USPTO Examiner Initiatives: Compact Prosecution and Interview Practice

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Compact Prosecution

• Corps-Wide Initiative

• Goal: To give examiners the information and tools they need to reduce the amount of work and time that is required between the first action and final disposal (e.g., allowance, abandonment or appeal)

• Workshop: Best Practices in Compact Prosecution
Compact Prosecution Workshop

FY 2009
- Developed compact prosecution workshop for managers and primary examiners
- Focus on strategies to reduce the number of office actions:
  - Claim interpretation
  - Comprehensive searching
  - Clear and concise Office actions
  - Complete response to an applicant’s reply
  - Allowable subject matter identification early in prosecution

FY 2010
- Continue workshops for junior examiners
- Development of follow-up materials (e.g., a best practices brochure) from ideas captured in the workshops
Participants: 50 to 70 TC Examiners per session
Two hour, interactive workshop
Facilitated by TC 1600 Supervisory Primary Examiners (SPE) and Quality Assurance Specialists (QAS) as facilitators and session recorders
TC 1600 Group Director: Workshop Introduction
1. Workshop Introduction: Director’s Welcome
2. Compact Prosecution Review
3. Facilitated Focus Session:
   - Examiner Break Out to Consider Topics
   - Examiner Report Out
4. Wrap Up
“Compact Prosecution” is:

• Conducting a complete initial search

• Issuing a comprehensive first Office action:
  - Citing pertinent art
  - Identifying allowable subject matter
Compact Prosecution Workshop: Introduction

- **Important Results of Compact Prosecution:**

  - **Promotes USPTO Goals:**
    - Aids in promoting new “count system” changes, particularly relating to putting more effort upfront
    - Reduces prosecution “churning” and actions/disposal
    - De-incentivize practices leading to RCE filings

  - **Facilitates Examiner/Customer Relations:**
    - Identify allowable subject matter as early as possible
    - Incentivize discussions with applicants
    - Encourage discussion with colleagues about best practices
Compact Workshop: Introduction

• **Examiner Benefits:**
  - Higher quality office actions (saves time)
  - Higher production (potential bonus money)
  - Better performance rating
  - Increased examiner job satisfaction
Compact Workshop: Introduction

• **USPTO Benefits:**
  
  - Improved pendency
  - Increased quality and efficiency
  - Improved employee morale
  - Timely examination spurs innovation
Compact Workshop: Introduction

- **Applicant Benefits:**
  - Facilitates business decision whether to continue prosecution
  - Faster resolution of issues leading to either allowance, abandonment or appeal
  - Improved applicant satisfaction and trust
Compact Prosecution:
Examiner Role

• How can the Examiner Help?
  • Proper Claim Interpretation
  • Thorough Search
  • Clear and Concise First Action on the Merits (FAOM)
  • Complete Response to Applicant’s Reply
  • Expedite Prosecution (facilitate prompt resolution)
Compact Prosecution: Focus Session Questions

Focus Session Questions:

1. Name at least five ways proper claim interpretation aids compact prosecution

2. Identify at least five effective searching techniques that aid in compact prosecution

3. Identify steps that you can take to avoid making a 2nd action non-final rejection or reopening prosecution

4. In your art, how do you identify the allowable subject matter prior to a first action on the merits

5. What are the advantages in contacting the Attorney/Agent during prosecution
Compact Prosecution: Focus Session Report Out

• Each table of 5-7 examiners considers and discusses amongst themselves one of the questions
• An Examiner from each table “reports out” the answers to the question when called upon by the Supervisor
• Facilitator(s) lead interactive discussion
• Other tables participate and voice their own opinions regarding another table’s answers
• Recorder notes each table’s answers
Compact Prosecution: Focus Session Results - Question 1

Five ways proper claim interpretation aids compact prosecution:

- Ensures a clear understanding of the claim scope
- Facilitates identification of allowable subject matter
- Enables Examiner to cite most pertinent prior art
- Enables Examiner to formulate a clear, concise and complete Office action
- Minimizes time to reach disposal in the application
- Claim interpretation aided by early attorney interviews
Five effective searching techniques to aid compact prosecution:

- Outline a proposed field of search
- Search broad claims and preferred embodiment
- Search inventive concept based on the disclosure
- Review all evidence of record
- Leverage search help when needed
- Search relevant databases
- Perform an early comprehensive search
Steps to avoid making a 2\textsuperscript{nd} action non-final rejection or reopening prosecution:

• Conduct a thorough initial search
• Carefully diagram claims
• Restrict early in the prosecution, if necessary
• Determine whether any benefit or priority claims are proper especially for CIPs
• Review all formal matters and account for all claims
• Initiate telephone interviews to resolve issues
• Set forth all grounds of rejection in FAOM
How to identify allowable subject matter pre-FAOM:

- Review background and summary section of the specification for critical elements of the invention
- Review related applications to identify relevant previous claim limitations drawn to allowable subject matter
- Review working examples for evidence of:
  - enablement
  - secondary considerations (overcome obviousness rejection)
How to identify allowable subject matter pre-FAOM:

- Look for dependent claims that distinguish over the prior art
- Review specification for explanation or definition of claim terminology
- Review record evidence to decipher broadest reasonable claim interpretation and to avoid citing irrelevant prior art
- Discuss allowable subject matter with colleagues/managers to obtain consensus
- Provide suggestions to overcome a rejection
Advantages in contacting the Attorney/Agent during prosecution:

