# Trilateral Examiner Exchange

## Biotechnology/Chemical/Pharmaceutical Customer Partnership

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Art Unit1634
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# 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.**

Trilateral Biotechnology Working Group Mandate 4-23-08

# 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

# Examiner Exchange

- **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

# Microarrays: Evolving Area

"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 Microarrys: History and Overview,**

**Humana Press, 2001.**

# 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

# Microarrays: Difficult to Examine

## 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

# Trilateral Examiner Exchange
## EPO-Munich, June 2008

### "Biotech Triplet"

Kenji Mihara

Henrik Knudsen

BJ Forman

# Articles/Sections of Respective Patent Laws

| | Patentable Subject Matter/ Statutory Invention | Industrial Applicability | Novelty | Inventive Step / Non-obvious | Enablement / Support / Written Description / Clarity |
|---|---|---|---|---|---|
| EPO | 52, 53 | 57 | 54 | 83,84 | 54,56 |
| JPO | 2(1) | 29(1) | 29(1) | 29(2) | 36(4)(6) |
| USPTO | 101 | 101 | 102 | 103 | 112 |

# 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

# 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.

# Issue #1: Patentable Subject Matter / Statutory Invention

- **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 Article29(1): Conditions for Patentability
  - An inventor of an invention that is industrially applicable may be entitled to obtain a patent for the said invention

# Issue #1: Patentable Subject Matter / Statutory 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

# Issue #1: Patentable Subject Matter / Statutory Invention

- **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

| | EPO | JPO | USPTO |
|---|---|---|---|
| In vitro Diagnosis of Humans | yes | no | yes |
| In vivo Diagnosis in Humans | no | no | yes |
| In vitro Diagnosis of Non-Human Animals | yes | yes | yes |
| In vivo Diagnosis in Non-Human Animals | no | yes | yes |
| Medical Treatment of Humans | no | no | yes |
| Medical Treatment of Animals | no | yes | yes |
| Kits or Compositions for Diagnosis or Treatment | yes | yes | yes |
| Gene Expression Profiles | no | no | no |
| Database e.g. sequence listing | no | no | no |
| Data Carrier e.g. signal | yes | no | no |

# 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.

# Issue #1: Patentable Subject Matter / Statutory Invention

## EPO

- 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.

# Issue #1: Patentable Subject Matter / Statutory Invention

## 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.

# Issue #1: Patentable Subject Matter / Statutory Invention

## USPTO

- 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: Nuitjen*.
  - 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

# Issue #1: Patentable Subject Matter / Statutory Invention-SUMMARY

- 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 mater
    - 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

| | EPO | JPO | USPTO |
|---|---|---|---|
| EPO | filing date | Pub. date | Pub. date |
| JPO | Pub. date | filing date | Pub. date |
| USPTO | Pub. date | Pub. date | filing date |

# Issue #2: Novelty

## 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.

# Issue #2: Novelty

## 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

# Issue #3: Inventive Step/Non-obvious

- 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.

# Issue #4: Clarity/Support/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

# Issue #4: Clarity/Support/Description

## Illustrative Examples

| | EPO | JPO | USPTO |
|---|---|---|---|
| Broad Claim, Limited Disclosure | Object<br>No search | Refuse<br>No Search | 112, 1st |
| Large Number of Inventions within Claim<br>Undue Burden or Complete Search Impossible | Object<br>No search | Refuse<br>No Search | Possible<br>Restriction |
| Claims lacking Clarity | Object<br>No search | Refuse<br>No Search | 112, 2nd |

# 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

# Trilateral Resources

- **Trilateral website**
  - Previous Examination Practice Reports
  - Glossary EPO/JPO/USPTO terms
  - Trilateral links & information

**www.trilateral.net**

# Conclusion

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