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NOTE
BROADENING THE SCOPE OF BIOTECHNOLOGY INVENTIONS BY DISCLOSING A SCIENTIFIC THEORY

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Much has been written about what is needed to enable the full scope for a biotechnology invention.[1] The courts have also decided a substantial number of cases in this area. Nevertheless, it is still difficult to advise an inventor on what to do to enable his invention for a genus, where he has performed his experiments in one or a few species.

There are several reasons for this difficulty. First, the factors cited by courts to determine the scope of enablement for an invention are either beyond the control of the inventor or are uninformative in the context of biotechnology. Second, the factors are only illustrative so they cannot be depended upon with any certainty. Third, the existing case law is highly fact-dependent with no bright line rules. Finally, commentators writing about the application of the enablement requirement to biotechnology inventions have mostly described Federal Circuit cases, without finding unifying themes or analyzing the decisions of district courts.

Although the *Wands* factors by themselves are not particularly helpful to inventors, adding a description of the scientific theory underlying the invention may help increase the scope of enablement. The presence of a scientific theory works to increase [*88*] the scope of enablement where it reduces the amount of experimentation necessary or increases the predictability of the invention. Many district courts already

consider the presence or absence of a scientific theory when evaluating the *Wands* factors, though not explicitly. On the other hand, the Supreme Court and Federal Circuit have placed limits on the ways in which the presence or absence of a scientific theory may be considered.

Part I of this note explains what the enablement requirement is and why it has been difficult to determine the scope of enablement for biotechnology inventions. The remainder of Part I describes the Federal Circuit's decision in *In re Wands*, the case most frequently relied on in assessing whether the enablement requirement has been met. Part II of this note explains why the *Wands* factors do not provide much guidance for advising biotechnology inventors attempting to claim a genus. Part III explains how the disclosure of a scientific theory may increase the scope of enablement. This section details the consideration of a scientific theory by both district and appellate courts. Part IV concludes with a recommendation that, when possible, inventors should describe in the specification the scientific theory underlying their inventions.

I. BACKGROUND

A. *The Enablement Requirement*

[*89*] The statutory basis for the enablement requirement is the first paragraph of 35 USC § 112. This provision states that the specification must contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

The enablement requirement is used in two contexts. First, 35 USC § 112 requires enablement per se, meaning that the disclosure must allow a person of ordinary skill in the art to make and use the invention. Although not explicitly stated in the statute, courts have read this to mean that the invention must be enabled to a person of ordinary skill in the art without "undue experimentation."[2] Second, it requires the scope of enablement provided in the disclosure to persons of ordinary skill in the art must be commensurate with the scope of the claims.[3] In this case, the disclosure enables some parts of the invention, but does not enable other parts.

The scope of enablement doctrine serves several important purposes by preventing inventors from obtaining patents that cover more than they invented. An overly broad claim that is not fully enabled stifles innovation in that area of research because other scientists in the field are afraid of infringing the patent.[4] Additionally, granting broad claims rewards those who invent a relatively small advance at the expense [*90*] of those who make large, but slightly less timely advances.[5] Therefore, scope of enablement is an essential part of the bargain between the patentee and society.

These policy goals are mitigated by the applicant's presumptive right to a patent as granted by 35 USC § 102. As a result of this presumption, the burden is initially on the examiner during prosecution to show that the applicant has not met the requirements for

patentability, including proper scope of enablement.[6] If successful in meeting its burden, the burden shifts to the applicant to show that the claims are fully enabled.[7] Once the patent issues, the presumption that the whole patent instrument is valid creates a presumption that the claims are of a scope commensurate with the specification. Therefore, the party challenging the patent carries the burden of showing by clear and convincing evidence that the scope of enablement is less than what is claimed.

B. *The Lack of a Bright Line Rule for Enablement*

The issue of enablement is highly fact-specific, without any bright line rules for guidance. This ad hoc approach is described by Judge Newman in her dissent in *In Re Wands*, where she states, "As illustrated in extensive precedent on the question of how much experimentation is 'undue,' each case must be determined on its own facts."[8] This [*91*] case-by-case approach to enablement offers little predictability to inventors trying to fulfill the enablement requirement.

The lack of a bright line rule is especially problematic in biotechnology. When an inventor describes several species, but claims a genus, she may find, for various reasons related to the nature of biotechnology, that the scope of enablement is limited to less than the full genus. For example, the genus may be broken down into classes in different ways. If all of the inventor's experimentation was performed in one organism, an accused infringer might claim that the invention is enabled only for the organism described,

despite a claim applying to all organisms. Even if the inventor's experiments were performed in several organisms, such as different types of bacteria, the opposing party might claim that the invention is not enabled for more complex cells, such as eukaryotes. For an invention embodied in a plant, the examiner may take the position that the invention is enabled for dicotyledonous but not the more commercially valuable monocotyledonous plants. Monocots and dicots are two types of flowering plants which have one leaf during early development (monocots) or two leaves (dicots).[9]

These dichotomies present difficulties for inventors for several reasons. First, there are many different classifications in biology, and it may not take an infringer much creativity to find a class of organisms for which the invention has not been enabled. Second, biotechnology is a highly unpredictable art. As a result, it is difficult for an inventor to demonstrate that his invention will work for all organisms contained in the genus. Third, the life sciences often focus on model organisms such as *E. coli* or yeast, which are not commercially valuable. These model systems are chosen because they are relatively easy to work with and share many characteristics of more complex [*92*] organisms.[10] However, once a discovery has been made in a model organism, inventors have many incentives to file their patent application as soon as possible.[11] Without performing additional experiments to confirm that the invention works in a broader class of cells, it is difficult to know whether it will work in other cells, absent some guiding principle.