- Establish a working relationship with the attorney/agent
- Clear up any misunderstandings between the examiner and the attorney/agent
- Obtain a clearer understanding of Applicant’s invention and goals to aid search and consideration of art
- Attorney/Agent feedback regarding claim interpretation and the correction of minor claim informalities
- Early discussion of allowable subject matter
- Examiner willingness to “work with” the attorney
Compact Prosecution: Final Thoughts

- Carefully consider claim limitations
- Ensure a thorough and complete search
- Strive for concise and complete 1st Office actions:
  - Apply the best available art
  - Avoid cumulative rejections
- To clarify issues or expedite allowance, INITIATE A TELEPHONE INTERVIEW (requires Negotiation Authority)
Interview Practice Workshop: Topics

- Effective Interviews
- Reaching Agreement
- Requesting Interviews
- Issues Discussed
- Documenting Interviews
Effective Interview

• What makes an interview effective?
  • Preparation
  • Cooperation
  • Communication
Effective Interview

• Preparation
  – Use an Agenda (preferably PTOL-413A)
  – Review record in advance
  – Consult with SPE or Primary if needed
  – Any suggested claim language?
Effective Interview

• Cooperation
  – Keep an Open Mind
  – Positive attitude
  – Seek common ground
  – Work on claim language
Effective Interview

• Communication
  – Active Listening
    • Eye contact
    • Body language
    • Proper tone and volume
  – Stay focused on agenda
  – Seek common understanding
Effective Interview

• **Outcome**
  – Issues are resolved, reduced or clarified
  – Better Understanding
  • Applicant’s Position
  • Examiner’s Position
  • Claim interpretation
Effective Interview

• Benefits
  – Better Understanding
    • The Invention
    • Applicant’s Position
    • Examiner’s Position
    • Claim Interpretation
  – Advances / Promotes Compact Prosecution
    • Increases the chance of disposal in next Office action
Increase Allowances:

Percentage of a Disposal after a Non Final Rejection

- FY04: 69.6%
- FY05: 65.9%
- FY06: 60.8%
- FY07: 54.7%
- FY08: 40.2%

With interview Disposal vs Without interview Disposal
Effective Interview

• Challenges
  – Lack of Agenda
    • “Fishing” expedition
  – Unprepared party
    • Applicant / Representative
    • Examiner
  – Time Concerns
    • Scheduling
Effective Interview

• Suggested Sequence for an Effective Interview
  – Applicant / Representative explains invention
  – Discuss how inventive concepts are (or are not) set forth in the claim language
  – Discuss prior art and rejections
  – Discuss any proposed language (from either party)
  – Establish common ground
Reaching Agreement

• Agreement is reached
  • Allowance
  • Reduce # of rejections
  • Resolve other issues or formalities
  • “Agree-to-Disagree” on topics
  • Decide on next step
Interview Requests

- Inquire about the purpose/intent
- Request an agenda (PTOL-413A)
- Any proposed amendments
- MPEP 713 (Interviews)
Interview Requests

• When can an interview be helpful?
  – Before 1\textsuperscript{st} Action ? (see MPEP 713.02)
  – After 1\textsuperscript{st} Action ?
  – After Final ? (see MPEP 713.09)

• When can the Examiner deny an interview?
  – After Final (particularly after Appeal Brief filed)

• Before 1\textsuperscript{st} Action Interview Program (Pilot)
  – Workgroup 1610
Interview Requests

• Granting Interviews
  – Examiners are instructed:
    • To be Accessible
    • To be Flexible
    • To adjust work schedule (within reason)
    • To use multiple formats (phone / in-person)
    • To find a common time and place that works
  – We simply ask that Applicant/Representative do the same
Typical Interview Topics

- Overview of the invention
- State of the art
- Claim interpretation
- Prior Art used in rejections
- Language in proposed amendment
- 35 U.S.C. 101
- 35 U.S.C. 112(1), 112(2), 112(6)
Documenting Interviews

• Interview Summary (PTOL-413)
  – What to include?
    • Details (enough to clarify the record)
    • Claim limitations discussed
    • Claim interpretation issues
    • Details of proposed amendment
    • Agenda Items
      – Topics resolved (agreed to)
      – Topics unresolved (not agreed to)
• What makes a discussion an “interview”?  
  – Any discussion that touches on the merits of the case (claim language, prior art analysis, clarification of a rejection, etc.)

• Prosecution “Off the Record” is Discouraged

• Note MPEP 713.04, 502.01 (fax), 502.02 (e-sig), & 502.03 (email)
First Action Interview Pilot Program

- Pilot Program Objectives:
  - Promote personal interviews prior to issuance of a first Office action on the merits
  - Advance examination of applications once taken up in turn
  - Facilitate resolution of issues for timely disposition of an application
First Action Interview Pilot Program

- Utility applications assigned to Workgroup 1610 filed on or before November 1, 2006
  - Including national stage applications under 35 USC 371
  - Excluding reissue applications

- The application contains:
  - No more than three independent and twenty total claims;
  - No multiple dependent claims

- The request to participate in the pilot program must be filed before the mailing of a first Office action on the merits (current pilot ends 9/30/2010)

- If restricted, election must be without traverse
First Action Interview Pilot Program

