Responding to Patent Office Actions: Sect. 101 and 112 Rejections
Assessing Response Alternatives to Rejections on Non-Statutory Subject Matter and on Technicalities

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Today’s faculty features:
Thomas L. Irving, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.
Dr. Lisa M. Matovcik, Senior Patent Attorney, Critical Care, Novartis Pharmaceuticals, East Hanover, N.J.
Lauren L. Stevens, Global Patent Group, San Francisco
Linda Thayer, Partner, Finnegan Henderson Farabow Garrett & Dunner, Boston

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Responding to Patent Office Actions: Sect. 101 and 112 Rejections
Assessing Response Alternatives to Rejections on Non-Statutory Subject Matter and on Technicalities

July 16, 2014

Dr. Lisa (Lee) Matovcik    Dr. Lauren Stevens    Linda Thayer    Tom Irving

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I. Strategic considerations for counsel before responding to an office action

II. Overcoming patent office rejections

III. Key problem areas to anticipate and prepare to respond and follow up

IV. Strategies for overcoming issues outlined in Patent Office Actions

What are the key considerations for patent counsel when responding to a § 101 or § 112 rejection?

What are the areas that have proven to be red flags for the PTO?

What other strategies should counsel implement to reduce the likelihood of rejection?
35 U.S.C. 101

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- Myriad
- Mayo v. Prometheus
- Abstract Ideas
Interim Guidelines Released

- **2012 Mayo Guidance; MPEP 2106.01**: Process claims involving Laws of Nature.

- **June 13, 2013 Memo**
  - Noted Supreme Court decision in *Myriad*: claims to isolated DNA not patent-eligible.
  - “As of today, naturally occurring nucleic acids are not patent eligible merely because they have been isolated.”

- **March 4, 2014 Memo: New Guidance Replaces Both**
  - Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena, and/or Natural Products
  - “all claims (i.e., machine, composition, manufacture and process claims) reciting or involving laws of nature/natural principles, natural phenomena, and/or natural products should be examined using the Guidance.”
  - “examination procedure set forth in the Guidance is effective today and supersedes the June 13, 2013 memo[.]”
USPTO Guidance to Examiners

- Not a statute
- Important USPTO policy document
  - Used to train patent examiners.
Where Does This Leave Us?

- Inconsistent district court decisions
  - Some courts may be extending the holdings of *Myriad* and *Prometheus* well beyond their intended scope -- others are much more conservative.
  - Fed. Cir. decisions may not be helpful, if judges’ comments at the DOLLY hearing are an indication of their frame of mind.

- Even more erratic and inconsistent examination for the foreseeable future—increasingly reduced predictability, increasing need to take cases through appeal process.

- Substantially increased uncertainty and IP expense for biotechnology and other industries that rely on natural products, methods of diagnosis, or methods of treatment.
Patent-Eligible Subject Matter

- **Ass’n for Molecular Pathology v. USPTO/Myriad**, 133 S.Ct. 2107 (U.S. June 13, 2013)
  - Cert. granted, 133 S.Ct. 694 (U.S. Nov 30, 2012) on one question only: *Are human genes patentable?*
    - NO: isolated DNA involved a naturally occurring segment of DNA, precluding patent eligibility; and
    - YES: synthetically created DNA (cDNA).
  - Supreme Court did not decide method claims.
  - Federal Circuit held that claims to “analyzing” and “comparing” not patent-eligible subject matter, method claims to screening are patent-eligible subject matter.

Note, *In re Roslin Institute*, 750 F.3d 1333 (Fed. Cir. 2014) that claims to cloned animals were unpatentable subject matter too.
Original claim:

1. A fungal strain *Beauveria* species bearing accession number MTCC 5184, wherein the said strain is deposited at MTCC, an International Depository recognized under the Budapest Treaty.
The § 101 Rejection

Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims as written, do not sufficiently distinguish over microbial cells as they exist naturally because the claims do not particularly point out any naturally occurring differences between the claimed products. In the absence of the hand of man, the naturally occurring products are considered non-statutory subject matter. See Diamond v. Chakrabarty, 447 U.S. 393, 206 USPQ 193 (1980).

The claims should be amended to indicate the hand of inventor. e.g., by insertion of phrase such as “purified or “isolated” (“An isolated strain …”) as taught on page 5, line 23, of specification. See MPEP 2105.
1. (Currently Amended) An isolated [[A]] fungal strain *Beauveria* species bearing accession number MTCC 5184, wherein the said strain is deposited at MTCC, an International Depository recognized under the Budapest Treaty.

Applicants have amended claim 1 as suggested in the Office Action to recite that the strain has been isolated. Accordingly, withdrawal of the rejection under 35 U.S.C. § 101 is respectfully requested.
• Original claim

Claim 1 (original): An isolated, purified or recombinant nucleic acid molecule comprising the nucleotide sequence as set forth in SEQ ID NO: 1, or a complementary nucleotide sequence thereof.
The § 101 Rejection

Claims 1 and 3 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The claimed invention is directed to a naturally-occurring nucleic acid or fragment thereof, whether isolated or not, that is not patent-eligible pursuant to the Supreme Court decision in Association for Molecular Pathology v. Myriad Genetics, Inc., -- U.S. -- (June 13, 2013).

If the gene from which the polynucleotide of SEQ ID NO:1 is expressed does not comprise introns, the polynucleotide of SEQ ID NO:1 is indistinguishable from the genomic polynucleotide of SEQ ID NO:1. Further, the construct comprising the nucleic acid molecule of claim 1 encompasses the genomic open reading frame fused to its native promoter. In view of the recent Myriad decision, both of these things are patent-ineligible regardless of whether they recite “isolated” or not.
Claims 1 and 3 were rejected as directed to non-statutory subject matter, specifically a naturally occurring nucleic acid. Applicant traverses. Claim 1 recites SEQ ID NO: 1, which is a cDNA coding sequence. It differs from the naturally occurring gene in that it does not include non-coding regions (i.e. introns). Claim 3 incorporates the cDNA sequence recited in claim 1. Accordingly, claims 1 and 3 recite non-naturally occurring nucleic acids, which constitute statutory subject matter. Withdrawal of the rejection is requested.
Patent-Eligible Subject Matter

• Mayo Collaborative Services v. Prometheus Laboratories, Inc., 132 S.Ct. 1289 (U.S. 2012)

Claim
A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) administering a drug providing 6-thioguanine to a subject; and

(b) determining the level of 6-thioguanine in the subject,

wherein a level of 6-thioguanine less than about 230 pmol per 8x10^8 red blood cells indicates a need to increase the amount of the drug and

wherein a level of 6-thioguanine greater than about 400 pmol per 8x10^8 red blood cells indicates a need to decrease the amount of the drug.

