Clarity and Markush Claims

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Disclaimer

- The views expressed in this presentation are mine, and are not to be attributed to my firm, its clients, or anyone else.
Claim Clarity is Important

- Clarity is required by 35 U.S.C. § 112(b)
- Current PTO policy focus on clarity
  - PTO Press Release 14-08: USPTO Launches New Glossary Pilot Program to Promote Patent Claim Clarity
    - Program called for in Obama administration executive actions to improve U.S. patent system
Markush Claims are Important

- About one out of every eight patents contains Markush phrase “selected from the group consisting of” in the claims
  - 1994 through 2013 (20 years)
    - 3,704,996 patents
    - 468,262 patents with Markush claims (at least)
Chemical Technology is Important

- Innovation: $56 billion spent on R&D in 2013
- U.S. Jobs: 793,000
- U.S. Patents: 17% related to chemistry

What is a Markush Claim?

- “A Markush-type claim recites alternatives in a format such as “selected from the group consisting of A, B and C.” See Ex parte Markush, 1925 C.D. 126 (Comm’r Pat. 1925).” (MPEP § 803.02)

- “When materials recited in a claim are so related as to constitute a proper Markush group, they may be recited in the conventional manner, or alternatively. For example, if ‘wherein R is a material selected from the group consisting of A, B, C and D’ is a proper limitation, then ‘wherein R is A, B, C or D’ shall also be considered proper.” (MPEP § 2173.05(h))
Common Issues in Markush Clarity

- “Consisting of” vs. “comprising”
  - “It is improper to use the term ‘comprising’ instead of ‘consisting of.’ Ex parte Dotter, 12 USPQ 382 (Bd. App. 1931).” (MPEP § 2173.05(h))
Double inclusion

“[T]he double inclusion of an element by members of a Markush group is not, in itself, sufficient basis for objection to or rejection of claims. . . For example, the Markush group, ‘selected from the group consisting of amino, halogen, nitro, chloro and alkyl’ should be acceptable even though ‘halogen’ is generic to ‘chloro.’” (MPEP § 2173.05(h))
Indefiniteness

“A Markush claim may encompass a large number of alternative species, but is not necessarily indefinite under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph for such breadth. In re Gardner, 427 F.2d 786, 788 (CCPA 1970) (‘Breadth is not indefiniteness.’). In certain circumstances, however, a Markush group may be so expansive that persons skilled in the art cannot determine the metes and bounds of the claimed invention. For example, a Markush group that encompasses a massive number of distinct alternative species may be indefinite under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph if one skilled in the art cannot determine the metes and bounds of the claim due to an inability to envision all of the members of the Markush group. In such a circumstance, an examiner may reject the claim for indefiniteness under 35 U.S.C. 112(b) or pre-AIA 35 U.S.C. 112, second paragraph.” (MPEP § 2173.05(h))
Common Issues in Markush Clarity

- **Subgenus claims**
  
  "Genus, subgenus, and Markush-type claims, if properly supported by the disclosure, are all acceptable ways for applicants to claim their inventions. They provide different ways to present claims of different scope. Examiners should therefore not reject Markush-type claims merely because there are genus claims that encompass the Markush-type claims.” (MPEP § 2173.05(h))
Process or combination vs. compound claims

“The materials set forth in the Markush group ordinarily must belong to a recognized physical or chemical class or to an art-recognized class. However, when the Markush group occurs in a claim reciting a process or a combination (not a single compound), it is sufficient if the members of the group are disclosed in the specification to possess at least one property in common which is mainly responsible for their function in the claimed relationship, and it is clear from their very nature or from the prior art that all of them possess this property.” (MPEP § 2173.05(h))
Common Issues in Markush Clarity

- Portions of chemical compounds
  - “Where a Markush expression is applied only to a portion of a chemical compound, the propriety of the grouping is determined by a consideration of the compound as a whole, and does not depend on there being a community of properties in the members of the Markush expression.” (MPEP § 2173.05(h))
Are Markush claims generic?