1st Action Interview Request

Improper Request

Pre-Interview Communication

Letter Requesting no Interview Request

Applicant Initiated Interview Request

Interview

Interview Summary

First-Action Interview Office Action

FOAM*

FOAM*

Amendment - Case returns to normal processing

Applicant

USPTO

Applicant

Applicant & USPTO

USPTO

Applicant

30 days

60 days

30 days

30 day extension available

* FAOM – first action on the merits
# Pre-Interview Communication

## Example 1

<table>
<thead>
<tr>
<th>#</th>
<th>Claim(s)</th>
<th>Reference(s) (if applicable)</th>
<th>Rejection Basis</th>
<th>Brief Explanation of Potential Rejection</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1-8</td>
<td>101</td>
<td>Legacy Binary Instructions</td>
<td>Claim 1 recites a binary translator with various components. The binary translator as claimed is software per se and software is not considered patentable subject matter. Claims 2-6 depend on 1 and do not include hardware so as to overcome the rejection.</td>
</tr>
<tr>
<td>2</td>
<td>1,8</td>
<td>112, 1st</td>
<td>Legacy Binary Instructions</td>
<td>Claim 1 recites the limitation of &quot;legacy disabled legacy binary instructions with native instructions.&quot; However, according to the specification, a core 5, lines 1-5, used to disable...insert new related instructions without... (see continuation below).</td>
</tr>
<tr>
<td>3</td>
<td>1,5, 7, 8</td>
<td>103(b)</td>
<td>Legacy Binary Instructions</td>
<td>Claim 1 (Figure 1, 1st para, 3rd para, Section 1.1 Components, 4th 85th paragraph - note the claims &quot;prevent[ing] access&quot; is interpreted as the CPU in fig. 11, 2 (Fig. 1), 3 (Section 3.1, 8th para); 4 (section 4.2, para 9 - note this... (see continuation below).</td>
</tr>
<tr>
<td>4</td>
<td>E</td>
<td>U.V.</td>
<td>Legacy Binary Instructions</td>
<td>U,V does not disclose what native instruction processor as claimed. U,V disclose this at section 2.1, 2nd paragraph. As one would understand to have better code for hot spots in order to improve performance (see U, section 2.1, it would have... (see continuation).</td>
</tr>
</tbody>
</table>

## Expanded/Supplementary Commentary

2. altering the original legacy instructions. Thus, the specification does not disclose replacing disabled legacy binary instructions. On the contrary, the specification specifically discloses not altering the original legacy binary instructions. The claim limitation of claim 1 contradicts with what the disclosure describes. Thus, this subject matter was not described in the specification in such a way to enable one skilled in the art to make and use the invention without undue experimentation.

3. section states that "any kind of memory can be used". 5 (Section 3.1 5th para); Claim 7 (Section 3, Mersenneable and Mersenneable Binary Translator) 8 (Section 3.1, 4th para).

4. been obvious to include the native instruction processor in the system described in V.

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**DATE:**

**Examiner Signature:**

**Primary Examiner Signature:**
Thank You!

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Examination of Claims containing Biological Sequences

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Technology Center 1600
Sequence Rules Compliance

• When an application discloses a nucleotide or an amino acid sequence anywhere in the application including specification, drawings, abstract
  – the nucleic acid sequence is a specific unbranched sequence of 10 or more nucleotides
  – the amino acid sequence is a specific unbranched sequence of 4 or more amino acids

• The application must be comply with the sequence rules (37 CFR 1.821-1.825)
  – See MPEP 2422 for Sequence Compliance Requirements
Incorporation by Reference

- 37 CFR 1.57 - 69 FR 56482 (Sept. 21, 2004); 1287 OG 67 (Oct. 12, 2004)

- 37 CFR 1.57(b) - an incorporation by reference must be set forth in the specification
  – must express a clear intent to incorporate by reference by using the root words “incorporat(e)” and “reference” (e.g., “incorporate by reference”); and
  – clearly identify the referenced patent, application, or publication

- 37 CFR 1.57(c) - essential material may be incorporated by reference, but only by way of an incorporation by reference to a U.S. patent or U.S. patent application publication, which patent or patent application publication does not itself incorporate such essential material by reference

- 37 CFR 1.57(g) - a correction is permitted only if the application as filed clearly conveys an intent to incorporate the material by reference
  – mere reference to material does not convey an intent to incorporate the material by reference
  – correction is only permitted for material that was sufficiently described to uniquely identify the document
Incorporation by Reference

What is Clear Intent?

• In making the determination of clear intent the examiner will consider
  – language used in referencing the sequence
  – the context in which it is disclosed
  – any additional arguments/evidence presented by applicants

• An original claim that identifies a sequence by database accession number will usually be accepted as clear intent to incorporate the sequence by reference

• Language identifying a source only in passing as other prior work of no identified relevance is unlikely to be considered as clear intent of incorporation by reference
When is a sequence uniquely identified?

- References to sequences by database accession or identification numbers may or may not uniquely identify a sequence
  - a sequence which has only one version submitted prior to the filing date may be considered uniquely identified

- In GenBank®
  - the accession number identifies the nature of the sequence and does not vary with different versions of the actual sequence that may change over time
  - “g” number (or version number) identifies the specific sequence and is unique to any specific sequence
  - look to the “Reports” link to determine the presence of multiple versions and to compare changes made
Example 1: Effective Incorporation of Essential Material

Claim 1. Isolated Protein ABC.

The amino acid sequence of Protein ABC is considered essential material because it is necessary to meet the requirements of 35 U.S.C. 112, 1st and 2nd paragraphs. 37 CFR 1.57(c).

Upon review, the examiner noticed that the specification did not include the amino acid sequence for Protein ABC. However, the specification included the following statement:

“The amino acid sequence of Protein ABC has been disclosed as SEQ ID No 1 in U.S. Patent 6,123,456 and is hereby incorporated by reference.”

U.S. Patent 6,123,456 contains SEQ ID No 1. The requirements of 37 CFR 1.57 are met.
Example 2: Ineffective Incorporation of Essential Material

Original Claim 1. Isolated Protein ABC.

