PRACTICAL CONSIDERATIONS IN RESTRICTION PRACTICE

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Topics

- Introduction
- Generic or Linking Claims
- Markush Practice
- Appeals
- Rejoinder
- 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.
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

\[ R_1 \]

Formula I
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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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
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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