- “While in the past the test for Markush-type claims was applied as liberally as possible, present practice which holds that claims reciting Markush groups are not generic claims (MPEP § 803) may subject the groups to a more stringent test for propriety of the recited members.” (MPEP § 2173.05(h)) (emphasis added)

- “This subsection deals with Markush-type generic claims which recite a plurality of alternatively usable substances or members. In most cases, a recitation by enumeration is used because there is no appropriate or true generic language.” (MPEP § 803.02) (emphasis added)
Common Issues in Markush Clarity

- Improper Markush Grouping
  - *In re Weber*, 580 F.2d 455 (CCPA 1978)
  - *In re Harnisch*, 631 F.2d 716 (CCPA 1980)
  - *Ex parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984) (non-precedential)
  - MPEP § 803.02 and § 2173.05(h) (9th Ed., March 2014)
Improper Markush Grouping

- *In re Weber* (CCPA 1978)

  Chemical compound claims rejected as “being improper Markush claims and misjoinder under 35 U.S.C. § 121”

1. A compound having the general formula

\[ R_1 - C - N - N - Y - R_2 \]

or an acid addition salt thereof in which formula $R_1$ is selected from the group consisting of:

- An at least mononuclear heterocyclic group having 4 to 10 carbon atoms in the ring system bound to the group $-C=\text{N}^-$ through a carbon atom and containing at least one oxygen, nitrogen or sulphur atom.
- Substitution products of A) containing at least one substituent selected from the group consisting of halogen, trifluoromethyl, hydroxy, alkoxy of 1 to 3 carbon atoms, unsubstituted amino, amino substituted by up to two alkyl groups each having 1 to 3 carbon atoms and alkyl groups having 1 to 6 carbon atoms.
- X is oxygen, sulphur or an NH-group, Y is an alkene group having 1 to 3 carbon atoms in the chain, or an alkyne group having 1 to 3 carbon atoms in the chain substituted by a) up to 3 alkyl groups each having up to 5 carbon atoms and a total of not more than 8 carbon atoms, or b) substituted by one or two phenyl groups.
- $R_2$ is selected from the group consisting of:
  - An at least mononuclear carbocyclic or heterocyclic group having 4 to 10 carbon atoms in the ring system, containing but one heteroatom in a ring.
  - Substitution products of C) containing at least one substituent selected from the group consisting of nitro, halogen, trifluoromethyl, alkyl having 1 to 6 carbon atoms, hydroxy, alkoxy having 1 to 3 carbon atoms, unsubstituted amino groups and amino groups substituted by up to two alkyl groups each having 1-3 carbon atoms.
  - $R_2$ is hydrogen or up to two substituents selected from alkyl groups having up to 2 carbon atoms and phenyl groups.
Improper Markush Grouping

- *In re Weber* (CCPA 1978)
  - “Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.”
  - Holding: “We hold that a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses.”
  - Misjoinder rejection reversed, improper Markush rejection remanded to Board
Improper Markush Grouping

- *In re Harnisch* (CCPA 1980)
  - Improper Markush rejection of chemical claims directed to certain coumarin dyes
  - Distinguished “concept of unity of invention” issue in this case from clarity and scope of enablement issues present in prior cases

- Court noted common use and structural similarity of the claimed compounds
  - “all of appellant's claimed compounds are dyes”
  - “they are all coumarin compounds which the board admitted to be ‘a single structural similarity.’”
Improper Markush Grouping

- **In re Harnisch** (CCPA 1980)
  - Holding: “We hold, therefore, that the claimed compounds all belong to a subgenus, as defined by appellant, which is not repugnant to scientific classification. Under these circumstances we consider the claimed compounds to be part of a single invention so that there is unity of invention . . . The Markush groupings of claims 1 and 3-8 are therefore proper.”
  - Recognized possibility of improper Markush grouping: “[W]e think it should be clear from our actions in Weber and Haas II that we there recognized the possibility of such a thing as an ‘improper Markush grouping.’” (emphasis in original)
Improper Markush Grouping

- *In re Harnisch* (CCPA 1980)
  - Explained reasoning for holding:
    - “Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an ‘improper Markush group.’ Reference to the widely recognized concept of ‘unity of invention’ has been made in order to suggest an appropriate term to apply where unrelated inventions are involved – inventions which are truly independent and distinct.⁷ This case, we find, does not involve such inventions.” (emphasis in original)

⁷ Having recognized the possibility of rejecting a Markush group type of claim on the basis of independent and distinct inventions, the PTO may wish to anticipate and forestall procedural problems by exercising its rulemaking powers under 35 USC 6(a), wherein the views of interested parties may be heard.
Improper Markush Grouping