The Court Asked
Do the patent claims add enough to their statements of the correlation between the level of the metabolite and therapeutic efficacy to allow the claimed method to qualify as a patent eligible method that applies the natural law?
Patent-Eligible Subject Matter


Claim
A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

(a) **administering a drug** providing 6-thioguanine to a subject; and

(b) **determining the level** of 6-thioguanine in the subject,

wherein a level of 6-thioguanine less than about 230 pmol per $8 \times 10^8$ red blood cells indicates a need to increase the amount of the drug and wherein a level of 6-thioguanine greater than about 400 pmol per $8 \times 10^8$ red blood cells indicates a need to decrease the amount of the drug.

Opinion of the Court
No.

- “Administering” merely refers to a preexisting audience
- “Determining” is merely a routine activity
- “Wherein” merely describes the natural law without instructing its application
Claim 1. (Original): A method of assessing whether a pregnant woman has an increased risk of developing preeclampsia, comprising:

a) measuring H2 relaxin concentration in a biological sample obtained from said pregnant woman prior to manifestation of a preeclampsia symptom; and

b) determining that said pregnant woman has an increased risk of developing preeclampsia when said H2 relaxin concentration is less than a cut-off value for a lowest quartile concentration of pregnant women.
The § 101 Rejection

Claims 1-6 and 8 are rejected under 35 U.S.C. 101 because the claimed invention is not directed to patent eligible subject matter. Based upon an analysis with respect to the claim as a whole, claim(s) 1-6 and 8-10 is/are determined to be directed to a law of nature/natural principle. The rationale for this determination is explained below.

The method of claim 1 determines the relationship between H2 relaxin concentrations and preeclampsia. Claim 8 provides a particular H2 relaxin concentration value. Claims 1 and 8 are directed to a naturally occurring relation or correlation (i.e. a natural principle). The method requires the additional step of measuring the H2 relaxin in a biological sample. These measurements and the added limitations of claims 2-6 would have been well known in the art and do not amount to significantly more than the natural principle itself.
Applicant’s Amendment and Response

Claim 1. (Currently amended): A method of assessing whether a pregnant woman has an increased risk of developing preeclampsia, comprising:

   a) obtaining a sample of plasma or serum from a woman during week 5-15 of pregnancy;

   [a][b] measuring the H2 relaxin concentration in a biological sample the plasma or serum by immunoassay obtained from said pregnant woman prior to manifestation of a preeclampsia symptom; and

   b) determining that said pregnant woman has an increased risk of developing preeclampsia when said H2 relaxin concentration is less than a cut-off value for a lowest quartile concentration of pregnant women about 500 pg/ml.

wherein an H2 relaxin concentration of less than about 500 pg/ml is an independent risk factor for preeclampsia.

Rejection of Claims 1-6 and 8, Under 35 U.S.C. § 101
The Office rejected claims 1-6 and 8, under 35 U.S.C. § 101, alleging they are directed to a law of nature and are therefore not directed to patent eligible subject matter. Applicant respectfully traverses with respect to the amended claims. The claims describe a process that transforms a correlation between relaxin levels and a risk for preeclampsia into a new and useful process for assessing an increased risk for preeclampsia. Accordingly, Applicant requests that the Office withdraw the rejection.
Original claim 1:

Claim 1. (Original): A method for determining the likelihood that a subject having a viral infection of the liver will be responsive to antiviral therapy comprising Interferon (IFN) treatment, the method comprising:

(a) analyzing a tissue sample from the subject having the viral infection for the level of expression of miR-122 and/or miR-296-5p and,
(b) comparing the level of expression of miR-122 and/or miR-296-5p in the tissue sample from the subject having the viral infection to the level of expression of miR-122 and/or miR-296-5p in a control tissue sample from a subject without viral infection,

wherein a significantly lower level of miR-122 in the sample from the subject having the viral infection as compared to the level of miR-122 in the control sample from the subject without viral infection indicates that the subject having the viral infection is not likely to respond to said antiviral therapy; and

wherein a significantly higher level of miR-296-5p in the sample from the subject having the viral infection as compared to the level of miR-296-5p in the control sample from the subject without viral infection indicate that the subject having the viral infection is not likely to respond to said antiviral therapy.
The essence of the claimed invention is the discovery of an asserted relationship between the amount of expression of miR-122 and/or miR-296-5p in a patient, and the nature of that patient’s response to antiviral therapy. However, such an asserted relationship is not an invention, instead it is essentially a phenomenon of nature, i.e. a law of nature, discovered by Applicant. Laws of nature are not considered to be patentable subject matter (see e.g. MPEP 2106 IV(A),(C)). The U.S. Supreme Court has found that if a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction “apply the law” (Mayo Collaborative Services v. Prometheus Laboratories Inc., 101 USPQ2d 1961 (U.S. 2012)).
The § 101 Rejection

In this case, the only active steps recited in the claimed method are an analysis of tissue samples and a comparison of observed levels of miR-122 and/or miR-296-5p expression. However, such steps are well-understood, routine, and conventional activities, previously engaged in by scientists in the field. For example, Varnholdt et al (HEPATOLOGY 2008;47:1223-1232) compared the amounts of miR-122 expressed in livers of hepatitis C patients and in normal livers. Therefore these steps do not limit the application of the law of nature in any inventive way, and are not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law. Accordingly the claims are drawn to non-statutory subject matter.
Applicant’s Amendment

1. (Currently amended) A method for determining the likelihood that treating a human subject having a hepatitis C viral infection of the liver will be responsive to antiviral therapy that includes stimulation of Interferon (IFN) activity, the method comprising:

   (a) analyzing a liver tissue sample from the subject having the viral infection for the level of expression of miR-122 and/or miR-296-5p and,

   (b) comparing the level of expression of miR-122 and/or miR-296-5p in the tissue sample from the subject having the viral infection to the level of expression of miR-122 and/or miR-296-5p in a control tissue sample from a subject without viral infection,

   wherein a significantly higher lower level of miR-122 in the sample from the subject having the viral infection as compared to the level of miR-122 in the control sample from the subject without viral infection indicates that the subject having the viral infection is not likely to respond to said antiviral therapy; and

   wherein a significantly lower higher level of miR-296-5p in the sample from the subject having the viral infection as compared to the level of miR-296-5p in the control sample from the subject without viral infection indicate that the subject having the viral infection is not likely to respond to said antiviral therapy; and

selectively administering Interferon (IFN) and ribavirin to the subject on the basis of the subject having either (1) a higher level of miR-122 in comparison to the control sample or (2) a lower level of the mi-296-5p in comparison to the control sample.
Applicant’s Response