Upon review, the examiner noticed that the specification did not include the amino acid sequence for Protein ABC. However, the specification included the following statement:

“The amino acid sequence of Protein ABC has been disclosed as SEQ ID No 1 in U.S. Patent 6,123,456.”

The statement does not use the root words “incorporat(e)” and “reference”

The examiner uses FP 6.19.01 to require applicants to comply with 1.57(b)(1) and makes any corresponding rejections under 112, 1st, paragraph.
Example 2: Ineffective Incorporation of Essential Material

Because Protein ABC is recited in an original claim, applicant may comply with 1.57(b)(1) by amending the specification under 1.57(g) as follows:

“The amino acid sequence of Protein ABC has been disclosed as SEQ ID No 1 in U.S. Patent 6,123,456 and is hereby incorporated by reference.”

Applicant must also respond to any other rejections or objections.

Best Practice Tip for Applicants: Amend the specification to include SEQ ID No 1 and comply with the sequence requirements.
Example 3: Incorporation of Essential Material

Claim 1. An isolated nucleic acid molecule encoding Protein ABC.

The amino acid sequence of Protein ABC is considered essential material because it is necessary to meet the requirements of 35 U.S.C. 112, 1st paragraph. 37 CFR 1.57(c).

Upon review, the examiner noticed that the specification did not include sequence for Protein ABC or for nucleic acid molecule which encoded Protein ABC.

However, the specification included an incorporation by reference statement incorporating essential material submitted at GenBank®.

“The Protein ABC is encoded by the sequence of Gene ABC, which has been submitted at GenBank® under Accession Number X-12345 and is incorporated by reference.”
Example 3: Incorporation of Essential Material

Only one version of the sequence has been submitted under Accession Number X-12345 prior to the filing date.

In an Office action, the examiner used FP 6.19 to require applicants to comply with 1.57(c) by

- providing a copy of the essential material,
- amending the specification to include the essential material,
- providing a statement under 1.57(e) and/or (f).

If applicant adds the sequence, Applicant should also comply with the sequence requirements 37 CFR 1.821-1.825. Applicant should respond to any corresponding rejections under 112, 1st.
Example 4: Non-essential Material Becomes Essential

Upon review of the specification, the examiner determined that the subject matter incorporated by reference to a sequence submitted to GenBank was “non-essential material” and therefore, did not object to the incorporation by reference.

In reply to a non-final Office action, applicant filed an amendment to the claims to add a new limitation that was supported only by the GenBank deposit.

The amendment filed by the applicant caused the examiner to re-determine that the incorporated subject matter was “essential material” under 37 CFR 1.57(c). The examiner rejected the claims that include the new limitation under 35 U.S.C. 112, first paragraph, in a final Office action. FP 6.19 was also included in the Office action.
Example 4: Non-essential Material Becomes Essential

Because the rejection under 35 U.S.C. 112, first paragraph was necessitated by the applicant’s amendment, the finality of the Office action is proper.

If the applicant wishes to overcome the rejection under 35 U.S.C. 112, first paragraph by filing an amendment under 37 CFR 1.57(f) to add the subject material disclosed in the GenBank into the specification, applicant may file the amendment as an after final amendment in compliance with 37 CFR 1.116.

Alternatively, applicant may file an RCE under 37 CFR 1.114 accompanied by the appropriate fee, and an amendment per 37 CFR 1.57(f) within the time period for reply set forth in the final Office action.
Upon review of the specification, the examiner noticed that the specification included an incorporation by reference statement incorporating essential material available at a website.

“The sequence has been submitted to www.geneseq.com.”

Because the source material exists on a hyperlink or other form of browser executable code, incorporation by reference is not permitted. See 37 CFR 1.57(d). The examiner would reject the claims under 35 USC 112, first paragraph. Applicant may incorporate by reference the sequence submitted to a website by

- providing a copy of the essential material,
- amending the specification to include the essential material,
- providing a statement under 1.57(e) and/or (f).
Highlights and Guidance

- Submit the sequence at time of filing

- Be specific as to version or use identifier unique to specific sequence

- Retain documentation of database source indicating exact sequence and date accessed
Official Gazette Notice 27 March 2007 rescinded the partial waiver of

• 37 CFR 1.141 et seq. for restriction practice in national applications filed under 35 U.S.C. 111(a), and

• 37 CFR 1.475 et seq. for unity of invention determinations in both PCT international applications and the resulting national stage applications under 35 U.S.C. 371.
For National applications filed under 35 U.S.C. 111(a), in accordance with MPEP Chapter 800, polynucleotide inventions will be considered for

- restriction,
- rejoinder and
- examination practice.

As for other type of molecule, claims to polynucleotide molecules will be considered for

- independence,
- relatedness,
- distinction and
- burden.
Restriction

For International applications and national stage filings of international applications under 35 U.S.C. 371, unity of invention will be determined in view of:

- PCT Rule 13.2,
- 37 CFR 1.475 and
- Chapter 10 of the ISPE Guidelines.

In general, polynucleotide molecules, as claimed, must share a technical feature which makes a contribution over the prior art.
Claim Interpretation

- “Comprising”
  - permits additional nucleic acids at either end of the sequence
  - includes plural species

- “Consisting essentially of”
  - permits additional nucleic acids at either end of the sequence, unless explicitly defined otherwise in specification
  - includes plural species

- “Consisting of”
  - prevents additional nucleic acids at either end of the sequence
  - generally claims a single fully defined sequence
  - the sequence listing permits use of variables which include upon more than one nucleotide
Example of a combination claim:

**Claim 1.** A kit comprising primers having SEQ ID NO: 1-100.

Example of a claim that uses alternative language to enumerate species, i.e., a Markush claim:

**Claim 2.** A primer selected from the group consisting of SEQ ID NO: 1-100.
Claim 1. An isolated nucleic acid comprising SEQ ID NO: 1.

