
THURSDAY, APRIL 26, 2018

1pm Eastern  |  12pm Central  |  11am Mountain  |  10am Pacific

Today’s faculty features:

Thomas L. Irving, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.
Adriana L. Burgy, Partner, Finnegan Henderson Farabow Garrett & Dunner, Washington, D.C.

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• Chapter 200
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We will do our best to hit the highlights
Discussion Topics

I. §101 guidance
II. Updates on the section on the duty of disclosure
III. Other amendments
IV. Best practices

• How will examiners apply the revised MPEP?
• How can patent counsel use the revised MPEP to bolster their arguments when patents are being examined?
• How does the USPTO’s disclosure standard differ from the courts’ positions?
Section 101 Guidance
Subject Matter Eligibility

• 35 U.S.C. § 101 sets forth the four categories of patentable subject matter:
  • 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.

• Judicially-created exceptions to patentable subject matter: subject matter that the courts have found to be outside of, or exceptions to, the four statutory categories of invention, and are limited to abstract ideas, laws of nature and natural phenomena (including products of nature). Alice Corp. Pty. Ltd. v. CLS Bank Int’l, 573 U.S. __, 134 S. Ct. 2347, 2354, 110 USPQ2d 1976, 1980 (2014) (citing Ass’n for Molecular Pathology v. Myriad Genetics, Inc., 569 U.S. __, 133 S. Ct. 2107, 2116, 106 USPQ2d 1972, 1979 (2013).

The revised MPEP includes guidance based on recent decisions on patent eligibility, incorporating its memos explaining its implementation of the § 101 framework.

§2106 (II): “It is essential that the broadest reasonable interpretation (BRI) of the claim be established prior to examining a claim for eligibility. The BRI sets the boundaries of the coverage sought by the claim and will influence whether the claim seeks to cover subject matter that is beyond the four statutory categories or encompasses subject matter that falls within the exceptions.”
BRI and Subject Matter Eligibility

- **MPEP §2106 (II)**
  - Claim interpretation to determine if subject matter fits within a statutory category.
    - *Mentor Graphics v. EVE-USA, Inc.*, 851 F.3d 1275, 112 USPQ2d 1120 (Fed. Cir. 2017): BRI “covered both subject matter that falls within a statutory category ...as well as subject matter that does not ..., [so] the claims as a whole were not to a statutory category and thus failed the first criterion for eligibility.”

- Claim interpretation to determine if subject matter directed to a judicial exception.

- Claim interpretation to determine if claim recites additional elements that amount to “significantly more.”
  - *Amdocs (Israel) Ltd. v. Openet Telecom, Inc.*, 841 F.3d 1288 (Fed. Cir. 2016): BRI supported argument that the claim entails an unconventional technical solution to a technological problem.
USPTO: Two (ish)-Step Analysis

1. Is the claim to a process, machine, manufacture, or composition of matter?

2A. Is the claim directed to a law of nature, a natural phenomenon, or an abstract idea? (Mayo Test Part 1)
   • Judicially-recognized exceptions.

2B. Does the claim recite additional elements that amount to significantly more than the judicial exception? (Mayo Test Part 2)
USPTO’s Analysis

• “directed to” appears to mean -- looks like, sounds like, smells like, or is somehow derived from or related to, a natural product, law, phenomenon.

• “markedly different” means from the “naturally occurring counterpart in its natural state.” May be expressed by structure, function, and/or other properties.
“The Supreme Court has not established a definitive rule to determine what constitutes an 'abstract idea' sufficient to satisfy the first step of the Mayo/Alice inquiry. See Alice, 134 S. Ct. at 2357. Rather, both this court and the Supreme Court have found it sufficient to compare claims at issue to those claims already found to be directed to an abstract idea in previous cases.”

“The Supreme Court has suggested that claims ‘purport[ing] to improve the functioning of the computer itself,’ or ‘improv[ing] an existing technological process’ might not succumb to the abstract idea exception. See Alice, 134 S. Ct. at 2358-59.”
Enfish (con’t)

17. A data storage and retrieval system for a computer memory, comprising:
   • means for configuring said memory according to a logical table, said logical table including:
     • a plurality of logical rows, each said logical row including an object identification
     • number (OID) to identify each said logical row, each said logical row corresponding to a record of information;
     • a plurality of logical columns intersecting said plurality of logical rows to define a plurality of logical cells, each said logical column including an OID to identify each said logical column; and
   • means for indexing data stored in said table.

“[T]he patented logical model includes all data entities in a single table, with column definitions provided by rows in that same table. The patents describe this as the ‘self-referential’ property of the database.”
Enfish (con’t)

• “Microsoft urges the court to view the claims as being directed to ‘the concepts of organizing data into a logical table with identified columns and rows where one or more rows are used to store an index or information defining columns.’ ... However, describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to §101 swallow the rule.”

• “In finding that the claims were directed simply to ‘the concept of organizing information using tabular formats,’ ... the district court oversimplified the self-referential component of the claims and downplayed the invention’s benefits.”

• “[W]e find that the claims at issue in this appeal are not directed to an abstract idea within the meaning of Alice. Rather, they are directed to a specific improvement to the way computers operate, embodied in the self-referential table.”

• “In contrast, the claims at issue in Alice and Versata can readily be understood as simply adding conventional computer components to well-known business practices.”
“Directed to”

• MPEP §2016.04(a)(1)(II): “The types of improvements that the courts have identified as indicative of eligibility in the first step of the Alice/Mayo test (Step 2A) are discussed in MPEP § 2106.05(a) and MPEP § 2106.06(b).”
  • 2106.05(a) Improvements to the Functioning of a Computer or To Any Other Technology or Technical Field
  • 2106.06(b) Clear Improvement to a Technology or to Computer Functionality

• MPEP §2016.04(a)(II): “examiners should consider the principles discussed in MPEP § 2106.04(a)(1) and MPEP § 2106.05(a) before making a conclusion as to whether a claim is directed to an abstract idea.”
  • 2106.04(a)(1) Examples of Claims That Are Not Directed To Abstract Ideas
  • 2106.05(a) Improvements to the Functioning of a Computer or To Any Other Technology or Technical Field
Abstract Ideas

MPEP 2106.04(a)(1) Examples of Claims That Are Not Directed To Abstract Ideas
I. If a claim is based on or involves an abstract idea, but does not recite it, then the claim is not directed to an abstract idea
II. If a claim recites an abstract idea, but the claim as a whole is directed to an improvement or otherwise clearly does not seek to tie up the abstract idea, then the claim is not directed to an abstract idea

MPEP 2106.04(a)(2) Examples of Concepts The Courts Have Identified As Abstract Ideas
I. Fundamental Economic Practices
II. Certain Methods of Organizing Human Activity
III. An Idea “Of Itself”
IV. Mathematical Relationships/Formulas”
Law of Nature/Product of Nature

• 2106.04(b) Laws of Nature, Natural Phenomena & Products of Nature

• Examples:

i. isolated DNA;

ii. a cloned farm animal;

iii. a correlation between variations in non-coding regions of DNA and allele presence in coding regions of DNA;

iv. a correlation that is the consequence of how a certain compound is metabolized by the body;

v. a correlation between the presence of myeloperoxidase in a bodily sample (such as blood or plasma) and cardiovascular disease risk;

vi. electromagnetism to transmit signals;

vii. qualities of bacteria such as their ability to create a state of inhibition or non-inhibition in other bacteria;

viii. single-stranded DNA fragments known as "primers";

ix. the chemical principle underlying the union between fatty elements and water; and

x. the existence of cell-free fetal DNA (cffDNA) in maternal blood.
USPTO’s Analysis (cont'd)

• What does “significantly more” mean?
  • 2016.05(d): “If, however, the additional element (or combination of elements) is no more than well-understood, routine, conventional activities previously known to the industry, which is recited at a high level of generality, then this consideration does not favor eligibility.”

