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# Patent Public Advisory Committee Quarterly Meeting

## Patent Examination Policy Update

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# Recent Federal Register Notice

- Written Description for Design Applications
- Subject Matter Eligibility

# Written Description for Design Applications

- Federal Register notice published April 15, 2016
  - Responsive to public concerns about examiners' application of the written description requirement in design applications
  - Proposes an examination approach on the written description requirement for design applications in certain limited situations

# Written Description for Design Applications

- Proposed approach set forth in April 2016 Federal Register notice:
  - Focuses on amended claims or claims in continuing design applications that include only a subset of originally disclosed elements (no new elements are introduced)
  - Addresses certain limited situations, where the subset of originally disclosed elements, although visible in the original disclosure, composes a later-claimed design that an ordinary designer might not have recognized in the original disclosure
  - Aims to promote consistent treatment of this issue in the examination of design applications and help applicants better draft claims in compliance with the written description requirement
- Written comments and examples that the public believes would be helpful to illustrate the proposed approach are due June 14, 2016

# Subject Matter Eligibility

- Federal Register notice published \_\_\_\_\_
- Announced:
  - Memorandum to the examining corps on best practices in formulating an eligibility rejection and evaluating applicant responses
  - Publication of life science examples
  - Open-ended comment period
  - Selection of subject matter eligibility rejections as a new case study under the Topic Submission for Case Studies Pilot Program

# Memorandum to the Examining Corps

- Responsive to public concerns about examiners' application of the 2014 Interim Eligibility Guidance and July 2015 Update
  - Provides guidance to examiners on how to properly articulate the grounds of rejection
    - Clarifies how to identify and explain the judicial exception recited in the claim and how to explain why the additional limitations do not amount to significantly more than the judicial exception
    - Highlights certain points, such as treating the claim as a whole by considering additional elements in combination
  - Provides instructions on evaluating an applicant's response to a rejection
    - Reminds examiners to reevaluate the rejection when applicant presents evidence and/or arguments in rebuttal
    - Offers tips on how to draft a proper rebuttal if the rejection is to be maintained.
- Training: Workshop style using hypothetical example, office action and response

# Life Science Examples

- Responsive to public comments indicating that published examples are useful and requesting additional examples, especially relating to diagnostics
- Six new examples drawn from case law and hypotheticals
  - Intended to show various ways to draft claims for eligibility
  - Two of the examples show a streamlined analysis
- Training: workshops featuring selected life science examples similar to abstract idea workshops

# Life Science Example Teaching Points

- Vaccines:
  - Nature based product claims that illustrate how to select counterparts and perform the markedly different characteristics analysis for combinations of natural products
- Diagnosing and Treating “Julitis”:
  - Method claims that illustrate the application of the significantly more analysis to diagnostic and treatment claims
- Dietary Sweeteners:
  - Product claims that are combinations of natural products that show different types of characteristics and what type of change is enough to be a “marked” difference
- Screening for Gene Alterations:
  - Method claim from *Myriad* contrasted with hypothetical claims that show how unconventional methods of gathering data can provide significantly more to a diagnostic claim

# Judicial Developments

- *Sequenom v. Ariosa*: petition for certiorari pending at Supreme Court

Question: Whether a novel method is patent-eligible where:

(1) a researcher is the first to discover a natural phenomenon;

(2) that unique knowledge motivates him to apply a new combination of known techniques to that discovery; and

(3) he thereby achieves a previously impossible result without preempting other uses of the discovery.

- The patent involves amplifying genetic material in the non-cellular portion of a maternal blood sample and identifying paternally inherited sequences to distinguish fetal and maternal DNA.

# Questions and Comments

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