

PRACTICAL CONSIDERATIONS IN RESTRICTION PRACTICE

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Topics

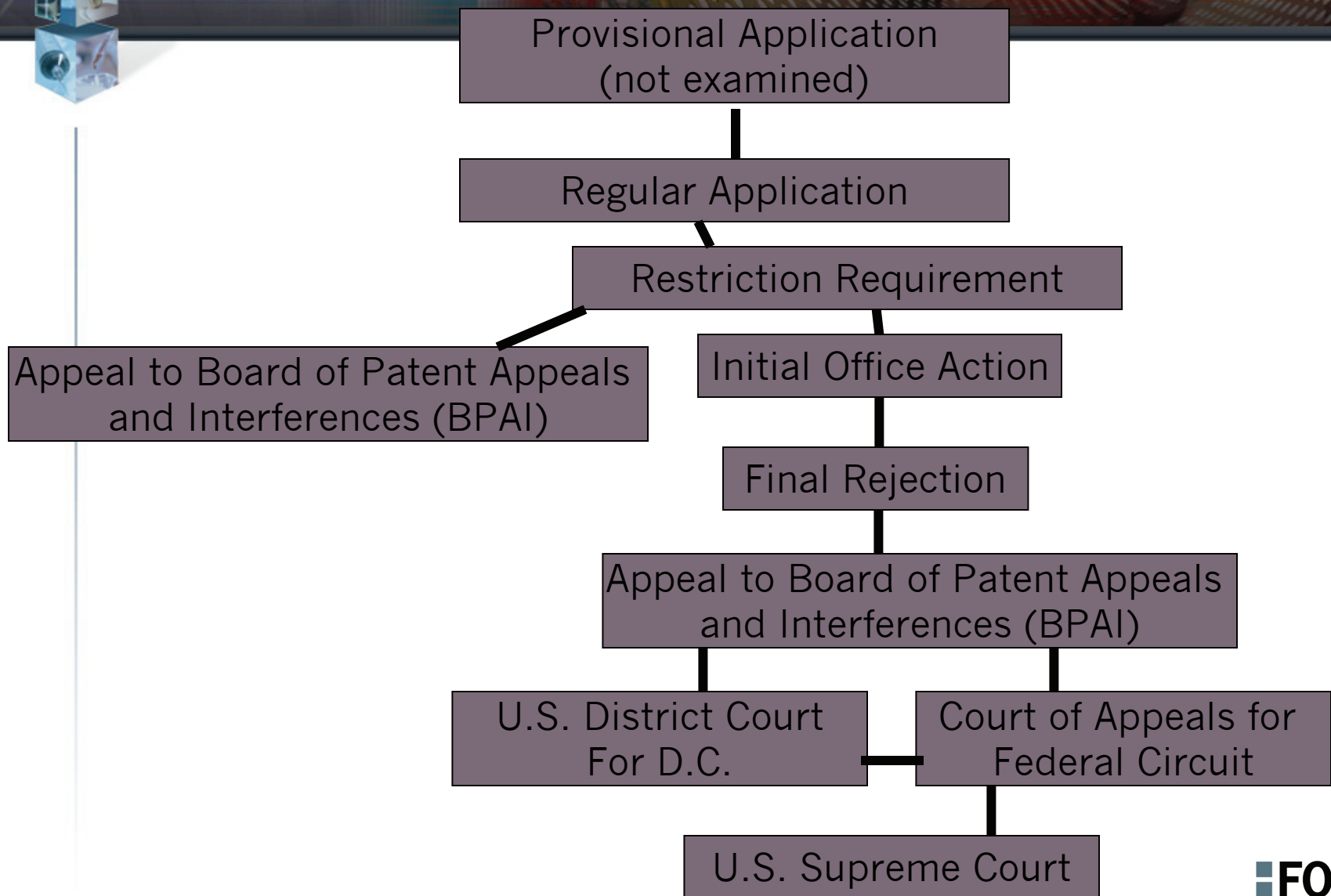
- Introduction
- Generic or Linking Claims
- Markush Practice
- Appeals
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- Conclusion

Importance of Restriction Practice



- Both the USPTO and EPO are reviewing limitations on the number of continuation and divisional applications
- The USPTO recently revoked its practice of examining up to 10 sequences together
- Multiple applications with species claims do not provide the same protection as a patent with a generic claim

U.S. Examination Process





Examination

- Applications are classified by the type of invention claimed and assigned to an examiner knowledgeable in the claimed technology
- Examiners conduct a search to review prior patents and publications relevant to the claims. The search helps determine if the patent is novel and the possible scope of allowable subject matter



Restriction Requirements

- If the Examiner believes the application contains two or more inventions, the Applicant will be required to limit the application to one of the inventions – a Restriction Requirement
- The remaining group(s) of claims can be pursued in a divisional application during the pendency of the application



Typical Restrictions

- Groups of claims drawn to different products
- Group I drawn to a product and other Groups drawn to methods for using the products (i.e., to treat diseases)
- Product and Process of Making the Product

Basic Restriction Requirement



- There are two criteria for a restriction between patentably distinct inventions:
 - 1) The inventions must be independent or distinct as claimed; and
 - 2) There must be a serious burden on the Examiner requiring restriction