One potential solution is to file an application immediately, but continue to experiment until a guiding principle is discovered. Even if the inventor is successful in

this endeavor, she may still face obstacles during prosecution and litigation under the enablement requirement.

First, the scientists performing the experiment may possess a much higher than ordinary degree of skill in the art. Because the enablement test requires a person of ordinary skill in the art to be able to use the invention without undue experimentation, such successes by a person of higher skill may not be relevant.

Second, the experiment may be successful only after an undue amount of experimentation. Publication of such results may allow a person of ordinary skill in the art to use the invention without undue experimentation. However, enablement requires that a person of ordinary skill be able to use the invention at the time of filing.[12] Therefore, this result would work against the inventor because it would show that undue experimentation was required at the time of filing.

[*93*] Finally, if the experiments are unsuccessful, these failures may be counted against the inventor in determining the scope of enablement.[13]

C. *The Standard Provided by In re Wands*

In *In re Wands*, the Federal Circuit set forth a series of factors to be used in determining whether the enablement requirement has been met.[14] The court held that for unpredictable arts such as biotechnology, undue experimentation is determined by a standard of reasonableness which can be assessed by examining eight factors: (1)

quantity of experimentation necessary (2) the amount of direction or guidance presented; (3) the presence or absence of working examples; (4) the nature of the invention; (5) the state of the prior art; (6) the relative skill of those in the art; (7) the predictability or unpredictability of the art; and (8) the breadth of the claims.[15]

Subsequent decisions have addressed how the factors should be applied. First, although *In re Wands* concerned enablement per se, the Federal Circuit has sanctioned the use of these factors to determine the scope of enablement.[16] However, none of the decisions applying the *Wands* factors has discussed how each factor should be weighed. As a result, it is difficult for an inventor to know how much disclosure is necessary to enable the full scope of his claims. Second, the Federal Circuit has held that the *Wands* [*94*] factors are merely illustrative.[17] Therefore, a court is free to choose which factors to examine, to create new factors to apply, or to ignore factors that are present. Third, although *In re Wands* was an ex parte case, the factors also apply to inter partes litigation because in both instances, the proper inquiry focuses on what would have been enabled at the time of filing.[18]

II. THE WANDS FACTORS

The *Wands* factors by themselves are of little use in helping an applicant determine how much disclosure is necessary to enable a genus without performing experiments on every species within that genus. One reason that the *Wands* factors are

not helpful to applicants is that several of the factors are beyond the control of the applicant. Therefore, the *Wands* factors by themselves do not allow an inventor to increase the scope of enablement by performing additional experiments or adding more information to the specification. The remaining factors are so vague that an applicant cannot be reasonably certain what she needs to do to enable the full scope of her invention.

[*95*] This part of the note will analyze the *Wands* factors through Federal Circuit opinions rather than district court opinions because enablement is ultimately a question of law that is reviewed de novo on appeal.[19]

A. *Factors Over Which Applicant Has No Control*

1. *Quantity of Experimentation Needed*

The factor "quantity of experimentation needed" is a misnomer. Discussing *In re Wands*, the Federal Circuit in *Johns Hopkins University v. CellPro, Inc.* stated that undue experimentation is "not merely quantitative," and that a considerable amount of experimentation is permissible.[20] The resolution of this apparent contradiction is that the court is concerned with the amount of non-routine experimentation, not the total quantity of experimentation. Some technologies are inherently unpredictable and require much repetition, even with a detailed disclosure.[21] Unfortunately, the inventor has no control

over how much repetition is inherent in the technology. The inventor also cannot control whether or not the experimentation is routine. Whether or not experimentation is routine depends on what is well-known in the art at the time of filing.[22] Because an inventor [*96*] cannot change what is well known in the art at the time of filing through the addition of information to his disclosure, this factor offers little help to the inventor.

2. *State of the Prior Art*

The existence of prior art at the time of filing is beyond the control of the patentee. However, the inventor has some control over this factor because he can alert the United States Patent and Trademark Office (PTO)or court by citation in his application to the existence of prior art that that tends to show that his invention is broadly enabled. Nevertheless, there are limitations on the use of this factor.

Prior art enjoys only a limited role in supporting enablement. Prior art can only be used to fill in small gaps in the disclosure. [23] In *Genentech II*, the patentee strongly relied on prior art to expand the scope of enablement for his invention.[24] The court rejected this extensive use of prior art, holding that prior art can only be used to supply minor details which are not described in the specification.[25] The court stated that prior art is "not a substitute for a basic enabling disclosure."

Even if the patentee is able to describe prior art that is helpful, by citing extensive prior art to describe his invention, he may make his invention appear to have been

obvious.[26] Therefore, not only does the inventor have no control over the state of the [*97*] prior art at the time of filing, an attempt to demonstrate the existence of such prior art may be irrelevant or even harmful to the applicant.

