Chicago-Kent Journal of Intellectual Property

Volume 3 | Issue 2 Article 4

4-1-2004

Bayer v. Schein Pharmaceuticals --Best Mode Requirement --In Chemical Inventions: When Does "Carrying Out the Invention" Start? --A Proposal for a Comprehensive Best Mode Compliance Test

Justin Charles Ward

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Bayer v. Schein Pharmaceuticals – Best Mode Requirement – -In Chemical Inventions: When Does "Carrying Out the Invention" Start?– A Proposal for a Comprehensive Best Mode Compliance Test.

JUSTIN CHARLES WARD*

> [T]he best mode requirement is intended to ensure that a patent applicant play 'fair and square' with the patent system. It is a requirement that the *quid pro quo* of the patent grant be satisfied. One must not receive the right to exclude others unless at the time of filing he has provided an adequate disclosure of the best mode known to him of carrying out his invention.[1]

I. INTRODUCTION

A scientist at a huge pharmaceutical company develops a secret process for making a chemical intermediate that is necessary for producing a life saving pharmaceutical compound. As this development proceeds, the scientist files a patent application claiming the life saving drug, but omits the information necessary for producing the chemical intermediate according to the inexpensive and efficient method that he has developed. The patent application discloses other, more expensive and inefficient methods, for producing the chemical intermediate. The net result of using the less efficient method for producing the chemical intermediate creates a higher cost to the purchasing public for the ultimate pharmaceutical drug. Should the scientist be permitted to withhold knowledge of cheaper and more efficient means for producing a chemical intermediate from the public (i.e., the best mode), electing instead to disclose only a workable embodiment (i.e., enabling disclosure)? [*120*]

In *Bayer v. Schein Pharmaceuticals*, the Federal Circuit held that inventors may withhold from the public knowledge cheaper and more efficient methods for producing an otherwise available and enabled chemical intermediate without violating the Best Mode requirement of Section § 112 of the Patent Act[2]. Said differently, should a material part of a claimed molecule be disqualified from legal status as a "limitation" of a patent claim just because it began as a mere "chemical intermediate"?[3]

This paper critiques both the majority and concurrence opinion in *Bayer*. The paper demonstrates that the majority's "if it doesn't affect the intrinsic characteristics" test is flawed.[4] In particular, there is scant agreement even on what is, or is not, an "intrinsic characteristic," and thus no operational or objective standards can exist for determining what does or does not affect such an undefined parameter. Also, the paper demonstrates that the bright-line "scope of the claims" test advocated in the concurring opinion is likewise substantially inoperable.[5] Specifically, the "scope of the claims" concept (at least as promulgated and applied by the Court) appears to be self-contradictory, as it ignores the chemical reality that the claimed molecule inherently retains within itself (and thus as its "claim element") the very reagents from which it is formed, including any chemical intermediate. Because neither of these tests sufficiently judges the adequacy of the best mode disclosure, this paper proposes a flexible, multi-factor test to determine whether section § 112 has been met.[6] [*121]

II. Background

A. Pioneer and generic drug companies

The plaintiff Bayer is a large international pharmaceutical company whose business is to underwrite and conduct basic research for new drugs.[7] In the industry,

Bayer is known as a "pioneer" drug company for undertaking the investment burden, such as the basic research and development costs for a new drug, and thus would be the initial company to bring the new drug to the market.[8] Currently, the level of initial expense to a "pioneer" in developing, patenting and marketing such a new drug may amount to several hundred million dollars.[9] This cost, per successful new drug, is further compounded because of the necessity to pay the research costs for "dry wells" *(*i.*e*., candidate drugs that, when tested, do not function adequately or prove to be unsafe).[10] The cost of marketing a new drug includes the widespread advertisement and adopting of a brand name, or trademark, for the new drug.[11] Moreover, the total cost, per successful drug, extends to several other areas, perhaps less immediately evident.[12] Combining all costs, a pioneer pharmaceutical company typically incurs a total initial expense of hundreds of millions of dollars per year -- a sum which is necessarily reflected in the often substantial retail price paid by the consumer for the drug.[13]

However, the costs to a generic drug company are much less in bringing out a second source of supply for the drug.[14] For example, when a patent on the "name brand" drug expires or is near expiration, a generic drug company can enter the market and improve upon, or essentially copy, the name brand pharmaceutical.[15] This competitive market function can generate substantial economic and social value for the public.[16] Thus, at that time a generic drug company can produce substantially the same drug –- via the "written description" provided in the pioneer drug company's patent – and then market the drug at a cost to the consumer which is substantially less than that of the brands with trademark protection.[17] [*122]

Schein Pharmaceuticals and Mylan Pharmaceuticals are examples of such generic drug companies.[18] Their principal business is to produce chemical and pharmacological equivalents of well-known drugs.[19] The general mode of operation for a generic drug company involves the filing of an Abbreviated New Drug Application at or near the end of the term of a patent covering the name brand drug developed and sold by the pioneer.[20] The ANDA law allows the generic drug company to "get a head start" by filing these proceedings with the FDA for the approval of equivalent drugs prior to the expiration of the relevant patent, and in a proper case without liability for patent infringement.[21] Thus, the generic drug company is at a substantial advantage in the area of costs, because the pioneer has already incurred the costs of basic research to create and screen the drug, the advertising and promotions to create a market for the drug.[22] Accordingly, the generic drug company can make the generic equivalent available to the public at a reduced cost.[23] However, some disadvantages to the public arise by reason of competition from generic drug companies.[24] In particular, the acceleration of generic drugs to the market place can result in consumer harm by reducing the incentive for innovation from pioneers drug companies.[25]

Hence, a constitutional and social policy trade-off exists, in that the pioneer has been accorded the advantage of excluding others from making, using and selling the drug for a period of 20 years after the patent filing. Thereafter the generic drug company has the advantage of producing an equivalent drug at substantially reduced costs.[26] The consuming public benefits from this mechanism.[27] [*123]

Because of the benefit to the public, there is scarcely an area of technology where full disclosure of the best mode of carrying out an invention is as important to public

policy as in pharmaceuticals.[28] To better understand why *Bayer* produces two unworkable tests, an examination of the chemistry involved is helpful.[29]

B. <u>General Chemical Principles</u>

Many aspects of chemistry, such as chemical synthesis, are often considered by scientists to be "more of an art than a science."[30] As one pharmaceutical company, specializing in creating and screening new drugs has stated:

> [T]his aspect of refining the structure of a lead compound, called lead development, is still more of an art than a science. Chemistry in many ways is still an empirical science, based on what works in the lab, but many new techniques such as molecular modeling and formalized rules governing structure-activity relationships (SAR) have been developed to aid the medicinal chemist in making the appropriate choices.[31]

In general terms, 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.[32] Thereafter, that molecule can be 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.[33]

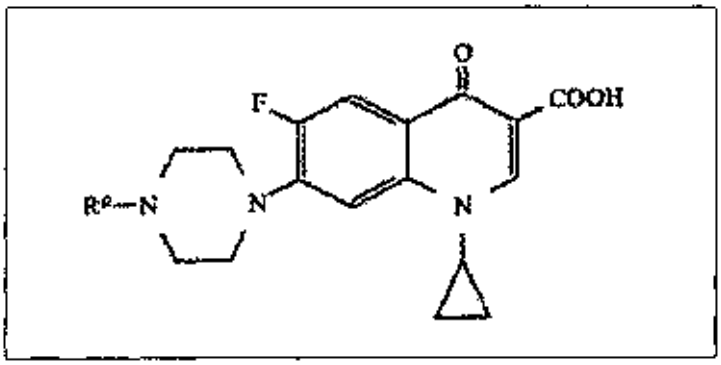
This process of "chemical synthesis" is usually a combination of several steps, using a reaction vessel into which the various reactants are introduced.[34] The synthesis mix is then subjected to conditions, such as temperature, pressure change, contact with catalysts, etc.[35] As indicated, the chemist 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.[36] Indeed, many chemical syntheses involve the production of such preliminary of final "intermediates."[37] In any event, the

ingredients, including any chemical intermediate molecules, are reacted together to form the final molecule.[38] [*124]

The creation of the final molecule is a series of steps that contain intermediates, and wherein the final product cannot be brought into existence without conducting the underlying predecessor steps.[39] Hence, it necessarily follows that the "final molecule" must inherently contain, as a material part thereof, the chemical intermediate molecules that had been used in or had been created in the synthesis process.[40] That is precisely the situation in the *Bayer* case, and indeed where the 6-FQA intermediate forms the clear majority of the final ciprofloxacin molecule.[41]

C. The *Bayer* Chemistry

The specific facts in the *Bayer* case are enlightening.[42]



[43]

> Ciprofloxacin has the above chemical formula, and wherein:
> [A] compound of the formula or a pharmaceutically acceptable acid addition salt or an alkali or alkaline earth metal salt thereof, in which A represents CR3, wherein R3 denotes a halogen atom, and Z represents C--H, and R1 and R2 together with the nitrogen atom which they substitute form a piperazino group.[44]

The following ingredients are reacted, in the following steps, to make ciprofloxacin: "(1) synthesis of the Klauke compound[45] (2) synthesis of 6-FQA via cycloaracyclation of the

Klauke compound[46]; and (3) addition of piperazine to 6-FQA to synthesize ciprofloxacin."[47]

The further pertinent facts are that the inventor, Dr. Grohe, indeed had a preferred method for making the 6-FQA intermediate by means of the "cycloaracyclation" method, but did not disclose this method in his patent application.[48] However, Dr. Grohe [*125] disclosed other, non-preferred methods for making the 6-FQA intermediate.[49] These non-preferred methods were conceded to be sufficient to meet minimal standards of "enablement" under 35 U.S.C. § 112.[50]

D. <u>Pre-Existing "the invention" Best Mode Law Analyzed</u>

From the beginning, the patent law of the United States has required that the inventor disclose various "modes" for practicing the invention.[51] In 1870, the statutory term "several modes" was changed to the language "best mode."[52] 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."[53] However, the Patent Act (perhaps wisely) does not further define what this broad language shall mean, particularly in terms of the scope of the terms "invention" and "carrying out" in the wide variety of circumstances that may occur in developing technology.[54]

Case law explaining the best mode requirement focuses on a two-prong inquiry.[55] First, the fact finder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention.[56] 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.[57] The first prong involves a subjective inquiry, focusing on the inventor's state of mind at

the time of filing.[58] The second prong involves an objective inquiry, focusing on the scope of the claimed invention and the level of skill in the art.[59] In dealing directly with the second prong of the best mode requirement, the extent of information that an inventor must disclose depends on the scope of the claimed invention.[60] [*126] Accordingly, an inventor need not disclose a mode for obtaining unclaimed subject matter unless the subject matter is novel and essential for carrying out the best mode of the invention.[61]The Federal Circuit has construed the statutory language in a wide variety of circumstances.[62] The Treatises have discussed many of these varying situations.[63] Most pertinent here are Federal Circuit pronouncements regarding the definition of the statutory term " the invention," and the pre-*Bayer* decisions on the most closely analogous circumstances.[64]