Claim 2. An isolated nucleic acid encoding a protein having SEQ ID NO: 2.

The specification discloses a nucleic acid comprising SEQ ID NO: 1 which contains the open reading frame for a protein having SEQ ID NO: 2.

Claims 1 and 2 are not distinct from each other because the claims merely define the nucleic acid using different limitations.

Restriction between Claims 1 and 2 would not be appropriate.
Example II: When sequences fully overlap

Claim 1. An isolated nucleic acid molecule comprising SEQ ID NO: 1.
Claim 2. An isolated nucleic acid molecule comprising SEQ ID NO: 2.
Claim 3. An isolated nucleic acid molecule comprising SEQ ID NO: 3.

SEQ ID NO: 1:ATGTGCGATA
SEQ ID NO: 2:ATGTGCGATA ATCTG
SEQ ID NO: 3:ATGTGCGATA ATCTGTTATA

Because nucleic acid molecules comprising SEQ ID NO: 1, 2 and 3 are not distinct as claimed, from each other, restriction to a single sequence of SEQ ID NO: 1, 2 and 3 would not be proper.
Practice Tip: To highlight the common region, consider providing a sequence alignment or using this claim format to refer to a single sequence:

Claim 1. An isolated nucleic acid molecule comprising residues 1-10 of SEQ ID NO: 3.

Claim 2. An isolated nucleic acid molecule comprising residues 1-15 of SEQ ID NO: 3.

Claim 3. An isolated nucleic acid molecule comprising SEQ ID NO: 3.
Example III: A Combination Claim

Claim 1. A kit comprising primers having SEQ ID NO: 1-100.

A combination of nucleotide molecules will generally not be subject to a restriction requirement.

The presence of one novel and nonobvious sequence within the combination will render the entire combination novel and nonobvious.

The combination will be searched until one nucleotide sequence or a combination of nucleotide sequences is found to be allowable.

The order of searching will be chosen by the examiner to maximize the identification of an allowable sequence(s).

If no individual nucleotide sequence or subset of sequences is found to be allowable, the examiner will consider whether the entire combination of sequences taken as a whole renders the claim allowable.
Claim 1. An isolated nucleic acid comprising SEQ ID NO: 1.
Claim 2. An isolated nucleic acid comprising SEQ ID NO: 2.

The specification teaches that
SEQ ID NO: 1 encodes a ribosomal protein and
SEQ ID NO: 2 encodes an enzyme.

Claim 1 and 2 are distinct from each other because:

Claim 1 and 2 requires the mutually exclusive characteristics of each individual sequence which is not encompassed by the other sequence

Examination of Claim 1 and 2 would be burdensome because each sequence requires a different search query and prior art teaching one sequence is not likely to teach another sequence.

Restriction between the nucleic acid molecules comprising SEQ ID NO: 1 and SEQ ID NO: 2 is proper.
Claim 1. An isolated nucleic acid consisting of SEQ ID NO: 1.

The sequence listing shows that SEQ ID NO: 1 is ATGSTAMATR, where

- S is G or C,
- M is A or C and
- R is G or A.

SEQ ID NO: 1 encompasses eight patentably distinct sequences:

- ATGGTAAATG
- ATGGTAAATAATGCTAAATG
- ATGCTAAATAATGGTACATG
- ATGGTACATAATGCTACATG
- ATGCTACATA

In this situation, the examiner may require an election of species using FP 8.02, generic claim encompasses the disclosed species.
Linking Claims

• Definition: A linking claim is a claim which, if allowable, would prevent restriction between two or more otherwise properly restrictable inventions.

• Most common types of linking claims are
  – A genus claim linking species claims or
  – A subcombination claim linking plural combinations

• Restriction can be required when there are linking claims and claims to distinct inventions.

• If a linked invention is elected, the linking claims are examined with the elected invention.

• If a linking claim is found allowable, the restriction requirement must be withdrawn and all linked inventions examined for patentability.

MPEP 809 and 809.03.
Linking Claims

Dependent Claims that refer to the linked inventions in the alternative are not linking claims.

A linking claim must be broader in scope than all the linked inventions.

A dependent claim which refers to two or more restrictable independent claims in the alternative is not a “linking claim.”
Claim 1. An isolated nucleic acid having SEQ ID NO: 1.

Claim 2. An isolated nucleic acid having SEQ ID NO: 2.

Claim 3. A vector comprising the nucleic acid of claim 1 or claim 2.

Claim 4. A host cell comprising the vector of claim 3.
A linking claim must be broader in scope than the linked claims.

Claims 3 and 4 are NOT linking claims because claims 3 and 4 are narrower in scope than claims 1 and 2.

The claims may be grouped as follows:

   Group I, claim 1, and claims 3 and 4, in part, drawn to nucleic acid, vector and host cell having SEQ ID NO: 1.

   Group II, claim 2 and claims 3 and 4, in part, drawn to nucleic acid, vector and host cell having SEQ ID NO: 2.
Searching Sequences

Smith-Waterman Analysis –

- Finds an optimal local alignment between two protein (p2p) or two nucleic (n2n) sequences.

- Uses a two-dimensional matrix to look for the highest scoring alignment.

- Similarity score is calculated based on:
  - Comparison matrix: provides probability scores for all substitutions between pairs of residues.
  - Gap penalties: cost of inserting or deleting residues in the alignment.