3. *Breadth of the Claims*

The claims discussed in this note are broad because this note concerns how to claim a genus where only species are disclosed.

B. *Factors Which Are Too Vague to be Helpful*

1. *Presence or Absence of Working Examples*

Although the Federal Circuit has indicated that it believes this factor is important, it has not provided much guidance on how it should be applied. The question of how many and what kinds of examples are needed is left unanswered.[27]

[*98*] The court in *Enzo II* also acknowledges the difficulty in evaluating the presence or absence of working examples, stating that a "recurring problem is whether a

specification that sets forth a single or a limited number of examples can be enabling of broad claims when the subject matter concerns biological materials or reactions, which are generally considered unpredictable."[28] More recently, the court in *Amgen, Inc. v. Hoechst Marion Roussel* has suggested that a single example is indeed enough, provided that "any gaps between the disclosures and the claim breadth could be easily bridged."[29] Reconciling these two views on the use of working examples highlights the uncertainties that inventors face in trying to determine how much disclosure is sufficient.

2. *Amount of Direction or Guidance Presented*

There are many examples in which the court articulates how to recognize an insufficiency of guidance, but fails to explain how much direction is enough. The court in *Enzo II* cautions that "[t]ossing out a mere germ of an idea does not constitute enabling disclosure."[30] Unfortunately, it does not describe how much disclosure is enough.

3. *Relative Skill / Predictability of the Art*

[*99*] Both relative skill in the art and the predictability of the art are ambiguous because court cases are divided as to how narrow the relevant field of art should be. In

some cases, the field of art is construed as biotechnology in general, and therefore the art is regarded as having a high level of skill and a high degree of unpredictability.[31] In other cases, the relevant field of art is a subfield of biotechnology. [32] Some subfields of biotechnology are highly predictable, while others require a relatively low level of skill.[33]

The level of ordinary skill may be hard to ascertain where multiple fields are involved. Some fields such as genetic engineering are highly specialized, and the invention therefore requires skill in several specializations. The court in *Enzo II* held that where an invention combines different specializations, the invention must be enabled for the "adepts of each art."[34] As a result, an inventor may face considerable difficulty in trying to determine the relative skill of one in the art.

Even if the inventor correctly determines in what field of art the court will place his invention in, there are additional uncertainties that arise in considering the predictability of the invention. Lack of predictability may be "not attributable to a failure of disclosure," but rather to the fact that the "technique was not foolproof."[35] This statement suggests that a certain amount of the unpredictability inherent in the technology will not be counted against the patentee. Unfortunately, the Federal Circuit does not provide a test for whether the unpredictability is the fault of the patentee. Thus, to the [*100*] extent that the unpredictability is inherent in the technology, the patentee has no control over it.

4. *Nature of the Invention*

This factor is virtually never referred to explicitly, presumably because it is too ambiguous. In one of the few instances in which it was explicitly mentioned, *Plant Genetic Systems, N.V. v. Dekalb Genetics Corp.*,[36] the court found the consideration of this issue to be moot. Plant Genetic Systems had argued that the pioneering nature of the invention must be considered in determining the scope of enablement and that the district court erred by not taking it into account.[37] The Federal Circuit rejected this argument, holding that the district court did not need to make such a finding.[38] As a result, it is unclear how applicants should consider this factor in writing their disclosure.

III. GETTING THE FULL BREADTH OF CLAIMS

[*101*] Despite the problems with the *Wands* factors, adding certain information to the disclosure increases the chances that a court will find the full breadth of the claims to be enabled. The information that should be included is the scientific theory underlying the invention. The theory can take many forms, including a description of the cellular or biochemical mechanism by which the invention works. However, in order to enable the species not already described, the theory must decrease the amount of experimentation needed or increase the predictability of the invention. In this way, the inclusion of a

scientific theory allows the inventor to have more control over how the *Wands* factors will be applied to his patent.

District courts already frequently consider the presence or absence of a scientific theory when evaluating the *Wands* factors. Part A of this section examines how district courts have analyzed the presence or absence of a scientific theory in biotechnology cases. Part B discusses the appellate cases that provide the limits on how the presence or absence of a scientific theory may be used.

A. District Courts' Consideration of Scientific Theory

District courts have frequently considered the presence or absence of a scientific theory offered by either side as a factor in determining the scope of enablement in biotechnology cases. This note examines cases in which the issue is the scope of enablement and not enablement per se. That is, the claims cover some subject matter that [*102*] is indisputably enabled, and some subject matter that may or may not be enabled. The presence of a scientific theory or mechanism of action may increase the scope of enablement by reducing the amount of experimentation needed and increasing the predictability of the invention.[39] In contrast, a scientific theory offered by a defendant may narrow the scope of enablement by showing differences between the particular species described and other species in the genus. Such a showing of differences would

reduce the scope of enablement if additional experimentation would be needed to use the invention in the non-disclosed species.

Although many commentators have analyzed Federal Circuit case law on this topic, little has been written about how decisions are made at the district court level.[40] This is striking because although enablement is a matter of law, it is based on underlying factual determinations.[41] This section will review the district court cases which have applied this factor.