Initially, the Federal Circuit has uniformly held that "the invention" involved in the best mode inquiry refers to, but is not confined to the invention expressly set forth in the patent claims.[65] However, apart from the illustrative application of this general rule to particular fact situations, Federal Circuit decisions have not provided clear standards for determining the circumstances under which unstated, but inherently present, component parts of the expressly claimed "invention" and/or its expressly claimed claim elements are to be included in the best mode requirement.[66]

Some Federal Circuit cases hold that only the item(s) set forth in *haec verba* in the patent claim need be subject to best mode disclose.[67] However, other Federal Circuit cases hold that additional disclosure must be made as to non-claimed subject matter which (a) either is novel, or (b) would materially affect the characteristics or functioning of the claimed subject matter.[68] [*127]

III. An

A. ***Bayer v. Schein***

In *Bayer*, the plaintiff Bayer filed suit against Schein Pharmaceuticals for patent infringement under 35 U.S.C. 271(e)(2), alleging that Schein's ANDA filing had infringed Bayer's '444 patent.[69] In its defense, Schein asserted invalidity of the Bayer '444 patent on the antibiotic ciprofloxacin ("Cipro©") based on a purported failure to disclose the "best mode."[70] Specifically, 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©.[71] The district court granted summary judgment in favor of Bayer, and the Federal Circuit affirmed on appeal.[72]

In focusing on the claimed invention (i.e., using a modified form of the "scope of the claimed inventions test," as discussed below), the Federal Circuit concluded that the preferred method for making the chemical intermediate did not materially affect the characteristics of the claimed molecule, and thus need not be disclosed.[73] Concurring 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.[74] However, Judge Rader disagreed with the majority's methodology in expanding the statutory test for Best Mode, and reasoned that no inquiry was necessary as to whether the non-disclosed information would materially affect the properties of the claimed subject matter.[75] In fact, Judge Rader disagreed with the majority in opining that the withheld information in reality did materially affect the properties if the claimed

molecule.[76] Instead, Judge Rader reasoned that the Best Mode test should be strictly limited to whether the allegedly withheld information fell within the scope of the claims -- if it did not, that should be the end of it.[77] [*128] Therefore, Judge Rader further reasoned, 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.[78]

B. <u>The Majority opinion Threatens to Create a New Rule</u>

The Federal Circuit's decision in the *Bayer* case threatens to create a special rule for pharmaceutical cases that is materially different from the best mode requirements applied to patents dealing with other types of technological subject matter. Specifically, the *Bayer* court proposes, without explanation, that the best mode requirement should apply only to require 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."[79] Further unfortunately, the Majority opinion also does not explain the standards by which the "intrinsicness" of the characteristics can be determined by the counseling practitioners in the profession.[80]

Accordingly, some scholars[81] may argue that a characteristic may be "intrinsic" for best mode purposes only if and when the Federal Circuit deems it to be – and long after the industry has had any realistic opportunity to base business decisions upon a reasoned legal analysis. The Due Process problems inherent in such an approach are evident, because a rule of law should give adequate "notice to the public."[82]

C. <u>The Majority Ignores the "Carrying Out" Statutory Language</u>

The developed case law bears out these conclusions in criticism of the *Bayer*

Majority's rule. Section 112 requires that the best mode of "carrying out" the invention be disclosed by the inventor.[83] In developing an analysis of the best mode question, and as both the Majority and Concurring opinions point out, certain inquiries must [*129] follow -- (a) what is the "invention" that the statute refers to; (b) what does "carrying out" the invention mean; and (c) when in time has the "carrying out of the invention" begun to occur?[84]

These inquiries are key elements in determining what must be disclosed by the inventor in the patent regarding the synthesis of a molecule that is used by the inventor in producing the Cipro© compound that is set forth expressly in the patent claims. The Federal Circuit's discussion was inherently based upon an analysis of these inquiries. "Notwithstanding that the best mode requirement keys only on carrying out the claimed invention, we have found violations of the best mode requirement for failure to disclose subject matter not strictly within the bounds of the claims . . ."[85] In the history of this court and our predecessor courts, we have held claims invalid for failure to satisfy the best mode requirement on only seven occasions. As we will see, these cases involved either failure to disclose a preferred embodiment, or else failure to disclose a preference that materially affected making or using the invention."[86] Whereupon, the Majority decided that the preferred method of making and using the intermediate was exempted from the best mode strictures of the statute. [*130]

D. <u>Prior Case Law Does Not Dictate the Majority's New Rule</u>

Moreover, the case law precedent cited by the Court in no manner requires the new rule promulgated by the Court. For example, in the case of *Application of Brebner*, the Court did not decide the best mode issue, but rather noted that the United States

Patent and Trademark Office was not equipped to make such an inquiry.[87] Accordingly, enablement was the issue there.[88] Hence, the Court's implication that the "issue" had somehow been raised in the *Brebner* cases is not correct.

The Court in *Bayer* also cited the case of *DeGeorge v. Bernier*.[89] The *DeGeorge* case dealt with an interference count (which is analogous to a patent claim), which was directed to electronic circuitry for use in a computer, but was not directed to the computer itself.[90] The case did not deal with a chemical intermediate, or with any other element that was found in or subsumed into the patent claim. In contrast, in the *Bayer* case, the chemical intermediate is a material part of the patent claims. Fundamentally, the atoms comprising the intermediate do not somehow "lose" their identity just because there is a further (and, in fact, relatively rather minor) chemical reaction which simply adds a side chain onto the intermediate main body to form the final Cipro© molecule. In fact, such an argumentative concept by the *Bayer* court flies in the face of the realities of chemical practice and synthesis.

Specifically, the manufacture of a molecule is a series of interdependent steps that exists as a physical reality separate and apart from any patent drafter's decision in describing the final product constituting the invention set forth in the patent claims.[91] The case of *Zygo v. Wyko* is similarly instructive.[92] The *Zygo* case dealt with a scientific instrument known as an interferometer. The applicant had subsequently taken the usual step of enclosing the interferometer in a box, but the box was not a part of the patent claim. The evidence was clear that the undisclosed item (i.e., the box) was not necessary to make a functional device. Thus, the Court held correctly that there had been not a best mode violation by reason of failing to disclose an unnecessary element. In stark contrast,

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. [*131]

In the case of *USG v. National Gypsum*, the patent claim was directed to a mixture of ingredients that included expanded Perlite[93]. The applicant was aware that one commercial brand of Perlite provided vastly superior qualities to the final mixture. Thus, the Court concluded that failure to disclose this necessary element constituted a best mode violation. Surely, it cannot be argued seriously that the chemical intermediate is somehow not a vital part of a molecule that merely adds a side chain to the intermediate in order to manufacture the Cipro© molecule.

Of the variety is the case of *Chemcast v. Arco*. There, the inventor did not disclose (a) the only material that he knew would function adequately, and (b) which had even been specifically developed for purposes of use in the invention.[94] This material was a PVC polymer used in manufacturing a grommet. The patent claim there referred both to the grommet and to the hardness of the material to be used in making the grommet. In fact, materials of this hardness were commercially available. Hence, a best mode violation was established. To argue that the *Bayer* situation is somehow different is to fail to appreciate any distinction as to scientific fact or as to law. In fact, it could be argued with force that the failure to disclose the preferred process in the *Bayer* case is far more blameworthy, because quite clearly a withheld process cannot be reverse-engineered by analyzing the commercial structural embodiment. Also, in the *Bayer* case, the chemical intermediate is a material element in the patent claim, inasmuch as the claimed Cipro© compound is merely the intermediate but with an ordinary side chain

attached by a simple, and well known, chemical reaction. [*132]

In the *Randomex v. Scopus* case, the patent claims covered a portable device for cleaning compact discs. The patent claims did not incorporate any cleaning solution as an element.[95] In any event, and most importantly, the inventor there had disclosed his preferred cleaning solution by its trade name. Thus, no best mode violation was found.

In *Dana*, the patent claims covered a valve stem seal for use in an internal combustion engine.[96] However, 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. It is believed that there is no reason of logic or scientific substance for treating the pharmaceutical industry differently from the motor industry. Concealment of a preferred process is concealment of a preferred process. Moreover, what was concealed in both cases was a material part of the patent claim.

The *Bayer* court also referred to the case of *In re Gay*. However, the *Gay* case really has very little to do with the present facts.[97] There, the subject matter of the claims was a cooking bag for cooking rice which was made of a material having a defined porosity. The Court correctly held that it was not necessary to disclose the commercial embodiment, particularly because the functional materials were well known. The details of the Cipro© inventor's secret process were (by definition) not already or independently known to the public.

The *Spectra Physics v. Coherent* case is similar to the *Bayer* situation.[98] There, the patent claims referred to the structure of an ion laser that included copper cups and

ceramic tubes that were required to be brazed together. The inventor had failed to disclose the particular 6-step brazing process that was preferred because of its vastly superior properties. A clear best mode violation was found. In the *Bayer* case, the inventor has 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.

Finally, the *Northern Telecom* case involved patent claims covering methods for storing data, but not the audio tapes that were used for such storage.[99] Nonetheless, the Federal Circuit found a best mode violation (albeit with little analysis or details of its reasoning).[100] In summary, none of the cases cited by the Court justifies the rule adopted by the Court.

E. The "Claimed Invention" Rule Has Many Exceptions

As to the first inquiry *(i.e.*, regarding the definition of the "invention" referred to in § 112), there was no controversy in the *Bayer* case that the invention referred to was the invention set forth in the patent claims. However, as analysis of prior Federal Circuit decisions will show, this is only a general rule, and there is considerable variation in carrying out such a rule.

The court said, [o]ur cases examining the scope of the best mode requirement demonstrate that the best mode disclosure requirement only refers to the invention defined by the claims."[101]

However, the Federal Circuit subsequently 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." [*133]

It is this exception that the Federal Circuit has failed to apply in a uniform or predictable fashion in the *Bayer* case. As Judge Rader pointed out in his Concurring opinion, 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.[102] 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."

F. The Concurring Opinion Criticizes the Majority's Logic, But Creates Even Greater Problems

As Judge Rader opines in his Concurring opinion, such a special rule involving undefined "characteristics" of an invention is unworkable, unjustified in law or logic, and further conflicts with prior decisions of the Court.[103] Each of these arguments of the Concurring opinion is dealt with below. However, none of Judge Rader's arguments against the errors of the Majority adequately supports the alternative approach advocated in the Concurring opinion, and Judge Rader's proposed rule of over-simplification is itself materially flawed. Specifically, the Concurring opinion proposes a "bright line" test – which concededly is easier to apply -- but which would permit the Constitutional social contract of full disclosure to the public to be thwarted by an aggressive pharmaceutical company.[104] The undesirable social result would be that pioneer pharmaceutical companies could maintain the higher price levels associated with patented drugs well after their dominant patent had expired, based upon efficiencies and advantages of concealed processes for making an intermediate.

