas in a specification in order to adequately cover an invention? In Union Oil Co of California v Atlantic Richfield Co the court specified that it did not matter that “the specification does not describe the exact chemical component of each combination that falls within the range claims of the ‘393 patent” which means an overall weaker written description requirement, at least in the field of chemistry.

The Best Mode Requirement

The best mode requirement is intended to guarantee that a patent applicant play ‘fair and square’ with the patent system which means that one must not be given the right to exclude others except at the time of filing he has provided an adequate disclosure of the best mode known to him of carrying out his invention. In Bayer v Schein Pharmaceuticals, the Federal Circuit held that inventors might withhold from the public knowledge cheaper and more competent methods for producing an otherwise available and enabled chemical intermediate without violating the best mode requirement of Section § 112 of the Patent Act. While if an applicant has complied with the best mode requirement of § 112 is a question
of fact, the question of the proper legal standard to apply to the best mode requirement is a question of law, which is reviewed de novo. Courts will usually determine if the best mode requirement is satisfied based upon whether the applicant has contemplated and subsequently concealed the best mode by not disclosing it.42

Organic chemistry involves the combining, through chemical bonding, various atoms of the basic building blocks known as elements (such as carbon, nitrogen, oxygen, etc.) to form a molecule and that molecule is used either as the final molecule of choice, or as the basis for one or a series of ‘chemical intermediate(s)’ in the synthesis of a yet larger molecule. The ingredients, including any chemical intermediate molecules, are reacted together to form the final molecule and the creation of the final molecule is a series of steps that enclose intermediates, and wherein the final product cannot be brought into existence without conducting the underlying predecessor steps. In patent law, the term chemical intermediate refers to the building base for forming a larger modified molecule. A synthesized molecule which has been used as a chemical intermediate can be a stable molecule and can be obtained from third party sources. It should be taken into account that a chemical intermediate can also be independently patented.43 In other words, an additional patent can cover the structure of the chemical intermediate. Chemical patents, must meet the patent requirements of novelty, utility, and non-obviousness. A patent must contain a description that enables one skilled in the art to make and use the claimed invention not having to explain every detail since his audience is those skilled in the art. Every detail does not have to be described otherwise patent specifications would turn into production specifications, which was never the intent.45

The patent law of the United States has required that the inventor disclose various ‘modes’ for practicing the invention but the current statute (the Patent Act of 1952) requires that the specification ‘shall set forth the best mode contemplated by the inventor of carrying out his invention.’ It is worth mentioning that the Patent Act does not define what this broad language shall mean, predominantly in terms of the scope of the terms ‘invention’ and ‘carrying out’ in the wide variety of circumstances that may occur in developing technology. Courts explaining the best mode requirement focused on a two-prong inquire first, the fact finder must find out whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention and second, if the inventor possessed a best mode, the fact finder must determine whether the written description disclosed the best mode such that one reasonably skilled in the art could practice it.46 The extent of information that an inventor must disclose depends on the scope of the claimed invention which means that an inventor need not disclose a mode for obtaining unclaimed subject matter except the subject matter is novel and indispensable for carrying out the best mode of the invention.47 Originally, the Federal Circuit has unvaryingly held that ‘the invention’ involved in the best mode inquiry refers to, but is not confined to the invention specifically set forth in the patent claims not providing apparent standards for determining the circumstances under which unstated, but essentially present, component parts of the specifically claimed ‘invention’ and/or its expressly claimed claim elements are to be included in the best mode requirement.48

Final molecules in a chemical synthesis are formed by joining together smaller, precursor chemical entities. In some cases, it was held that only the item(s) set forth in haec verba in the patent claim need be subject to best mode disclosure and in others held that supplementary disclosure must be made as to non-claimed subject matter which (a) either is novel, or (b) would materially affect the uniqueness or functioning of the claimed subject matter.49 Nevertheless, whether an invention’s smaller constituent parts are held together by chemical bonds (as the case of a molecular invention), by covalent or physical mixture means (as in the case of composition of matter inventions), or by mechanical means (as in the case of a mechanical device or apparatus invention), is not deemed to be conceptually distinct. Is there a need for a different best mode analysis based upon the various methods of joinder of the elements of the various kinds of chemical, composition of matter, and/or apparatus inventions? In Eli Lilly & Co v Barr Labs50, the court considered the various constituent parts of a molecule (reflecting the smaller molecules from which it is formed) to be essentially different from the various constituent parts of mechanical and/or composition of matter inventions. Chemical or molecular inventions, which are formed from smaller chemical moieties, may
accurately be considered to be analogous to (a) compositions of matter, which are composed of a variety of elements mixed together, or (b) mechanical devices having a number of elements which are mechanically connected to effectuate the functioning of the device. Is there a need to disclose relevant information regarding such a component part of the claimed invention to be within the scope of the best mode analysis?