• 2106.05(c) Particular Transformation

  • Relevant factors
    1. The particularity or generality of the transformation. ...Therefore, a more particular transformation would likely provide significantly more.
    2. The degree to which the recited article is particular. A transformation applied to a generically recited article or to any and all articles would likely not provide significantly more than the judicial exception. A transformation that can be specifically identified, or that applies to only particular articles, is more likely to provide significantly more.
    3. The nature of the transformation in terms of the type or extent of change in state or thing. A transformation resulting in the transformed article having a different function or use, would likely provide significantly more, but a transformation resulting in the transformed article merely having a different location, would likely not provide significantly more....
    4. The nature of the article transformed. Transformation of a physical or tangible object or substance is more likely to provide significantly more than the transformation of an intangible concept such as a contractual obligation or mental judgment.
    5. Whether the transformation is extra-solution activity or a field-of-use (i.e., the extent to which (or how) the transformation imposes meaningful limits on the execution of the claimed method steps).
MPEP § 2106.06 – Streamlined Analysis

- Examiners may use a streamlined eligibility analysis (Pathway A) when the eligibility of the claim is self-evident, e.g., because the claim clearly improves a technology or computer functionality.

- The results of the streamlined analysis WILL always be the same as the full analysis, thus the streamlined analysis is not a means of avoiding a finding of ineligibility that would occur if a claim were to undergo the full eligibility analysis.

- May not be apparent examiner conducted streamlined analysis.
  - No rejection on eligibility grounds or may include clarifying remarks.
MPEP § 2106.06 (a)

• Examples (MPEP § 2106.06(a) Eligibility is Self-Evident)
  
  • **Robotic arm assembly** = using certain mathematical relationships; not an attempt to tie use of the mathematical relationships
  
  • **Nature-based product** = No attempt to tie up the nature-based product; does not require a markedly different characteristics analysis
  
  • **Artificial hip prosthesis coated with natural mineral** = Not an attempt to tie up the mineral
  
  • **Inclusion of nature-based components** = claims do not attempt to improperly tie up the nature-based product
MPEP § 2106.06(b)
Clear Improvement to a Technology or to Computer Functionality

• “As explained by the Federal Circuit, some improvements to technology or to computer functionality are not abstract when appropriately claimed, and thus claims to such improvements do not always need to undergo the full eligibility analysis. Enfish, LLC v. Microsoft Corp., 822 F.3d 1327, 1335-36, 118 USPQ2d 1684, 1689 (Fed. Cir. 2016).”

• Claims directed to clear improvements held eligible at step 1 of the Alice/Mayo test as not directed to an abstract idea and therefore do not require full eligibility analysis.
  • Same holds true for improvements to other technologies or technological processes, beyond computer improvements

• “Close call” claims, full eligibility analysis should be performed.
MPEP § 2106.07 Formulating and Supporting Rejections For Lack Of Subject Matter Eligibility

• “Eligibility rejections must be based on failure to comply with the substantive law under 35 U.S.C. 101 as interpreted by judicial precedent. The substantive law on eligibility is discussed in MPEP § 2106.03 through 2106.06. Examination guidance, training, and explanatory examples discuss the substantive law and establish the policies and procedures to be followed by examiners in evaluating patent applications for compliance with the substantive law, but do not serve as a basis for a rejection. Accordingly, while it would be acceptable for applicants to cite training materials or examples in support of an argument for finding eligibility in an appropriate factual situation, applicants should not be required to model their claims or responses after the training materials or examples to attain eligibility.”

• That may well be so, but modeling claims seems like a good idea
MPEP § 2106.07  Formulating and Supporting Rejections For Lack Of Subject Matter Eligibility

• “...The evaluation of whether the claimed invention qualifies as patent-eligible subject matter should be made on a claim-by-claim basis, because claims do not automatically rise or fall with similar claims in an application. For example, even if an independent claim is determined to be ineligible, the dependent claims may be eligible because they add limitations amounting to significantly more than the judicial exception recited in the independent claim. Thus, each claim in an application should be considered separately based on the particular elements recited therein.”

• Examiner rejection “should set forth a prima facie case of ineligibility under the substantive law. The concept of the prima facie case is a procedural tool of patent examination, which allocates the burdens going forward between the examiner and applicant. In particular, the initial burden is on the examiner to explain why a claim or claims are ineligible for patenting clearly and specifically, so that applicant has sufficient notice and is able to effectively respond.”
MPEP § 2106.07(a)  Formulating and Supporting Rejections For Lack Of Subject Matter Eligibility

• Under the principles of compact prosecution, a complete examination should be made for every claim under each of the patentability requirements (§§ 102, 103, 112, and 101) and non-statutory double patenting.
  • EXAMINERS should state all non-cumulative reasons and bases for rejection claims in the first Office Action.

• I. When Making a Rejection, Identify and Explain the Judicial Exception Recited in the Claim Step (Step 2A)
• II. When Making a Rejection, Explain Why the Additional Claim Elements Do Not Result in the Claim As A Whole Amounting to Significantly More than the Judicial Exception (Step 2B)
• III. Evidentiary Requirements in Making a § 101 Rejection
USPTO Subject Matter Eligibility Memo
April 2, 2018

• Finjan Inc. v. Blue Coat Systems, Inc., 879 F.3d 1299 (Fed. Cir. 2018) and Core Wireless Licensing S.A.R.L., v. LG Electronics, Inc., 880 F.3d 1356 (Fed. Cir. 2018), “are consistent with a growing body of case law, including Enfish and McRO, confirming that software-based innovations can make "non-abstract improvements to computer technology" and be deemed patent-eligible subject matter at the first step of the Alice/Mayo analysis (Step 2A in the Office's subject matter eligibility guidance, see MPEP § 2106.04 et seq.).”

• See also https://www.uspto.gov/patent/laws-and-regulations/examination-policy/subject-matter-eligibility
  • Decisions holding claims eligible and identifying abstract ideas (quick reference sheet updated March 14, 2018)
  • Chart of subject matter eligibility court decisions (updated March 14, 2018)
USPTO: Decisions holding claims eligible and identifying abstract ideas
(quick reference sheet updated March 14, 2018)

March 2018: Eligibility Quick Reference Sheet
*Identifying Abstract Ideas* (Part 1)

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<td>• Organizing and manipulating information through mathematical correlations (Digitech)</td>
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<td>• Providing a vehicle valuation through the collection and use of vehicle information (Audatex. N. America)†</td>
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<td>• Receiving, authenticating, and publishing data (Easyweb innovations)†</td>
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<td>• Using a marking affixed to the outside of a mail object to communicate information about the mail object (Secured Mail Solutions)</td>
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<td>• Relaying mailing address data (Return Mail)</td>
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<td>• Testing operators of any kind of moving equipment for any kind of physical or mental impairment (Vehicle Intelligence)†</td>
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<td>• Virus screening (Int. Ventures v. Symantec ‘610 patent)</td>
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## "An Idea ‘Of Itself’" – MPEP 2106.04(a)(2) Part (III)

### A. Concepts Relating To Data Comparisons That Can Be Performed Mentally Or Are Analogous To Human Mental Work
- Anonymous loan shopping (*Mortgage Grader*)
- Collecting and comparing known information (*Classen*)
- Comparing data to determine a risk level (*Perkin-Elmer*)
- Comparing information regarding a sample or test subject to a control or target data (*Amby/Myriad CAFC*)
- Comparing new and stored information and using rules to identify options (*Smartgene*)
- Diagnosing an abnormal condition by performing clinical tests and thinking about the results (*Grams*)
- Obtaining and comparing intangible data (*CyberSource*)

### B. Concepts Relating To Organizing Or Analyzing Information In A Way That Can Be Performed Mentally Or Is Analogous To Human Mental Work
- Collecting and analyzing information to detect misuse and notifying a user when misuse is detected (*FairWarning*)
- Collecting, displaying, and manipulating data (*Int. Ventures v. Cap One Financial*)
- Collecting information, analyzing it, and displaying certain results of the collection and analysis (*Electric Power Group; West View*)
- Collection, storage, and recognition of data (*Smart Systems Innovations*)
- Creating an index, and using that index to search for and retrieve data (*Int. Ventures v. Erie Indemnity I: ’434 patent*)
- Data recognition and storage (*Content Extraction*)
- Determining a price, using organizational and product group hierarchies (*Versata*)
- Encoding and decoding image data (*ReconCip Corp*)
- Identification of unwanted files in a particular field (*Int. Ventures v. Erie Indemnity II*)