Notwithstanding this dangerous potential for post-expiration price level maintenance, the Concurring opinion proposes that, in pharmaceutical cases, only the

subject matter expressly set forth in the claim should be deemed to be the "invention" referred to in the best mode requirement of the statute.[105] Quite apart from its potentially undesirable economic and social impact, such a "bright line" rule does not serve the Constitutional purpose of the law requiring that the invention be placed fully in the public domain at the expiration of the patent. [*134]

G. Judge Rader's Bright Line Test Is Not Functional

Judge Rader attempts to justify this "bright line" rule by arguing that, if the inventor has not expressly claimed the chemical intermediate structure and/or the process by which it is made, someone else supposedly will do so, and thus secure a "blocking patent." The Concurring opinion does not explain the mechanism by which the competitor will necessarily make these "discoveries," and indeed this undocumented theory of "discovery" is a rather far-fetched notion. Moreover, the withheld intermediate structure molecule would most likely be unpatentable to such a later "discovering" competitor. In particular, the chemical intermediate molecule, by definition, would have been used commercially to make the final product, and thus would be an item that most likely would have been "used or sold" in the United States for more than one year before the discoverer's patent filing date, thus disqualifying the intermediate chemical structure from being a patentable invention of anyone, after such one year of use by the concealing pioneer company.[106] Moreover, such a third party would have to be a real inventor, not merely a copyist, even to qualify as a patentee.[107] Hence, the "blocking patent" argument of the Concurring opinion on the chemical structure of the intermediate is pure speculation, and in fact most unlikely. And most importantly, it is also highly unlikely that there would be any detriment to the withholding pharmaceutical company by means

of any valid "blocking patent" occurring as a result of such withholding of the chemical structure from the public. [*135]

But in any event, it should be remembered that in *Bayer* it was the process of making the intermediate that was new and greatly beneficial to the public, apparently because of its high efficiency. The Concurring opinion does not explain how a process that is necessarily carried out in secret will be "discovered" by the competitor. Clearly, there is nothing about the chemical structure that teaches the skilled chemist the important details of the process by which it was made. Hence, there is every reason to suppose that, given the decision in the *Bayer* case, the factual pattern of concealment of a secret process (which by its very nature cannot be reverse engineered) would be the factual pattern of concealment that would be repeated in the future.[108]

However, Judge Rader is absolutely correct that there should be no legitimate basis for a different rule for pharmaceutical subject matter, and indeed the creation of such a rule cannot be supported based upon analysis of the Court's prior case law. Moreover, and given the public–policy purposes behind ANDA law and the litigation based thereon, there is likewise no basis in social policy for providing special provisions for drug companies -- whether pioneer or otherwise. The large pharmaceutical companies should be held to the same social contract of providing a full and fair teaching to the public in exchange for the limited right to exclude others. This is especially true where the Federal Circuit has created a rule which in application requires at least two major exceptions, and even then can be applied only inconsistently to the various different technologies. [*136]

Specifically, the Federal Circuit has in essence created the convoluted rule that

the best mode requirement is to be confined to the specific subject matter of the patent claim, except where the omitted subject matter materially affects the invention, and also except further where the omitted information affects certain undefined "intrinsic characteristics" of the claimed subject matter.[109]

IV. PROPOSAL

There are several critically important considerations of public policy for proposing that the Federal Circuit reconsider and modify the unworkable "bright-line-but-with- exceptions–(sometimes)-for pharmaceutical-subject-matter- only" test created by the *Bayer* case. Comparing "bright line" tests with "balancing" tests may be helpful in the process of ultimately selecting the type of test that is most appropriate under the factual and legal circumstances present here.

Upon evaluation of all the facts and circumstances having significant impact in chemical and/or pharmaceutical cases, it is concluded that a "balancing of the factors" or a "rule of reason" test would form a more appropriate vehicle for analyzing and determining whether a patentee has met the *quid pro quo* obligations of disclosure to the public that accompanies the granting of a patent.

In many circumstances, a "bright line" test has considerable advantages over a "balancing test" (i.*e.,* a test which involves the identification) evaluation and utilization of a multiplicity of factors. For example, lawyers in advising their clients can give more definitive legal advice where a "bright line" test is to be used in the legal analysis. In these circumstances, the law is deemed to be more predictable. [*137]

In contrast, a balancing of the factors test is usually more flexible, as it can more often successfully accommodate a wider variety of factual circumstances without

breaking down, and hence creating the necessity for the formulation of an entirely new test. Also, balancing tests tend to be more equitable in their result, as they allow this wide variety of differing circumstances to be taken into account.

Unfortunately, as we have seen, *supra*, in the *Bayer* case the Federal Circuit has opted to promulgate a test which appears to be in the nature of a quasi-"bright line" test, and thus which suffers all of the disadvantages of the "bright line" test model, but which ultimately provides none of the countervailing advantages typically associated with "bright line" tests. In particular, and most fundamentally, the *Bayer* court's test does not meet the seminal Constitutional purpose of providing, for the historical record, disclosure of the full particulars of the invention to the public, in exchange for the statutory right to exclude the public from practicing the invention for a limited time.[110]

As the analysis herein has shown (and as the *Bayer* Concurring opinion confirms), the new test proposed and adopted by the Federal Circuit provides neither set of possible advantages to patent lawyers and/or to the public. Specifically, the Federal Circuit has opined that in cases involving pharmaceutical or chemical subject matter, 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. [*138]

The Majority opinion struggles to attempt to reconcile its *Bayer* pronouncement with developed Federal Circuit precedent, but ultimately cannot, as the Concurring opinion so eloquently states. In so doing, the Federal Circuit creates the irony that its

purported "bright line" test conflicts with the very purpose for bright line tests((and often only advantage) – *i.e*., predictability in the law). As pointed out in the analysis hereof (and moreover in the Concurring opinion), the "bright line" test argued for by the Majority is not a fair summarization of developed Federal Circuit precedent. Indeed, the Federal Circuit has in the past accommodated a well-defined exception that itself comprises a "balancing test" of sorts. Specifically, the Federal Circuit Majority has had no problem in stepping back from the "bright line" where the "undisclosed subject matter materially affected the properties of the claimed invention."[111] But then the Majority unaccountably (but necessarily for its argument) implies 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! However, as the Concurring opinion also points out, the Majority cannot logically apply its proposed rule consistently with a finding of no Best Mode violation under the facts of the case.[112]

And perhaps even worse for the *Bayer* test, the Concurring opinion identifies the contradiction of the Majority, but proposes to harmonize it by making the Majority's "bright line" test yet more "bright," by eliminating any inquiry into any factor which goes beyond the bare strictures of the patent claims, *per se.*

As such, the approach of the Concurring opinion becomes even more inflexible, and most importantly, comes no closer than the Majority towards meeting the Constitutional *quid pro quo* purpose of the patent grant.[113] Hence, it is against this background that a proposal for a workable solution to these problems should be made.

In order to eliminate or materially reduce the problems associated with prior Best Mode analyses, the Federal Circuit should adopt a "rule of reason," or balancing of the

factors test. More particularly, the Federal Circuit should expand upon, rather that to diminish, the factual analysis begun in those cases, *supra*, which inquired as to whether the concealed material had "materially affected" the operation or properties of the invention.

The proposed "rule of reason" test advocated in this paper would permit the Best Mode analysis to be determined under the entirety of the facts of each case as to whether the best mode requirement has been satisfied.[114] Such a "rule of reason" test would weigh and take into account at least the following factors, in pharmaceutical or chemical cases, as well as all other types of cases:

> 1. The scope of the patent claims;
> 2. The nature and characteristics of the final product;
> 3. The nature, characteristics, and novelty of the chemical intermediate compound;
> 4. The various methods, disclosed and undisclosed, for making the chemical intermediate;
> 5. An economic analysis of the entirety of the synthesis procedure, particularly focusing upon the difference in cost effectiveness or quality between the disclosed and the undisclosed methods for making the intermediates; and
> 6. Any other relevant fact bearing on the conclusion on whether the inventor has failed to teach the public fully and fairly how to implement all aspects of his invention.

This proposed "rule of reason" test may come to be criticized, *inter alia*, on the same grounds set forth in the Concurring opinion, which in turn criticized the Federal Circuit's prior use of non-"bright line" tests for conducting Best Mode analyses.[115] Several of these anticipated objections can be disposed of now. For example, the [*139] Concurring opinion argues that the non-bright line test of the *Dana* case "could sponsor a potentially boundless inquiry into any undisclosed method or property that could affect the satisfactory performance of the invention."[116] However, the "factual inquiry" test

developed by the Supreme Court for an obviousness analysis under 35 U.S.C. § 103 is similarly open-ended in allowing the inclusion of any relevant factor, but has not proved to be beyond the abilities of busy District Court judges to supervise.[117] Another example in the patent law is the rule that a patent Specification is directed to those of "ordinary skill in the art."[118] But this, too, involves a factual inquiry involving several factors to determine. Trial courts on a daily basis carry out "balancing" tests in a wide variety of circumstances.[119]

Finally, the entire basis of equity jurisdiction is grounded upon the standard of the "conscience of the Court" (*i.e.*, the conscience of the King's Chancellor sitting in equity). It cannot be argued in good conscience that a trial court should somehow relinquish its equity jurisdiction because too many factors might be present!

