Trilaterial Examiner Exchange
Biotechnology/Chemical/Pharmaceutical Customer Partnership
September 2008

BJ Forman, Primary Examiner
Art Unit 1634
571-272-0741
Trilateral Examiner Exchange
Munich, 2008
Introduction

- Trilateral Examiner Exchange
  - Biotechnology Working Group (TBWG)
    - Goal
    - Focus- Microarrays
  - EPO-Munich, June 2008
    - Examination Practice
      - 101-Statutory Subject Matter
      - 102-Novelty
      - 103-Obviousness
      - 112-Support/Written Description
Trilateral Examiner Exchange

- Biotechnology Working Group
  - Initiated 1988
  - EPO, JPO, USPTO
  - Mandate
    - To facilitate practice in evolving areas of biotechnology and patent law
Mandate

Agreement April 2008

- Conduct substantive cooperative studies regarding search and examination practice topics.
- Foster greater understanding, trust and confidence in the substance and quality of our respective work products.
- Enhance and maximize mutual exploitation of the respective Offices’ work product for work-sharing purposes.
Mandate

- Examination Practice Issues
  - Patent Eligible Subject Matter / Statutory Invention
  - Unity of Invention / Restriction
  - Determining Effective Priority Date
  - Clarity / Support / Written Description
  - Preparing Search Strategies and Analysis of Search Results
  - Extent of examination required for Complex Applications
  - Novelty
  - Sufficiency / Enablement
  - Industrial Applicability / Utility
Prior to Examiner Exchange

- Select Topic for study (e.g. microarray)
- Select Examination Practice Issues (e.g. novelty)
- Select Example Claims for analysis
- Each Office summarizes practice
  - Draft-Paper is prepared summarizing examination practice for selected issues
Examiner Exchange

During Examiner Exchange
- Discuss practical aspects of examination practice
- Further refine examination practice in a memorandum
- Enhanced understanding of Examination Practice between Offices

Following Examiner Exchange
- Final Report
  - All examination practice issues as per Mandate
Examiner Exchange

- Previous Examination Practice Reports
  - Polymorphisms & Haplotypes (2003)
  - Protein 3-D structure (2002)
  - Reach-through claims (2001)

- www.trilateral.net
Topic Selection: Microarrays

- Evolving area of biotechnology
- Obvious need of the user community
- Difficult to construct claims
- Difficult to examine
“It has been clear for more than a decade that array-based methods are a key platform for genomics. Few other methods offer their massively parallel scale of analysis.”

Edwin M. Southern,
DNA Microarrays: History and Overview,
Microarrays: Community Need

- Universal Use of Microarrays
- Versatile tool
- Application filings in the three Offices
  - Different criteria between the Offices
  - Same invention, different examination
Microarrays: Difficult to Claim

- **Product**
  - **Composition**
    - Specific probes
    - Linker chemistry
    - Modified bases
    - Labeling components
  - **Structure**
    - Probe Density
    - Surface properties
    - Microarray components e.g. cartridge

- **Method**
  - Diagnosis
  - Genotyping
  - Expression analysis
  - Microarray production
Product or Method

A microarray containing at least thirty different DNA fragments selected from SEQ ID Nos. 1-1,000.

MPEP § 803.04(c)

Number of possible combinations and possible inventions: $10^{304}$
Selected Examination Practice Issues

Issue #1: Patent-Eligible Subject Matter / Statutory Invention / Industrial Applicability

Issue #2: Novelty

Issue #3: Inventive Step

Issue #4: Clarity / Support / Written Description
# Articles/Sections of Respective Patent Laws

<table>
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<tr>
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<th>Patentable Subject Matter/Statutory Invention</th>
<th>Industrial Applicability</th>
<th>Novelty</th>
<th>Inventive Step / Non-obvious</th>
<th>Enablement / Support / Written Description / Clarity</th>
</tr>
</thead>
<tbody>
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<td>52, 53</td>
<td>57</td>
<td>54</td>
<td>83, 84</td>
<td>54, 56</td>
</tr>
<tr>
<td>JPO</td>
<td>2(1)</td>
<td>29(1)</td>
<td>29(1)</td>
<td>29(2)</td>
<td>36(4)(6)</td>
</tr>
<tr>
<td>USPTO</td>
<td>101</td>
<td>101</td>
<td>102</td>
<td>103</td>
<td>112</td>
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</tbody>
</table>
Examination Terminology

- Differing terminology used in each Office
  - Refuse (JPO) = Object (EPO) = Reject (USPTO)
  - JPO - comprising and consisting
    - No equivalent difference between terms when translated to Japanese
Issue #1:
Patentable Subject Matter / Statutory Invention
EPO Article 52: Patentable Inventions

(1) European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application.