### D. Other Concepts
- Mental process for logic circuit design (*Synopsys*)
- Organizing and manipulating information through mathematical correlations (*Digitech*)
- Parsing and comparing data (*Berkheimer*)
- Relaying mailing address data (*Return Mail*)
- Retaining information in navigation of online forms (*Internet Patents*)
- Storing, gathering, and analyzing data (*TDE Petroleum*)
- Using categories to organize, store and transmit information (*Cyberfone*)

### C. Concepts Described As Ideas Having No Particular Concrete Or Tangible Form
- Assigning hair designs to balance head shape (*Brown*)
- Determining a price, using organizational and product group hierarchies (*Versata*)
- Displaying an advertisement in exchange for access to copyrighted media (*Ultramercial*)

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*FINNEGAN*
Quick Reference Sheet (con’t)

### Mathematical Relationships / Formulas – MPEP 2106.04(a)(2) Part (IV)

**A. Concepts Relating To Mathematical Relationships Or Formulas**
- The Arrhenius equation (*Diehr*)
- An algorithm for converting binary coded decimal to pure binary (*Benson*)
- An algorithm for calculating and comparing regions in space (*Coffelt*)
- A formula describing certain electromagnetic standing wave phenomena (*Mackay Radio*)
- A formula for computing an alarm limit (*Flook*)
- A mathematical formula for hedging (*Bilski claims 4-8, 10, 11*)

**B. Concepts Relating To Performing Mathematical Calculations**
- An algorithm for calculating parameters indicating an abnormal condition (*Grams*)
- Calculating the difference between local and average data values (*Abele*)
- Managing a stable value protected life insurance policy (*Bancorp*)
- Organizing and manipulating information through mathematical correlations (*Digitech*)
- Using an algorithm for determining the optimal number of visits by a business representative to a client (*Maucorps*)
# March 2018: Eligibility Quick Reference Sheet

## Decisions Holding Claims Eligible

### Claims eligible in Step 2A

| Claim is not directed to an **abstract idea**
|---|
| See MPEP 2106.04(a), 2106.04(a)(1) and 2106.06(b)

- **Core Wireless**
  (GUI for mobile devices that displays commonly accessed data on main menu)

- **DDR Holdings**
  (matching website “look and feel”)
  see Example 2

- **Enfish**
  (self-referential data table)

- **Finjan v. Blue Coat Sys.**
  (virus scan that generates a security profile identifying both hostile and potentially hostile operations)

- **McRO**
  (rules for lip sync and facial expression animation)

- **Thales Visionix**
  (using sensors to more efficiently track an object on a moving platform)

- **Trading Tech. v. CQG †**
  (GUI that prevents order entry at a changed price)

- **Visual Memory**
  (enhanced computer memory system)

| Claim is not directed to a **law of nature or natural phenomenon**
|---|
| See MPEP 2106.04(b)

- **Ebel Process**
  (gravity-fed paper machine)
  see Example 32

- **Rapid Lit. Mgmt. v. CellzDirect**
  (cryopreserving liver cells)

- **Tilghman**
  (method of hydrolyzing fat)
  see Example 33

| Claim is not directed to a **product of nature**
|---|
| (because the claimed nature-based product has markedly different characteristics)
| See MPEP 2106.04(c)

- **Chakrabarty**
  (genetically modified bacterium)
  see Example 13 (NBP-5)

- **Myriad**
  (cDNA with modified nucleotide sequence)
  see Example 15 (NBP-7)
### Quick Reference Sheet (con’t)

**Claims eligible in Step 2B**

(claim as a whole amounts to significantly more than the recited judicial exception, i.e., the claim recites an inventive concept)

See MPEP 2106.05 and 2106.05(a) through (h)

<table>
<thead>
<tr>
<th>Claim</th>
</tr>
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<tbody>
<tr>
<td>Abele (tomographic scanning)</td>
</tr>
<tr>
<td>Amdocs (field enhancement in distributed network)</td>
</tr>
<tr>
<td>BASCOM (filtering Internet content) see Example 34</td>
</tr>
<tr>
<td>Classen (processing data about vaccination schedules &amp; then vaccinating)</td>
</tr>
<tr>
<td>Diehr (rubber manufacturing) see Example 25</td>
</tr>
<tr>
<td>Exergen v. Kaz † (measuring core body temperature)</td>
</tr>
<tr>
<td>Mackay Radio (antenna)</td>
</tr>
<tr>
<td>Myriad CAFC (screening method using transformed cells)</td>
</tr>
<tr>
<td>RCT (digital image processing) see Example 3</td>
</tr>
<tr>
<td>SiRF Tech (GPS system) see Example 4</td>
</tr>
</tbody>
</table>
MPEP § 2106.07(b)  
Evaluating Applicant’s Response

- Applicant’s response: (1) AMEND the claims and/or (2) ARGUE.
- If the applicant properly challenges the examiner’s findings BUT examiner MAINTAINS the rejection, a rebuttal must be provided in the next Office Action. Examples of appropriate examiner responses are provided:

  1) If applicant challenges the identification of an abstract idea that was based on a court case and the challenge is not persuasive, an appropriate response would be an explanation as to why the abstract idea identified in the claim is similar to the concept in the cited case.

  2) If applicant responds to an examiner’s assertion that something is well-known, routine, conventional activity with a specific argument or evidence that the additional elements in a claim are not well-understood, routine, conventional activities previously engaged in by those in the relevant art, the examiner should reevaluate whether it is readily apparent that the additional elements are in actuality well-known, routine, conventional activities to those who work in the relevant field.
Evaluating Applicant’s Response

- (3) If applicant amends a claim to add a generic computer or generic computer components and asserts that the claim recites significantly more because the generic computer is 'specially programmed' (as in Alappat, now considered superseded) or is a 'particular machine' (as in Bilski), the examiner should look at whether the added elements provide significantly more than the judicial exception.

- (4) If applicant argues that the claim is specific and does not preempt all applications of the exception, the examiner should reconsider Step 2A of the eligibility analysis, e.g., to determine whether the claim is directed to an improvement to the functioning of a computer or to any other technology or technical field.
MPEP § 2106.07(c)
Clarifying the Record

• When the claims are deemed patent eligible, the examiner may make clarifying remarks on the record.

• The clarifying remarks may be made at any point during prosecution as well as with a notice of allowance.

• Clarifying remarks may be useful in explaining the rationale for a rejection as well.
Challenge in Life Sciences: “Diagnosing” Claims

- **USPTO’s guidelines issued on May 4, 2016, Example 29**
  - **Ineligible** - directed to a judicial exception (either a law of nature or an abstract idea), and the recited additional elements do not amount to significantly more than the exception.
    - 2. A method of diagnosing julitis in a patient, said method comprising:
      a. obtaining a plasma sample from a human patient;
      b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
      c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.
  - **Eligible** - recites specific and unconventional reagents and/or treatments that amount to significantly more than the exception.
    3. A method of diagnosing julitis in a patient, said method comprising:
      - obtaining a plasma sample from a human patient;
      - detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with a porcine anti-JUL-1 antibody and detecting binding between JUL-1 and the porcine antibody; and
      - diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.
“Diagnosing and Treating” Claims

• USPTO’s guidelines issued on May 4, 2016, Example 29
  • www.uspto.gov/sites/default/files/documents/ieg-may-2016-ex.pdf

• **Eligible** – “significantly more”; The totality of these steps including the recitation of a particular treatment (administration of an effective amount of anti-TNF antibodies) in step d integrate the exception into the diagnostic and treatment process, and amount to more than merely diagnosing a patient with juliitis and instructing a doctor to generically “treat it.” Further, the combination of steps, which is not routine and conventional, ensures that patients who have juliitis will be accurately diagnosed (due to the detection of JUL-1 in their plasma) and properly treated with anti-TNF antibodies.