In *Bayer v Schein Pharmaceuticals*, Schein argued that Bayer had failed to disclose the inventor’s preferred method for making a certain necessary chemical ingredient (i.e., the ‘intermediate’ molecule (6-FQA)), even though Bayer’s application had disclosed the preferred method of converting the intermediate into the final product, Cipro®. The Federal Circuit held that the preferred method for making the chemical intermediate did not materially affect the characteristics of the claimed molecule, and consequently need not be disclosed which means that the best mode test should be firmly limited to whether the allegedly withheld information fell within the scope of the claims. Judge Rader in reaffirming the truly ‘bright-line test’ used by the district court stated that the best mode requirement ‘does not compel disclosure of the unclaimed method’ because the alleged best mode was an intermediate and not the claimed invention regardless that the withheld information in reality did materially affect the properties of the claimed molecule. The atoms comprising the intermediate do not somehow ‘lose’ their identity just because there is a further chemical reaction which simply adds a side chain onto the intermediate main body to form the final Cipro® molecule. The manufacture of a molecule is a series of interdependent steps that exist as a physical reality separate and apart from any patent drafter’s decision in describing the final product that constitutes the invention set forth in the patent claims. Taking into account the quite simple final step in forming the Cipro® molecule, the patentee could not argue that the entirety of the chemical process, including the preferred method for synthesis of the intermediate, was not a material part of the ‘invention’. If the patentee had raised such an argument, the District Court might very well have considered the Cipro® ‘invention’ to be invalid for obviousness under 35 U.S.C. § 103. Is there a need for the creation of a ‘new test’ for best mode involving additional inquiry into the effect of the withheld information upon the claimed subject matter? According to the *Bayer v Schein Pharmaceuticals* outcome the creation of a ‘new test’ for best mode involving additional inquiry into the effect of the withheld information upon the claimed subject matter should not be required. The *Bayer* court proposes that the best mode requirement should apply only to oblige the disclosure of subject matter which materially affects the physical (or ‘intrinsic’) properties of the claimed subject matter, but not to other non-physical characteristics that appear to be just as ‘intrinsic’. How the ‘intrinsicness’ of the characteristics can be determined? A characteristic may be ‘intrinsic’ for best mode purposes only if and when the Federal Circuit deems it to be.

Compliance with best mode disclosure requirement for patent specifications is a question of fact which means that first, the fact finder must determine whether, at the time of filing the application, the inventor possessed a best mode for practising the invention, and this prong is exceedingly subjective focusing on the inventor’s state of mind as of the date of filing the application, and, second, if the inventor subjectively considered one mode to be preferred over all others, then the inquiry is whether the inventor’s disclosure is sufficient to enable one of ordinary skill in the art to practice the best mode of the invention, and this inquiry is objective depending upon the scope of the claimed invention and the level of skill in the relevant art. A patent is invalid for the failure to satisfy the best mode requirement in two specific situations, which means that first patents are invalidated when the parties do not sufficiently disclose a preferred embodiment of the invention. As a result, if an inventor fails to disclose the preferred embodiment of the invention, the best mode requirement is not satisfied. Second, the court has invalidated patents when the patentee failed to disclose ‘aspects of making or using’ the claimed invention and the undisclosed matter ‘materially affected the properties’ of the claimed invention.

Section 112 requires that the best mode of ‘carrying out’ the invention be disclosed by the inventor and the best mode requirement for disclosures in patent specification is not satisfied if an inventor fails to disclose the preferred embodiment of the invention, or fails to disclose aspects of making or using the claimed invention and the undisclosed matter materially affected the properties of the claimed invention. Can non-preferred methods be conceded to be adequate to meet minimal standards of
‘enablement’ under 35 U.S.C. § 112? The enablement requirement ensures that "that a specification shall disclose an invention in such a manner as will enable one skilled in the art to make and utilize it." The best mode requirement is ‘separate and distinct’ from enablement and ‘requires an inventor to disclose the best mode contemplated by him, as of the time he executes the application, of carrying out the invention’. To obtain a patent the applicant must provide a sufficient disclosure to enable any person skilled in the art to practice the invention which means that the patent specification must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation. In fact, courts generally require a full range of disclosure pertaining to the operation of the claim.