- There are two gap penalty models:
  - Non-affine: a single gap penalty value is applied to any unmatched residue.
  - Affine: a penalty for a gap is calculated as $gapop + gapext \times l$, where $gapop$ is the penalty for opening a gap, $gapext$ is the penalty for extending the gap, and $l$ is the length of the gap.

Searching Sequences

• Query using the full length of the SEQ ID NO (up to 10 Kb in size)
  – useful for finding full length hits
  – hit size could be limited to a size range by requesting a “length-limited” search (range provided by the examiner)
  – the search parameters are the default parameters - Gap Opening Penalty 10 & Gap Extension Penalty of 1
Searching Sequences

• Interpretation of the search results is needed to find fragments and genomic sequences
  – Fragments are buried in the hit list
  – The presence of introns in the database sequence results in low scores
Searching Sequences

• For a large sequence, 10 kb or greater, multiple large subsections of the sequence are used as a query to search the databases

• For a genomic sequence,
  – If exons and their boundaries are known, several exons are searched
  – If exons are not known, multiple large subsections of the sequence are used as a query to search the database
Searching Sequences

• Publically Available Databases for Nucleic Acid Sequences
  – GenEMBL
  – N_Genseq
  – Issued_Patents_NA
  – EST
  – Published_Applications_NA
Searching Sequences

- Publically Available Databases for Protein Sequences
  - A-Geneseq
  - UniProt
  - PIR
  - Published_Applications_AA
  - Issued_AA
Searching Sequences

• USPTO Databases Searched at Allowance
  – Published_Applications_NA
  – Issued_NA
  – Pending_Applications_NA
  – Published_Applications_AA
  – Issued_AA
  – Pending_Applications_AA
Claim 1

• Claim:
  – An isolated polynucleotide comprising SEQ ID NO:1.

• Claim Interpretation:
  – Comprising: must have all of SEQ ID NO:1, may include any flanking sequences, as in the claim above
  – Consisting of: limited to only SEQ ID NO:1, with No flanking sequences

• Search Strategy:
  – A standard search looking for full length hits
Claim 2

- **Claim:**
  - An isolated polypeptide comprising SEQ ID NO: 2.

- **Claim Interpretation:**
  - Comprising: must have all of SEQ ID NO:2, may include any flanking sequences, as in the claim above
  - Consisting of: limited to only SEQ ID NO:2, with No flanking sequences

- **Search Strategy:**
  - A standard search looking for full length hits is performed in all the amino acid databases
Claim 3

• Claim:
  – An isolated polynucleotide comprising a nucleotide sequence of SEQ ID NO:1.

• Claim Interpretation:
  – This claim includes any fragment of SEQ ID NO:1 due to the language “--a nucleotide sequence of--”
    – This could be obviated by amending to read “--the nucleotide sequence of--”

• Search Strategy:
  – A standard nucleotide sequence search as well as a standard oligomer search is performed using SEQ ID NO:1 as a query
Claim 4

• Claim:
  – An isolated polynucleotide comprising a polynucleotide with at least 90% identity over its entire length to SEQ ID NO:1.

• Claim Interpretation:
  – This claim encompasses any sequence that has 90% or higher sequence identity over its entire length to SEQ ID NO:1

• Search Strategy
  – A standard search looking for full length hits performed
  – Hits having at least 90% identity will appear in the results
Claim 5

• Claim:
  – An isolated polynucleotide comprising a polynucleotide encoding the amino acid sequence of SEQ ID NO:2.

• Claim Interpretation:
  – The claim encompasses any polynucleotide that encodes the polypeptide of SEQ ID NO:2

• Search Strategy:
  – SEQ ID NO:2 is “back translated” into a nucleic acid sequence, which is used as a query to search the nucleic acid databases
Claim 6

• Claim:
  – An isolated polynucleotide comprising a polynucleotide which hybridizes under stringent conditions to SEQ ID NO: 1.

• Claim Interpretation:
  – Claim is interpreted as including any sequence with less than 100% complementarity or identity to SEQ ID NO:1

• Search Strategy
  – A standard oligomer search as well as a standard search is performed
Claim 7

• Claim:
  – An isolated polynucleotide comprising at least 15 contiguous nucleotides of SEQ ID NO:1.

• Claim Interpretation:
  – The claim embraces any fragment of 15 nucleotides or greater of SEQ ID NO:1

• Search Strategy:
  – A standard oligomer search is performed with a length of 15 nucleotides set as the lower limit for a hit
Claim 8

• Claim:
  – An isolated polypeptide comprising at least 15 contiguous amino acids of SEQ ID No:2.

• Claim Interpretation:
  – The claim embraces any fragment of 15 amino acids or greater of SEQ ID NO:2

• Search Strategy:
  – A standard oligomer search is performed with a length of 15 amino acids set as the lower limit for a hit
Claim 9

- Claim:
  - An oligonucleotide consisting of 8 to 20 nucleotides which specifically hybridizes to the nucleic acid sequence of SEQ ID NO:1.

- Claim Interpretation:
  - The specification teaches that oligonucleotides which specifically hybridize need not have 100% sequence correspondence

- Search Strategy
  - A Score/Length search is performed with 8 and 20 as lower and upper limits respectively
Claim 10

• Claim:
  – A nucleic acid comprising SEQ ID NO:1 where the nucleotide at position 101 is a T.

• Claim Interpretation:
  – The Claim encompasses any sequence comprising SEQ ID NO:1, with a T at position 101

• Search Strategy:
  – A standard nucleotide sequence search is performed for SEQ ID NO:1
  – The examiner manually searches for any changes at position 101
Examination Guidelines

• http://www.uspto.gov/patents/law/exam/examguide.jsp
  – Utility
  – Written Description
  – Obviousness
Thank You!