The cases cover situations in which the patentee, the accused infringer, both, or neither offer a scientific theory. Even in the cases where the patentee produces evidence of a theory at trial, the relevance of this theory can depend on how the theory is presented. The theory is more likely to be considered where it was disclosed in the specification, either explicitly or by reference. It is less likely to be considered where it was not disclosed in the patent, but instead the patentee argues that it was known to exist by one of ordinary skill in the art at the time of filing.

An important theme that occurs throughout the cases is whether the theory presented by either party affects the predictability of the invention. In this way, the [*103*] scientific theory factor allows at least one of the *Wands* factors to offer guidance as to how to enable a broad genus. Even though a scientific theory is not required, it helps broaden the scope of enablement for the invention to the extent that it renders the technology more predictable. Thus, a scientific theory is more likely to be needed in an unpredictable field like biotechnology.

1. *Hopkins v. CellPro*

In *Johns Hopkins University v. Cellpro, Inc.*, the patentee Hopkins discloses in its specification the scientific theory underlying its invention.[42] The Hopkins patent teaches how to use one antibody to an antigen, along with a description of the biochemical mechanism by which the antibody attaches to the antigen.[43] This mechanism represents Hopkins' theory and, it argues, allows Hopkins to claim all antibodies against that antigen because the same mechanism is common for all the members of that genus. The court explains that its finding of enablement is based in part on the fact that "the specification describes the entire fusion process."[44] CellPro does not offer any counter-theory or refutation of Hopkins's theory. As a result, there is no dispute as to whether Hopkins's theory is empirically correct. This case therefore represents straightforward evidence that district courts do look to scientific theory as a factor of enablement.

[*104*] 2. *Gentech v. Novo Nordisk*

Genentech v. Novo Nordisk[45] is similar to *CellPro I* in that the patentee has a scientific theory and the accused infringer does not present a counter-theory or refute the validity of the patentee's theory. What is different about this case is that the theory is not

described in the specification of the patent. The theory is described in the literature, some of which is explicitly referenced by the patent and some of it which is not.

The disclosed species in this case is a method for purifying hGH by the use of one proteolytic enzyme, trypsin. Genentech argues that because all proteolytic enzymes are similar in their action, the claims of their patent to all proteolytic enzymes are enabled by the disclosure of using a single enzyme. The theory that all proteolytic enzymes share a common mechanism of action is described in various articles that were available at the time of filing. There are two subclasses of proteolytic enzymes, exopeptidases and endopeptidases, and the literature describes how they are similar. The literature, some referenced in the patent and some not, describes very specifically what each enzyme does and how it works. The district court does not distinguish between referenced articles and those that were not. It considers both in reaching its conclusion.

The consideration of the scientific theory as a factor in Genentech relies on the extent to which it makes the technology more predictable. Here, unlike *CellPro I*, the accused infringer challenges the validity of the scientific theory by arguing that Genentech had not actually used its invention with any other enzymes, and therefore [*105*] could not back up its theory with evidence.[46] Thus, there is a dispute of fact over the validity of the scientific theory. The court makes a factual finding about the correctness of the scientific theory when it states that "the activities of exopeptidases and endopeptidases are the same."[47] The court does not find convincing the fact that none of these other enzymes has actually been tested. Having found the theory convincing, the court concludes that the claims are enabled for the entire genus because they make the use of other enzymes easily predictable.[48]

3. *Amgen v. Hoechst*

In *Amgen v. Hoechst*[49], the patentee Amgen articulates a theory at trial, but that theory was neither explicitly in the specification nor included by reference. However, Amgen argues that such a theory would have been known to one of ordinary skill in the art at the time of filing. The accused infringer offers no theory.

Dr. Lin of Amgen invented a process for producing erythropoietin in cells. The specification discloses examples of how to use the invention in two different mammalian cells. The invention is covered by two patents, one which claims the invention in all [*106*] vertebrate cells, and another which claims the invention in all mammalian cells.[50] (Mammalian cells are one type of vertebrate cell.)

Amgen's theory for the first patent is that "all vertebrate cells produce and secrete hormones by the same fundamental process" and for the second patent, that "mammalian cells specifically, make proteins and process them in the same way."[51] As the accused infringer does not offer a counter-theory or refute the theories offered, the court accepts the undisputed theory as fact. The court seems to indicate that it would have been amenable to hearing evidence of a counter-theory when it notes that there is no record that shows human cells are somehow different from other mammalian cells.[52] On this point, Amgen's expert testified that human cells could in fact be made to produce EPO.[53]

4. *PGS v. DeKalb*

PGS v. DeKalb presents the opposite situation from the previous three cases. In this case, the patentee does not have a scientific theory as to how any of the three possible methods of carrying out its invention works.[54] For the first technique, the accused infringer relies on the patentee's lack of theory as a basis for its argument that the invention is enabled for only a small set of plants. In the second method, the accused infringer does have a scientific theory as to why the patent is not enabled with respect to [*107*] that method. The third method is inoperable and therefore the court does not address the matter of scientific theory.