The ‘invention’ for § 112 best mode purposes should be the same ‘invention’ relied upon by the patentee for non obviousness under § 103. In Teleflex Inc v Ficosa N Am Corp the majority in Bayer v Schein Pharmaceuticals decided that the preferred method of making and using the intermediate was exempted from the best mode strictures of the statute. In Zygo v Wyko the applicant had taken the usual step of enclosing the interferometer in a box, but the box was not a part of the patent claim and the undisclosed item (i.e., the box) was not necessary to make a functional device. Consequently, the Court held that there had been not a best mode violation by reason of failing to disclose an unnecessary component. However, in the Bayer case not only is the intermediate molecule ‘necessary’ to the claimed Cipro© molecule, but indeed the Cipro© molecule cannot exist without pre-existence of the intermediate molecule. Hence, it cannot be argued sincerely that the chemical intermediate is somehow not a vital part of a molecule that simply adds a side chain to the intermediate in order to manufacture the Cipro© molecule. To that extent in the case of USG v National Gypsum, the patent claim was directed to a mixture of ingredients that included expanded Perlite and the applicant was aware that one commercial brand of Perlite provided superior qualities to the final mixture and the Court held that failure to disclose this indispensable element constituted a best mode violation. Moreover, in Chemcast v Arcot the inventor did not disclose (a) the only material (a PVC polymer) that he knew would function adequately, and (b) which had even been specifically developed for purposes of use in the invention. Hence, a best mode violation was established. Most of the cases in which the best mode requirement was violated addressed situations where the inventor failed to disclose non-claimed elements that were nonetheless essential to practice the best mode. In the Randomex v Scopus case, the patent claims covered a portable device for cleaning compact discs and regardless that the patent claims did not incorporate any cleaning solution as an element, the inventor there had disclosed his preferred cleaning solution by its trade name. Thus, no best mode violation was found. In Dana Corp v IPC Ltd Partn the patent claims covered a valve stem seal for use in an internal combustion engine where the inventor had not disclosed the fluoride surface treatment that was required to give vastly improved functioning to the seals. Hence, and as in the Bayer case, the preferred method of making one of the elements of the claimed invention had been withheld, and a best mode violation was found. There is no reason of logic or scientific substance for treating the pharmaceutical industry in a different way from the motor industry. Additionally, what was concealed in both cases was a material part of the patent claim. The subject matter of the claims in re Gay was a cooking bag for cooking rice which was made of a material having a defined porosity and the Court held that it was not crucial to disclose the commercial embodiment, above all because the functional materials were well known. On the other hand, the details of the Cipro© inventor’s secret process were not already or independently known to the public. The inventor in Spectra Physics v Coherent had failed to disclose the particular 6-step brazing process that was preferred because of its vastly superior properties and a best mode violation was found. In the Bayer case, the inventor had failed to disclose the preferred process for making a specific molecule that is the largest part of the patent claim. Indeed, there is absolutely no distinction between the two cases.

The scope of the best mode requirement demonstrates that the best mode disclosure requirement only refers to the invention defined by the claims but the Federal Circuit then acknowledged the exception to the general rule that there is a legal
obligation to give the full particulars of methods, structures, or other details where the omitted subject matter would materially affect this strictly defined ‘invention.’ To that extent, Judge Rader comments on the fact that the majority has broadened the scope of a best mode analysis without the necessary support from case law or statutory law and so “With the ‘scope of the claimed invention’ rule governing the identification of best modes, the court claimed that it should have halted its analysis when the district court correctly applied that rule. Up to the point of acknowledging the claimed invention, this Bayer opinion reflects well the bulk of this court's best mode jurisprudence. Then, inexplicably and without support in the statute or case law, this Bayer opinion widens its best mode net to capture the properties of the claimed invention and further sweeps in any material effect or impact on those properties.” Moreover, the Bayer inventor’s failure to disclose the preferred method of making the chemical intermediate molecule does indeed materially affect the making of the invention and in fact, the process used to make the intermediate forms the very essence of the making of the Cipro® molecule, which is the claimed ‘invention’ It is argued that the subject matter explicitly set forth in the claim should be deemed to be the ‘invention’ referred to in the best mode requirement of the statute and so the extent of information that an inventor must disclose depends on the scope of the claimed invention.