Thus, there is no reason to speculate that the District Courts somehow are not qualified to carry out the "rule of reason" test advocated herein, and to do so with the same relative ease and considerable success that Common Law and Equity courts have experienced for a millennium. While the Law of Patents does present new challenges, most of these challenges are premised on the need for laymen to understand new technologies, rather than any inadequacies of generations-old legal principles/techniques. Thus, the patent law does not stand alone in its need for consideration of all relevant facts before rendering important decisions that may seriously impact upon the rights of the entirety of the public – whether innovator or competitor. [*140]

V. CONCLUSION

A proper legal analysis should start with the Constitution, and then proceed to the applicable statute(s). Thereafter, and against this fundamental background, the developed

case law should be construed and analyzed. Most definitely, the courts should take special care in avoiding the temptation to "legislate" judicially, for example, by creating tests or rules that (a) are not found in, or (b) conflict with, the provisions of the Constitution or the statutory purpose. The Federal Circuit's rule set forth in *Bayer* does not reflect the Constitutional or statutory purpose, because, *inter alia*, the *Bayer* rule would allow (or perhaps even promote) concealment of important aspects of the very *res* from which the inventor has excluded the public by the patent grant -- and particularly where, as here, the excluded subject matter is a novel chemical intermediate. For example, the patentee would have, through the patent grant, achieved competitive advantage and/or exclusion of the public through the doctrine of contributory infringement.[120] This arises because the intermediate would not, by definition, be a standard commodity of commerce, but rather would be specially manufactured for making the claimed invention constituting the final product.[121]

It is most fundamental that, under the Constitutional "*quid pro quo*" contract, good and sufficient consideration must be given.[122] Specifically, the patentee should not be able to reap the exclusionary "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. [*141]

Contrary to the unarticulated premise of both of the Majority and the Concurring opinions of the Federal Circuit in the *Bayer* case, Section 112 of the Patent Act does not read "the best mode of the invention," or even "the best mode of the claimed invention." Instead, the statute unambiguously requires that the inventor's Best Mode of "carrying out" the invention be disclosed. Indeed, it can be argued with considerable force that the

necessary implication of the *Bayer* holding is that the words "carrying out" must be read out of the Statute. To reiterate an obvious legal truth, courts should not legislate. Moreover, every word of the statute should be given force and effect.[123]

Thus, it is appropriate that scholars should consider a more comprehensive, workable and equitable test. A "rule of reason" test, where a variety of pertinent factors would be taken into account, would do much to reduce the capacity for mischief that is potentially presented by the (but thinly) modified "scope of the claimed invention" test set forth in the *Bayer* case. By so doing, the inventor would continue to receive a reward that is commensurate in scope with the teaching provided to the public, and the public would receive the full scope of the teaching and all the benefits of the invention upon expiration of the patent. Thus, such a highly functional "rule of reason" test would meet both the Constitutional purpose and the public policy doctrines underpinning the statute and requiring that the Best Mode for "carrying out" the invention be disclosed to the public. [*142]

[*] J.D. Candidate I.P., May 2004, The John Marshall Law School, Chicago, Illinois. Bachelor of Science – Molecular and Cellular Biology, The University of Arizona, Tucson, Arizona.

[1] *Amgen, Inc. v. Chugai Pharm. Co., Ltd.*, 927 F.2d 1200, 1209-10 (Fed. Cir. 1991) (Judge Lourie providing the purpose behind the best mode requirement).

[2] *Bayer Corp. v. Schein Pharm. Co., Inc.*, 301 F.3d 1306, 1306-28 (Fed. Cir. 1991); 35 U.S.C. § 112 (2000); whether an applicant has complied with the best mode requirement of § 112 is a question of fact. *Chemcast Corp. v. Arco Indus. Corp.*, 913 F.2d 923, 928 (Fed. Cir. 1990). But, the question of the proper legal standard to apply to the best mode requirement is a question of law, which is reviewed *de novo*. *Id.* at 1035.

[3] Chemical intermediates have been a frequent topic in recent patent litigation and patent infringement suits. *See Brenner v. Manson*, 383 U.S. 519 (1966); *Eli Lilly & Co. v. Barr Labs.*, 251 F.3d 955 (Fed. Cir. 2001); *Chem. Indus. v. U.S.*, 170 F. Supp. 2d 1335 (2d Cir. 2001); Baoding Yude; *Murphy Oil U.S. v. U.S.*, 81 F. Supp. 2d 942 (Ark. 1999); *Eli Lilly & Co. v. Am. Cyanamid Co.*, 82 F.3d 1568 (Fed. Cir. 1996); *Lonza, Inc. v. U.S.*, 46 F.3d 1098 (Fed. Cir. 1995); *E.T. Horn Co. v. U.S.*, 945 F.2d 1540 (Fed. Cir. 1995); *Am. Color & Chem. Corp. v. Tenneco Polymers*, 918 F. Supp. 945 (S.C. 1995); *Kalipharma, Inc. v. Bristol-Myers Co.*, 707 F. Supp. 741 (N.Y. 1989).

[4] *Bayer*, 301 F.3d at 1308-23.

[5] *Id.* at 1323-28

[6] For a recitation of the test, *see supra Chemcast*, 913 F.2d at 968; 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." *In re Gay*, 309 F.2d 769, 772 (C.C.P.A. 1962). An enabling disclosure by definition turns upon the objective understanding of a skilled artisan. Thus, the enablement requirement can be met by reference to the knowledge of one of ordinary skill in the relevant art. *Bayer*, 301 F.3d at 1314.

[7] Laura D'Andrea Tyson, *For Developing Countries, Health is Wealth,* BUSINESS WEEK, Jan. 14, 2002. The pharmaceutical companies are presenting their side of the case regarding why patents should be enforced. *Ten Misconceptions About Pharmaceutical Patent Litigation*, July 16, 2002 (available at <http://www.phrma.org/mediaroom/press/releases/16.07.2002.457.cfm> (last visited Nov. 16, 2003)); Frank R. Lichtenberg, *Are the Benefits of Newer Drugs Worth Their Cost? Evidence from the 1996 MEPS,* HEALTH AFFAIRS 20, September/October 2001, at 5-6; Herman Saftlas, *1984-2000 Actual Data*: IMS HEALTH, 2001; Frank R. Lichtenberg, *The Effect of Pharmaceutical Utilization and Innovation oh Hospitalization and Morality,* National Bureau of Economic Research, January 1996; *Bayer*, 301 F.3d at 1306-28.

[8] *In Re Ciprofloxacin Hydrochloride Antitrust Litigation*, 166 F. Supp. 2d 740, 750 (Fed. Cir. 2001). According to the Pharmaceutical Research and Manufacturers of America: PhRMA represents the country's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives (available at <http://www.phrma.org/whoweare/members/> (last visited Nov. 16, 2003)); Some examples of various drug pioneer companies (available at <http://www.phrma.org> (last visited Nov. 16, 2003)).

[9] *Moraine Prod. v. ICI Am., Inc.*, 538 F.2d 134, 140 (Fed. Cir. 1976). For example, according to PhRMA, the pioneer drug companies has invested more than $30 billion dollars in the year of 2001 in discovering, developing, patenting and marketing new medicines. (Available at [*143] http://www.phrma.org/whoweare/(last visited Nov. 16, 2003)). PhRMA claims that the pioneer companies are leading the way, in comparison with generic drug companies, in the search for new cures and to sustain human life. David Leonhardt, *Health Care as a Main Engine: Is That So Bad?,* N.Y. TIMES, Nov. 11, 2001; Michael J. Mandel, *Health Care May Be Just What the Economy Ordered,* BUSINESSWEEK, Sept. 17, 2001.

[10] Available at <http://www.phrma.org>(last visited Nov. 16, 2003)); *see* examples of candidate drugs, that when tested do not function adequately or prove to be unsafe (available at <http://www.fda.gov> (last visited Nov. 16, 2003)). Large members in the Pharmaceutical industry have made huge contributions to candidates in the Federal Election Commission:

> [O]verall, pharmaceutical industry PACs doled out $ 3.4 million to candidates in the 1994 elections. Leading the pack is GlaxoWellcome giving $ 441,000 in 1994 and more than $ 300,000 for the 1996 elections. Federal Election Commission results reveal that GlaxoWellcome's PAC more than doubled its contributions to members of Congress during the last report period, compared to the same period two years ago. GlaxoWellcome's PAC gave $ 94,300 to Republicans and $ 28,500 to Democrats in the first half of 1995.

Mary Jacoby, *Drug War in D.C.: Brands vs. Generics; PACs, Lobbyists Woo Lawmakers in Battle over Patent Rights*, CHI. TRIB., July 23, 1996, at 1; As many of these drugs are used by the elderly or the infirm, the price of the drug to the consumer has been a continuing important social and political issue, often involving electoral politics in the United States. David Leonhardt, *Health Care as a Main Engine: Is That So Bad?,* N.Y. TIMES, Nov. 11, 2001; Peter Passell, *Exceptional Returns: The Economic Value of America's Investment in Medical Research,* FUNDING FIRST, Lasker Foundation, May 2000 (available at <http://www.fundingfirst.org/reports/reports.html> (last visited Nov. 16, 2003)

[11] Holly A. Brown, *The Need For Regulation Mandating Labeling of Inactive Ingredients in Pharmaceuticals*, 8 Admin. L.J. Am. U. 291, 296,299 (1994) (discussing the importance of Labeling and Branding Pharmaceuticals); *see* generally 21 C.F.R. § 211.122 (2000) (setting forth additional labeling requirements for pharmaceuticals). Branding is the adoption, publicization, and marketing of a trademark, by which the public comes to deem the product or service as originating from a particular source. *Brand Management for Pharmaceuticals Conference*, held at the Crowne Plaza Center, Philadelphia, Pennsylvania on June 13, 2002. (Conference overview available at <http://www.iirusa.com/pharmabrand/index.cfm/Link=1/NewSection=Yes> (last visited Nov. 16, 2003)).

[12] John Carey and Amy Barret, *Drug Prices, What's Fair,* BUSINESS WEEK, Dec. 10, 2001; *see* also Morton Kondracke, *Investing Billions in Health Research Can Save Trillions,* ROLL CALL, May 25, 2000. The FTC criticized the brand name pharmaceutical companies for manipulating the system to delay the entry of competitive generic drugs. *Id.* "FTC Testifies on Competition in the U.S. Pharmaceutical Industry: Activities Involving Brand and Generic Patent Settlement Cases" Detailed, May 21, 2001. (Available at <http://www.ftc.gov/opa/2001/05/drugtest.htm> (last visited Nov. 16, 2003)).

[13] *Moraine Prod.*, 538 F.2d at 140. Only 10% of compounds tested pass the preclinical stage. Of those compounds that make it to the human testing stage, more than 80% fail at that stage. Michael Malinowski & Maureen O'Rourke, *A False Start? The Impact of Federal Policy on the Genotechnology Industry,* 13 YALE J. ON REG. 163, 206-208 (1996).

[14] *Eli Lilly*, 251 F.3d at 963. *See also* Jeremy Shure, *High Court Declines Prozac Patent Review, Handing Victory to Generic Maker: Eli Lilly & Co. v. Barr Laboratories, Inc.,* 28 Am. J. L. and Med. 136 (2002)(discussing how the ruling in *Eli Lilly* case will benefit Generic Drug makers).

[15] *Eli Lilly*, 251 F.3d at 955-72. See also Gary J. Buehler, *Office of Generic Drugs Update*, 2002 Fall Technical Workshop presentations, presented Oct. 15, 2002 (available at <http://www.gphaonline.org> (last visited Feb. 23,2003)); Christine Mundkur,*Generic Industrie's Perspective on the New GMP Initiative and PAT*, 2002 Fall Technical Workshop presentations, presented Oct. 15, 2002 *Id.*

[16] *Eli Lilly*, 251 F.3d at 955-72. *See also* Harry G. Brittian, *Polymorphism and Solvatomorphism: Overview of Science and Impact on Generic Companies*, 2002 Fall Technical Workshop presentations, presented Oct. 15, 2002 (available at <http://www.gphaonline.org> (last visited Nov. 16, 2003)).