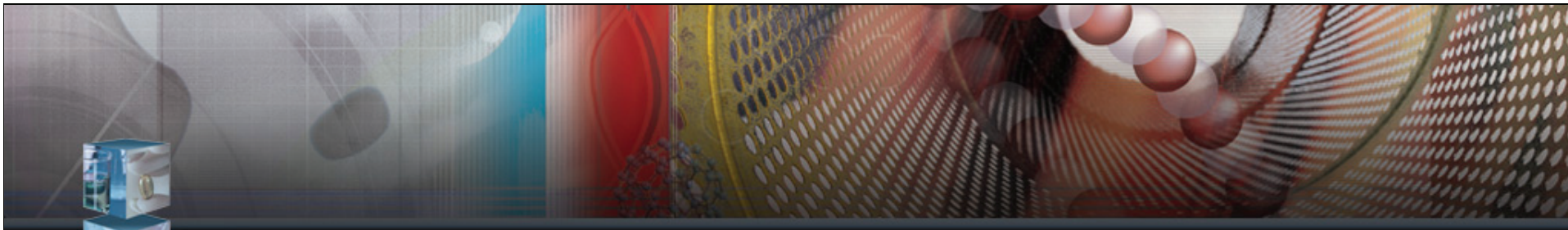
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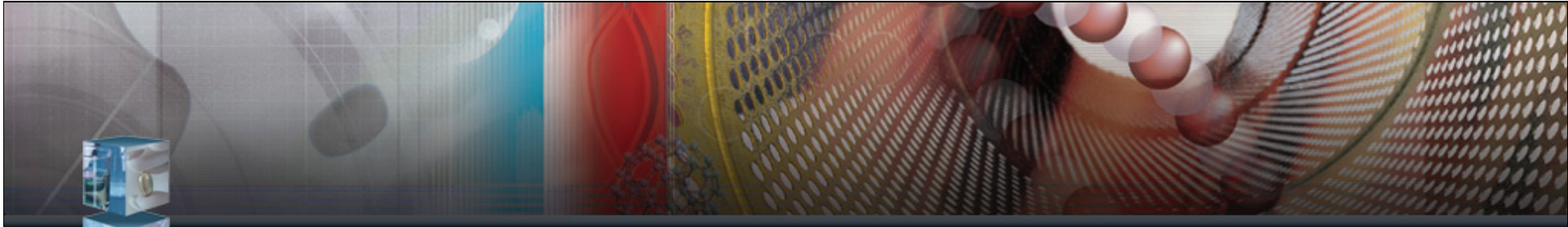


Generic or Linking Claims

- Applicants have a right to receive examination of generic claims which include multiple, independent inventions
- Example - Generic claims linking species claims
- The Examiner may require an Applicant to elect one species for examination – an election requirement
- Generic Claims drawn to the elected species must be examined along with the species claim



- Claim 1 – A composition for reducing HIV viral load in an HIV infected patient, comprising an agent which inhibits viral replication and a pharmaceutically acceptable carrier
- Claim 2 – The composition of claim 1, wherein the agent is a polypeptide having the amino acid sequence SEQ ID No: 2
- Claim 3 – The composition of claim 1, wherein the agent is a polynucleotide having the nucleotide sequence SEQ ID No: 3



- Claim 1 – A method for treating a neurodegenerative disease comprising administering a peptide to a patient
- Claim 2 – The method of claim 1, wherein the disease is Alzheimer's disease
- Claim 3 – The method of claim 1, wherein the disease is multiple sclerosis
- Claim 4 – The method of claim 1, wherein the disease is encephalitis



Generic or Linking Claims

- When a Generic Claim is found allowable, the restriction requirement must be withdrawn
- Properly drafted and examined linking claims can lead to genus and species claims in the same application



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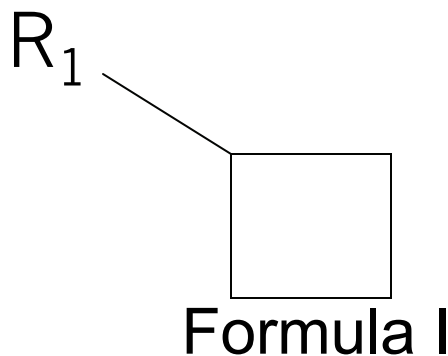


Markush Practice

- Claims containing compounds
 - 1) sharing a common utility and
 - 2) substantial structural similarity
- Must be examined in a single application even if they are directed to independent and distinct inventions
- If a claim meets the above criteria, a restriction requirement is inappropriate

Markush Claims

- Claim 1 - A compound of formula I:
where R_1 is selected from the group
consisting of X, Y, and Z
- Claim 2 – A method of treating diabetes
comprising administering a compound of
formula I, where R_1 is selected from the
group consisting of X, Y, and Z





Markush Claims

- Examiner may require Applicant to elect a single species from the Markush group for searching purposes, but if no art anticipates or renders the election obvious, the entire Markush claim must be examined



Markush Claims

- Consider drafting Markush claims for inventions with similar compounds or sequences



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Appeals

- To challenge the merits of a restriction requirement, Applicants may file a petition reviewed by the Technology Center Directors
- Restriction of the subject matter in a single claim may be reviewed by the BPAI and the courts



Case Law for Appeal

- *Haas I* – Applicant has the right to appeal a restriction requirement or other procedural action effectively withdrawing a generic claim
- *Haas II* and *In re Weber* – It is not appropriate for an Examiner to refuse examination of a Markush claim using a restriction requirement
- Applicants can immediately appeal Examiner's action to the BPAI



Appeals

- If rules limiting future continuation practice are implemented, use of the appeals process to insure an Application is fully examined will increase



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Rejoinder - *In re Ochiai*

- Following a restriction between product and process claims
- Product claims found allowable
- Process claims which depend from or include all of the limitations of the allowable product claims should be rejoined



Rejoinder

- Amend withdrawn process claims during prosecution in parallel with examined product claims
- Do not cancel claims until the possibility of rejoinder is lost



Conclusion

- Claim drafting will become more important with additional limitations on the number of divisional and continuation applications
- Generic and Markush Claims are effective tools for receiving broader examination
- Examiner's restriction of Generic or Markush claims can be appealed at an early stage of examination
- When applicable use rejoinder to avoid the filing of additional applications



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