Claims 1, 5-8, and 13 stand rejected under 35 U.S.C. § 101 as allegedly directed to non-statutory subject matter. Applicant has amended the claims to define a process which includes additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize a law of nature itself. Specifically, Applicant has amended claim 1 to include the step of selectively administering Interferon (IFN) and ribavirin to the subject on the basis of the subject having either (1) a higher level of miR-122 in comparison to the control sample or (2) a lower level of the mi-296-5p in comparison to the control sample. This additional step integrates the natural principle into the claimed invention such that the natural principle is practically applied to ensure that the claim is more than the natural principle itself. That is, a human subject having HCV will only be administered IFN and ribavirin if the subject has either (1) a higher level of miR-122 in comparison to the control sample or (2) a lower level of the mi-296-5p in comparison to the control sample. Previously, all subjects were given IFN. Now, only those with a likelihood of success based on the miR-122 and/or mi-296-5p levels will be treated.

Avoids preemption by selectively administering a specific treatment in a final step based on the subject having a particular biomarker.

Integrates the natural law into the claim by correlating the biomarker with the disease and using the natural law to take the action of administering a therapy.
Single Actor Claims May Avoid Enforcement Problems

Dual Actor Claim
A method of treating a subject with [disease] comprising:
(a) assaying a biological sample from the subject for [biomarker]; and
(b) administering [treatment] to the subject if the sample has [biomarker] or administering [standard of care] to the subject if the sample does not have [biomarker].

Single Actor Claim
A method of selectively treating [disease] comprising:
(a) selecting a subject for treatment with [agent] on the basis of the patient having [biomarker] and;
(b) selectively administering [agent] to the patient.

- Under § 271(a), direct infringement of a method claim requires that all steps be attributable to a single party
- The entity that carries out the assay step may be different from the entity that administers the treatment and may not be joint tortfeasors
- Thus, a risk there will be no direct infringement

Limelight Networks, Inc. v. Akamai Technol., Inc., et al., 572 S.Ct. ___ (U.S. 2014)
- in the absence of direct infringement, there can be no inducement of infringement
- but it remains unsettled whether a party that performs some steps of a method patent and encourages others to perform others may induce infringement
Defenses to § 101 Rejections

• Ensure that the claim applies the law of nature and does not preempt the field by covering all practical applications of that law.

• Add features that are more than well-understood, purely conventional or routine to the claims.

• Include specific methods, ranges or other relevant limitations, keeping the intended commercial indication in mind.

• Recite structural differences, if any, between the claimed subject matter and the natural product.

• Argue that Examiner has not accorded proper weight to factors weighing toward eligibility, as stated in the Eligibility Guidance of March 4, 2014.
Patent-Eligibility of Computer-Implemented Inventions

• *Alice Corp. Pty. Ltd. v. CLS Bank Int’l et al.*, __ S.Ct. __ (U.S. June 19, 2014)

• **Question Presented:**
  – Whether claims to computer-implemented inventions — including claims to systems and machines, processes, and items of manufacture — are directed to patent-eligible subject matter within the meaning of 35 U.S.C. § 101 as interpreted by the Supreme Court.

• **Holding**
  – 9-0, claims drawn to an abstract idea that merely require generic computer implementation fail to transform the abstract idea into a patent-eligible invention.
  – All claims held to be patent ineligible
Court Applies Mayo’s Two-Part Framework

**Mayo Step 1:** Claim is directed towards …

- An abstract idea of intermediated settlement, with “no meaningful distinction” from the risk hedging in Bilski.

**Mayo Step 2:** Does claim contain an “inventive concept” which amounts to “significantly more”

- No. Implementation on generic computers does not transform ineligible abstract idea into patent-eligible one.
Other Alice Guidance

- The “concern that drives this exclusionary principle [of § 101] as one of pre-emption.”
  - Monopolization of tools/building blocks impedes innovation

- Applications of abstract concepts “to a new and useful end” remain patent-eligible
USPTO Issues Preliminary Examination Instructions in View of Alice

• Issued June 25, 2014
• *Mayo* framework shall be used to analyze all claims under § 101
• Same analysis should be sued for all categories of claims (e.g. product and process claims).
• USPTO’s June 30th Federal Register Notice (79 Fed. Reg. 36786) titled “Request for Comments and Extension of Comment Period on Examination Instruction and Guidance Pertaining to Patent-Eligible Subject Matter”
  – Comments due July 31, 2014
  – alice_2014@uspto.gov (abstract ideas)
  – myriad-mayo_2014@uspto.gov (laws of nature/natural products)
• Examples of abstract ideas:
  – fundamental economic practices (*Alice, Bilski*);
  – certain methods of organizing human activities (*Bilski*);
  – an idea of itself (Benson);
  – mathematical formulas (*Flook, Benson*).

• Limitations that may be enough to qualify as "significantly more"
  – Improvements to another technology or technical fields (*Diehr, Alice*);
  – Improvements to the functioning of the computer itself (*Diehr, Alice*);
  – Meaningful limitations beyond generally linking the use of an abstract idea to a particular technological environment (*Bilski*).

• Limitations that are not enough to qualify as "significantly more"
  – Adding the words "apply it" (or an equivalent) with an abstract idea, or mere instructions to implement an abstract idea on a computer (*Bilski*);
  – Requiring no more than a generic computer to perform generic computer functions that are well-understood, routine and conventional activities previously known to the industry (*Mayo*).
Practical Tips for Drafting Specification

- Explain the technical implementation in detail
  - stress improvements in functioning of computer
- Emphasise technical problem solved and technical effects achieved over the prior art
- Avoid generic computer description
  - emphasize specialized components (sensors, GPS, etc.)
- Generalize terminology to avoid words of a commercial nature to distance invention from business method
  - e.g. “advertisement” -> “multimedia content file”
Practical Tips for Drafting Claims

- Draft method and system claims differently (not visibly parallel)
- Draft and prosecute narrow claims first
  - limit to practical application
- Focus on specialized components of invention
- Prosecute system claims first
  - save others for later but put in Summary of Invention now
- Avoid elements that read on mental steps
- Use claims to data structures or GUIs
- Return of means-plus-function claims?
Responding to § 101 Rejections

• Challenge definition of abstract idea
  – argue lack of pre-emption or monopolization of whole field

• Amend to add components that are specialized (sensor, GPS)
  – argue ways computer-implemented methods could not be performed by humans

• Amend claims to require “specific” ordered way of accomplishing inventive process
  – leaves other ordered ways available to public

• Argue improvement to technical field to which claims are applied
  – If possible, argue that claims could not be performed without claimed specialized component or combination of components, and that the components add “significantly more”
Enablement

- 35 U.S.C. 112(a)

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.
Testing Required Undue Or Routine?