— 6. A method of diagnosing and treating juliitis in a patient, said method comprising:
  a. **obtaining** a plasma sample from a human patient;
  b. **detecting** whether JUL-1 is present in the plasma sample;
  c. **diagnosing** the patient with juliitis when the presence of JUL-1 in the plasma sample is detected; and
  d. **administering** an effective amount of anti-tumor necrosis factor (TNF) antibodies to the diagnosed patient.
Patent Eligibility: Successful Biotech Example

Rapid Litigation Management Ltd. v. CellzDirect, Inc., 827 F.3d 1042 (Fed. Cir. 2016)

Claim 1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, ..., said method comprising:

(A) subjecting hepatocytes ...to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes, (B) recovering the separated viable hepatocytes, and (C) cryopreserving....


Claims focused on a process with steps for achieving this desired outcome, not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles.

Distinguishable from type of claims held patent-ineligible in Myriad (well-known process) and Ariosa (patent ineligible natural product).
Patent Eligibility: Successful Biotech Example

Rapid Litigation Management Ltd. v. CellzDirect, Inc.,
827 F.3d 1042 (Fed. Cir. 2016)

**Teachings:** Include process implementation details in claims.
Incorporate the specific features of the rules as claim limitations.
PTAB Bound by USPTO Guidance?


  • Claim 71. A nucleic acid construct, the construct comprising:
    - a vector; and
    - a continuous open reading frame coding sequence that encodes a nonbioluminescent Anthozoan chromo- or fluorescent polypeptide or chromo- or fluorescent mutant thereof, wherein the polypeptide or mutant thereof has an average molecular weight of 17.5 to 32.5 kDa, comprises a β-can fold and a chromophore or fluorophore, and has an absorbance maximum in the range of 300-700 nm and an emission maximum in the range of 400-800 nm.

  • Rejected for, inter alia, directed to ineligible subject matter.
    - “The Examiner finds that ‘[t]he claimed invention encompasses a coding sequence that is naturally occurring[,]’”

  • Reversed rejection of claim 71 and dependent claims 72-74, 76-78, and 109: “the Examiner has not established that it is more likely than not that claim 71 reads on a naturally occurring nucleic acid construct, or one that is not markedly different from a naturally occurring nucleic acid construct.
PTAB Bound by USPTO Guidance?

- PTAB says “no.”
  - *Lukyanov* (con’t)
    - Claim 88 recites a continuous open reading frame nucleic acid encoding chromo- or fluorescent mutant polypeptide of a nonbioluminescent Anthozoa chromo- or fluorescent polypeptide, having the characteristics of the polypeptide recited in claim 71.
    - “Appellants cite as support the USPTO’s 2014 Interim Guidance on Patent Subject Matter Eligibility (“Interim Guidance”)
      - Claim 2 of Example 7 in the Interim Guidance’s Nature-Based Product Examples: “2. Isolated nucleic acid comprising a sequence that has at least 90% identity to SEQ ID NO: 1 and contains at least one substitution modification relative to SEQ ID NO: 1.”
    - “We are not persuaded. As an initial matter, we are not bound by the Interim Guidance. Furthermore, we find the instant claims distinguishable from the example in the Interim Guidance, which requires a specific type of mutation (substitution) and specifies that ‘[n]o substitution modifications of [the gene at issue] are known to occur in nature.’”
    - Affirmed examiner rejection of claims 88, 91, 93, 95, 97, 99, 103, 114 as directed to patent-ineligible subject matter.
PTAB Bound by USPTO Guidance?

- Claim 1. A method of optimizing a response of a computer based digital message campaign using computer based processing, the method comprising:
  - A. electronically accessing…;
  - B. creating a first plurality of digital messages…;
  - C. sending said first plurality of digital messages…;
  - D. electronically tracking at least one selected response event occurring after said first plurality of digital messages is sent to said first plurality of digital message addresses of said first plurality of targeted recipients;
  - E. segmenting the library of elements …;
  - F. modifying, without human intervention, at least one of the one or more campaign rules based upon the relationship result;
  - G. electronically accessing a second plurality of digital message addresses…;
  - H. creating a second plurality of digital messages, …; and
  - I. sending said second plurality of digital messages from a server over an electronic network to said second plurality of digital message addresses of said second plurality of targeted recipients, wherein
  
  the relationship result is a correlation between (i) ...and (ii) ...; and
  
  the modifying (F) comprises ..., thereby causing the first combination of elements to be present in a higher or lower percentage of the second plurality of digital messages than in the first plurality of digital messages.
PTAB Bound by USPTO Guidance?

• PTAB says “no.”
  • Yadav (con’t)
    — Alice Step 1
      — Examiner: the claims are directed to “an abstract idea of optimizing a digital message campaign and providing for target population discovery and/or validation based on an evaluation of user activity.” (Alice Step 1)
        — “Also, the steps of the claims could be performed through the use of organized human activities given enough time. … Additionally, the claims are directed to an abstract idea of optimizing a digital message campaign and providing for target population discovery and/or validation based on an evaluation of user activity ….”
    — Alice Step 2
      — Examiner: “[t]he claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the claims do not provide improvements to another technology or technical field, improvements to the functioning of the computer itself, and do not provide meaningful limitations beyond general linking the use of an abstract idea to a particular technological environment.”
        — “no more than a generic computer, a network, and software to perform generic computer, network, and software functions that are well-understood, routine, and conventional activities previously known to the industry.”
PTAB Bound by USPTO Guidance?

• PTAB says “no.”
• Yadav (con’t)
  – In effort to show patent-eligible subject matter, Appellant raised “claim 2 of Example 21 of the July 2015 Update Appendix 1 of the 2014 Interim Guidance Matter Eligibility, which was found to be patentable under 35 U.S.C. § 101 in Google Inc. v. Simpleair, Inc., Covered Business Method Case No. CBM 2014-00170 (Jan. 22, 2015)[.]”

– Claim 2 of Example 21. A method of distributing stock quotes over a network to a remote subscriber computer, the method comprising:
  – providing a stock viewer application to a subscriber for installation on the remote subscriber computer;
  – receiving stock quotes ..., wherein the microprocessor
  – filters the received stock quotes ...;
  – generates a stock quote alert ...;
  – formats the stock quote alert ...; and
  – transmits the formatted stock quote alert over a wireless communication channel to a wireless device associated with a subscriber based upon the destination address and transmission schedule,
  – wherein the alert activates the stock viewer application to cause the stock quote alert to display on the remote subscriber computer and to enable connection via the URL to the data source over the Internet when the wireless device is locally connected to the remote subscriber computer and the remote subscriber computer comes online.
PTAB Bound by USPTO Guidance?

- PTAB says “no.”
  - **Yadav (con’t)**
    - PTAB: Rejection sustained.
      - The claim in the example “is not a strong basis for arguing that claim 1 on appeal is patent-eligible.”
      - “[C]laim 2 of Example 21 is a hypothetical claim[].”
      - The holding was not of subject matter eligibility, it was that the petitioner had not sufficiently shown claim directed to patent-ineligible subject matter.
      - Claim at issue not comparable to claim 2.
      - “reliance on examples in USPTO guidance is problematic at best. The Board decides cases in accordance with the law, not in accordance with hypothetical ‘examples [] intended to be illustrative only’.”
      - Appellant did not address case law cited by the Examiner.
PTAB Bound by USPTO Guidance?

• PTAB says “no.”
  • Yadav (con’t)

  — PTAB: Rejection sustained.

  — “The question is not whether claim 1 is similar to a hypothetical claim the USPTO might consider to be patent-eligible but whether claim 1 includes an element or combination of elements sufficient to ensure that the claim 1 subject matter in practice amounts to significantly more than to be about the abstract idea that the Examiner determined the claim to be directed to[.]”

  — “claim 1 calls for using a “computer,” and provides no further details. Reasonably broadly construed, the computer technology recited in claim 1 covers generic computers. And the tasks recited in claim 1 -- such as accessing addresses, creating a message, sending a message from a server over a network to addresses, and tracking responses -- are common computer functions. “Taking the claim elements separately, the function performed by the computer at each step of the process is ‘[p]urely conventional.’”
PTAB Bound by USPTO Guidance?