[17] 35 U.S.C. § 112; Elizabeth H. Dickinson, *Current Issues in Generic Drug Labeling*, 2002 Fall Technical Workshop presentations, presented Oct. 15, 2002 (available at <http://www.gphaonline.org> (last visited Nov. 16, 2003)). [*144]

[18] *Bayer*, 301 F.3d 1306; *Am. Home Prod. Corp., et al. v. Mylan Labs., Inc. et al.*, 510 U.S. 1197 (1994). Some examples of generic drug companies, many of which are members of Generic Drug Company Society, are available at <http://gphaonline.org/members/index.html > (last visited Nov. 16, 2003).

[19] *Id.* for *Bayer* and *Am. Home*. Deborah Jaskot, *Labeling Overview*, 2002 Fall Technical Workshop presentations, presented Oct. 15, 2002 (available at <http://www.gphaonline.org>); Joan Janulis, *An Overview of Labeling Issues and Their Impact on Generic Market Formation*, 2002 Fall Technical

Workshop presentations, presented Oct. 15, 2002 (available at <http://www.gphaonline.org> (last visited Feb. 23, 2003).

[20] *Eli Lilly and Co. v. Medtronic, Inc.*, 496 U.S. 661 (1990) "ANDA" means an Abbreviated New Drug Application, as defined under 21 U.S.C. § 355(j), *et seq*.;

> [A]n Abbreviated New Drug Application (ANDA) contains vital information which is then submitted to FDA's Center for Drug Evaluation and Research and the Office of Generic Drugs which provides for the review and ultimate approval of a generic drug product. Once approved, an applicant may manufacture and market the generic drug product to provide a safe, effective, low cost alternative to the American public;

> 21 U.S.C. § 355 (j) (1984);
>
> Using bioequivalence as the basis for approving generic copies of drug products was established by the Drug Price Competition and Patent Term Restoration Act of 1984. This Act expedites the availability of less costly generic drugs by permitting FDA to approve applications to market generic versions of brand-name drugs without conducting costly and duplicative clinical trials. At the same time, the brand-name companies can apply for up to five additional years longer patent protection for the new medicines they developed to make up for time lost while their products were going through FDA's approval process.

Id. (available at

<http://www.fda.gov/cder/regulatory/applications/ANDA.htm> (last visited Nov. 16, 2003)); Heidi Grygiel, *Now They GATT Worry: The Impact of the GATT on the American Generic Pharmaceutical Industry*, 6 U. Balt. Intell. Prop. J. 47,49 (1997)(discussing the importance and impact of the GATT (General Agreement on Tariffs and Trade) on the Generic Pharmaceutical Industry).

[21] *Id.* for *Eli Lilly*; *see also* Louis S. Sorell, *The Application of the Doctrine of Equivalents to Chemical Inventions: A Primer*, 11 Alb. L.J. Sci. & Tech. 225, 235 (2001) (Providing examples of chemical inventions and ANDA); Judge Rader has commented on ANDA and generic drug manufacturers in past cases:

> [A] generic-drug manufacturer may file an ANDA if the active ingredient of the generic drug is the "bioequivalent" of the listed drug. . . . [T]he listed drug's patent "is invalid or will not be infringed by the manufacture, use, or sale of the new drug" disclosed in the ANDA. . . . An ANDA certified under Paragraph III cannot be certified until the applicable patent expires . . . " Where "the ANDA "is to sell [a] well-defined compound, then the "ultimate question of infringement is usually straightforward . . ." [*145]

Integra Life sciences I, Ltd. v. Merck KgaA, 331 F.3d 860 (Fed. Cir. 2003). In *Yamanouchi Pharmaceutical Company v. Danbury Pharmacal, Incorporated*, the court held that a submission of an ANDA can qualify as an infringement if the purpose of the ANDA is to gain approval to market or manufacture the generic drug. *Yamanouchi* 231 F.3d 1339, 1346 (Fed. Cir. 2000). Economic adversarial relationship between pioneer drug companies and generic drug companies has resulted in frequent ANDA and other patent litigation over a wide range of pharmaceuticals, and wherein the tension between innovation and lower prices for the consuming public remains a recurrent theme. *See Allergan, Inc. v. Alcon Labs.*, 200 F. Supp. 2d 1219 (Fed. Cir. 2002); *Allergan, Inc. v. Alcon Labs.*, 200 F. Supp. 2d 1219 (C.D. Cal. 2002); ; *Glaxo Inc. v. Novopharm Ltd.*, 110 F.3d 1562 (Fed. Cir. 1997); *Medtronic*, 496 U.S. 661 (1990); among many others.

[22] *Mylan Pharm., Inc. v. Thompson*, 268 F.3d 1323 (Fed. Cir. 2001). During the lifetime of a patent, the advertising must amount to making the drug well known to ensure sales and pay for investment.

[23] *Id.* for *Mylan*; *see* also Peter Steele, *Generic Drug Companies and Patents – A Multi-faceted Issue*, BUSINESS BRIEFING: PHARMAGENERICS, Jan. 1, 2002 at 24-6 (available at <http://www.wmrc.com> (last visited Feb. 23, 2003)).

[24] *Id.* for *Mylan*. An example is the Hatch-Waxman act. *Valley Drug Co. v. Geneva Pharm.*, 344 F.3d 1294 (Fed. Cir. 2003). Generic drug companies have argued that the Act, passed in 1984, has allowed innovator drug companies to retain incentives to continue R&D while giving generic drug companies considerably greater access to the market. *Id.* However, Pioneer drug companies have argued that reopening Hatch-Waxman "would seriously erode the incentive and protection for innovation that enables new drug development, and would be a devastating blow to America's patients," says Richard I. Smith, vice president of the Pharmaceutical Research and Manufacturers of America (PhRMA), the brand-name trade association in Washington, D.C. (available at <http://www.dddmag.com> (last visited Nov. 16, 2003)).

[25] *Id.* for *Mylan*. A recent study finds that accelerating "generics" to the market by generic drug company harms consumers by reducing innovation leading to new prescription drugs. J. Hughes, M. Moore & E. Snyder, *'Napsterizing' Pharmaceuticals: Access, Innovation, and Consumer Welfare,* NATIONAL BUREAU OF ECONOMIC RESEARCH WORKING PAPER #9229**,** October 2002 (available at <www.nber.org/papers/w9229> (last visited Nov. 16, 2003)); For example, on net consumers lose from accelerating generic entry into the prescription drug market. *Id.* Consumers gain one billion dollars on net from accelerating generic entry into the market. *Id.* However, the consumers lose three billion dollars from reduced pharmaceutical innovation. *Id.* Government patents granted under statutory standards make it possible for pharmaceutical companies to invest the $800 million needed to bring a drug to market. *Id.* Without patents, companies that do not make the Research and Development investment needed to invent new medicines could immediately copy the drug and undercut the innovator's price, making it impossible for the innovator to generate funds to invest in discovering new medicines. *Id.* Seven out of ten brand-name drugs brought to market never recover their initial research investment. *Id.*

> [P]harmaceutical innovation has made great strides in improving health care. In that time, the generics' share of the prescription drug market has also grown from 19 percent to 47 percent. Despite the generic industry's claims that its market share has stagnated, Wall Street analysts and economists predict that by 2005, generics will account for 57 percent of the market by volume.

Id.; The Generics' share of U.S. Prescription Drug Market has increased from 19% in 1984 to 51% in 2001. *Id.*

[26] *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1360-30, (Fed. Cir. 2002); *see also* the Quid Pro Quo of the patent system requires that the public must receive meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time. *Enzo Biochem*, 296 F.3d at 1360-30. This is extremely damaging to the pioneer drug companies. Many Insurance companies will only pay for the cheaper, less expensive generic equivalent. *Id.*

[27] *Id.*

[28] *Id.*

[29] *Bayer*, 301 F.3d at 1306. [*146]

[30] Jessica Gorman, *Perfecting Porosity: Better Living Through Holey Chemistry,* SCIENCE NEWS Vol. 159 No. 25, June 23, 2001; *see also* Kevin Fitzpatrick, Ph.D., *"Industrial Synthesis of Optically Active Compounds",* TRIP REPORT, May 10-12, 2000; *The Talent Challenge in Biologics Manufacturing*, IN VIVO: THE BUSINESS & MEDICINE REPORT, July 2002 at 63; Khan, M.I., *Novel Extended Solids Composed of Transition Metal Oxide Clusters,* JOURNAL OF SOLID STATE CHEMISTRY, June 2000; Müller, A., *Giant Ring-Shaped Building Blocks Linked to Form a Layered Cluster Network with Nanosized Channels,* CHEMISTRY- A EUROPEAN JOURNAL, Jan. 1999; Chemistry is more of an art than a science: William D. Marsillo, *How Chemical Nomenclature Confused the Courts,* 6 U. Balt. Intell. Prop. J. 29, 30 (1997).

[31] Albany Medical Research, Inc.: "Success: From Lead Discovery to Lead Development" (available at <http://www.albmolecular.com/company/departments/medchem/medchem.shtml> (last visited Nov. 16, 2003)).

[32] K. Peter C. Vollhardt & Neil E Schore, ORGANIC CHEMISTRY (2d ed. 1994); *see also* Roger Lombard, INTRODUCTION TO CHEMISTRY: GENERAL PRINCIPLES OF NOMENCLATURE (1st ed. 1990); William D. Marsillo, *How Chemical Nomenclature Confused the Courts,* 6 U. Balt. Intell. Prop. J. 29 (1997); D. CHISUM, PATENTS § 4.02[1] (1986).

[33] *Id.* for *Vollhardt* at 3-9, 246, 264-67, 610-14. In the invention set forth in the Bayer '444 patent, several precursor molecules were synthesizes, that were then combined together to form the chemical intermediate 6-fluoroquinolinic acid ("6-FQA") that is the subject matter of the dispute in the Bayer case. *Bayer*, 301 F.3d at 1310-11.

[34] *Id.* for *Vollhardt* at 3-9, 246, 264-67, 610-14. In patent law, the term chemical intermediate refers to the building base for forming a larger modified molecule. *Bayer*, 301 F.3d at 1310-11. A synthesis molecule which has been as used as a chemical intermediate can be a stable molecule and can be obtained from third party sources. *Id.* for *Vollhardt* at 264-67, 610-14. Such a chemical intermediate can also be separately patented, in a proper case, as in the Bayer situation. *Id.* for *Bayer*. In fact, Bayer had obtained the U.S. Patent Numbers 4,439,620 and 4,620,007 respectively, on two separate intermediates used in sequence to make the final Cipro© molecule (i.e., the intermediate Klauke compound, which was then used to make the 6-FGA further intermediate via the cycloacycyclation process). *Bayer*, 301 F.3d at 1309-15; *see also* William D. Marsillo, *How Chemical Nomenclature Confused the Courts,* 6 U. Balt. Intell. Prop. J. 29 (1997).