The applicant has no duty to disclose in the patent application the preferred method (i.e., the best mode) for making the preferred intermediate compound, even though the intermediate compound itself may be novel (as here), and even though the withheld method for making the critical intermediate compound may be far better than any method of making otherwise available to the public. Is it possible that the undisclosed method of making the intermediate somehow does not affect the properties of the final compound, which scarcely could even be made without making the very intermediate? It could be said that the Federal Circuit’s rule set forth in Bayer does not mirror the Constitutional or statutory purpose, because, inter alia, the Bayer rule would permit concealment of significant aspects of the very res from which the inventor has excluded the public by the patent grant -- and predominantly where the excluded subject matter is a novel chemical intermediate. The patentee should not be able to obtain the ‘benefits’ of the patent grant without suffering the ‘detriment’ of providing a full and fair teaching to the public of the “best mode for carrying out the invention,” under Section 112. The statute clearly requires that the inventor’s best mode of ‘carrying out’ the invention be disclosed.

**Conclusion**

It could be argued that biotechnology developments on DNA and proteins needed patenting, are less predictable having to do with the human creation and the unknown of the human body as material and spirit and their interrelation which makes the impact of each other upon the creation undiscoverable than classical chemical patents which makes necessary at least the need for adaptation of the Act into the needs of interpretation to encompass the new developments. Biotechnology and chemistry inventions should have the same high written description standard injecting some reasonableness into the written description requirement in these regards. The vital considerations should focus on the predictability associated with those specific circumstances at the patent filing date. It should be taken into consideration that biotechnology and chemical patents should not become so specific that they no longer allow scientists to protect their inventions, in this manner decreasing the incentive to invest in biotechnology and chemistry. According to the author a test examining, evaluating and utilizing the key factors making the substance/structure of every patent would form a more appropriate vehicle for analysing and determining whether a patentee has met the *quid pro quo* obligations of disclosure to the public that accompanies the granting of a patent. There is a need for disclosure of the full particulars of the invention to the public. The discrepancies between chemical and biotechnology patenting specified in this analysis must be diminished in order to avoid double standards and so establishing predictability adding to the inventive prospects of firms.

Another approach could be to distinguish between classical chemical patenting for substances not involved with chemical molecules existing in biotechnology/chemical patenting and so to talk about a new area of chemistry with its own characteristics closer to human creation and body which needed a new approach and so different patenting standards which could be more strict and clear but harmoniously standard than those applied to classical
chemical patents. Consequently, chemical/biotechnology patenting will establish different standards than the already established chemical standards which have to become definite and consistent rather than changeable according to the power of the producing company. There is a need for a scientific standardization of the biotechnology/chemical developments not only as biotechnology/chemical/medical knowledge, but also as new inventions and products as well. Even a different approach is needed regarding the definition of what is inventionable for biotechnology/chemical patenting as distinguished to classical patents and chemical patents. Finally, it might be useful to have a new Act at the national and international level for patents. It might be useful to have a new Act regarding the definition of what is inventions and products as well. Even a different chemical/medical knowledge, but also as new chemical patents. Consequently, chemical/medical standards which have to become definite and consistent rather than changeable according to the power of the producing company. There is a need for a scientific standardization of the biotechnology/chemical developments not only as biotechnology/chemical/medical knowledge, but also as new inventions and products as well. Even a different approach is needed regarding the definition of what is inventionable for biotechnology/chemical patenting as distinguished to classical patents and chemical patents. Finally, it might be useful to have a new Act at the national and international level for patents. It might be useful to have a new Act regarding the definition of what is inventions and products as well. Even a different chemical/medical knowledge, but also as new chemical/patents and patenting.