• PTAB and the examining corps operate separately.

• Guidance still helpful to practitioners.
  • Use it to highlight why applicant should succeed.

• Use case law cited in the MPEP as starting point for legal research and reasoning.

• Cite both MPEP and case law
  – Examiners receptive to MPEP citations, but then case law support is there if end up before PTAB or court.
Duty of Disclosure

• Note about proposed changes to Rule 56

• MPEP §2000.01 Introduction [R-08.2017]
  • “...On October 28, 2016, the Office issued a Notice of Proposed Rulemaking .... Specifically, the Office is considering harmonizing the materiality standard for the duty of disclosure to adopt the "but-for" materiality standard for inequitable conduct as set forth in *Therasense* and adopted in subsequent inequitable conduct cases, which will result in revisions to 37 CFR 1.56 and 37 CFR 1.555. While these proposed rule changes have not yet been finalized, it is still important for Office stakeholders to recognize the split in how materiality may be considered within the Office and in the courts. Some of the more instructive recent cases on inequitable conduct have been incorporated in the discussion below to provide guidance on compliance with the duty of disclosure regardless of the materiality standard.”
Materiality Standard under Current Rule 56

• 37 C.F.R. 1.56 Duty to disclose information material to patentability.

  b) Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, and

  1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or

  2) It refutes, or is inconsistent with, a position the applicant takes in:

     i. Opposing an argument of unpatentability relied on by the Office, or

     ii. Asserting an argument of patentability.
Duty of Candor and Good Faith

• Broader than duty to disclose material information.

• 37 C.F.R. 1.56

a) Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section. No patent will be granted on an application in connection with which fraud on the Office was practiced or attempted or the duty of disclosure was violated through bad faith or intentional misconduct.
USPTO Proposed Rule Change


• § 1.56 Duty to disclose information material to patentability.

  b) Information is but-for material to patentability if the Office would not allow a claim if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.
USPTO Proposed Rule Change


- § 1.555 Information material to patentability in ex parte reexamination and inter partes reexamination proceedings.

  b) Information is but-for material to patentability if, for any matter proper for consideration in reexamination, the Office would not find a claim patentable if the Office were aware of the information, applying the preponderance of the evidence standard and giving the claim its broadest reasonable construction consistent with the specification.
No Change To 37 C.F.R. §1.105(a)(1)

• Note, no change to 37 C.F.R. §1.105(a)(1):

• “In the course of examining or treating a matter in a pending or abandoned application filed under 35 U.S.C. 111 or 371 (including a reissue application), in a patent, or in a reexamination proceeding, the examiner or other Office employee may require the submission, from individuals identified under § 1.56(c), or any assignee, of such information as may be reasonably necessary to properly examine or treat the matter,...”

• See MPEP 704.14
Duty of Disclosure

• MPEP §2001.06 Sources of Information under 37 CFR 1.56 [R-08.2017]

  “Materiality controls whether information must be disclosed to the Office, not the circumstances under which or the source from which the information is obtained. If material, the information must be disclosed to the Office. The duty to disclose material information extends to information such individuals are aware of prior to or at the time of filing the application or become aware of during the prosecution thereof.

• Individuals covered by 37 CFR 1.56 may be or become aware of material information from various sources such as, for example, co-workers, trade shows, communications from or with competitors, potential infringers, or other third parties, related foreign applications (see MPEP § 2001.06(a)), prior or copending United States patent applications (see MPEP § 2001.06(b)), related litigation and/or post-grant proceedings (see MPEP § 2001.06(c)) and preliminary examination searches.”
Duty of Disclosure

- **MPEP §2001.06(b) Information Relating to or From Copending United States Patent Applications [R-08.2017]**

  “The individuals covered by 37 CFR 1.56 have a duty to bring to the attention of the examiner, or other Office official involved with the examination of a particular application, information within their knowledge as to other copending United States applications which are ‘material to patentability’ of the application in question. This may include providing the identification of pending or abandoned applications filed by at least one of the inventors or assigned to the same assignee as the current application that disclose similar subject matter that are not otherwise identified in the current application. ...
Duty of Disclosure

- **MPEP §2001.06(b) (con’t)**

- ...cannot assume that the examiner of a particular application is necessarily aware of other applications which are ‘material to patentability’ of the application in question, but must instead bring such other applications to the attention of the examiner. See *Regeneron Pharm., Inc. v. Merus B.V.*, 144 F. Supp. 3d 530, 560 (S.D.N.Y. 2015), and *Dayco Prod., Inc. v. Total Containment, Inc.*, 329 F.3d 1358, 1365-69, 66 USPQ2d 1801, 1806-08 (Fed. Cir. 2003). For example, if a particular inventor has different applications pending which disclose similar subject matter but claim patentably indistinct inventions, the existence of other applications must be disclosed to the examiner of each of the involved applications. Similarly, the prior art references from one application must be made of record in another subsequent application if such prior art references are ‘material to patentability’ of the subsequent application. See *Dayco Prod.*, 329 F.3d at 1369, 66 USPQ2d at 1808.”
Regeneron Pharm., Inc. v. Merus B.V.,
144 F. Supp. 3d 530 (S.D.N.Y. 2015)

• Claim 1. A genetically modified mouse.

• Merus: Regeneron’s patent unenforceable for inequitable conduct because prosecutors withheld four documents during prosecution, .
  • Disclosed in related U.S. patent prosecution and European opposition, false and misleading statements, and false and misleading results.

• Regeneron: Admittedly knew of the withheld documents during prosecution, but alleged that those documents were not but-for material and were cumulative of references PTO relied upon. Asserted no specific intent to deceive.
“But-for” Material

  - FC: Affirmed inequitable conduct.

  - Withheld references were, to the claims as construed, but-for material and not cumulative.
    - “the references both individually and in combination teach one of skill in the art to genetically modify mice by inserting exogenous, including human, variable region gene segments endogenously into a mouse immunoglobulin locus. The references, ...also provide the motivation to combine these references to develop the genetically modified mouse.”
Duty of Disclosure

- MPEP §2001.06(c) Information From Related Litigation and/or Trial Proceedings [R-08.2017]

- “The America Invents Act (AIA) added trial proceedings to be conducted by the Patent Trial and Appeal Board (PTAB) including inter partes review proceedings, post-grant review, covered business method reviews, and derivation. In many instances, these trial proceedings yield information that may be considered material to pending related patent applications. Where the subject matter for which a patent is being sought is or has been involved in litigation and/or a trial proceeding, or the litigation and/or trial proceeding yields information material to currently pending applications, the existence of such litigation and any other material information arising therefrom must be brought to the attention of the examiner or other appropriate official at the U.S. Patent and Trademark Office.”
Duty of Disclosure

• **MPEP §2001.06(c) (con’t)**

  • “In particular, material information that is raised in trial proceedings that is relevant to related applications undergoing examination should be submitted on an Information Disclosure Statement for the examiner’s consideration. Examples of such material information include evidence of possible prior public use or sales, questions of inventorship, prior art, allegations of ‘fraud,’ ‘inequitable conduct,’ and ‘violation of duty of disclosure.’ Another example of such material information is any assertion that is made during litigation and/or trial proceeding which is contradictory to assertions made to the examiner. *Environ Prods., Inc. v. Total Containment, Inc.*, 43 USPQ2d 1288, 1291 (E.D. Pa. 1997). Such information might arise during litigation and/or trial proceeding in, for example, pleadings, admissions, discovery including interrogatories, depositions, and other documents and testimony.”
MPEP §2001.06(c) (con’t)

“Where a patent for which reissue is being sought is, or has been, involved in litigation and/or trial proceeding which raised a question material to examination of the reissue application, such as the validity of the patent, or any allegation of ‘fraud,’ ‘inequitable conduct,’ or ‘violation of duty of disclosure,’ the existence of such litigation and/or trial proceeding must be brought to the attention of the examiner by the applicant at the time of, or shortly after, filing the application. Such information can be disclosed either in the reissue oath or declaration, or in a separate paper, preferably accompanying the application, as filed. Litigation and/or trial proceedings that begin after filing of the reissue application should be promptly brought to the attention of the Office. The details and documents from the litigation and/or trial proceedings, insofar as they are ‘material to patentability’ of the reissue application as defined in 37 CFR 1.56, should accompany the application as filed, or be submitted as promptly thereafter as possible. See Critikon, Inc. v. Becton Dickinson Vascular Access, Inc., 120 F.3d 1253, 1258-59, 43 USPQ2d 1666, 1670-71 (Fed. Cir. 1997) (patent held unenforceable due to inequitable conduct based on patentee’s failure to disclose a relevant reference and for failing to disclose ongoing litigation).”
A Need For Supplemental Examination To Clear The Path To Enforceability?