• *In re Wands*, 858 F.2d 731 (Fed. Cir. 1988)
  
  – Claim: immunoassay methods for detection of hepatitis B surface antigen by using high-affinity monoclonal antibodies of IgM isotype.

  – PTO: data presented by Wands to show products of antibodies unpredictable and/or unreliable. Of 143 hybridomas, only 4 of 9 tested fell within claims.

  – FC: “Wands’ Factors.” Routine nature of testing and high level of skill in the art. Claims enabled.

    • In monoclonal antibody art, experiment is entire procedure of making a monoclonal antibody against particular antigen.
    • Wands tried 3 times and each time made at least one antibody satisfying all the claim limitations.
## Testing Required Undue Or Routine?

<table>
<thead>
<tr>
<th>UNDUE</th>
<th>ROUTINE</th>
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<tbody>
<tr>
<td>Claim 1: A process for producing lipids comprising: ...</td>
<td>Claim 4: A process according to claim 1 where [x] is of the order [T].” Claim 5: A process according to claim 1 where [x] is selected from the group consisting of [T], [S], and mixtures thereof.</td>
</tr>
<tr>
<td><strong>invalid</strong> for lack of enablement -&gt; claim potentially covered about 10,000 organisms with one working example in the specification.</td>
<td>Valid as enabled -&gt; Claims encompassed only 22 possibilities,</td>
</tr>
</tbody>
</table>
## Testing Required Undue Or Routine?

<table>
<thead>
<tr>
<th>UNDUE</th>
<th>ROUTINE</th>
</tr>
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<tbody>
<tr>
<td>Specification contained two working examples describing claimed formulation at 5 and 40 mg dosages.</td>
<td>Invention: transcatheter heart valve When patent application filed, prosthesis had been implanted only in pigs.</td>
</tr>
<tr>
<td><strong>invalid</strong> for lack of enablement -&gt; One of skill in the art would have had to resort to undue experimentation in order to make claimed formulations beyond those disclosed in the patent's two working examples.</td>
<td>Valid -&gt; non-enablement had not been proved by clear and convincing evidence Stent/value prosthetic device was successfully implanted in pigs, in accordance with the specification; pigs standard experimental animal for heart valve research.</td>
</tr>
</tbody>
</table>
1. (Original) A compound of Formula I

or a pharmaceutically acceptable salt thereof, wherein

A is optionally substituted aryl, optionally substituted heteroaryl or optionally substituted heterocycloalkyl;

B is an optionally substituted mono- or bicyclic heterocycloalkyl;
Claims 1-5, 7-10, 16-20, 40, 41, 43-44, 46 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is “undue”. These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).
Discussion of Selected *Wands* Factors

*Predictability/unpredictability of the art*

The high degree of unpredictability is well recognized structure and activity relationship in the enzyme inhibition art indicated for a given ligand specific structure is required and deviation from such structure would not be predictable of binding/inhibiting activity.

The state of the prior art in therapeutic compounds through enzyme inhibition is that it involves screening *in vitro* and *in vivo* to determine which compounds exhibit the desired enzyme inhibiting activities. There is no absolute predictability even in view of the seeming high level of skill in the art. The existence of these obstacles established that the contemporary knowledge in the art would prevent one of ordinary skill in the art from accepting any treatment regimen on its face.

Prior art of record indicated the particularity in chemical structure (Duval et al. whole article) and currently, none of the known transglutaminase 2 inhibitors draw structural similarity with the instant claims (Caccamo et al.).

*The amount of direction or guidance and the presence or absence of working examples*

On p.312-33 compounds with piperidinyl core with exclusively 4-acrylamide substitution were described to have enzyme inhibition activity as measured by method of p.335-336. The specification provided no variation as to the 4-acrylamide substitution to support broadening of such structure to support the same utility. WO2011/116161 (recited on 1449) indicated that when R3, R4, R5 are substituents, such compounds have different utility which is CCR3 modulators; or Biedermann et al. US 6451816, col. 117-118#338, has antitumor activity.

*The breadth of the claims*

The breadth of the claims are drawn to the broad genus containing myriads of substituents at variation of position even limited to the elected m=n=1 core. Which is inconsistent with the conventional evidence of record (see supra) and the support from the specification.
112, 2nd Paragraph, Improper Markush Group

Claims 1-5, 7-10, 16-20, 40, 41, 43-46 are rejected under 35 U.S.C. 112(b) or 35 U.S.C. 112 (pre-AIA), second paragraph, because the metes and bounds of the claims are unclear and are drawn to improper Markush grouping.

A “Markush” claim recites a list of alternatively useable species. Problem arises when a Markush group is so expansive that persons skilled in the art cannot determine the meets and bounds of the invention. The test is whether one of ordinary skill can envision all the members of the Markush group.

A claim contains an “Improper Markush grouping” if

1. The species of the Markush group do not share a “single structural similarity” -meaning they do not belong to the same recognized physical or chemical class or same art-recognized class, or
2. The species do not share a common use, -meaning they are not disclosed in the specification or known in the art to be functionally equivalent.
Improper Markush Grouping

The nonstatutory Markush grouping rejection is based on a judicially approved “improper Markush grouping” doctrine. A Markush claim contains an “improper Markush grouping” if: (1) The species of the Markush group do not share a “single structural similarity,” or (2) the species do not share a common use. Members of a Markush group share a “single structural similarity” when they belong to the same recognized physical or chemical class or to the same art-recognized class. Members of a Markush group share a common use when they are disclosed in the specification or known in the art to be functionally equivalent. When an examiner determines that the species of a Markush group do not share a single structural similarity or do not share a common use, then a rejection on the basis that the claim contains an “improper Markush grouping” is appropriate. See the Federal Register, Vol. 76, No. 27, dated February 9, 2011, page 7166.

Claims 1, 3-4, 7-12, 22, 30, 32-34, 44 and 49-51 are rejected under improper Markush grouping as the claims contain an improper grouping of alternatively useable species.
Enablement of MOT Claims: Strattera® Patent and Claims


[54] TREATMENT OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

[75] Inventors: John H. Heiligenstein; Gary D. Tollefson, both of Indianapolis, Ind.