The patent discloses a genetically engineered plant and provides examples of how to perform the genetic manipulation in various dicotyledonous plants. However, the claims read on all plants, including both monocotyledonous and dicotyledonous species.[55] Because none of the techniques disclosed in the patent work in monocots, PGS relies on techniques that would have been known to one skilled in the art at the time of filing. At trial, PGS argues that three techniques, agrobacterium-mediated infection, elctroporation and microprojectile bombardment were known to those skilled in the art at the time of filing and could have successfully been used to transform monocot plants. DeKalb is able to demonstrate nonenablement by stressing the fact that PGS did not provide a scientific theory. It provides "clear and convincing evidence that the so-called

'monocot barrier' was still firmly in place"[56] by refuting the effectiveness of each of the techniques.

Neither PGS nor DeKalb has a theory as to how agrobacterium-mediated infection works at a cellular level. However, DeKalb is able to prove nonenablement by this technique because it is able to demonstrate two things. First, it shows that the technology is highly unpredictable.[57] Second, DeKalb shows that PGS does not have any idea how the technology works, let alone a theory which might cure this predictability problem.[58] DeKalb shows that the technology was unpredictable by drawing out testimony from PGS's expert that PGS conducted experiments after the patent issued in order to figure out why agrobacterium in monocots did not work. This also demonstrates [*108*] that PGS thought a theory would be helpful in determining how to enable the invention for monocots. Additionally, DeKalb demonstrated the lack of a theory by getting PGS to admit that the agrobacterium method is a "complete black box."[59] As a result, the court is convinced that the lack of a curative theory is an important factor, stating that "[s]cientific research involves attempting to understand why and how things – in this case biological processes – work."[60] It therefore finds this method does not provide enablement.

Although PGS does not have a theory as to how electroporation works, DeKalb demonstrates why the technique will not work in monocots.[61] DeKalb's scientist achieved success with electroporation only in a special type of corn. Based on this experiment, DeKalb's scientist concluded that the experiment was successful in that special strain of corn because it was able to reform its cell walls. However, "ordinary

corn cells would not reform the cell walls"[62] and therefore would not be susceptible to electroporation.

Neither side has a theory on how the third technique, microprojectile bombardment, works. However, this technique is inoperable and therefore the scientific theory does not play a part in the court's decision on this point.

5. *Enzo Biochem v. Calgene, Inc.*

[*109*] In *Enzo Biochem v. Calgene, Inc.*[63], both sides offer a scientific theory. The patentee's theory, however, is very general and does not render the invention more predictable. The infringer's theory on the other hand, explains how the invention works, as well as why the method will only work in certain cells.

Enzo's invention is a method for using antisense technology. The specification discloses examples of using this method in three different genes in *E.coli*.[64] However, the claims are much broader and read on all genes in all organisms. The main point of dispute is whether Enzo's disclosure enables the use of antisense in eukaryotic as well as prokaryotic cells.

Enzo argues that the invention on its face is a "basic principle or theory."[65] The court accepts this argument, but finds the theory insufficient to fully enable the claims because it does not reduce the unpredictability of the invention.

Enzo's theory does not help to predict which cells are capable of being used for antisense. Enzo's expert states that the unpredictability is due to the "instability of individual RNAs of the individual cells."[66] Calgene's expert expands on this statement by testifying that case-by-case experimentation was necessary to figure out if antisense would work in eukaryotes. Enzo's expert later concedes that the technology is highly unpredictable and describes it as "witchcraft."[67]

Calgene takes its nonenablement argument a step further by offering its own theory. Its expert testifies that antisense technology works only in prokaryotes because "eukaryotic cells have 'posttranscriptional aberrant processing,' a process not found in [*110*] prokaryotic cells."[68] This theory, therefore, is able to predict which cells can be used with antisense technology. The court accepts this theory and its corresponding predictions and states that there is no "credible evidence that success was achievable in eukaryotic cells."[69] Therefore a theory which does not reduce the unpredictability of an invention is not of much value in demonstrating enablement.

6. *Amgen v. Chugai*

In *Amgen, Inc. v. Chugai Pharmaceutical Co.,*[70] neither the patentee, Amgen, nor the accused infringer Chugai, offers a scientific theory as to how the invention works. Although such disclosure is not required of either side, the district court considers the absence of a scientific theory as a factor tending towards nonenablement.[71]

Amgen argues that the invention is less unpredictable than is alleged by Chugai, but does not offer a scientific theory that would enable a scientist to predict the outcome of an experiment. The claimed invention in this case is the gene coding for erythropoietin (EPO)and all EPO analogs. Analogs are genes that have been altered, but still have many of the same biological properties as the original gene. Amgen suggests that "a scientist [*111*] might be able to predict the activity of some analogs but not others."[72] It further states that most analogs will have similar biological activity. Amgen therefore argues that the invention is predictable without supporting that argument with a scientific theory.

Chugai refutes Amgen's claim that the technology is predictable by pointing to the lack of a scientific theory. Chugai argues that "scientists have not yet sorted out which particular amino acid residue is required for biological activity, and the data is incomplete."[73] Had Amgen or another group of scientists figured out which amino acid residue is important, this knowledge could have formed the basis for a theory that presumably could have been used to increase the predictability of the technology. Chugai strengthens this argument by having its own expert testify that "[t]here is no theory that tells us what to look for."[74] Chugai's argument is that prediction requires a theory and that there is no such theory currently available.