• 35 U.S.C. § 257(a): “A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent[.]”

• the “patent shall not be held unenforceable on the basis of ... information ...considered, reconsidered, or corrected during a supplemental examination of the patent.” (§ 257(c))

• Does not apply against allegations already raised in district court or ANDA notice para. IV before date of filing request (§257(c)(2)(A)), or any defenses raised in ITC litigation/district court litigation unless SE and any reexam ordered there from is finished before the date on which the action is brought (§257(c)(2)(B)).

• See MPEP §2800 et. seq.
Reissue Amendment

- Another purge opportunity? Amendment to §§ 251, 253:
  - Whenever any patent is, through error without any deceptive intention, deemed wholly or partly inoperative or invalid, by reason of a defective specification or drawing, or by reason of the patentee claiming more or less than he had a right to claim in the patent, the Director shall, on the surrender of such patent and the payment of the fee required by law, reissue the patent....

- Would one use a combination of Reissue and Supplemental Examination to insulate reissued claims from allegation of inequitable conduct? Or just reissue? Why?

Note: 37 CFR 1.16(e) Basic fee for filing each application for the reissue of a patent is $300! (with small/micro entity reductions available)
Note From *Intellect Wireless*: “Dancing Around The Truth” Not Good Enough

- *Intellect Wireless, Inc. v. HTC Corp.*, 732 F.3d 1339 (Fed. Cir. 2013)
  - DC: Patents unenforceable due to inequitable conduct.
    - Inventor submitted false Rule 131 declaration that claimed invention was reduced to practice.
    - “[N]o evidence that any of the false statements in any of the declarations were actually withdrawn, specifically called to the attention of the PTO or fully corrected.”
  - Intellect: Prosecuting attorney corrected false declaration, explained relying upon constructive reduction to practice, and Examiner relied upon constructive reduction to practice.
Note From Intellect Wireless: “Dancing Around The Truth”
Not Good Enough

- **Intellect Wireless, Inc. v. HTC Corp.** (con’t)
    - “[O]riginal declaration contains multiple unmistakably false statements.”
    - “Intellect argues that ...revised declaration...corrected these misrepresentations. We do not agree.
    - When an applicant files a false declaration, we require that the applicant ‘expressly advise the PTO...’ ...Finally, the applicant must ‘take the necessary action...openly. It does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome[.]”
      - cites *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572 (Fed. Cir. 1983), which was also cited in *Therasense*, with approval.
Need To Be Express

• Federal Circuit:

• “At best, the revised declaration obfuscated the truth....it never expressly negated the false references to actual reduction to practice in the original declaration.”

• “Nowhere did the declaration openly advise the PTO of Mr. Henderson’s misrepresentations, as our precedent clearly requires.”

• Federal Circuit quotes from *Rohm & Haas*:
  — “When an applicant files a false declaration, we require that the applicant ‘expressly advise the PTO of [the misrepresentation’s] existence, stating specifically wherein it resides.’”

  — “if the misrepresentation is of one or more facts, the PTO [must] be advised what the actual facts are.”

  — “applicant must ‘take the necessary action...openly. it does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate his own conclusions.’”
MPEP §2003.01 Disclosure After Patent Is Granted [R-08.2017]

I. BY CITATIONS OF PRIOR ART AND WRITTEN STATEMENTS UNDER 37 CFR 1.501

“Where a patentee or any member of the public (including private persons, corporate entities, and government agencies) has certain information which they desire to have made of record in the patent file, they may file a citation of such information with the Office pursuant to 35 U.S.C. 301 and 37 CFR 1.501. Such citations will be entered in the patent file without comment by the Office.”

Information “filed under 37 CFR 1.501 is limited to prior art patents, printed publications or written statements of the patent owner filed by the patent owner in a proceeding before a federal court or the Office in which the patent owner took a position on the scope of any patent claim.”
MPEP §2003.01 (con’t)

II. BY EX PARTE REEXAMINATION

III. BY SUPPLEMENTAL EXAMINATION

“35 U.S.C. 257(c)(1) states that "[a] patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent." Therefore, a patent owner may insulate the patent from being held unenforceable based on information submitted in a properly filed supplemental examination request.

“not limited to patents, printed publications, and patent owner written statements under 35 U.S.C. 301. The "information" may include any information that the patent owner believes to be relevant to the patent.”
Error on the Side of Disclosure

- MPEP §2004 Aids to Compliance With Duty of Disclosure [R-08.2017]

- “10. When in doubt, it is desirable and safest to submit information. Even though the attorney, agent, or applicant doesn’t consider it necessarily material, someone else may see it differently and embarrassing questions can be avoided. The court in *U.S. Industries v. Norton Co.*, 210 USPQ 94, 107 (N.D. N.Y. 1980) stated "[i]n short, the question of relevancy in close cases, should be left to the examiner and not the applicant." See also *LaBounty Mfg., Inc. v. U.S. Int’l Trade Comm’n*, 958 F.2d 1066, 22 USPQ2d 1025 (Fed. Cir. 1992).”
JMM’s

- MPEP §2004 Aids to Compliance With Duty of Disclosure [R-08.2017] (con’t)

- “15. Watch out for information that might be deemed to be prior art under pre-AIA 35 U.S.C. 102(f) and (g).... In addition, the AIA provides that the provisions of pre-AIA 35 U.S.C. 102(g) apply to each claim of an AIA application for patent if the patent application: (1) contains or contained at any time a claim to a claimed invention having an effective filing date as defined in 35 U.S.C. 100(i) that occurs before March 16, 2013; or (2) is ever designated as a continuation, divisional, or continuation-in-part of an application that contains or contained at any time a claim to a claimed invention that has an effective filing date before March 16, 2013.”
Duty of Disclosure During Reissue

- **MPEP §1418 Notification of Prior/Concurrent Proceedings and Decisions Thereon, and of Information Known To Be Material to Patentability [R-08.2017]**

- “37 CFR 1.178(b) requires reissue applicants to call to the attention of the Office any prior or concurrent proceeding in which the patent (for which reissue is requested) is or was involved and the results of such proceedings. These proceedings would include interferences or trials before the Patent Trial and Appeal Board, reissues, reexaminations, and litigations. Litigation would encompass any papers filed in the court or issued by the court, which may include, for example, motions, pleadings, and court decisions. This duty to submit information is continuing, and runs from the time the reissue application is filed until the reissue application is abandoned or issues as a reissue patent.”
In re Reissue Application of Roger Debrie

- Reissue Application No. 10/430,435
- Mixtures of Particular LMW Heparinic Polysaccharides for the Prophylaxis Treatment of Acute Thrombotic Events

Preliminary Amendment

““In the specification, please replace the paragraph beginning at ... with the following:

In addition, in humans, the mixtures of the invention display excellent bioavailability, as measured by the anti-Xa activity. Thus, this value is approximately 30 [IU] % for heparin but is approximately 90 [IU] % for the mixtures of the invention. This too is desirable in that it permits the doses administered to be reduced and the therapeutic potential to be improved.”
Aventis Pharma S.A. v. Amphastar Pharmaceuticals, Inc.,

• Claim: mixtures of low molecular weight herapin ("LMWH") used to prevent blood clots (Lovenox®)

• In Example 6, Aventis compared the half-life of a product allegedly covered by the ’618 patent ("Debrie LMWH") at a 40 mg dose to the half-life of a prior art product ("EP 40,144 LMWH" or "Mardiguian LMWH") at a 60 mg dose.