Chouinard, et al., Psychopharmacology, 83, 126–128

1. A method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of toomoxetine.
Enablement of MOT Claims:

• Dt. Ct.: Held all of the ’590 patent claims invalid for lack of “enablement/utility.” The court held that utility was not established because experimental data showing the results of treatment of ADHD were not included in the specification.

• Fed. Cir.: Disagreed
  – “The defendants do not dispute that the ’590 patent describes the utility of tomoxetine for treatment of ADHD, and that the utility is correctly described.”
  – “Lilly agrees that human test data were not available at the time the patent application was filed, because human tests were prohibited without FDA authorization.”
  – “It was not disputed that persons experienced in this field would require actual human tests to verify the effectiveness of this use.”
Enablement of MOT Claims:

- Fed. Cir.:

  “During examination of the ’590 application, the patent examiner did not require the submission of data showing treatment of ADHD with atomoxetine, although it is not disputed that such data were obtained shortly after the patent application was filed. The utility of this product to treat ADHD is not so incredible as to warrant the special procedures that are authorized for use when the examiner doubts the described utility, as in In re Swartz, 232 F.3d 862 (Fed. Cir. 2000) (cold fusion); Newman v. Quigg, 877 F.2d 1575, modified 886 F.2d 329 (Fed. Cir. 1987) (perpetual motion); and for subject matter in once notoriously intractable areas such as cures for baldness or cancer.”

- “[E]vidence of the described utility of atomoxetine was not requested by the patent examiner, although experimental verification was obtained soon after the filing of the patent application.”

Query: Would there be advantages to submitting data during prosecution even if not requested by the Office?
Consider Enablement: Reliance on Journals

  
  - 1. A method for treating or delaying the onset of a T cell mediated inflammatory autoimmune disease in a human subject comprising orally administering to the subject an effective dose of ACTH (adrenocorticotropic hormone).

- Examiner:
  
  - The Specification “does not reasonably provide enablement for a method of treating or delaying the onset of all autoimmune diseases, comprising orally administering to the subject an effective amount of … ACTH.” The Examiner acknowledged that the Specification enables a method of treating or delaying the onset of multiple sclerosis by teaching that oral administration of ACTH significantly improved recovery from EAE, experimental allergic encephalomyelitis, which is a model for multiple sclerosis. However, the Examiner found that “it is not predictable that all of the encompassed ‘T cell mediated inflammatory autoimmune diseases’… are treatable or able to be delayed” similarly.” (*Citations omitted*)
Consider Enablement: Reliance on Journals

• Applicant:
  – Specification describes not only that “EAE is a T cell mediated inflammatory autoimmune process of the central nervous system (CNS) that resembles the human demyelinating disease multiple sclerosis (MS),” but also that EAE “provides a useful animal system for the evaluation of potential therapies for human autoimmune [] disease.”
  – Submits Lehmann, a scientific journal article, which also considers “EAE as a model for T-cell mediated autoimmune disease, in general, and multiple sclerosis in particular….”

• PTAB reverses the enablement rejection.

• See, also, *Ex parte* Gleave (Appeal 2005-2477 (Bd. Pat. App. & Inter. 2006)).
Written Description

• 35 U.S.C. 112(a)

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor or joint inventor of carrying out the invention.
Genus-Species Problem

• *AbbVie v. Janssen Biotech and Centocor Biologics* (Fed. Cir. 2014)

  – 29. A neutralizing isolated human antibody, or antigen-binding portion thereof that binds to human IL-12 and disassociates from human IL-12 with a Koff rate constant of $1 \times 10^{-2}$ s$^{-1}$ or less, as determined by surface plasmon resonance.

  – Dt. Ct.: Invalid for lacking a sufficient written description, lacking enablement, and also for obviousness.
AbbVie (cont’d)

• Fed. Cir.: Agreed
  – AbbVie did not disclose any structural features common to the members of the genus; only described one type of structurally similar antibody rather than antibodies representative of the full scope of the genus
  – [While] AbbVie’s patents need not describe the allegedly infringing [compound] in exact terms . . . [t]he patents must at least describe some species representative of antibodies that are structurally similar to [the accused compound]
  – Because the patent document lacked any such structural description, the court confirmed that the corresponding claims were invalid under 112(a)
Claim to Solvate

• Claim: "17β-N-(2,5-bis (trifluoromethyl)) phenylcarbamoyl-4-aza-5α-androst-1-en-3-one or a pharmaceutically acceptable solvate thereof."

• Specification:

Those skilled in the art of organic chemistry will appreciate that many organic compounds can form complexes with solvents in which they are reacted or from which they are precipitated or crystallized. These complexes are known as “solvates”. For example, a complex with water is known as a “hydrate”. Solvates of [dutasteride] are within the scope of the invention.

It will also be appreciated by those skilled in organic chemistry that many organic compounds can exist in more than one crystalline form. For example, crystalline form may vary from solvate to solvate. Thus, all crystalline forms of [dutasteride] or the pharmaceutically acceptable solvates thereof are within the scope of the present invention.

• Issue: Is the claim valid under 112, 1st paragraph, written description?
GlaxoSmithKline LLC v. Banner Pharmacaps, Inc., 744 F.3d 725 (Fed. Cir. 2014)

- Dutasteride

- As summarized in the Federal Circuit opinion, the district court construed “solvate” of dutasteride to mean
  - A complex formed by dutasteride with a solvent in which dutasteride is reacted or from which it is precipitated or crystallized.

- The parties agreed that the district court’s claims construction encompasses three ways of forming dutasteride solvates:
  - by a reaction of dutasteride with a solvent;
  - by precipitation of a complex from a solution of dutasteride and a solvent;
  - by crystallization of a complex from a solution of dutasteride and a solvent

- The parties also agreed that the district court’s claims construction does not require the resulting complex to be crystalline.
**GlaxoSmithKline** (cont'd)

• Fed. Cir.:

  – Whether or not the term “solvate” required a crystalline structure, the written description requirement was satisfied

  – Noted that the patent “provides a description by structure and process of creation that matches the claimed term, whichever construction is preferable,” citing this passage from the patent:

    • Those skilled in the art of organic chemistry will appreciate that many organic compounds can form complexes with solvents in which they are reacted or from which they are precipitated or crystallized. These complexes are known as “solvates”. For example, a complex with water is known as a “hydrate”. Solvates of [dutasteride] are within the scope of the invention. It will also be appreciated by those skilled in organic chemistry that many organic compounds can exist in more than one crystalline form. For example, crystalline form may vary from solvate to solvate. Thus, all crystalline forms of [dutasteride] or the pharmaceutically acceptable solvates thereof are within the scope of the present invention.
GlaxoSmithKline (cont'd)

- **Fed. Cir.:**
  - The patent “defines the claimed genus by two properties”:
    - Structurally, as being “a complex of dutasteride molecules and solvent molecules” and
    - By the process(es) by which it is made.