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Obviousness Post-KSR:
An Unpredictable Season?

Jean C. Witz
Quality Assurance Specialist
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Cases Post-KSR

- Takeda Chemical Industries v. Alphapharm Pty, Ltd., 492 F.3d 1350, 83 USPQ2d 1169 (Fed. Cir. 2007)
- Pharmastem Therapeutics, Inc. v. Viacell, Inc., 491 F.3d 1342, 83 USPQ2d 1289 (Fed. Cir. 2007)
- Forest Laboratories v. Ivax Pharmaceuticals, 501 F.3d 1263, 84 USPQ2d 1099 (Fed. Cir. 2007)
Cases Post-KSR

- Daiichi Sankyo Co. v. Apotex, Inc., 501 F.3d 1254, 84 USPQ2d 1285 (Fed. Cir. 2007)
- Aventis v. Lupin, 499 F.3d 1293, 84 USPQ2d 1197 (Fed. Cir. 2007)
- McNeil-PPC, Inc. v Perrigo Company, 443 F. Supp. 2d 492 (S.D. N.Y. June 5, 2007), aff’d by Fed. Cir. in April 2008 without published decision
Cases Post-KSR

• In re Omeprazole Patent Litigation, 490 F. Supp. 2d 381 (S.D. N.Y. June 1, 2007), aff’d by Fed. Cir. in June 2008 in a non-precedential decision

• Ortho-McNeil v. Mylan, 520 F.3d 1358, 86 USPQ2d 1196 (Fed. Cir. 2008)

• Eisai v. Dr. Reddy’s, 533 F.3d 1353, 87 USPQ2d 1452 (Fed. Cir. 2008)
Cases Post-KSR

• Sanofi-Synthelabo v. Apotex, 550 F.3d 1075, 89 USPQ2d 1370 (Fed. Cir. 2008)
• Boston Scientific Scimed v. Cordis, 554 F.3d 982, 89 USPQ2d 1704 (Fed. Cir. 2009)
• In re Kubin, 561 F.3d 1351, 90 USPQ2d 1417 (Fed. Cir. 2009)
• Procter & Gamble v. Teva, 566 F.3d 989, 90 USPQ2d 1947 (Fed. Cir. 2009)
• Bayer Schering v. Barr, 575 F.3d 1341, 91 USPQ2d 1569 (Fed. Cir. 2009)
Takeda v. Alphapharm

- Claim – piaglitazone (anti-diabetic compound)

- Prior Art – another TZD compound varying via homologation and ring-walking
Takeda v. Alphapharm

• Court’s Rationale
  – No “finite number of identifiable, predictable solutions”
  – Prior art provided “broad selection of compounds”
  – Closest prior art compound exhibited negative properties

• Holding
  – Patent not invalid – compound unobvious
Pharmastem v. Viacell

• Claim – umbilical cord hematopoietic stem cells

• Prior Art – recognized presence and potential use of stem cells in umbilical cord blood
Pharmastem v. Viacell

Court’s rationale
- Could not reconcile expert testimony with statements in the specification
- Did not agree with expert that art terminology was “flawed”
- Prior art references to “stem cells” were consistent with Applicants’ statements in the specification
- Citing KSR, determined that invention was confirmation of what was already believed to be true

• Holding
  - Patent invalid - composition obvious
Forest v. Ivax

- Claim – substantially pure S enantiomer of escitolopram
- Prior Art – racemate of escitolopram
Forest v. Ivax

• Court’s Rationale
  – Evidence of failure of others to separate the enantiomers permitted conclusion that prior art reference was not enabling with regard to the suggestion to isolate the (S) enantiomer

• Holding
  – Patent not invalid – compound unobvious
Daiichi Sankyo v. Apotex

• Claim – treatment of otopathy with ofloxacin

• Prior Art – treatment of otopathy with ciprofloxacin
Daiichi Sankyo v. Apotex

• Court’s Rationale
  - District Court erred in the determination of the level of skill
  - By finding the level of skill in the prior art to be too high, prior art teaching was dismissed by the District Court

• Holding
  - Patent invalid - method obvious
Aventis v. Lupin

- Claim – substantially pure 5S stereoisomer of ramipril

- Prior Art – racemate separation and similar activity of related compounds
Aventis v. Lupin

• Court’s Rationale
  – Obviousness flowed from recognition of the properties of similar prior art compounds combined with recognition of the presence of the claimed isomer in the prior art mixture

• Holding
  – Patent invalid – compound obvious
McNeil v. Perrigo

- Claim – coated famotidine combined with antacids (Pepcid Complete®)

- Prior art – uncoated famotidine and antacids and conventional coating techniques
• Court’s Rationale
  - The combination of coated famotidine and the antacids provided no more than predictable results, citing KSR
  - Costs alone are not indicative of non-obviousness

• Holding
  - Patent invalid – formulation obvious
In re Omeprazole

- Claims – omeprazole (Prilosec®) with a subcoating and enteric coating

- Prior Art – omeprazole and subcoating techniques
In re Omeprazole

- Court’s Rationale
  - References taught away from subcoated formulation
  - Expert testimony of “multitude of possible paths and dead-ends” in formulation attempts

- Holding
  - Patent not invalid – formulation unobvious
Score at Half-Time

• Unobvious: 3
• Obvious: 4
• Claim
  - Topirimate (Topomax®)