• Initially did not disclose dosage of prior art product.

• DC (475 F.Supp.2d 970): Judgment of unenforceability for inequitable conduct.

• FC (525 F.3d 1334 (Fed. Cir. 2008): Affirmed.
  • Material: improved half-life as compared to the EP ’144 compound referred to at least four times during prosecution, including that the difference in mean half-life was statistically significant.

  • Intent: Failure to disclose dosage information “evidenced intent to deceive.”
Filing Protest in Reissue

- MPEP §1441.01  Protest and Preissuance Submission in Reissue Applications [R-08.2017]

I. PROTESTS, BUT NOT PREISSUANCE SUBMISSIONS, ARE PERMITTED IN REISSUE APPLICATIONS

“A protest pursuant to 37 CFR 1.291 may be filed throughout the pendency of a reissue application, before the date of mailing of a notice of allowance, subject to the timing constraints of the examination, as set forth in MPEP § 1901.04.”

- MPEP § 1901.04: “a protest may be filed in a reissue application throughout the pendency of the reissue application prior to the date of mailing of a notice of allowance subject to the timing constraint of the examination. A protest with regard to a reissue application should, however, be filed within the 2-month period following announcement of the filing of the reissue application in the Official Gazette.”
- May petition and pay fee to submit after 2-month period.

- May be way to raise patent owner estoppel?
Reissue and Other Proceedings

- MPEP §1442.01 Litigation-Related or PTAB Trial-Related Reissues [R-08.2017]

  - “During initial review, the examiner should determine whether the patent for which the reissue has been filed is involved in litigation or a pending trial before the Patent Trial and Appeal Board (PTAB), and if so, the status of that litigation or pending trial before the PTAB.”

  - “If the examiner becomes aware of litigation involving the patent sought to be reissued during examination of the reissue application, the examiner should first check MPEP § 1442.02 to determine whether prosecution in the reissue application should be suspended. If prosecution will not be suspended, and applicant has not made the details regarding that litigation of record in the reissue application, the examiner, in the next Office action, will inquire regarding the specific details of the litigation.”
Reissue and Other Proceedings

- **MPEP §1442.02  Concurrent Litigation or Trial Before the Patent Trial and Appeal Board [R-08.2017]**

  - “To avoid duplicating effort, action in reissue applications in which there is an indication of concurrent litigation will generally be suspended sua sponte. Also, if there is a pending trial before the Patent Trial and Appeal Board (PTAB), the PTAB may suspend action in the reissue application. If it is evident to the examiner, or the applicant indicates, that any one of the following applies:

    A. a stay of the litigation is in effect;
    B. the litigation or trial before the PTAB has been terminated;
    C. there are no significant overlapping issues between the application and the litigation or pending trial before the PTAB; or
    D. it is applicant’s desire that the application be examined at that time;

- then the Office may or may not suspend the reissue application using its discretion based upon the facts of the situation.
Filing a Reissue with Copending IPR

• In Greene’s Energy Group, LLC v. Oil States Energy Services, LLC, IPR2014-00216, PTAB noted that if the Patent Owner filed a reissue application, it had to inform PTAB:
  – “Patent Owner indicated that it was considering filing an application to reissue at least one of the patents involved in these inter partes reviews. We reminded Patent Owner that, because the Board exercises jurisdiction over the patents, see 37 C.F.R. § 42.3(a), Patent Owner must contact the Board before filing any reissue application concerning the ’053 or ’993 patents.”
  • 37 C.F.R. § 42.3(a) The Board may exercise exclusive jurisdiction within the Office over every involved application and patent during the proceeding, as the Board may order.

• In Focal Therapeutics, Inc. v. Senorx, Inc., IPR2014-00116, during a conference call, the Patent Owner indicated it wanted to file a reissue application. PTAB stated:
  – “The Board explained that authorization or permission by the panel is not required in this regard. If it so wishes, Patent Owner may go through usual channels to request such action before the Office. We explained, however, that given our one year statutory deadline for completing an inter partes review, we would not grant a stay of this proceeding pending the outcome of a request for certificate of correction and/or reissue application. We also indicated that if Patent Owner takes such action, it shall keep the panel and Petitioner apprised of relevant events by filing a copy of relevant papers with the Board promptly.”
IPR Proceeding Can Effect The Reissue Application

- **35 U.S.C. §315(d):**
  - (d) MULTIPLE PROCEEDINGS.—Notwithstanding sections 135(a), 251, and 252, and chapter 30, during the pendency of an inter partes review [post grant review], if another proceeding or matter involving the patent is before the Office, the Director may determine the manner in which the inter partes review [post grant review] or other proceeding or matter may proceed, including providing for stay, transfer, consolidation, or termination of any such matter or proceeding.

- **37 C.F.R. §42.122**
  - (a) Multiple proceedings. Where another matter involving the patent is before the Office, the Board may during the pendency of the inter partes review [post grant review] enter any appropriate order regarding the additional matter including providing for the stay, transfer, consolidation, or termination of any such matter.
• Request to stay reissue more likely to be granted if (1) reissue application filed after IPR petition and (2) at time of request for stay, no examination of reissue claims has occurred.

• PTAB may deny request if made prior to institution decision, but request may be repeated after institution.

Concurrent Reissue and IPR

Legend3D, Inc. v. Prime Focus Creative Services Canada Inc. IPR2016-00806

- Claims in reissue application “nearly identical” to claims in IPR Motion to Amend.
- Stay granted.
- Later, PO argued for lift of stay, asserting that because the IPR was complete and because the “second preliminary amendment [in the reissue application would]... present claims that Patent Owner believes are patentably distinct from the original patent claims,” there was no longer concern about duplicate efforts within the Office and inconsistencies between the proceedings. The Board agreed and lifted the stay.
Concurrent Reissue and IPR

Valeo North America, Inc. v. Schaeffler Tech. AG & Co. KG
IPR2016-00502

- IPR instituted then Motion to Amend (proposed claims 14-25) and reissue application (new claims 14-36, claims 14-25 identical to proposed claims 14-25).
- Final Written Decision: all original and substitute claims 14-18 and 20-24 claims unpatentable but substitute claims 19 and 25 patentable.
- Claims 14-25 in reissue were cancelled.
- Petitioner’s Request to Stay denied: no overlapping claims and no copending IPR.
Concurrent Reissue and IPR

Smart Microwave Sensors GmbH v. Wavetronix, LLC
IPR2016-00488

• A Final Written Decision entered on July 17, 2017.
• Patent Owner filed a Notice of Appeal to the Federal Circuit.
• Board no longer had jurisdiction to grant a stay of the reissue application.
  • Board is divested of jurisdiction at the time either party files a notice of appeal to the Federal Circuit and citing In re Allen, 115 F.2d 936, 939 (CCPA 1940).
• Accordingly the Board was unpersuaded that it had the authority to issue a stay as requested by Petitioner.
Improper Markush

- Addition of a new “improper Markush grouping” section, MPEP §706.03(y), which authorizes patent examiners to reject a claim on the basis that it contains an improper listing of alternative elements.

- MPEP §706.03(y) Improper Markush Grouping [R-08.2017]

- III. REJECTION BASED ON IMPROPER MARKUSH GROUPING
  - “When an examiner determines that the members of a Markush group lack either a single structural similarity or a common use, or if the single structural similarity is a substantial structural feature of a chemical compound that is not essential to the common use, then a rejection on the basis that the claim contains an ‘improper Markush grouping’ is appropriate (see subsection II). Note that this is a rejection on the merits and may be appealed to the Patent Trial and Appeal Board in accordance with 35 U.S.C. 134 and 37 CFR 41.31(a)(1). Use Form Paragraph 8.40 to reject a claim on the basis that it includes an improper Markush grouping.”
Improper Markush

¶ 8.40  Improper Markush Grouping Rejection

“Claim [1] rejected on the basis that it contains an improper Markush grouping of alternatives. ...The Markush grouping of [2] is improper because the alternatives defined by the Markush grouping do not share both a single structural similarity and a common use for the following reasons: [3 [i.e., why the alternatives are not all members of the same recognized physical or chemical class or the same art-recognized class; and/or why the members are not considered to be functionally equivalent and have a common use; and/or why (if the Markush grouping describes alternative chemical compounds), the alternatives do not share both a substantial structural feature and a common use that flows from the substantial structural feature.]].”