The court sides with Chugai. The court "relies in particular on the lack of predictability in the art, as demonstrated by the testimony of Dr. Goldwasser and Dr. Elliot."[75] The court explains that the part of the testimony it is referring to is that "according to Dr. Goldwasser, there is no theory which tells leading scientists in the field what combination of amino acids will have the biological property claimed in the

patent."[76] Thus, the lack of a theory renders the invention unpredictable and therefore leads to a smaller scope of enablement.[77] On the flip side, a scientific theory that [*112*] increases predictability in a generally unpredictable field like biotechnology would also lead to a greater scope of enablement.

B. *Limitations on how the presence or absence of a scientific theory may be used*

A large number of cases establishes the principal that a scientific theory cannot be required.[78] However, three themes are apparent from these cases. First, there is no mention of whether a theory can be considered. Second, the theory need not be correct in a strict scientific sense, provided that it increases the predictability or reduces the quantity of experimentation needed. Finally, the articulation of a theory does not limit the scope of the claims.

1. Theory as a consideration

Although a theory cannot be required, the question of whether an inventor who provides a scientific theory can benefit from this disclosure is left open.[79] *Newman v. Quigg* is frequently cited for the proposition that a scientific theory is not a requirement

[*113*] of patentability.[80] The court in this case stated that "it is not a requirement of patentability that the inventor correctly set forth, or even know how or why the invention works."[81] In other words, the absence of a theory is not fatal to patentability. Other cases that discuss scientific theory only prohibit its use as a requirement.[82]

Scientific theory has also been used as a consideration in other contexts. For example, an examiner may rely on a scientific theory in rejecting an application as obvious.[83] However, the examiner must not only explain the theoretical mechanism, but also show that the theory would have led one of ordinary skill in the art to make the claimed invention.[84] This analogy to nonobviousness is helpful for two reasons. First, it suggests that *Newman* should not be read to eliminate scientific theory as a consideration. Because the PTO uses scientific theory as a consideration for obviousness, it must not believe that there are any cases that prohibit it from using scientific theory as a consideration, rather than a requirement. Second, the application of scientific theory to obviousness suggests how it might be applied to enablement. The Board held that scientific theory may only apply to obviousness if it contributes to the determination of whether the standard for obviousness is met. That is to say that the presence of a scientific theory is not a helpful factor per se. In the context of enablement, similar logic would suggest that a scientific theory would only be useful if it contributes to a determination of the extent to which the factors defining scope of enablement have been met. Thus, a scientific theory that increases the predictability of the invention or reduces [*114*] the amount of experimentation needed would be considered in determining the scope of enablement.

2. Correctness

The court's statement in *Newman* also only addresses the requirement for a correct theory. The inventor does not need to "correctly set forth a theory."[85] In turn, *Newman* relies on *Diamond Rubber Co. of New York v. Consolidated Rubber Tire Co.* which states that "it is not necessary that [the inventor] understand or be able to state the scientific principles underlying his invention, and it is immaterial whether he can stand a successful examination as to the speculative ideas involved."[86]

There are several ways to interpret these two quotes together. First, if the inventor need not set forth a correct theory, yet it is immaterial whether or not his theory is correct, then the inventor need not submit any theory. While this may be an accurate legal statement, it does not provide a better understanding of the relevance of correctness. In fact, it makes the word "correctly" superfluous in the statement that an inventor need not "correctly set forth a theory." A second reading that is not incompatible with either statement is that a theory may be required, but a correct theory cannot be required. This would imply that there is a requirement that a patentee submits a theory, but it is just a formality, as its correctness is irrelevant. This is an absurd result which finds support [*115*] nowhere in patent law. A third reading makes more sense. Although correct theory is not required, neither statement speaks to whether any theory offered may be considered. There are several reasons to believe that a scientific theory may be considered, if offered. When the court says that a successful examination of the

"speculative ideas" is irrelevant, the plain meaning is the "theoretical rather than demonstrable"[87] ideas. In other words, if a scientific theory is offered, the empirical predictions may be considered, but there cannot be a requirement that the underlying logic of the hypothesis is correct. This is in accord with the district court cases which considered scientific theory as a factor, but only to the extent that they can demonstrably reduce uncertainty.[88]

This interpretation which differentiates empirical from theoretical aspects of scientific theory is also supported by case law and PTO rules. In *In re Grose*, the court held that the use of a scientific theory, in order to be relevant, must be accompanied by evidence that demonstrates the existence and meaning of that theory.[89] Therefore, the influence of a scientific theory should depend on its empirical and demonstrable aspects and not its underlying logic. Additionally, this case and rule confirm that a scientific theory may be considered in determining patentability. [90]

3. Impact of theory on claims

[*116*] The patentee will not be penalized for including a theory in the specification that is narrower than the claims because the court will not use the theory to limit the scope of the claim. The court reasoned that because a theory is not required, it should not be used to limit the scope of a claim.[91] This is consistent with several cases that have held that limits in the specification should not be imported into the claims.[92]

IV. Conclusion

Inventors should describe the cellular or biochemical mechanism by which their invention works. This information, if it can decrease the unpredictability or amount of experimentation needed, can increase the scope of enablement. It is one of the few affirmative steps that an applicant can make at the time of filing which can influence the way the *Wands* factors will be applied. Without a theory, the scope of enablement will be determined in an unpredictable, fact-specific manner using the *Wands* factors or any other factors the district court believes to be relevant. Additionally, the absence of a theory provided by the patentee may negatively impact the scope of enablement where the patent is challenged by a party with its own theory that demonstrates that undue experimentation would be needed to use the invention in the non-disclosed species.