[35] *Vollhardt* at 264-7, 610-14.

[36] *Id.* For example, in *Bayer*, there is an additional patent covering the structure of the chemical intermediate. *Bayer*, 301 F.3d at 1310-12, 1321-24.

[37] *Vollhardt* at 3-9, 246, 264-7, 610-14.

[38] *Id.*

[39] *Id.*

[40] *Id.*

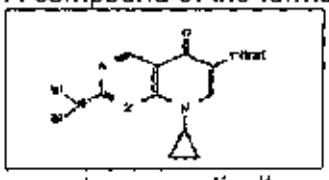
[41] *Bayer*, 301 F.3d at 1310.

[42] *Id.*

[43] *Id.* at 1321.

[44] *Id.*

A compound of the formula

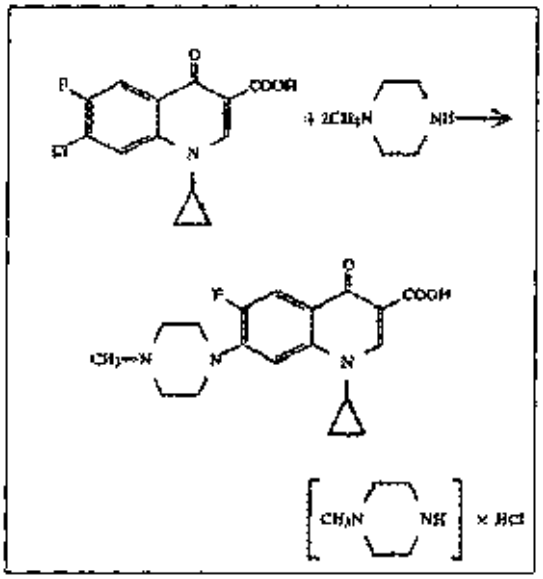


or a pharmaceutically acceptable acid addition salt or an alkali or alkaline earth metal salt thereof,
in which A represents CR^3,
wherein R^3 denotes a halogen atom,
and
Z represents C—H,
and R^1 and R^2 together with the nitrogen atom which they substitute form a piperazino group.

Id. [*147]

[45] *Bayer*, 301 F.3d at 1310; 2,4-dichloro-5-flourobenzoyl chloride.

[46] *Id.*



[47] *Id.*

The first of these reactants is the 6-FQA intermediate and the second, smaller molecule is known as piperazine. *Id.* Hence, the synthesis of ciprofloxacin may be summarized as follows: 6-FQA + piperazine = ciprofloxacin. *Bayer*, 301 F.3d at 1310-21; The chemical predecessor of the 6-FQA intermediate is a class of compounds know as Klauke compounds, but the Klauke compounds, *per se*, were conceded to be available to those of ordinary skill in the art. *Bayer*, 301 F.3d 1306-28.

[48] *Id.* Chemical patents, must meet the patent requirements of novelty, utility, and nonobviousness. 35 U.S.C. § 101 (1995), 35 U.S.C. § 102 (1994), 35 U.S.C. § 103 (1995); *Id.* for *Bayer*;

> [D]uring the 1970s a group of scientists at Bayer experimented with a group of similar antibiotics, and they discovered that substitution of a cyclopropyl at the 1-position increased the potency of the resulting antibiotic. In 1980, Dr. Klaus Grohe, a Bayer scientist, attended a conference in which a Japanese firm disclosed the structure of norfloxacin. Norfloxacin is a broad-spectrum antibiotic that it developed. The structure of norfloxacin is identical to ciprofloxacin, except for the variation that norfloxacin has an ethyl rather than a cyclopropyl group on the ring nitrogen. Dr. Grohe's earlier research resulted in personal knowledge of the concept that substituting a cyclopropyl group for the ethyl group of norfloxacin would increase antibiotic activity. After the conference Dr. Grohe was interested in making the compound.

The general synthetic route to Dr. Grohe's desired compound involves construction of the bicyclic ring structure with the addition of the amino group to provide the final product. A key example of the final step is—addition of an amine to the previously-constructed bicyclic ring to give the desired antibiotic and a byproduct. Using generic chemical terms for the types of chemical compounds involved, the final reaction step can be described as follows: starting bicyclic + amine = final product.*Id.*

[49] *Bayer*, 301 F.3d at 1310-11. [*148]

[50] *Id.* for *Bayer*; Act of April 10, 1790, ch. 7, § 6, 1 Stat. 109; A patent must contain a description that enables one skilled in the art to make and use the claimed invention. *Atlas Powder*, 750 F.2d at 1576; An inventor does not have to explain every detail since his audience are those skilled in the art. *In re Howarth*, 654 F.2d at 105. Every detail does not have to be described, otherwise patent specifications would turn into production specifications, which was never the intent." *In re Gay*, 309 F.2d at 774. Some experimentation is necessary does not preclude enablement; the amount of experimentation, however, must not be unduly extensive. *Atlas Powder*, 750 F.2d at 1576; *see also W.L. Gore & Associates,*

Inc. v. Gaarlock, Inc., 721 F.2d 1540, 1557 (Fed. Cir. 1990); 469 U.S. 851 (1984); *In re Angstad*, 537 F.2d 498 (C.C.P.A. 1976).

[51] Act of Feb.21, 1793, ch.11, Sec.3, 1 Stat. 318.

[52] Act of July 8, 1870, ch.230, Sec. 26, 16 Stat. 198.

[53] Patent Act, § 112.

[54] *Id.*

[55] *Chemcast*, 913 F.2d at 927-28.

[56] *Fonar Corp. v. General Elec. Co.*, 107 F.3d 1543, 1548 (Fed. Cir. 1997); *U.S. Gypsum Co. v. Natl. Gypsum Co.*, 74 F.3d 1209, 1212 (Fed. Cir. 1996).

[57] *Fonar*, 107 F.3d at 1548; *U.S. Gypsum*, 74 F.3d at 1212.

[58] *U.S. Gypsum*, 74 F.3d at 1212; *Chemcast*, 913 F.2d at 928.

[59] *Id.*

[60] *Engel Indus. v. Lockformer Co.*, 946 F.2d 1528, 1531 (Fed. Cir. 1991).

[61] *Applied Med. Res. Corp. v. United States Surgical Corp.*, 147 F.3d 1374, 1377 (Fed. Cir. 1998); *see also* Roy E. Hofer, L. Ann Fitzgerald, *A Review Of The Recent Decisions Of The United States Court Of Appeals For The Federal Circuit: Article: New Rules For Old Problems: Defining The Contours Of The Best Mode Requirement In Patent Law,* 44 Am. U.L. Rev. 2309 (1995) (Discussing the recent changes in the best mode requirement in the year 1995). This includes two of the most important pronouncements from the Federal Circuit: 1. *Chemcast*, which established a two-step analytical method for evaluating best mode compliance, and 2. *Transco Prods. Inc. v. Performance Contracting, Inc.*, which answered many questions about the need to update best mode disclosure in continuing application practice. *Chemcast*, 913 F.2d at 928; *Transco Prods.*, 38 F.3d at 553 (Fed. Cir. 1994); *see also* Donald S. Chisum, Patents 7.05[2] n.1 (1991); *In re Honn*, 364 F.2d 454, 462-4 (C.C.P.A. 1966); *Tofe v. Winchell*, 645 F.2d 58, 65-7 (C.C.P.A. 1981).

[62] *Bayer*, 301 F.3d at 1306-28

[63] Chisum, § 7.05 "The Best Mode Requirement", 7-317, *et seq*.

[64] *Id.* for Chisum.

[65] *Eli Lilly*, 251 F.3d at 963; *see also* Chisum, Setion § 7.05[1][e], n.131; *Chemcast*, 913 F.2d at 927.

[66] *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1567 (Fed. Cir. 1996); *see also Wahl Instruments, Inc. v. Acvious Inc.*, 950 F.2d 1575, 1579 (Fed. Cir. 1991).

[67] *Chemcast*, 913 F.2d at 927; *N. Telecom, Ltd. v. Samsung Elec. Co., Ltd.*, 215 F.3d 1281, 1288 (Fed. Cir. 2000); The *Bayer* case deals with the disclosure requirements, if any, for the best mode of methods for making a novel chemical intermediate upon which other standard chemical reagents are chemically bonded to form the final Cipro© molecule, which is the express subject matter of the patent claims. *Bayer*, 301 F.3d at 1306-28. Conceptually, it is fundamental chemistry that final molecules in a chemical synthesis are formed by joining together smaller, precursor chemical entities. *Vollhardt* at 3-9, 246, 264-7, 610-14. Likewise, various different categories of inventions are similarly formed from their constituent parts, and when set forth expressly in patent claims are frequently called "claim elements". *Id.* for *Bayer*. However, whether an invention's smaller constituent parts are held together by chemical bonds (in the case of a molecular invention), by covalent or physical mixture means (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. *Vollhardt* at 3-9, 246, 264-7, 610-14. There is not any discussion in the Federal Circuit cases calling forth any distinction requiring 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. *Eli Lilly*, 251 F.3d at 963; *N. Telecom*, 215 F.3d at 1288. Nor do the Federal Circuit decisions develop or discuss any rationale for unique best mode standards for use in chemical cases based upon any considerations of public policy. *Id.* Accordingly, chemical or molecular inventions, which are formed from smaller chemical moieties, may properly be considered to be analogous to (a) compositions of matter, which are composed of various elements admixed together, or (b) mechanical devices having several elements which are mechanically connected to effectuate the functioning of the device. *Id.* for *Vollardt*. Indeed, the Federal Circuit has deemed failure to [*149] disclose relevant information regarding such a component part of the claimed invention to be within the scope of the best mode analysis. *Id.* for *Bayer*. However, the Federal Circuit in the *Eli Lilly* case and now the *Bayer* case

sub silentio deems the various constituent parts of a molecule (reflecting the smaller molecules from which it is formed) to be fundamentally different from the various constituent parts of mechanical and/or composition of matter inventions. *Id.* for *Bayer* and *Eli Lilly*.

[68] *Dana Corp. v. IPC Ltd. Partn.*, 860 F.2d 415 (Fed. Cir. 1988); *Spectra-Physics v. Coherent Inc.*, 827 F.2d 1524 (Fed. Cir. 1997); *Applied Med. Res. Corp. v. U.S. Surgical Corp.*, 147 Fed. 1374, 1377 (Fed. Cir. 1998); *Eli Lilly*, 251 F.3d at 955. This judicial dichotomy is highlighted in the differing approaches of the Majority and Concurring opinions in the Bayer case. *Bayer*, 301 F.3d at 1306-28.

[69] *Id.*

[70] *Id.*; *see also* 35 U.S.C. § 102(d).