“To overcome this rejection, Applicant may set forth each alternative (or grouping of patentably indistinct alternatives) within an improper Markush grouping in a series of independent or dependent claims and/or present convincing arguments that the group members recited in the alternative within a single claim in fact share a single structural similarity as well as a common use.”
Improper Markush

- MPEP §706.03(y) (con’t)

  “. . . In addition to a rejection based on an improper Markush grouping, the claim should also be rejected under 35 U.S.C. 112(b) if one skilled in the art cannot determine the metes and bounds of the Markush claim due to an inability to envision all of the members of the Markush grouping. In other words, if a boundary cannot be drawn separating embodiments encompassed by the claim from those that are not, the claim is indefinite and should be rejected under 35 U.S.C. 112(b). See also MPEP § 2173.05(h).”
Improper Markush

- More rejections of patent applications based on improper Markush grouping?

- An improper Markush grouping rejection can be overcome by
  - (1) amending the Markush group to include only members that share a single structural similarity and a common use;
  - (2) argue why the Markush grouping is not improper.

- “In addition, even if the applicant does not take action sufficient to overcome the improper Markush grouping rejection, when all of the claims are otherwise in condition for allowance the examiner should reconsider the propriety of the improper Markush grouping rejection. If the examiner determines that in light of the prior art and the record as a whole the alternatives of the Markush grouping share a single structural similarity and a common use, then the rejection should be withdrawn. Note that no Markush claim can be allowed until any improper Markush grouping rejection has been overcome or withdrawn, and all other conditions of patentability have been satisfied.”
Markush Grouping Examples

- **MPEP §706.03(y) (con’t)**

  - *In re Harnisch*, 631 F.2d 716 (CCPA 1980): *Proper*; all of the compounds shared "a single structural similarity" which is the coumarin core.

    - Claim 1. Coumarin compounds which in one of their mesometric limiting structures correspond to the general formula...
      
      - wherein
        
        - X represents aldehyde, azomethine, or hydrazone,
        - \( R^1 \) represents hydrogen or alkyl,
        - \( Z^1 \) represents hydrogen, alkyl, cycloalkyl, aralkyl, aryl or a 2- or 3-membered alkylene radical connected to the 6-position of the coumarin ring and
        - \( Z^2 \) represents hydrogen, alkyl, cycloalkyl, aralkyl or a 2- or 3-membered alkylene radical connected to the 8-position of the coumarin ring
        - and wherein
        - \( Z^1 \) and \( Z^2 \) conjointly with the N atom by which they are bonded can represent the remaining members of an optionally benz-fused heterocyclic ring which, like the ring A and the alkyl, aralkyl, cycloalkyl and aryl radicals mentioned, can carry further radicals customary in dye-stuff chemistry.
Markush Grouping Examples

• MPEP §706.03(y) (con’t)

• *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Interf. 1984) Appeal No. 559-94, Application No. 06/257,771: *Proper*; all of the compounds shared "a single structural similarity."
  
  – Claim 1. A compound of the formula:...
    – wherein
      • wherein
      • n is an integer of 1 to 15;
      • R1 is C6-26 alkyl, C6-26 alkenyl or C6-26 alkynyl, each of said groups being unsubstituted or substituted by hydroxyl, mercapto, amino, oxo, carbamoyl, carboxyl, halogen, C3-7 cycloalkyl or phenyl; and
      • R2, R3 and R4 are independently hydrogen or C1-5 alkyl, or ... epresents cyclic ammonio selected from the group consisting of pyridinio, oxazolio, thiazolio, pyridazinio, quinolinio, isoquinolinio, N-C1-4 alkylmorpholinio and N-C1-4 alkylpiperazinio, each of said groups being unsubstituted or substituted by C1-4 alkyl, hydroxyl, hydroxyethyl, aminoethyl, amino, carbamoyl or ureido,
      • or a pharmaceutically acceptable salt thereof.
Markush Grouping Examples

- **MPEP §706.03(y) (con’t)**

- Based On PCT Search and Examination Guidelines Example 23

- **Claim 1:** A herbicidal composition consisting essentially of an effective amount of the mixture of (a) 2,4-D (2,4-dichloro-phenoxy acetic acid) and (b) a second herbicide selected from the group consisting of copper sulfate, sodium chlorate, ammonium sulfamate, sodium trichloroacetate, dichloropropionic acid, 3-amino-2,5-dichlorobenzoic acid, diphenamid (an amide), ioxynil (nitrile), dinoseb (phenol), trifluralin (dinitroaniline), EPTC (thiocarbamate), and simazine (triazine) along with an inert carrier or diluent.

- **Improper:** “The claim sets forth an improper Markush grouping because the alternatives are not all members of the same recognized physical or chemical class or the same art-recognized class, nor do the alternative chemical compounds share both a substantial structural feature and a common use that flows from the substantial structural feature.”
Double Patenting

• **MPEP §804 V. DOUBLE PATENTING REJECTIONS AND PRIOR ART EXCEPTION UNDER 35 U.S.C. 102(b)(2)(C) and 102(c)**

  • For AIA applications, a commonly assigned/owned patent or application may be excepted as prior art under 35 U.S.C. 102(a)(2). See 35 U.S.C. 102(b)(2)(C). Also, if the requirements of 35 U.S.C. 102(c) are met, common ownership can be established by a joint research agreement. ....

  • An examiner should make both a prior art rejection under either 35 U.S.C. 102(a)(2) or 103 and a double patenting rejection over the same reference when the facts support both rejections. ...Rejections under 35 U.S.C. 102(a)(2) or 103 should not be made or maintained if the reference is not prior art because of the exception under 35 U.S.C. 102(b)(2)(C). See MPEP § 717.02 [Prior Art Exception for Commonly Owned or Joint Research Agreement Subject Matter under AIA 35 U.S.C. 102(b)(2)(C)]....
Double Patenting

- **MPEP §804 VI. DOUBLE PATENTING REJECTIONS ONCE A JOINT RESEARCH AGREEMENT IS ESTABLISHED**

  - Under both pre-AIA and AIA law, until applicant establishes the existence of a joint research agreement, the examiner cannot apply a double patenting rejection based upon a reference that was made by or on behalf of parties to the joint research agreement. If in reply to an Office action applying a prior art rejection, applicant disqualifies the relied upon reference as prior art under the joint research agreement provision of 35 U.S.C. 102(c) or pre-AIA 35 U.S.C. 103(c) and a subsequent nonstatutory double patenting rejection based upon the disqualified reference is applied, the next Office action may be made final even if applicant did not amend the claims (provided the examiner introduces no other new ground of rejection that was not necessitated by either amendment or an information disclosure statement filed during the time period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p)). The Office action is properly made final because the new nonstatutory double patenting rejection was necessitated by the applicant’s amendment of the application.
Common Inventors But Not Common Ownership -> No TD Option Available

_In re Hubbell, 709 F.3d 1140 (Fed. Cir. 2013)_

- Inventors Hubbell and Schense at CalTech
  - Research resulted in ‘509 application (earliest priority April 3, 1997), patent assigned to CalTech.
- Hubbell and Schense left CalTech to join ETHZ
  - Research resulted in ‘685 patent (earliest priority August 27, 1998), patent assigned to ETHZ and Universitat Zurich, and issued first.
- Examiner rejected ’509 application based on ODP over ’685 patent and Board affirmed.

- FC: Affirmed.
  - No common ownership or JRA, so terminal disclaimer not available.
  - No two-way obviousness analysis: Hubbell partially responsible for delay that caused ’685 patent to issue first.
Thank You!

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