[*117*] However, an inventor must recognize that there are limitations to how the presence or absence of a scientific theory may be treated by the courts. Although the theory does not need to live up to the stringent standards of peer-reviewed science, it must either be able to increase the predictability of the circumstances in which the invention will work or else decrease the amount of experimentation needed to use the invention. The sooner and more explicitly an inventor discloses the theory, the better. A theory included in the specification is much more likely to be looked upon favorably by a court then one that is first presented at trial.

Finally, the inventor need not worry that a theory included in the specification will be used to limit his claims. Therefore, whenever doubts arise as to whether the claims in a biotechnology patent are fully enabled, an inventor should be advised that the addition of a scientific theory is a good insurance policy.

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[1] Alison E. Cantor, Note, *Using the Written Description and Enablement Requirements to Limit Biotechnology Patents*, 14 Harv. J. Law & Tec 267 (2000); Matthew D. Kellam, Note, *Making Sense out of Antisense: The Enablement Requirement in Biotechnology After Enzo Biochem v. Calgene*, 76 Ind. L.J. 221 (2001); Margaret Sampson, Note, *The Evolution of the Enablement and Written Description Requirements Under 35 U.S.C. 112 in the Area of Biotechnology*, 15 Berkeley Tech. L.J. 1233 (2000).
[2] In re Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991).
[3] In re Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).
[4] Karen S. Canady, *The Wright Enabling Disclosure for Biotechnology Patents*, 69 WASH L. REV. 455, 462 (Apr. 1994).
[5] *Canady, supra* note 4.
[6] In re Wright, 999 F.2d 1557, 1561-62 (Fed. Cir. 1993).
[7] *Id.*
[8] In re Wands, 858 F.2d 731, 742 (Fed. Cir. 1988).
[9] PGS v. Dekalb 315 F.3d 1335, 1338 (Fed. Cir. 2003).
[10] In re Wright, 999 F.2d 1557, 1560 (Fed. Cir. 1993).
[11] See Susan Murtha Jaffe, *Paulik V. Rizkalla: Allowing a First Inventor's Resumed Activity to Refute a Finding of Supression and Concealment*, 35 AM. U.L. REV. 1177, 1177 (1986).
[12] Hybritech, Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1384 (Fed. Cir. 1986).
[13] See Enzo Biochem, Inc. v. Calgene, Inc., 188 F.3d 1362, 1372 (Fed. Cir. 1999) [hereinafter *Enzo II*].
[14] In re Wands, 858 F.2d 731, 742 (Fed. Cir. 1988).
[15] In re Wands, 858 F.2d 731, 738 (Fed. Cir. 1988).
[16] In re Wright, 999 F.2d 1557, 1561 (Fed. Cir. 1993).
[17] Amgen, Inc. v. Chugai Pharm. Co., 927 F.2d 1200, 1213 (Fed. Cir. 1991) [hereinafter *Chugai II*].
[18] *Enzo II*, 188 F.3d 1362, 1371-72 (Fed. Cir. 1999).
[19] 999 F.2d 1557, 1561 (Fed. Cir. 1993).
[20] Johns Hopkins Univ. v. CellPro, Inc., 152 F.3d 1342, 1360 (Fed. Cir. 1998) [hereinafter *CellPro II*].
[21] *Id.*
[22] *Chugai II*, 927 F.2d 1200, 1210-11 (Fed. Cir. 1991).
[23] Genentech v. Novo Nordisk, 108 F. 3d 1361, 1366 (Fed. Cir. 1997) [hereinafter *Genentech II*].
[24] *Id.* at 1364.
[25] *Id.* at 1366.
[26] *Canady, supra* note 4 at 461.
[27] In re Goodman, 11 F.3d 1046, 1050-51 (Fed. Cir. 1993) (holding that a single example is not enough to enable a broad genus); see also in re Wright, 999 F.2d 1557, 1562 (Fed. Cir. 1993) (holding that a single example merely invites experimentation). But see Hoechst II, 314 F.3d 1313, 1336 (Fed. Cir. 2003) (holding that a single example may enable a broad claim scope where the example is reasonably understood to meant that other types of cells may be used).
[28] *Enzo II*, 188 F.3d 1362, 1374 (Fed. Cir. 1999).
[29] Amgen, Inc. v. Hoechst Marion Roussel, 314 F.3d 1313, 1336 (Fed. Cir. 2003) [hereinafter *Hoechst II*].
[30] 188 F.3d 1362, 1374.
[31] 188 F.3d 1362, 1374.
[32] See In re Wright, 999 F.2d 1557, 1564 (Fed. Cir. 1994)(holding that the subfield of avian RNA virus vaccines was not as predictable as applicant had claimed).