(2) Not regarded as inventions:

- (a) discoveries, scientific theories and mathematical methods;
- (b) aesthetic creations;
- (c) schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers;
- (d) presentations of information.
■ EPO Article 53 (a-c): Exceptions to Patentability

— a) inventions the commercial exploitation of which would be contrary to "ordre public" or morality; such exploitation shall not be deemed to be so contrary merely because it is prohibited by law or regulation in some or all of the Contracting States;

— (b) plant or animal varieties or essentially biological processes for the production of plants or animals; this provision shall not apply to microbiological processes or the products thereof;

— (c) methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods.
Issue #1: Patentable Subject Matter / Statutory Invention

- **JPO Article 2(1): Definition of Invention**
  - Highly advanced creation of technical idea utilizing laws of nature

- **JPO Article 29(1): Conditions for Patentability**
  - An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention
JPO: Non-Patentable Subject Matter

- Examination Guidelines for Patent and Utility Model in Japan
- Part II: Requirements for Patentability
  - § 1.1 List of Non-Statutory Inventions
    - Those contrary to a law of nature
  - § 2.1 List of Industrially Inapplicable Inventions
    - Methods of treatment of the human body by surgery, therapy or diagnosis

http://www.jpo.go.jp/cgi/linke.cgi?url=tetuzuki_e/t_tokkyo_e/1312-002.e.htm
USPTO § 101: Patentable Inventions

- 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.

- Judicial Exceptions:
  - Laws of nature, natural phenomena, abstract ideas
## Issue #1: Patentable Subject Matter / Statutory Invention

<table>
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<th>EPO</th>
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</tr>
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<tbody>
<tr>
<td>In vitro Diagnosis of Humans</td>
<td>yes</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>In vivo Diagnosis in Humans</td>
<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>In vitro Diagnosis of Non-Human Animals</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>In vivo Diagnosis in Non-Human Animals</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Medical Treatment of Humans</td>
<td>no</td>
<td>no</td>
<td>yes</td>
</tr>
<tr>
<td>Medical Treatment of Animals</td>
<td>no</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Kits or Compositions for Diagnosis or Treatment</td>
<td>yes</td>
<td>yes</td>
<td>yes</td>
</tr>
<tr>
<td>Gene Expression Profiles</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Database e.g. sequence listing</td>
<td>no</td>
<td>no</td>
<td>no</td>
</tr>
<tr>
<td>Data Carrier e.g. signal</td>
<td>yes</td>
<td>no</td>
<td>no</td>
</tr>
</tbody>
</table>
Issue #1: Patentable Subject Matter / Statutory Invention

EPO/JPO/ USPTO agree:

- Patentable subject matter
  - In vitro diagnosis of non-human animal
  - Diagnostic kits/compositions
- Non-Patentable subject matter
  - Gene expression profile
  - Database
Issue #1: Patentable Subject Matter / Statutory Invention

- **Claim 1:** A data carrier comprising a list of at least one/two/three/four... of the marker genes as specified in Table X.

- **Claim 2:** A data carrier characterized by comprising a list consisting of the set of marker genes as specified in Table X.
The EPO would interpret a “data carrier” as a support having information thereon (e.g. piece of paper, CD-ROM, black board etc.).

Claims to a data carrier thus define a product and are always technical and are not excluded from patentability.

Examination:
- Claims 1 and 2 meet the requirements of Article 52
- EPO would search and examine claims 1 and 2.
JPO

- The JPO would consider a data carrier as a mere presentation of information which is not a technical idea utilizing a law of nature.

- Examination:
  - Claims 1 and 2 do not meet the requirements of Article 2.
  - The JPO would refuse claims 1 and 2 as non-statutory and lacking clarity.
  - The JPO would not search or examine the claims.
The USPTO would consider claims drawn to a signal as non-statutory subject matter.

See, *In re Nuijten*, 500 F.3d 1346 (Fed. Cir. 2007).

**Examination:**

- Non-statutory claims would be rejected under 35 U.S.C. § 101 as per *In re: Nuijten*.
- Regardless of whether a 101 rejection is made, the USPTO would search and examine claims 1 and 2 under 35 U.S.C. § 112, 102 and 103.

see MPEM 2106 IV B
Examination following determination of Non-Patentable Subject Matter

- **EPO**
  - Object to the claims
  - Further examination *ONLY* if a patentable invention is clearly defined in the specification.

- **JPO**
  - Refuse the claims
  - No prior art search

- **USPTO**
  - Rejection under 35 U.S.C. § 101 if claim is interpreted as being drawn to non-patentable subject matter
  - Examine Claims under 35 U.S.C. § 112, 102, 103
    - See MPEP § 2106 IV B.
Issue #2: Novelty
Issue #2: Novelty

Prior Art

- EPO Article 54 (1)(2)
  - Everything made public by written or oral means before date of filing.

- JPO Section 29(1)
  
  Anything publicly known or worked before date of filing
### Issue #2: Novelty

**Patent Applications as Prior Art**

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<td>Pub. date</td>
<td>Pub. date</td>
<td>filing date</td>
</tr>
</tbody>
</table>
Recitation of intended use in the preamble:

Claim 1: A microarray for analysis of disease AB, the microarray having a probe to gene X.