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4. Kevles Daniel & Berkowitz Ari, The gene patenting controversy: A convergence of law, economic interests, and ethics, 67 Brook. L and Rev. 233, 248 (Fall 2001). “Given that the human genome is widely regarded as a common birthright of people everywhere, governments may feel increasing pressure to limit the property rights sought in DNA sequences.” In re O’Farrell, 853 F.2d 894 (Fed. Cir. 1988)

5. State Street Bank & Trust Co v Signature Fin Group Inc, 149 F.3d 1368, 1373, 47 USP.Q.2d (BNA) 1596, 1600 (Fed. Cir. 1998) (reasoning that Congress’ repeated use of the term ‘any’ in § 101 indicates its expansive understanding of permissible subject matter)

6. State Street Bank, 149 F.3d at 1375, 47 USP.Q.2d (BNA) at 1602 (“The question of whether a claim encompasses statutory subject matter should not focus on which of the four categories of subject matter a claim is directed to ... but rather on the essential characteristics of the subject matter, in particular, its practical utility”). In re Ziegler, 992 F.2d 1197, 1203, 26 USP.Q.2d (BNA) 1600, 1605 (Fed. Cir. 1993) (explaining that the potential role of an object cannot satisfy the utility requirement); Utility Examination Guidelines, 66 Fed. Reg. 1092, 1098 (5 January 2001) (recommending that patent applications should be rejected based on lack of utility if a person of ordinary skill in the art would not consider the asserted utility specific, substantial, and credible based on all the evidence in the record)

7. Cross v Iizuka, 753 F.2d 1040, 1044 (Fed. Cir. 1985), Brenner v Manson, 383 US 519, 534 (1966) (“The basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility.”) Warner-Jenkinson Co v Hilton Davis Chem Co, 520 US 17, 40, 41 USP.Q.2d (BNA) 1865, 1875 (1997) (expecting that the Federal Circuit will refine its formulation of legal tests on a case-by-case basis)

8. Brenner v Manson, 383 US 519 (1966). The applicant had filed for a patent for a steroidal compound and the examiner rejected the application because it failed to disclose utility. 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. 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”

9. Roy-Bellet v Engelhardt, 493 F.2d 1380, 1385 (CCPA 1974), Kridl v McCormick 105 F.3d 1446, 1447 (Fed. Cir. 1997), In re Thorne, 777 F.2d 695, 697, 227 USP.Q. (BNA) 964, 965-66 (Fed. Cir. 1985) (explaining that novelty and non-obviousness of the product are not assured by the novelty or non-obviousness of the process)

10. In re Bruna, 51 F.3d 1560, 1564 (Fed. Cir. 1995), In re Fouche, 439 F.2d 1237, 1243 (C.C.P.A. 1971), Process Control Corp v HydReclaim Corp, 190 F.3d 1350, 1358, 52 USP.Q.2d (BNA) 1029, 1034-35 (Fed. Cir. 1999), Brooktree Corp v Advanced Micro Devices Inc, 977 F.2d 1555, 1571,
24 USP.Q.2d (BNA) 1401, 1412 (Fed. Cir. 1992) (clarifying that if the subject matter of a patent is inoperable, then the patent may fail to meet both the utility requirement and the enablement requirement)


12 66 Fed. Reg. 1092 (5 January 2001). The guidelines also make clear that, “if 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.” Nucleic acid is the chemical building blocks of which DNA is composed. “When 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 the examiner unless the Office has sufficient evidence or sound scientific reasoning to rebut such an assertion”

13 Utility Examination Guidelines, 66 Fed. Reg. at 1094. 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

14 Matiba B et al., The CD95 System and the Death of a Lymphocyte, Seminars in Immunology, 9(1) 1997, 59-68. “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.” Q L Deveraux & J.C. Reed, IAP Family Proteins-Suppressors of Apoptosis, 13 Genes and Development, 1999, 239-52. “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”

15 Graham v John Deere Co, 383 US 1, 17 (1966). In re Dillon, 919 F.2d 688, 692 (Fed. Cir. 1990). “Structural 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 prima facie case of obviousness, and that the burden (and opportunity) then falls on an applicant to rebut that prima facie case”

16 In re Papesch, 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 identify what is being patented, as the metes and bounds of a deed identify a plot of land, the 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 of the former compound to the latter

17 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. In re Baird, 16 F.3d 380 (Fed. Cir. 1994); “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 . . . .”