- *Ex parte Hozumi* (B.P.A.I. 1984) (non-precedential)
  - Improper Markush rejection of chemical claims directed to compounds having antimycotic activity
  - Reviewed facts and holding of Harnisch: “Thus, all of the claims had in common a functional utility related to a substantial, structural feature disclosed as being essential to that utility.” (emphasis added)
  - Holding: Reversed rejection because “there is a substantial structural feature of the class of compounds claimed disclosed as being essential to at least one disclosed utility, e.g., antimycotic activity.”
Improper Markush Grouping

- *Ex parte Hozumi* (B.P.A.I. 1984) (non-precedential)
  - “**NOTICE:** ROUTINE OPINION. Pursuant to the Patent Trial and Appeal Board Standard Operating Procedure 2, the opinion below has been designated a routine opinion.” (1984 Pat. App. LEXIS 11)

- “The Board enters thousands of opinions every year. This volume may obscure the value of certain electronically posted Board opinions. This SOP provides a mechanism for highlighting certain opinions by designating Board opinions as: 1. Precedential, 2. Informative, or 3. Routine.” (PTAB Standard Operating Procedure 2 (Revision 8) § I.C.)

- “A routine opinion should not be cited as authority, but may be cited when necessary as a relevant fact.” (PTAB Standard Operating Procedure 2 (Revision 8) § V.C.)

- “An opinion is not precedential simply because it has been published in a commercial reporter, involves an expanded panel, or includes an *ex officio* member on the panel. Such factors may, however, augment the persuasiveness of the opinion.” (PTAB Standard Operating Procedure 2 (Revision 8) § III.I.)
35 U.S.C. § 112
Supplementary Examination Guidelines

Biotechnology/Chemical/Pharmaceutical Customer Partnership Meeting

September 13, 2011

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Markush Claims

1. Indefiniteness Rejection
2. “Improper Markush Grouping” Rejection
1. Indefiniteness Rejection under § 112, ¶2

- A “Markush” claim recites a list of alternatively useable species.
  - It is commonly formatted as: “selected from the group consisting of A, B, and C,” but this format is not a requirement.
- Problem arises when a Markush group is so expansive that persons skilled in the art cannot determine the metes and bounds of the invention.
- The test is whether one of ordinary skill can envision all of the members of the Markush group.
- If not, the Markush claim may be rejected as indefinite under § 112, ¶2 because the metes and bounds of the claim are unclear.
2. “Improper Markush Grouping” Rejection

- A Markush claim may be rejected under the judicially approved “improper Markush grouping” doctrine when the claim contains an improper grouping of alternatively useable species.

- A claim contains an “improper Markush grouping” if:
  1. The species of the Markush group do not share a “single structural similarity,”
     - Meaning they do not belong to the same recognized physical or chemical class or same art-recognized class, or
  2. The species do not share a common use,
     - Meaning they are not disclosed in the specification or known in the art to be functionally equivalent.
     - If 1 or 2 apply, then an “improper Markush grouping” rejection should be made.
• An appropriate applicant response includes:
  – Amending the claims to include only the species that share a single structural similarity and a common use, or
  – Presenting a sufficient showing that the species in fact share a single structural similarity and a common use.

• An election of species can be required in order to conduct examination directed to a species or group of indistinct species.
  – If the species or group of indistinct species is not found in the prior art, extend the search to the species that share a single structural similarity and common use.

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Markush Claims (Definition)

- A “Markush” claim:
  - recites a list of alternatively useable species; and
  - is commonly formatted as: “selected from the group consisting of A, B, and C”

- However, the phrase “Markush claim” as used in these guidelines means any claim that recites a list of alternatively useable species regardless of format.

- See Supplemental 112 Guidelines.
A Markush claim may be rejected under the judicially approved “improper Markush grouping” when the claim contains an improper grouping of alternatively claimed species in which:

(1) the species do not share a “single structural similarity,”

or

(2) the species do not share a common use

• e.g. they are not disclosed in the specification to share a common use or known in the art to be functionally equivalent.

➤ If (1) or (2) apply, then an “Improper Markush Grouping” rejection is proper.

➤ case-by-case nature of the inquiry.
MPEP § 803.02: Markush Claims

• MPEP § 803.02 explains that a Markush grouping is proper when the embodiments of the invention share both a common use and a substantial structural feature essential to that use. See Ex parte Hozumi, 3 USPQ2d 1059 (B.P.A.I. 1984).