EPO and JPO: the recitation of intended use may define a contribution over the prior art.

USPTO: the recitation intended use would not distinguish over a prior art microarray having probe to gene X if the prior art microarray could be used for the analysis of AB.

MPEP 2111.02 II: statements in the preamble reciting the purpose or intended use of the claimed invention must be evaluated to determine whether the recited purpose or intended use results in a structural difference (or, in the case of process claims, manipulative difference) between the claimed invention and the prior art.
Analysis of the Claims for Intended Use

- **Product Claims:**
  - Intended use preamble
  - Method steps reciting use

- **Method Claims:**
  - Intended use in preamble

EPO & JPO: recitations of intended use may define a contribution over the prior art.

USPTO: may reject as anticipated (MPEP 2111-2112).
Issue #3:

Inventive Step/Non-obvious
Issue #3: Inventive Step/Non-obvious

- EPO: Article 56: Inventive Step
  - Guidelines EPO C-IV 11.7
  - Problem and solution approach
    - An inventive step is rarely acknowledged for the provision of an alternative marker for a phenotype based on expression
  - Exception
    - Unexpected effect may provide inventive step
Issue #3: Inventive Step/Non-obvious

- JPO: Section 29(2): Inventive Step
  - Inventive step relative to prior art
  - Non-inventive
    - Ordinary creativity applied to prior art
    - Exception-
      - Advantageous effects relative to state of the art
Case 1: Provision of an expression marker, no prior art

- EPO, the solution (i.e. marker) would be considered routine screening. Not inventive because no problem is solved.

- JPO/USPTO, a new association between expression of marker and a disease might be considered inventive.
Issue #3: Inventive Step/Non-obvious

- Case 2: Claim not supported by specification
  - EPO, would object to the claim for lack of inventive step because the specification is insufficient to show that technical problem has been solved.
  - JPO/USPTO, would not raise the issue of lack of inventive step/obviousness based on non-supporting specification. The issues of support or enablement would be raised to address this issue.
Issue #3: Inventive Step/Non-obvious

Summary

- EPO- examination using problem-solution approach.
- JPO & USPTO- inventiveness based on prior art reference.
Issue #4:
Clarity/Support/Description
Issue #4: Clarity/Support/Description

- **EPO: Article 83: Sufficiency of Disclosure**
  - The European patent application must disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.

- **EPO: Article 84: Clarity and Support**
  - The claims shall define the matter for which protection is sought. They shall be clear and concise and be supported by the description.
JPO: Section 36(4): Description and Enablement

- The detailed description of the invention under the preceding Subsection (iii) shall state the invention, as provided for in an ordinance of the Ministry of Economy, Trade and Industry, in a manner sufficiently clear and complete for the invention to be carried out by a person having ordinary skill in the art to which the invention pertains.

JPO: Section 36(6): Clarity of Claims

- statements setting forth the invention for which a patent is sought and which is clear and concise;
Issue #4: Clarity/Support/Description

- EPO/JPO: Clarity
  - No meaningful search:
    - Claims lacking support or description
      - Broad claim, limited disclosure
    - Claims lacking conciseness
      - Large number of inventions within a claim
        - Unduly burdensome
        - Complete search impossible
    - Claims lacking clarity
      - No meaningful comparison to the prior art
        - Unknown parameter

EPO Guidelines: B, VIII 1-3
### Illustrative Examples

<table>
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<tr>
<th>Issue</th>
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<tr>
<td>Broad Claim, Limited Disclosure</td>
<td>Object No search</td>
<td>Refuse No Search</td>
<td>112, 1&lt;sup&gt;st&lt;/sup&gt;</td>
</tr>
<tr>
<td>Large Number of Inventions within Claim</td>
<td>Object No search</td>
<td>Refuse No Search</td>
<td>Possible Restriction</td>
</tr>
<tr>
<td><strong>Undue Burden or Complete Search Impossible</strong></td>
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<td></td>
</tr>
<tr>
<td>Claims lacking Clarity</td>
<td>Object No search</td>
<td>Refuse No Search</td>
<td>112, 2&lt;sup&gt;nd&lt;/sup&gt;</td>
</tr>
</tbody>
</table>
Future Goals

- Additional Examination Practice Issues for Microarrays
  - Unity of Invention/Restriction
  - Examination of Complex Applications
  - Claim Interpretation

- Final Report on Microarray Examination Practice

- Other Possible Goals
  - Expand Glossary of EPO/JPO/USPTO terms
  - Create Applicant’s Guide to Trilateral Filings
Trilaterial Resources

- Trilaterial website
  - Previous Examination Practice Reports
  - Glossary EPO/JPO/USPTO terms
  - Trililateral links & information

www.trilateral.net
Conclusion

- Thank-you to those who selected me.
- Special thank-you,
  - Julie Burke
  - Ram Shukla
  - Jeanine Goldberg
  - Sarae Bausch

BJ Forman, Ph.D.

Primary Examiner, Art Unit: 1634
571-272-0741