18 In re Deuel, 51 F.3d 1552, 1553-54. In re Baird, 16 F.3d 380 (Fed. Cir. 1994). In re Mayne, 104 F.3d 1339 (Fed. Cir. 1997)

19 Monarch Knitting Mach Corp v Sulzer Morat GMBH, 139 F.3d 877, 881 (Fed.Cir. 1998). In re Beattie, 974 F.2d 1309, 1311 (Fed. Cir. 1992) (discussing what the prior art teaches as a question of fact, which is reviewable under the clearly erroneous standard)

20 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.” “Though 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 explained above, is the claimed salt sufficiently similar in structure to those specifically disclosed in Richter as to render it prima facie obvious”

21 927 F.2d 1200

22 In re Bell, 991 F.2d 781, 784 (Fed. Cir. 1993); “Because of the degeneracy of the genetic code, there are a vast number of nucleotide sequences that might code for a specific protein . . . . In the case of IGF [protein at issue], Bell has argued without contradiction that the . . . amino acid sequences could be coded for by more than 1036 different nucleotide sequences, only a few of which are the human sequences that Bell now claims.” “[G]iven the nearly infinite number of possibilities suggested by the prior art, and the failure of the cited prior art to suggest which of those possibilities is the human sequence, the claimed sequences would not have been obvious . . . . [A]bsent anything in the cited prior art suggesting which of the possible sequences suggested by Rinderknecht [prior art] corresponds to the IGF gene, the PTO has not met its burden of establishing that the prior art would have suggested the claimed sequences.” In re Deuel, 51 F.3d 1552, 1559 (Fed. Cir. 1995). “A prior art disclosure of the amino acid sequence of a protein does not necessarily render particular DNA molecules encoding the protein obvious because the redundancy of the genetic code permits one to hypothesize an enormous number of DNA sequences coding for the protein. No particular one of these DNAs can be obvious unless there is something in the prior art to lead to the particular DNA and indicate that it should be prepared.” “There must, however, still be prior art that suggests the claimed compound in order for a prima facie case of obviousness to be made out. . . . A general incentive does not make obvious a particular result . . . .”
written description when “the claim or claims have possession of a genus . . . .”.

The PTO rejects patent applications for lack of enablement, written description, and best mode requirements. Purdue Pharma L.P v Faulding Inc, 230 F.3d 1320, 1323, 56 USP.Q.2d (BNA) 1481, 1483 (Fed. Cir. 2000) (explaining that the test for whether the written description requirement has been met must be assessed on a case-by-case basis).

Accordingly, such a formula is normally an adequate description of the claimed genus. In re Lockwood v Biomet Inc., 156 F.3d 1154, 1158 (Fed. Cir. 1998).

In re Vaeck, 947 F.2d 488, 496 (Fed. Cir. 1991) (“Where, as here, a claimed genus represents a diverse and relatively poorly understood group of microorganisms, the required level of disclosure will be greater than, for example, the disclosure of an invention involving a ‘predictable’ factor such as a mechanical or electrical element.”)

But Fonar Corp v Gen Elec, Co, 107 F.3d 1543, 1549, 41 USP.Q.2d (BNA) 1801, 1805 (Fed. Cir. 1997) (finding, in the context of software, that disclosure of the function was adequate in that art).

In re Wilder, 736 F.2d 1516, 1521, 222 U.S.P.Q.(BNA) 369, 372-73 (Fed. Cir. 1984) (affirming a rejection for lack of written description where the specification merely outlined the goals the inventors sought to achieve). But Fonar Corp v Gen Elec, Co, 107 F.3d 1543, 1549, 41 USP.Q.2d (BNA) 1801, 1805 (Fed. Cir. 1997) (finding, in the context of software, that disclosure of the function was adequate in that art).

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 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”.

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 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 . . . .” Lockwood v American Airlines, Inc, 107 F.3d 1565, 1572 (Fed. Cir. 1997).

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. 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 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 . . . .”


In re DiLeon, 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.” 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.”)

Fiers v Revel, 984 F.2d 1164, 1171 (Fed. Cir. 1993).

Fiers v Revel, 984 F.2d 1164, 1169 (Fed. Cir. 1993). “We thus determined that, irrespective 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.” “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”

Lilly, 119 F.3d at 1566. “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 interest] DNA. Describing a method of preparing a cDNA or even describing the protein that the cDNA encodes . . . does not necessarily describe the cDNA itself”