- The court concluded:
  - [T]he description remains entirely based on structure of the compound and its process of creation. We have no precedent under which this two-condition description, matching the claim scope, would be insufficient.

- In reaching its conclusion, the court noted that the claims do not involve “functional claim language”

- Affirmed the district court’s finding that the defendants failed to establish invalidity for lack of written description.
1. (Currently Amended) Provided is at least one chemical entity chosen from compounds of Formula I

![Formula I diagram]

provided that the compound of Formula I is not

6-(4-methoxy-phenyl)-pyrimidine-4-carboxylic acid;

6-(3,4-Dichloro-phenyl)-2-methyl-pyrimidine-4-carboxylic acid;
Claims 1, 13 and 21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because Applicant amended claim 1 to remove two specific compounds from the claimed genus by proviso, but the specification as filed does not provide sufficient written description for this amendment.
Response

Applicant reminds the Office of M.P.E.P. 2173.05(i) which states:

If alternative elements are positively recited in the specification, they may be explicitly excluded in the claims. See *In re Johnson*, 558 F.2d 1008, 1019, 194 USPQ 187, 196 (CCPA 1977) ("[the] specification, having described the whole, necessarily described the part remaining."). See also *Ex parte Grasselli*, 231 USPQ 393 (Bd. App. 1983), *aff’d mem.*, 738 F.2d 453 (Fed. Cir. 1984).

As acknowledged by the Office, the two specific compounds that were removed by proviso are “specifically claimed in claim 28 as filed and are listed in the specification at pages 23 and 20 respectively, as an embodiment of the invention.” Being thus, positively recited, those compounds can be removed from the scope of the claims per the language of M.P.E.P. 2173.05(i) and the cases cited therein.

Furthermore, *In re Wertheim*, 541 F.2d 257 (C.C.P.A. 1976), recites the proposition that an Applicant is allowed to change his view of what his invention is during the prosecution of his application:

That what appellants claim as patentable to them is less than what they describe as their invention is not conclusive if their specification also reasonably describes that which they do claim. Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable.

*Id.* at 263. Similarly, "[i]t is not necessary that the application describe the claim limitations exactly, . . . but only so clearly that persons of ordinary skill in the art will recognize [it] from the disclosure . . . ." *Id.* at 262.
Reasons for Allowance

However, based on Applicant's arguments given in the Examiner Interview conducted April 11, 2013, particularly in view of *In re Johnson*, and the fact that Applicant specifically disclosed both the Ambinte and Wortmann compounds in the specification as filed, the § 112 rejection is hereby withdrawn.\(^1\) *In re Johnson*, 194 USPQ 187 (CCPA 1977) (if alternative elements are positively recited in the specification as filed, such specification supports a later claim excluding the disclosed alternatives).

\(^1\) The Ambinte and Wortmann compounds are disclosed in Applicant's specification at pages 23 and 20 respectively, as an embodiment of the invention.
In re Johnson, 558 F.2d 1008 (C.C.P.A. 1977)

- 1963 application: genus of polymers, included 26 examples describing 15 species of polyarylene polyethers (including species “1” and species “2”).

- To exclude subject matter, Johnson filed CIP with claims stating that the two precursor compounds “may not both include a divalent sulfone group [or]” a divalent carbonyl group linking two aromatic nuclei.”

  • 1972 Claim: linear thermoplastic polyarylene polyether polymers composed of recurring units of two precursor compounds, both bonded to ether oxygens through aromatic carbon atoms.

  • Proviso excluded species “1” and species “2.”

• CCPA: Entitled to benefit of 1963 filing date. Appellant is claiming less than the full scope of his disclosure. “It is for the inventor to decide what bounds of protection he will seek.”
But Consider Santarus

- Santarus, Inc. v. Par Pharmaceutical, Inc., 694 F.3d 1344 (Fed. Cir. 2012)
  - Claim 1: A method for treating an acid-caused gastrointestinal disorder comprising the step of administering to a subject suffering from said disorder a solid pharmaceutical composition comprising:
    - (a) about 10mg to about 40mg of non-enteric coated omeprazole; and
    - (b) sodium bicarbonate in an amount of 0.2 mEq to 5 mEq per 2mg omeprazole;
  - wherein the composition contains no sucralfate, the acid-caused gastrointestinal disorder is selected from the group consisting of duodenal ulcer, gastric ulcer, gastroesophageal reflux disease, and erosive esophagitis, and the sodium bicarbonate is present in the composition in an amount sufficient to substantially prevent or inhibit acid degradation of at least some of the omeprazole by gastric acid upon administration to the subject.
**Santarus (con’t)**

- Specification: “H2 antagonists, antacids, and sucralfate ... have certain disadvantages associated with their use.”

- **DC:** No support for “no sucralfate” limitation.
  - Specification does not “show why a person of ordinary skill in the art reading the application would believe that sucralfate was ‘contraindicated’ in the claimed composition.”

- **FC:** Reversed
  - “This exclusion narrowed the claims, as the patentee is entitled to do.”
  - “Negative claim limitations are adequately supported when the specification describes a reason to exclude the relevant limitation. Such written description support need not rise to the level of disclaimer....The claim limitation that the Phillips formulations contain no sucralfate is adequately supported by statements in the specification expressly listing the disadvantages of using sucralfate.”
And *In re Bimeda*

- *In re Bimeda Research & Development Ltd.*, 724 F.3d 1320 (Fed. Cir. 2013)
  - Original claim: A prophylactic method of controlling infection in a mammary gland by a mastitis-causing organism comprising sealing a teat canal of a mammary gland with a seal formulation so as to provide a physical barrier in the teat canal.
  
  - New claims:
    - “wherein the seal formulation is free of an agent that is antiinfective…” ALLOWED
    
    - seal formulation “has no bacterial action.” ALLOWED
    
    - seal canal had an “acriflavine-free” formulation REJECTED
      - acriflavine well-known, but no mention of in original disclosure so no demonstration of possession.
**Bimeda (cont’d)**

- **Bimeda**
  - broad description of invention free from antiinfectives
  - Example 1 did not include acriflavine as an ingredient

- **Examiner**
  - “specific exclusion of acriflavine introduces new concept” not supported in original disclosure.

- **Board: Upheld rejection**
  - No “blaze marks” guiding POSITA to exclusion of particular species
  - No support for claim excluding specific antiinfective but permitting others.