• Thus a proper Markush group possessing a “single structural similarity” means the members possess:
  1. a substantial structural feature (prong 1),
  2. from which the common use must flow (prong 2).

• If a claim that includes a Markush grouping which reads on two or more patentably distinct inventions, a provisional election of species requirement may be made at the examiner’s discretion. Supplemental Guidelines.
Improper Markush Claim (Analysis)

• Analyze the claim as a whole and determine whether the alternative species share a common use and a substantial structural feature essential to that use.

• If the species lack either:
  • a common substantial structural feature or
  • a common use; or
  • if the shared structural feature is not essential to the common use,

➢ then a rejection on the basis that the claim contains an “improper Markush grouping” is appropriate.

• use Form ¶ 8.40 Improper Markush Grouping Rejection.
Claim[1] rejected on the judicially-created basis that it contains an improper Markush grouping of alternatives. See *In re Harnisch*, 631 F.2d 716, 721-22 (CCPA 1980) and *Ex parte Hozumi*, 3 USPQ2d 1059, 1060 (Bd. Pat. App. & Int. 1984). The improper Markush grouping includes species of the claimed invention that do not share both a substantial structural feature and a common use that flows from the substantial structural feature. **The members of the improper Markush grouping do not share a substantial feature and/or a common use that flows from the substantial structural feature for the following reasons:** [2]. In response to this rejection, Applicant should either amend the claim(s) to recite only individual species or grouping of species that share a substantial structural feature as well as a common use that flows from the substantial structural feature, or present a sufficient showing that the species recited in the alternative of the claims(s) in fact share a substantial structural feature as well as a common use that flows from the substantial structural feature. This is a rejection on the merits and may be appealed to the Board of Patent Appeals and Interferences in accordance with 35 U.S.C. §134 and 37 CFR 41.31(a)(1) (emphasis provided).

**Examiner Note:**
1. In bracket 1, insert claim number(s) and “is” or “are” as appropriate.
2. In bracket 2, explain why these species do not share a substantial structural feature as well as a common use that flows from the substantial structural feature.
3. If an election of species requirement is appropriate, this form paragraph can only be used after applicant has made an election.
Improper Markush Grouping

- *Ex parte deGrado* (BPAI 2012) (non-precedential)
  - Appeal of double patenting rejection
  - Board ordered further briefing under 37 § CFR 41.50 regarding: “Whether Claim 16 is a proper ‘Markush Claim.’”
  - Appellant filed lengthy reply
  - Board affirmed double patenting rejection
  - “Because we have affirmed the Examiner’s double patenting rejection, it was unnecessary to reach and we have not considered the matters addressed in the briefing under 37 CFR § 41.50(d).”
Improper Markush Grouping

- Foreword to MPEP (9th Ed., March 2014)
  
  “This Manual is published to provide U.S. Patent and Trademark Office (USPTO) patent examiners, applicants, attorneys, agents, and representatives of applicants with a reference work on the practices and procedures relative to the prosecution of patent applications before the USPTO. It contains instructions to examiners, as well as other material in the nature of information and interpretation, and outlines the current procedures which the examiners are required or authorized to follow in appropriate cases in the normal examination of a patent application. The Manual does not have the force of law or the force of the rules in Title 37 of the Code of Federal Regulations.” (emphasis added)
Improper Markush Grouping

- MPEP (9th Ed., March 2014)
  - Retained discussion of “unity of invention” concept
    - “Since the decisions in In re Weber, 580 F.2d 455, 198 USPQ 328 (CCPA 1978) and In re Haas, 580 F.2d 461, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention. In re Harnisch, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); and Ex parte Hozumi, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.” (MPEP § 803.02, 9th Ed. (March 2014); 8th Ed. Rev. 9 (August 2012) and 8th Ed. Rev. 8 (July 2010))

  - Revised to include functional language aspects of 2011 Guidelines
Improper Markush Grouping

- MPEP (9th Ed., March 2014)
  - Various Improper Markush Grouping aspects of the 2011 Guidelines not incorporated into current MPEP
    - Express guidance that “a Markush claim may be rejected under the judicially approved ‘improper Markush grouping’ doctrine” not incorporated into current MPEP
  - Current MPEP retained “essential to that utility” language: “Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.” (MPEP § 803.02) (emphasis added)
  - Form ¶ 8.40 not incorporated into current MPEP
Improper Markush Grouping