Enzo Biochem Inc v Gen-Probe Inc, 296 F.3d 1316 (Fed. Cir. 2002). The technique of depositing biological materials originally arose as a way to satisfy the enablement requirement. By letting the public have the material, they were enabled to use it. “We hold that reference in the specification to a deposit in a public depository, which makes its contents accessible to the public when it is not otherwise available in written form, constitutes an adequate description of the deposited material sufficient to comply with the written description requirement of § 112 1.” at 1326 “Although the structures of those sequences, i.e., the exact nucleotide base pairs, are not expressly set forth in the specification, those structures may not have been reasonably obtainable and in any event were not known to Enzo when it filed its application . . . .”. Amgen Inc v Hoechst Marion Roussel Inc, 314 F.3d 1313 (Fed. Cir. 2003). “In Enzo-Biochem, we clarified that Eli Lilly did not hold that all functional descriptions of genetic material necessarily fail as a matter of law to meet the written description requirement; rather, the requirement may be satisfied if in the knowledge of the art the disclosed function is sufficiently correlated to a particular, known structure.” The paradox of this court’s affirmation of the holding of Enzo is that the Enzo court required no disclosure of the structure of the DNA. See supra note 133. Thus, the Amgen court failed to acknowledge what the court actually did in Enzo. The Federal Circuit has yet to apply the Enzo precedent”

35 The written description requirement is codified in 35 U.S.C. § 112, which states that in a patent: “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.”

36 According to the USPTO, the requirement “promotes the progress of the useful arts by ensuring that patentees adequately describe their inventions in their patent specifications in exchange for the right to exclude others from practicing the invention for the duration of the patent’s term.” Mueller Janice M, The evolving application of the written description requirement to biotechnological inventions, Berkeley Technology Law Journal, 13 (2) 1998, 615, 620–21 “Today, the written description, rather than notifying the public at the time of patent issuance of the asserted scope of the patentee’s property right, serves as a manifestation of what was within the scope of the patentee’s inventive contribution as of his filing date. Thus, the written description requirement takes a “snapshot” view of the inventor’s contribution based on the disclosure in her specification as originally filed, and asks whether that “snapshot” reasonably conveys to persons of ordinary skill that any subsequently-claimed subject matter was truly and fairly part of that contribution”

37 In re Raschig, 379 F.2d 990 (C.C.P.A. 1967). In re Barker, 559 F.2d 588, 591–93 (C.C.P.A. 1977). “A specification may contain a disclosure that is sufficient to enable one skilled in the art to make and use the invention and yet fail to comply with the description of the invention requirement.”Vas-Cath Inc v Mathurkar, 935 F.2d 1555, 1563 (Fed. Cir. 1991). “This court in Wilder (and the CCPA before it) clearly recognized, and we hereby reaffirm, that 35 U.S.C. § 112, first paragraph, requires a ‘written description of the invention’ which is separate and distinct from the enablement requirement”

38 Lockwood, 107 F.3d 1565 (Fed. Cir. 1997). In re Marzocchi 439 F.2d 220, 223 (C.C.P.A. 1971), the CCPA stated, “In the field of chemistry, generally, there may be times when the well-known unpredictability of chemical reactions will alone be enough to create a reasonable doubt as to the accuracy of a particular broad statement put forward as enabling support for a claim”

39 208 F.3d 989 (Fed. Cir. 2000), reh’g en banc denied, No 99-1066, 2000 US App. 12720 (Fed. Cir. May 18, 2000), cert. denied, 531 U.S. 1183 (2001). (“The inquiry for adequate written description simply does not depend on a particular claim format, but rather on whether the patent’s description would show those of ordinary skill in the petroleum refining art that the inventors possessed the claimed invention at the time of filing”)

40 Amgen, Inc v Chugai Pharm Co Ltd, 927 F.2d 1200, 1209-10. N Telecom Ltd v Samsung Elecs Co, 215 F.3d 1281, 1288, 55 USP.Q.2d (BNA) 1065, 1070 (Fed. Cir. 2000) (holding that the best mode requirement was satisfied even though thin-line etching, an unclaimed, preferred method for the process for gaseous etching of aluminum and aluminum oxides, was not disclosed in the specification because the claim sufficiently described a general process of plasma etching and the best mode for carrying out that process)

41 Bayer Corp v Schein Pharm Co Inc, 301 F.3d 1306, 1306-28 (Fed. Cir. 1991). In the invention set forth in the Bayer ‘444 patent, several precursor molecules were synthesized, that were then combined together to form the chemical intermediate 6-fluorouquinolinic acid (6-FQA) that is the subject matter of the dispute in the Bayer case

42 Chemcast Corp v Arco Indus Corp, 913 F.2d 923, 928 (Fed. Cir. 1990). Fujikawa v Wattanasit, 93 F.3d 1559, 1570, 39 USP.Q.2d (BNA) 1895, 1994 (Fed. Cir. 1996) (requiring only that the disclosure in the application ‘reasonably convey’ to those skilled in the art that the inventor possessed the disputed subject matter)