> [A] person shall be entitled to a patent unless . . . (d) the invention was first patented or caused to be patented, or was the subject of an inventor's certificate, by the applicant . . . in a foreign country prior to the date of the application for patent in this country on an application for patent or inventor's certificate filed more than twelve months before the filing of the application in the United States . . .

Bayer, 301 F.3d at 1306-28; Steven B. Walmsley, *Best Mode: A Plea To Repair Or Sacrifice This Broken Requirement Of United States Patent Law,* 9 Mich. Telecomm. Tech. L. Rev. 125 (2002) (Discussing the importance of the Best Mode requirements and whether the requirement should be saved and repaired or completely abandoned).

[71] *Bayer*, 301 F.3d at 1306-28. The business of developing, producing and marketing chemical intermediates has achieved an important status within the chemical industry. *Id.* Prominent companies in this field include: Celanese (available at <http://www.Celanese.com> (last visited Nov. 16, 2003); Mittsubishi Chem. Corp. (available at <http://mitsubishi-api.com>(last visited Nov. 16, 2003)); Cipro© (ciprofloxacin hydrochloride) is an antibiotic used to treat bacterial infections in many different parts of the body. Cipro Info page (available at <http://www.fda.gov/cder/drug/infopage/cipro> (last visited Nov. 16, 2003)). It does not work for viral infections (for example, the common cold). *Id.* Cipro© is approved for the inhaled form of anthrax after an individual has been exposed. *Id.* Safety and effectiveness in pediatric patients and adolescents less than 18 years of age have not been established, except for use in inhalational anthrax (post-exposure). *Id.*

[72] *Bayer*, 301 F.3d at 1308. The court reviews the district court's grant of summary judgment *de novo*. *Johnson Worldwide Assocs., Inc. v. Zebco Corp.*, 175 F.3d 985, 988 (Fed. Cir. 1999); Summary judgment is appropriate when, based on the record, no genuine issue exists as to any material fact, and the moving party is entitled to judgment as a matter of law. Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury could find for the nonmoving party. *Id.* A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Id.* Summary judgment is appropriate when "there is no genuine issue as to any material fact and . . . the moving party is entitled to a judgment as a matter of law." Fed. R. Civ. P. 56(c); *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, (Fed. Cir. 1998); *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 975 (Fed. Cir. 1995); *Jamesbury Corp. v. Litton Indus. Prods., Inc.*, 756 F.2d 1556 (Fed. Cir. 1985); 517 U.S. 370 (1996); *see also Deimer v. Cincinnati Sub-Zero Prods., Inc.*, 58 F.3d 341, 343 (7th Cir. 1995); *Shearing v. Iolab Corp.*, 975 F.2d 1541, 1544, (Fed. Cir. 1992); Fed. R. Civ. P. 56(c). A genuine issue exists if the evidence is such that a reasonable jury could find for the nonmoving party. *Id.* A disputed fact is material if it might affect the outcome of the suit such that a finding of that fact is necessary and relevant to the proceeding. *Eli Lilly*, 251 F.3d at 962; *Id.* for *Bayer*.

[73] *Bayer*, 301 F.3d at 1323-28. The federal circuit did not discuss the details of the involved chemistry and specifically that the chemical intermediate (6-FQA) physically and chemically constituted a material part of the final molecule described as the patent claims. *Id.* Chemical Intermediates have utility and can be patented. *Id.*; *see also* Cohen & Schwartz, *Do Chemical Intermediates Have Patentable Utility?,* 29 GEO. WASH. L. REV. 87, 89-91 (1960). Stated differently, the atoms constituting the chemical intermediate 6-FQA could not be removed from the Cipro© molecule as described in the claims without destroying the fundamental and beneficial characteristics of the ciprofloxacin molecule. *Id.* for *Bayer*.

[74] *Id.* [*150]

[75] *Id.*

[76] *Id.*

[77] *Id.*

[78] *Id.*

[79] *Id.* at 1306-1324; *see also* 35 U.S.C. § 112; Compliance with best mode disclosure requirement for patent specifications is a question of fact composed of two subsidiary factual inquiries: first, the fact finder must determine whether, at the time of filing the application, the inventor possessed a best mode for practicing the invention, and this prong is highly subjective and focuses 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 adequate to enable one of ordinary skill in the art to practice the best mode of the invention, and this inquiry is objective and depends upon the scope of the claimed invention and the level of skill in the relevant art. *Id.*

[80] *Bayer*, 301 F.3d at 1306-24. The *Bayer* court has held: a patent invalid for the failure to satisfy the best mode requirement in two particular situations. *Id.* First, invalidated patents where the parties do not adequately disclose a preferred embodiment of the invention. *Id.* As a result, if an inventor fails to disclose the preferred embodiment of the invention, the best mode requirement is not satisfied. *Id.* 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. *Id.*

For example, in *Spectra Physics* and *Nobelpharma*, the inventors failed to disclose subjective preferences that related to making the inventions, and the undisclosed information "materially affected the properties" of the claimed invention. Nobelpharma AB v. Implant Innovations, 141 F.3d 1059 (Fed. Cir. 1998); *Spectra-Physics*, 827 F.2d at 1532. In the *Dana* and *Great Northern* cases, the inventors failed to disclose the preferred embodiment of the claimed inventions, and the undisclosed information "materially affected the properties" of the claimed inventions. *Dana*, 860 F.2d at 415-18; *N. Telecom*, 908 F.2d at 940.

[81] *Bayer*, 301 F.3d at 1324-28. And perhaps future panels of the Federal Circuit, based upon the reasoning of the Concurring opinion. *Id.*

[82] U.S. Const. Amend. V, §1. The United States Constitution, Amendment XIV § 1 holds;

> [N]o person shall 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.

Id.; *see* for example, *Whisenhunt v. Spradlin*, 464 U.S. 965 (1983); *Kaluzynski v. Armstrong*, 2001 U.S. Dist. LEXIS 11040 (D. Me. 2001); *Ostergren v. Village of Oak Lawn*, 125 F. Supp. 2d 312 (N.E.2d 2000); *U.S. v. Lokey*, 945 F.2d 825 (5th Cir. 1991); *McSherry v. Block*, 880 F.2d 1049 (9th Cir. 1989); *Trans-Pacific Freight Conference v. Fed. Maritime Com.*, 209 U.S. App. 27 (2d Cir. D.C. Cir. 1980); *Harper v. Lindsay*, 616 F.2d 849 (5th Cir. 1980).

[83] 35 U.S.C. § 112; 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. *Id.*

[84] *Wahl*, 950 F.2d at 79; *see also Christianson v. Colt Indus. Operating Corp.*, 822 F.2d 1544, 1563 (Fed. Cir. 1987.)

[85] *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1330 (Fed. Cir. 2002); 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. 35 U.S.C. § 112.

[86] *Bayer*, 301 F.3d at 1316. [*151]

[87] *In re Brebner*, 455 F.2d at 1404; The Court of Pennsylvania limited the scope of the appropriate best mode inquiries to the scope of the claims. *Id.*

[88] *Id.*

[89] *DeGeorge v. Bernier*, 768 F.2d at 1318 (Fed. Cir. 1985).

[90] *Id.*;

> [T]he counts concern electrical circuitry in word processors (or typewriters) designed to obtain automatic indentation of a block or paragraph of text so that subsequent lines of the block (or paragraph) are indented from the left line regardless of the recorded codes for the subsequent lines. The invention, to be used with a word processor (or typewriter), was referred to by the board as a two-counter comparison paragraph indent (TCCPI) circuit.

Id.

Count 1 reads as follows:

> [A]pparatus for controlling the operation of a data processing system printer having printing mechanism for printing characters and functional mechanism for selecting the location of printing of characters, first means for sensing a first characteristic operation of the printer, second means enabled in response to the sensing of said first characteristic operation for counting a first succession of second characteristic functional operations including first storage means for storing the count of said second characteristic functional operation, comparison circuit means for counting a second succession of said second characteristic functional operations, and means limiting said second succession of second characteristic functional operations when the count of said second succession bears a pre selected relationship to the count of said first succession of second characteristic functional operations.

Id.

[91] *Bayer*, 301 F.3d at 1306-28. Given the relatively simple final step in forming the Cipro© molecule, it would be strange indeed for the patentee to 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". *Id.* 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. *Id.* The Court did not discuss this apparent inconsistency. 35 U.S.C. § 103 states:

[C]onditions 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.

35 U.S.C. § 103.

The Patent Law, like other areas of the law, should be consistent. The "invention" for § 112 best mode purposes should be the same "invention" relied upon by the patentee for non obviousness under § 103; 35 U.S.C. § 103, 35 U.S.C. § 112.

[92] *Zygo*, 79 F.3d at 1563.

[93] *Gypsum*, 440 F.2d at 510.

[94] *Chemcast*, 913 F.2d at 927. The *Bayer* court has purported to apply the best mode beyond the scope of the claims: "Most of the cases in which we have said that the best mode requirement was violated addressed situations where the inventor failed to disclose non-claimed elements that were nevertheless necessary to practice the best mode." *Bayer*, 301 F.3d at 1306-28.

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

[96] *Dana*, 860 F.2d at 418. [*152]

[97] *In re Gay*, 309 F.2d at 772. 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." *Id.* 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." *Id.*

[98] *Spectra-Physics*, 827 F.2d at 1527.

[99] *N. Telecom*, 215 F.3d at 1285.

[100] *Id. Northern Telecom* applies the claimed invention rule and eschews a "material effect on properties" test to identify a best mode. *Id.*

[101] *Bayer*, 301 F.3d at 1315. 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.

> [W]ith 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.

Id. at 1306-28.

[102] *Id.* at 1321.

[103] *Id.* at 1324-28. A counter argument to my newly proposed balancing test is in direct support of the concurring opinion. *Id.* The argument is that the district court correctly decided this "easy" Best Mode case. *Id.* The court did not need to plant any new traps in the best mode minefield. *Id.*; *see also Best Mode Provision 'Significantly' Expanded in Concurring Decision,* MEALEY'S LITIGATION REPORT: INTELLECTUAL PROPERTY, Vol. 10. #22 (August 19, 2002); *Prior Foreign Patents Don't Invalidate Cipro© Patent,* ANDREWS PUBLICATION p. 3 (2002)(Discussing the impact of broadening the scope of the best mode requirement by Judge Radar); *Inventor's Preferences Need Not Be Disclosed Absent Material Effect on Claimed Invention,* NEWS WASHINGTON, Sec. Patent/Best Mode, ISSN 0148-7965 (Aug. 16 2002)(Discussing the importance and support of Judge Radars Concurring opinion); In *Bayer*, the court explained the *Dana* relationship test which could "potentially sponsor a boundless inquiry into any undisclosed method or property that could affect the satisfactory performance of the invention". *Bayer*, 301 F.3d at 1325; "Patent law in general is not concerned with the performance of an invention, let alone its satisfactory performance." *Hildreth v. Mastoras*, 257 U.S. 27, at 34,42 (1921). The *Bayer* opinion "incorporates *Dana* within its "material effects" test:

"In *Dana*, . . . the inventors failed to disclose subjective preferences that related to the use of the claimed inventions, and the undisclosed information materially affected the properties of the claimed inventions." *Bayer*, 301 F.3d at 1319.