- **Federal Circuit: Affirmed**
  - Disclosure inconsistent with formulation that excludes acriflavine but could include other antiinfectives or antibiotics.
  - Excluding species invalid for lack of written description when the specification describes exclusion of the entire genus.
Expert Declarations Jan. 9, 2014 and April 11, 2014 Dealing with § 112 Issues

• From Targretin® Reissue 13444651: Written Description

From that factual evidence, the POSITA would have known to a reasonable certainty to derive the range of 60 to 140 mg recited in claim 27. Declaration, ¶ 22-23. That range is within the general range for active ingredient recited in the ’731 patent. Declaration, ¶ 19. And the legal authority supporting the POSITA’s application of the facts in the ’731 patent to derive the 60-140 mg range is even stronger than that in In re Wertheim, 541 F.2d 257 (CCPA 1976), relied on by the Office in MPEP 2163.05 (III).
Expert Declarations Jan. 9, 2014 and April 11, 2014 Dealing with § 112 Issues

• From Targretin® Reissue 13444651: Written Description

And if the Office does not accept expert testimony regarding why the POSITA would conclude that the co-inventors were in possession of the subject matter of claim 27, the Office must provide either an affidavit or detailed reason to explain it non-acceptance as set forth in MPEP 2163 II A:

... and MPEP § 2163.04 (“If applicant amends the claims and points out where and/or how the originally filed disclosure supports the amendment(s), and the examiner finds that the disclosure does not reasonably convey that the inventor had possession of the subject matter of the amendment at the time of the filing of the application, the examiner has the initial burden of presenting evidence or reasoning to explain why persons skilled in the art would not recognize in the disclosure a description of the invention defined by the claims.”).
Indefiniteness

• 35 U.S.C. 112(b)

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the inventor or a joint inventor regards as the invention.
Nautilus and Packard: Indefiniteness

  - Questions:
    - Does the Federal Circuit's acceptance of ambiguous patent claims with multiple reasonable interpretations—so long as the ambiguity is not “insoluble” by a court—defeat the statutory requirement of particular and distinct patent claiming?
    - Does the presumption of validity dilute the requirement of particular and distinct patent claiming?
    - Federal Circuit decision: claim term “spaced relationship” not indefinite; could be calculated knowing the intended functionality of the claim.

Supreme Court Decision Unanimous

  – Vacate and remand.
    • 35 U. S. C. § 112, ¶2: a patent specification “conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as [the] invention.”

    • Federal Circuit standard: § 112, ¶2 met if claim is “amenable to construction,” and the claim, as construed, is not “insolubly ambiguous.”

    • this “does not satisfy the statute’s definiteness requirement.”

    • USSC standard: “a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention.”
“Delicate Balance”

“On the one hand, the definiteness requirement must take into account the inherent limitations of language. …Some modicum of uncertainty, the Court has recognized, is the ‘price of ensuring the appropriate incentives for innovation.’”

At the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby ‘appris[ing] the public of what is still open to them.”
USSC Standard

• “To determine the proper office of the definiteness command, therefore, we must reconcile concerns that tug in opposite directions. Cognizant of the competing concerns, we read § 112, ¶2 to require that a patent’s claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. The standard we adopt accords with opinions of this Court stating that ‘the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter.’”
“Insolubly Ambiguous”
“Breed[s]…Confusion”

• Federal Circuit’s standard: “amenable to construction” or “insolubly ambiguous”

• USSC: “such terminology can leave courts and the patent bar at sea without a reliable compass” and “breed lower court confusion, for they lack the precision § 112, ¶2 demands. It cannot be sufficient that a court can ascribe some meaning to a patent’s claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc. To tolerate imprecision just short of that rendering a claim ‘insolubly ambiguous’ would diminish the definiteness requirement’s public-notice function and foster the innovation-discouraging ‘zone of uncertainty,’ …against which this Court has warned.”
• 75. The method of claim 74, wherein the N-(3-aminopropyl)-N-[(R)-1-(3-benzyl-7-chloro-4-oxo-4H-chromen-2-yl)-2-methyl-propyl]-4-methyl-benzamide, pharmaceutically acceptable salt thereof, a solvate thereof, or a solvate of a pharmaceutically acceptable salt thereof is N-(3-aminopropyl)-N-[(R)- 1-(3-benzyl-7-chloro-4-oxo-4H-chromen-2-yl)-2-methyl-propyl]-4-methyl-benzamide hydrochloride hydrate.

• 76. The method of claim 75, wherein the N-(3-aminopropyl)-N-[(R)-1-(3-benzyl-7-chloro-4-oxo-4H-chromen-2-yl)-2-methyl-propyl]-4-methyl-benzamide hydrochloride hydrate has powder XRPD peaks ($2\theta$) chosen from those having approximately the following values: 4.8, 9.7, 20.0, and 23.7.
Claims 71, 76, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claims are duplicates of 70 and 75 respectively. The claims cite inherent property of the compound in claims 70 and 75. Under the US patent practice inherent property is not a limitation of a product or compound. See *In re Best*, 562 F.2d 1252; 195 USPQ 430 (CCPA, 1977), *Titanium Metals Corp. v Banner*, 778 F.2d 775 (Fed. Cir. 1985), *Continental Can Co. v Monsanto Co.*, 948 F.2d 1264 (Fed. Cir. 1991), *In re Cruciferous Sprout Litig.*, 301 F.3d 1343 (Fed. Cir. 2002), *In re Crish*, 393 F.3d 1253 (Fed. Cir. 2004). By deleting the claims the rejection would be overcome.
Applicant’s Response

Claim Rejections Under 35 USC § 112, Second Paragraph

Claim 76 is rejected under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter. Applicant regards as the invention because the claim allegedly recites an inherent property of the compound in claim 75. Applicants respectfully traverse this rejection.

Claim 76 recites a specific polymorph of the compound in claim 75 as identified by its characteristic x-ray powder diffraction (XRPD) peaks. Pharmaceutical compounds often exist in different polymorphic forms, each of which exhibit different physical characteristics, including melting point, solubility, and X-ray crystal and diffraction patterns. Thus, the XRPD peaks recited in claim 76 are not necessarily inherent to all polymorphs of the compound. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.
Means Plus Function

• 35 U.S.C. 112(f)

An element in a claim for a combination may be expressed as a means or step for performing a specified function without the recital of structure, material, or acts in support thereof, and such claim shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.
How Do You Set Up § 112, ¶6 (f) Claims at the PTO?