[33] [*118*] For example, the court in *Enzo II* upheld the district court's focus on the subfield of antisense technology, noting that it is a particularly unpredictable area of biotechnology. 188 F.3d 1362, 1372.
[34] *Enzo II*, 188 F.3d 1362, 1373 (Fed. Cir. 1999).
[35] *CellPro II*, 152 F.3d 1342, 1360 (Fed. Cir. 1998).
[36] Plant Genetic Sys., N.V. v. Dekalb Genetics Corp., 315 F.3d 1335, 1339 (Fed. Cir. 2003) [hereinafter *PGS II*].
[37] *Id.*
[38] *Id.*
[39] See e.g., *Hoechst I* (pagination not available).
[40] *See Cantor, Kellam, Sampson*, *supra* note 1.
[41] In re Vaeck, 947 F.2d 488, 495 (Fed. Cir. 1991).
[42] U.S. Patent No. 4,965,204 (issued Oct. 23, 1990).
[43] Johns Hopkins Univ. v. CellPro, Inc., 931 F.Supp. 303, 324 (D.De 1996) [hereinafter *CellPro I*].
[44] *Id.*
[45] Genentech v. NovoNordisk, 935 F.Supp. 260 (S.D.NY, 1996) [hereinafter *Genentech I*].
[46] *CellPro I*, 935 F.Supp. 260, 277.
[47] *Id.* at 276.
[48] *Genentech I*, 935 F.Supp. 260, 276 (S.D.NY, 1996).
[49] Amgen, Inc. v. Hoechst Marion Roussel, Inc., 126 F.Supp.2d. 69 (D.MA 2001) (no pagination available) [hereinafter *Hoechst I*].
[50] U.S. Patent No. 5,756,349 (issued May 26, 1998); U.S. Patent No. 5,955,422 (issued Sep. 21, 1999).
[51] 126 F.Supp.2d. 69.
[52] *Id.*
[53] *Hoechst I*, 126 F.Supp.2d. 69 (D.MA 2001) (no pagination available)
[54] PGS v. DeKalb, 175 F.Supp.2d 246 (D.CT 2001) [hereinafter *PGS I*].
[55] U.S. Patent No. 5,561,236 (issued Oct. 1, 1996).
[56] *PGS I*, 175 F.Supp.2d 246 (D.MA 2001).
[57] *Id.*
[58] *Id.*
[59] *Id.*
[60] *Id.*
[61] *Id.*
[62] *PGS I*, 175 F.Supp.2d 246 (D.MA 2001).
[63] Enzo Biochem v. Calgene, Inc., 14 F.Supp.2d 536, no pagination (D.DE 1998) [hereinafter *Enzo I*].
[64] U.S. Patent No. 5,190,931 (issued Mar. 2, 1993).
[65] *Enzo I,* 14 F.Supp.2d 536.
[66] *Id.*
[67] *Id.*
[68] *Id.*
[69] *Enzo I*, 14 F.Supp.2d 536, (D.DE 1998).
[70] Amgen, Inc. v. Chugai Pharm. Co., 1989 U.S. Dist. LEXIS 16110 (D.MA 1989) [hereinafter *Chugai I*].
[71] *See Id.* (stating that the structural requirements for biological activity must be disclosed).
[72] *Id.*
[73] *Id.*
[74] *Id.*
[75] Chugai I, 1989 U.S. Dist. LEXIS 16110 (D.MA 1989).
[76] *Id.*
[77] *Id.*; *see* In re Fisher, 427 F.2d 833, 839 (C.C.P.A. 1970).
[78] *See, e.g.*, In re Isaacs, 52 CCPA 1791, 1798 (1965); Newman v. Quigg 877 F.2d 1575, 1581 (Fed Cir. 1989).
[79] In none of the appeals from the six cases described in III.A did the Federal Circuit affirm or reject the use of a scientific theory in determining the scope of enablement.
[80] Newman v. Quigg, 877 F.2d 1575, 1581-82 (Fed. Cir. 1989).
[81] This oft-quoted passage is actually dicta, as demonstrated by the court's statement that "the matter of the scientific explanation of the claimed results became moot." *Id.*
[82] E.g., In re Cortright, 165 F.3d 1353, 1359 (Fed. Cir. 1999).

[83] [*119*] PATENT & TRADEMARK OFFICE, MANUAL OF PATENT EXAMINING PROCEDURE § 2144.02 (8th ed. 2003).
[84] In re Grosse, 592 F.2d 1161 (CCPA 1979).
[85] Newman v. Quigg, 877 F.2d 1575, 1581 (Fed. Cir. 1989).
[86] Diamond Rubber Co. v. Consol. Rubber Tire Company, 220 U.S. 428, 435-36 (1911).
[87] MERRIAM-WEBSTER ONLINE DICTIONARY (2002).
[88] *See, e.g., Hoechst I*, 126 F.Supp. 2d 69.
[89] In re Grose, 592 F.2d 1161, 1168 (C.C.P.A. 1979).
[90] *See also* In re Goodman, 11 F.3d 1046, 1049 (Fed. Cir. 1993)(stating that the plant functional region must be disclosed).
[91] "Fromson's theory and belief was unnecessary to meet the enablement requirements of 35 USC § 112 (that a patentee describe how to make and use the invention)." Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570 (Fed. Cir. 1983).
[92] *E.g.*, Intervet Am., Inc. v. Kee-Vet Lab., Inc., 887 F.2d 1050, 1053 (Fed. Cir. 1989).