43 This process of ‘chemical synthesis’ is a combination of several steps, using a reaction vessel into which the various reactants are introduced. The synthesis mix is then subjected to conditions, such as temperature, pressure change, contact with catalysts, etc. A chemist may choose to make one or more sequential “chemical intermediates” to be used for further steps in the synthesis, or alternatively, the ‘intermediates’ may come from another source. Enzo Biochem, Inc v Gen-Probe Inc, 296 F.3d 1316, 1360-30, (Fed. Cir. 2002). Brenner v Manson, 383 US 519 (1966); Eli Lilly & Co v Barr Labs, 251 F.3d 955 (Fed. Cir. 2001); Chem Indus v US, 170 F. Supp. 2d 1335 (2d Cir. 2001); Baoding Yude; Murphy Oil US v US, 81 F Supp. 2d 942 (Ark. 1999); Eli Lilly & Co v Am Cyanamid Co, 82 F.3d 1568 (Fed. Cir. 1996)


46 Fonar Corp v General Elec Co, 107 F.3d 1543, 1548 (Fed. Cir. 1997); US Gypsum Co v Natl. Gypsum Co, 74 F.3d 1209, 1212 (Fed. Cir. 1996)

47 Engel Indus v Lockformer Co, 946 F.2d 1528, 1531 (Fed. Cir. 1991). Applied Med Res Corp v United States Surgical Corp, 147 F.3d 1374, 1377 (Fed. Cir. 1998); Transco Prods, Inc v Performance Contracting, Inc Transco Prods, 38 F.3d 553

48 Zygo Corp v Wyko Corp, 79 F.3d 1563, 1567 (Fed. Cir. 1996); Wahl Instruments, Inc v Acuvision Inc, 950 F.2d 1575, 1579 (Fed. Cir. 1991)


50 251 F.3d 955 (Fed. Cir. 2001)

51 35 U.S.C. § 103 states: Conditions for patentability; non-obvious subject matter 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 would have 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

be held to answer for a capital, or otherwise infamous crime, unless on a presentment or indictment of a grand jury, except in cases arising in the land or naval forces, or in the militia, when in actual service in time of war or public danger; nor shall any person be subject for the same offense to be twice put in jeopardy of life or limb; nor shall be compelled in any criminal case to be a witness against himself, nor be deprived of life, liberty, or property, without due process of law; nor shall private property be taken for public use, without just compensation. *Kaluzynski v Armstrong*, 2001 US Dist. LEXIS 11040 (D. Me. 2001); *Ostergren v Village of Oak Lawn*, 125 F. Supp. 2d 312 (N.E.2d 2000).

53 *Hybritech Inc v Monoclonal Antibodies Inc*, 802 F.2d 1367, 1384 (Fed. Cir. 1986) (specifying that no amount of experimentation is preclusive if merely routine in nature). (stating that the enablement requirement is still satisfied with the necessity of experimentation, so long as the experimentation is not unduly extensive). *Genentech Inc v Novo Nordisk*, 108 F.3d 1361, 1366, 42 U.S.P.Q.2d (BNA) 1001, 1005 (Fed. Cir. 1997) (clarifying that the patent monopoly is given in exchange for enabling disclosure, “not for vague intimations of general ideas that may or may not be workable”); *Brenner v Manson*, 383 U.S. 519, 536, 148 U.S.P.Q. (BNA) 689, 696 (1966) (“[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion.”)

54 *PPG Indus Inc v Guardian Indus Corp*, 75 F.3d 1558, 1564, 37 USP.Q.2d (BNA) 1618, 1623 (Fed. Cir. 1996) (“In unpredictable art areas, this court has refused to find broad generic claims enabled by specifications that demonstrate the enablement of only one or a few embodiments and do not demonstrate with reasonable specificity how to make and use other potential embodiments across the full scope of the claim.”)


56 79 F.3d 1563

57 440 F.2d 510

58 *Chemcast Corp v Arco Indus Corp*, 913 F.2d 923, 928 (Fed. Cir. 1990)

59 *Randomex Inc v Scopus Corp*, 849 F.2d 585-600 (Fed. Cir. 1998)

60 *Dana Corp v IPC Ltd Partn*, 860 F.2d 415 (Fed. Cir. 1988);

61 309 F.2d 772


63 *Bayer*, 301 F.3d at 1315