The Federal Circuit has continued to identify best mode situations for twenty years without a material effect or properties test. *Id.*

> [M]oreover, the Federal Circuit already has a claimed invention rule based on the language of Section § 112 In expanding the best mode test to accommodate Dana, the new Bayer test creates new conflicts with many cases in which this court found no best mode. Thus this new material effect test contravenes much of the calculus the Federal Circuit has employed in best mode cases.

Id.;

In *Eli Lilly*, the court showed the difficulty of expanding the best mode test: it seems as though the court missed a lot of its significance. *Id.* "The *Bayer* opinion characterizes *Eli Lilly* as within its new rule based on a few words in *Eli Lilly* that distinguish the starting material from the "intrinsic quality" of the invention." *Id.*A review of the totality of the Circuit's best mode cases, shows that this court does not use an "effect on properties" test to identify best modes, but instead uses a scope of the claimed invention test. *Id.* at 1325. The opinion fails in its effort to erect a new test that is, in any event, beyond the facts of this case. *Id.* at 1325. [*153]

[104] *Bayer*, 301 F.3d at 1306-24. Many other courts and law review articles have criticized the use of "bright line" tests in patent law and have encouraged a fact specific test approach. *Miranda v. Ariz.*, 384

U.S. 436, 444 (Fed. Cir. 1966); *see also* Kathryn E. Crossley, *Patent Law and Policy Symposium: Re-Engineering Patent Law: Recent Development: Much Ado About Miranda*, Wash. U. J.L. & Pol'y 569, 574 (2000); Honorable Arthur J. Gajarsa, Evelyn Mary Aswad, Joseph S. Cianfrani, *How Much Fuel To Add To The Fire of Genius? Some Questions about Repair/Reconstruction Distinction in Patent Law,* 48 Am. U.L. Rev. 1205, 1222 (1999) (Discussing "bright line" tests).

[105] *Bayer*, 301 F.3d at 1306-24. The "scope of the claimed invention" rule; Title 35 requires disclosure of "the best mode contemplated by the inventor of carrying out his invention." 35 U.S.C § 112. The most important words in this phrase are "his invention." *Id.* These words invoke the claims. *Id.* Based on this direct statutory language, the bulk of this court's precedent states that the disclosure necessary to satisfy the best mode requirement depends on the scope of the claimed invention." *Teleflex*, 299 F.3d at 1329-33; *see also Eli Lilly*, 251 F.3d at 963. The extent of information that an inventor must disclose depends on the scope of the claimed invention. *Bayer*, 301 F.3d at 1324.

[106] 35 U.S.C. § 102(b).

[107] *See* 35 U.S.C. § 102(g).

[108] *Bayer*, 301 F.3d at 1319-20. In fact, in *Bayer* the salient chemical intermediate had been made by two different routes, one much better than the other. *Id.*

[109] *Bayer*, 301 F.3d at 1322.

[110] U.S. Const. Art. 1 § 8.

[111] *Bayer*, 301 F.3d at 1315.

[112] *Bayer*, 301 F.3d at 1321. This *Bayer* case's bare characterization does not contend, nor could it, that a starting material does not materially affect the properties of the invention. *Id.*

[113] 35 U.S.C. § 112. There are several aspects of the Concurring opinion, apart from its advocacy for a simple "bright line" rule, that present cause for concern to the patent profession. *Bayer*, 301 F.3d at 1306-24. In particular, the precedental value of the Court's decision is significantly undermined by the Concurring opinion's characterization of the Majority opinion as constituting "dicta", and further by the Concurring opinion's outcome determinative approach – *i.e*., the district court got it exactly right. *Id.* at 1322. In so doing, the concurring opinion presents "no harm, no foul" reasoning. *Id.* at 1324-28. For example, as justification for adopting the simplistic "scope of the claims" standard used by the District Court, the concurring opinion cites with approval the *non sequitur* that there had been full disclosure of the novel intermediate in a different application. *Id.* In fact, as this court's opinion notes, the inventor fully disclosed the intermediate, but not in this patent's specification. *Id.* Instead the inventor disclosed the intermediate in a separate (but albeit later) patent application. *Id.* at 1321. Then, in aggravation, the Concurring opinion added the further irrelevancy that, "The proposed best mode in the case was so far removed from the scope of the claimed invention that it was itself a separate invention." *Id.* However, this novel reasoning ignores the well-developed concept of sub-combination claims. *Id.* Hence, neither the novelty of the intermediate, nor its disclosure in a different application does anything whatsoever to "remove" the subject matter of the intermediate from the claimed invention. *Id.* Indeed, as the chemistry itself shows, the so-called "intermediate" is a material (if not huge) part of the final Cipro© molecule. *Id.* And, yet additionally, the novelty of the intermediate virtually assures that unauthorized producers of this non-standard commodity of commerce would be subject to a suit for contributory infringement under the '444 patent. *Id.*

[114] *Bayer*, 301 F.3d at 1324-28. The concurring opinion itself recognizes the need for a definitive test for determining best mode, but implies that the District Courts would not be adequate to determine what is "dicta", what rule to apply, or even how substantively to determine best mode issues, absent a very simple (i.e., "bright line") rule. *Id.* The next district judge encountering a best mode case would have to ask several imponderable questions: What is the Federal Circuit statement of the best mode rule? Even under this case, what is the test to identify a best mode – scope of the claimed invention, necessary relationship to performance of the claimed invention, or material effect on the properties of the claimed invention? What is a "property?" What is a "material effect?" How "material" is "material?" Whereupon, the concurring opinion tellingly used the term "easy" in describing the most important characteristic of any good best mode test. *Id.* The district court correctly decided this easy best mode case. *Id.* This court certainly did not need to plant any new traps in the best mode minefield. *Id.* [*154]

[115] *Bayer*, 301 F.3d at 1324-28. Because the *Bayer* court does not discuss the matter, it is assumed for purposes of this analysis that the "ease" being referred to by the Concurring opinion was intended to be

ease of application by the District Courts, rather than ease of review by the Federal Circuit. *Id.* Notwithstanding the Concurring opinion's assessment of the abilities of the District Courts, what should be determined by whatever best mode test were to be adopted is the fundamental question: Did the public get from the inventor what the public had "paid for" in granting a patent to the inventor? *Id.* If the District Courts must determine purportedly "difficult" issues, such as the definition of a "property" or what is "material", or even what is "dicta", these are the very sort of issues that the federal trial courts were established to determine. *Id.* Hence, ease of application is not a genuine issue here. *Id.* But even so, mere convenience to the courts would not be an appropriate substitute for accuracy, or for correctness, whether under the Constitution, or under the Patent Statute. And the ease of an appellate court in reviewing the decision of a trial court, or even whether such appellate review would be essentially *de novo,* entitled to the presumptive correctness of a jury verdict, or some other standard, are not factors to be given any substantial weight in determining which test should be used to determine best mode compliance; the Federal Circuit is no stranger to the type of balancing test that is stated in this paper.

Specifically in the case of *EZ Dock, Inc. v. Schafer Sys. Inc.*, the Federal Circuit promulgates a balancing test and names thirteen specific factors to be decided on the issue of the "on-sale" bar under 35 U.S.C. § 102. *EZ Dock, Inc.*, 276 F.3d 1347, 1351 (Fed. Cir. 2002); *see also Pfaff v. Wells Elec., Inc.*, 525 U.S. 55, 142 L. Ed. 2d 261, 119 S. Ct. 304 (1998); *Micro Chem., Inc. v. Great Plains Chem. Co.*, 103 F.3d 1538, 1544 (Fed. Cir. 1997); *Weatherchem Corp. v. J.L. Clark, Inc.*, 163 F.3d 1326, 1333 (Fed. Cir. 1998); *Gould Inc. v. U.S.*, 579 F.2d 571, 583 (Ct. Cl. 1978); *Kolmes v. World Fibers Corp.*, 107 F.3d 1534, 1540 (Fed. Cir. 1997).

[116] *Bayer*, 301 F.3d at 1320-21.

[117] *Graham v. John Deere*, 383 U.S. 1, 17 (Fed. Cir. 1966). The *Graham* case provides a listing of factors to be considered in determining obviousness under § 103. *Id.* The courts have had no substantial problems in carrying out this multi-factored test. *Id.* These factors are as follows: [W]hile the ultimate question of patent validity is one of law, *A. & P. Tea Co. v. Supermarket Corp.*, *340 U.S.147, 153-5 (1950)*; the § 103 condition, which is but one of three conditions, each of which must be satisfied, lends itself to several basic factual inquiries. Id. Under § 103, 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. *Id.* Against this background, the obviousness or non-obviousness of the subject matter is determined. *Id.* Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. *Id.* As indicia of obviousness or non-obviousness, these inquiries may have relevancy. *Id.* at 17.

[118] 35 U.S.C § 112.

[119] *Union Pacific Res. Co. v. Chesapeake Energy Co.*, 236 F.3d 684 (Fed. Cir. 2001); *Keystone v. Midstates Dist. Co. Inc.*, 235 F.supp. 2d 901 (Fed. Cir. 2002). For example, in those frequent instances where it is necessary for the trier of the fact to use the "reasonable person standard" in assessing the scope of a legal duty and/or the adequacy of the performance carried out thereunder.

[120] 35 U.S.C. § 271 1952.

[121] 35 U.S.C § 271(c) states:

> (c) Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial non infringing use, shall be liable as a contributory infringer. [*155]

See Aro Mfg. Co. v. Convertible Top Replacement Co., 377 U.S. 476 (Fed. Cir. 1964); *Fina Research, S.A. v. Baroid, Ltd.*, 141 F.3d 1479 (Fed. Cir. 1988); *Eldon Indus., Inc. v. Vanier Mfg., Inc.*, 1990 U.S. App. LEXIS 19775 (Fed. Cir. 1990); *Sticker Indus. Supply Corp. v. Blaw-Knox Co.*, 367 F.2d 744 (United States Court of Appeals for the Seventh Circuit, 1966); *Natl. Coupling Co. v. Press Seal Gasket Corp.*, 323 F.2d 629 (Fed. Cir. 1963); *Sidel v. Uniloy Milacron, Inc.*, 34 Fed. App. 683 (Fed. Cir. 2001).

[122] *Amgen*, 927 F.2d at 1201.
[123] *Atchison, T. & S.F.R. Co. v. Sowers*, 213 U.S. 55, 55-69 (1909).