MPEP 2181(I) provides a template:

• A claim limitation should be interpreted according to § 112(f) if it meets the following 3-prong analysis:

  A. The claim limitation uses the terms “means” or “step” or “a non-structural term … that is simply a substitute for the term ‘means for’” (“nonce word”);

  B. The term “means for” or “step for” or the nonstructural term is modified by functional language; and

  C. The phrase is not modified by sufficient structure or material for performing the claimed function
MPEP 2181: § 112, ¶6 (f)
Claims Must Satisfy § 112, ¶2 (b)

• 112, 6, states that a claim limitation expressed in means-plus-function language “shall be construed to cover the corresponding structure…described in the specification and equivalents thereof.”

• “If one employs means plus function language in a claim, one must set forth in the specification an adequate disclosure showing what is meant by that language. If an applicant fails to set forth an adequate disclosure, the applicant has in effect failed to particularly point out and distinctly claim the invention as required by the second paragraph of section 112.”
MPEP 2181: Link Material to Function
In a § 112, ¶6 (f), Claim to Satisfy § 112, ¶1 (a)

• Structure disclosed in the specification is corresponding structure only if the specification or prosecution history clearly links or associates that structure to the function recited in the claim. This duty to link structure to function is the quid pro quo for employing 112, paragraph 6.
Nonce-sense

• The following terms have been held to invoke ¶f:
  – mechanism for
  – module for
  – device for
  – unit for
  – component for
  – element for
  – member for
  – apparatus for
  – machine for
  – system for

• The following terms have been held not to invoke ¶f:
  – circuit for
  – detent mechanism
  – digital detector for
  – reciprocating member
  – connector assembly
  – perforation
  – sealingly connected joints
  – eyeglass hanger member
Means for displaying a result

- Prong A: Explicit recitation of “means”
- Prong B: f(x) recitation “for displaying a result”
- Prong C: No structure that performs the function

Means configured to display a result

- Prong A: Explicit recitation of “means”
- Prong B: f(x) recitation “configured to display a result”
- Prong C: No structure that performs the
**Module for displaying a result from a search query**

*Specification: the module can be hardware (such as a circuit), software (such as a program driver) or a combination thereof (such as a programmed microprocessing unit)*

- **Prong A:** “Module” is being used as a generic placeholder that is a substitute for “means” based on an evaluation of the specification
- **Prong B:** f(x) recitation “for displaying a result”
- **Prong C:** No structure that performs the function

Note that the claim limitation is limited to the hardware or the combination of hardware and software. Corresponding structure must be structural, it cannot read on software alone.

- “If the specification discloses only software as the corresponding structure, the claim must be rejected as indefinite under § 112, ¶ 2, as no corresponding structure has been identified.”
USPTO Examples: § 112(f) not invoked

A **display** means

*Specification: the display is described in accordance with its common understanding in the art, specifically as a computer monitor or video screen.*

- **Prong A:** Explicit recitation of “means”
- **Prong B:** No associated function recited
  - Displaying is functional; display is structural
- **Prong C:** Not applicable because no function recited

A **display** means *for displaying a result*

*Specification: the display is described in accordance with its common understanding in the art, specifically as a computer monitor or video screen.*

- **Prong A:** Explicit recitation of “means”
- **Prong B:** f(x) recitation “for displaying a result”
- **Prong C:** Structure, in the form of a display, is recited to perform the function
Determine that § 112(f) is invoked when a claim element with functional language uses:
- Means or a generic placeholder
- Coupled to a function
- With no structure to perform the function

Case-by-case basis using claim language, specification, and knowledge in the art as a guide

Treatment of elements that invoke means-plus-function is evolving
- Office has sought public input on examination of § 112(f) elements
- Examination guidance may be adjusted when appropriate in response to public feedback and judicial developments

• **Who Was P.J. Federico?**

• Author of Commentary on the New Patent Act (U.S.C. 1952)

• Republished in JPOS: March 1993

• Friend and Colleague of the late, great Giles S. Rich
“The last paragraph of section 112 relating to so-called functional claims is new. It provides that an element of a claim for a combination (and a combination may be not only a combination of mechanical elements, but also a combination of substances in a composition claim, or steps in a process claim) may be expressed as a means or step for performing a specified function, without the recital of structure, material or acts in support thereof.”

- Federico further explained, regarding the last clause:

  “This relates primarily to the construction of such claims for the purpose of determining when the claim is infringed (note the use of the word "cover"), and would not appear to have much, if any, applicability in determining the patentability of such claims over the prior art, that is, the Patent Office is not authorized to allow a claim which ‘reads on’ the prior art.”
The Zits Be Gone Issue

• New lawyer takes over after 8 years of unsuccessful efforts and obtains patent in 6 months on:

1. A physiologically acceptable aqueous gel composition for once-daily treatment of common acne comprising antiacne actives consisting of
   - pepper,
   - salt, and
   - further comprising gelling agent X.
• Zits be Gone application presents a claim invoking § 112, ¶6:

1. A physiologically acceptable aqueous gel composition for once-daily treatment of common acne comprising antiacne actives consisting of
   - pepper,
   - salt, and
   - means for enhancing the stability of said pepper and salt in said aqueous gel composition.
Zits Be Gone

• The PTO accepted the claim as proper under § 112, ¶6.
  – Not single means;
  – Linking was proper; and
  – No recitation of structure or materials in claim to achieve stability.
• *That quid pro quo requirement of 35 U.S.C. § 112, paragraph 1, is clearly met because, as explained above, Example 6, by comparative experimentation, links the [specific] gelling agent in Example 2, an example of the "means for" of claim 1, to the stability of the salt and pepper in the aqueous gel composition.*
• Battle shifts to 102/103 patentability.

• PTO finds salt and pepper in prior art acne composition.

• Finds gelling agent recited in spec.

• Makes a combination rejection.
Using MPF Claims

• **Benefits**
  – Link to specification to avoid prior art.
  – Statutory equivalents to what is linked to the specification, but such statutory equivalents are considered in the context of literal infringement, not doctrine of equivalents.

• **Challenges/Limits**
  – Narrowsness and linking to the specification
  – Defining statutory equivalents
  – USPTO treatment

• **Further resources, see:** Wanli Tang, “Revitalizing The Patent System To Incentivize Pharmaceutical Innovation: The Potential Of Claims With Means-plus-function Clauses,” 62 Duke L.J. 1069 (February 2013)
Lisa (Lee) Matovcik  
862.778.5442  
lisa.matovcik@novartis.com

Dr. Lauren Stevens  
650.387.3813  
Lstevens@globalpatentgroup.com

Linda Thayer  
617.646.1680  
linda.thayer@finnegan.com

Tom Irving  
202.408.4082  
tom.irving@finnegan.com