• Prior Art
  - Materials produced during discovery indicating inventor interest in preparing FBPase inhibitors as useful in controlling blood glucose levels in diabetic patients
• **Court’s Rationale**
  - a person of ordinary skill would have to
    • start with 2,3:4,5 di-isopropylidene fructose (DPF)
    • have some reason to select the exact route that produced topiramate as an intermediate
    • stop at that intermediate and test it for properties far afield from the purpose for the development in the first place (diabetes)

• **Holding**
  - Patent not invalid – compound unobvious
Esai v. Dr. Reddy’s

- Claim
  - Rabeprazole and its salts (Aciphex®)

- Prior Art
  - Lansoprazole
  - Omeprazole
  - Review article of class of compounds of which all three compounds are a member having anti-ulcerative activity
Esai v. Dr. Reddy’s

• Court Rationale
  – No reason for a skilled artisan to begin with lansoprazole only to drop the very feature, the fluorinated substituent, that gave an advantageous property

• Holding
  – Patent not invalid – compound unobvious
Sanofi-Synthelabo v. Apotex

• Claim
  - Hydrogen sulfate of the D isomer of clopidegrel substantially separated from the L isomer (Plavix®)

• Prior Art
  - Patent to the racemate
Sanofi-Synthelabo v. Apotex

• Court Rationale
  - A person of ordinary skill would not have had the expectation that separating the enantiomers would be likely to produce an isomer having absolute stereoselectivity as to the favorable antiplatelet activity and lacking the unfavorable neurotoxicity

• Holding
  - Patent not invalid – compound unobvious
Boston Scientific v. Cordis

• Claim
  - An implantable metallic stent covered with a coating containing a biologically active material comprising an undercoat incorporating the biological material and a non-thrombogenic topcoat substantially free of an elutable material

• Prior Art
  - Patent disclosed two separate embodiments next to each other in the same figure, each with different combinations of elements all present together in the claimed stent
Boston Scientific v. Cordis

- Court’s Rationale
  - Even though identified as separate embodiments, the immediate juxtaposition of the two embodiments would have suggested a third embodiment with all the elements

- Holding
  - Patent invalid – device obvious
In re Kubin

- **Claim**
  - An isolated nucleic acid molecule comprising a polynucleotide encoding a polypeptide at least 80% identical to amino acids 22 – 221 of SEQ ID NO: 2, wherein the polypeptide binds CD48

- **Prior Art**
  - Reference disclosed p38 protein (same protein as NAIL) and methods of isolation by using mAbs as well as methods of obtaining the polynucleotide sequence but does not disclose the sequence of p38
  - Reference disclosed the nucleic acid sequence of the highly conserved murine version of p38 and identified a human homologue
In re Kubin

• Court’s Rationale
  - Appellants used conventional techniques to isolate a gene sequence for NAIL
  - Claim required only finding a gene sequence within the genus claimed

• Holding
  - BPAI affirmed – compound obvious
• Claim
  - Risedronate (Actonel®)

• Prior Art
  - Prior patent to P&G identifies 36 polyphosonates as treatment candidates, and 8 preferred compounds including 2-pyr EHDP
Procter & Gamble v. Teva

• Court’s Rationale
  – No direction to identify closest structure as lead compound
  – Unpredictability of bisphosphonate characteristics
  – Secondary indicia outweighed any assertion of obviousness

• Holding
  – Patent not invalid – compound unobvious
• Claim
  - Oral contraceptive containing micronized drospirenone (Yasmin®)

• Prior Art
  - Drospirenone was known as a poorly water-soluble, acid-sensitive compound with contraceptive effects
  - Micronization improves the solubility of poorly water soluble drugs
Bayer Schering v. Barr

- Court’s Rationale
  - The prior art would have funneled the formulator toward two options (enteric coating and micronization) who would not have been required to try all possibilities in a field unreduced by the prior art
  - The prior art was not vague in pointing toward a general approach or area of exploration, but rather guided the formulator precisely to the use of either a normal pill or an enteric-coated pill

- Holding
  - Patent invalid – formulation obvious
Final Score

- Unobvious: 7
- Obvious: 7
• When inconsistencies occur between the specification and other evidence, the specification may be considered to be more probative

• Arguments that the prior art is above the level of ordinary skill may not be persuasive

• Scope of claim impacts a finding of obviousness
• Context of disclosures in a prior art document may suggest an obvious embodiment.

• Recognition that stereoisomers may exhibit different properties may not be sufficient evidence of obviousness if prior art does not teach which results may ensue or how to separate any given enantiomer.
Highlights and Guidance

• Structural relationships often provide the requisite motivation to modify known compounds to obtain new compounds.

• An obviousness rationale based on structural similarity may depend on a preliminary finding that one of ordinary skill in the art would have selected the prior art compound as a lead compound.
Highlights and Guidance

• Obvious To Try

  - An invention would not have been obvious to try when the inventor would have had to try all possibilities in a field unreduced by direction of the prior art (Bayer v. Barr at 1347)

  - When “what would have been 'obvious to try' would have been to vary all parameters or try each of numerous possible choices until one possibly arrived at a successful result, where the prior art gave either no indication of which parameters were critical or no direction as to which of many possible choices is likely to be successful,” an invention would not have been obvious. (Bayer v. Barr at 1347)
• Obvious To Try
  – An invention is not obvious to try where vague prior art does not guide an inventor toward a particular solution (Bayer v. Barr at 1347)

  – A finding of obviousness would not obtain where "what was 'obvious to try' was to explore a new technology or general approach that seemed to be a promising field of experimentation, where the prior art gave only general guidance as to the particular form of the claimed invention or how to achieve it" (Bayer v. Barr at 1347)
Thank You!

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