- MPEP (9th Ed., March 2014)
  - Requires examination of certain claims having arguably improper Markush grouping
    - “If the members of the Markush group are sufficiently few in number or so closely related that a search and examination of the entire claim can be made without serious burden, the examiner must examine all the members of the Markush group in the claim on the merits, even though they may be directed to independent and distinct inventions.” (MPEP § 803.02)
Markush Clarity Scorecard

- Reasonably clear
  - “Consisting of” vs. “comprising”
  - Double inclusion
  - Indefiniteness
  - Subgenus claims
  - Process or combination vs. compound claims
  - Portions of chemical compounds

- Needs more clarity
  - Are Markush claims generic?
  - Improper Markush Grouping
Questions for Discussion

- Is Improper Markush Grouping a rejection or an objection?
- Does current PTO policy authorize Improper Markush Grouping rejection/objection?
- If Improper Markush Grouping is an authorized rejection/objection, then how should it be applied?
Questions for Discussion

- Is Improper Markush Grouping a rejection or an objection?

  “The refusal to grant claims because the subject matter as claimed is considered unpatentable is called a “rejection.” The term “rejected” must be applied to such claims in the examiner’s action. If the form of the claim (as distinguished from its substance) is improper, an “objection” is made. An example of a matter of form as to which objection is made is dependency of a claim on a rejected claim, if the dependent claim is otherwise allowable. See MPEP § 608.01(n). The practical difference between a rejection and an objection is that a rejection, involving the merits of the claim, is subject to review by the Patent Trial and Appeal Board, while an objection, if persisted, may be reviewed only by way of petition to the Director of the USPTO. Similarly, the Board will not hear or decide issues pertaining to objections and formal matters which are not properly before the Board. These formal matters should not be combined in appeals to the Board.” (MPEP § 706.01)
Questions for Discussion

- Is Improper Markush Grouping a rejection or an objection?
  - Maybe rejection, because:
    - *Harnisch* referred to it as a rejection
    - 2011 Guidelines, 2011 TC 1600 Presentation and Form ¶ 8.40 referred to it as a rejection
  - Maybe objection, because:
    - So-called “unity of invention” concept is procedural in nature, analogous to restriction
    - Not on the merits: no court has ever invalidated a claim on basis of Improper Markush Grouping
      - Analogous to § 112(4) (was objection, now rejection)
    - 2011 Guidelines, 2011 OPLA Presentation, 2011 TC 1600 Presentation and Form ¶ 8.40 used permissive language
    - Current MPEP does not expressly authorize rejection
      - Requires examination of arguably “improper” claims
Questions for Discussion

- Does current PTO policy authorize Improper Markush Grouping rejection/objection?
  - Maybe yes, because:
    - 2011 Guidelines authorize it
    - *Harnisch* recognized possibility
  - Maybe no, because:
    - Current MPEP supersedes 2011 Guidelines
      - MPEP “outlines the current procedures which the examiners are required or authorized to follow…”.
        (Foreword to MPEP) (emphasis added)
    - No express authorization in current MPEP
      - No Form ¶ 8.40 in current MPEP
Questions for Discussion

- If Improper Markush Grouping is an authorized rejection/objection, then how should it be applied?
  - Maybe as stated in 2011 Guidelines: “A Markush claim contains an ‘improper Markush grouping’ if: (1) The species of the Markush group do not share a “single structural similarity,” or (2) the species do not share a common use.”
    - Does not include “essential to that use” or “use that flows from the substantial structural feature” terminology because *Hozumi* not precedential.
  - Maybe as stated in 2011 TC 1600 Presentation: “[A] Markush grouping is proper when the embodiments of the invention share both a common use and a substantial structural feature essential to that use.” (emphasis added)
    - Include “essential to that use” or “use that flows from the substantial structural feature” based on *Harnisch*, as recognized in *Hozumi*. 
Questions for Discussion

- If Improper Markush Grouping is an authorized rejection/objection, then how should it be applied?
  - Maybe as held in *Harnisch*: “We hold, therefore, that the claimed compounds all belong to a subgenus, as defined by appellant, which is not repugnant to scientific classification. Under these circumstances we consider the claimed compounds to be part of a single invention so that there is unity of invention . . . The Markush groupings of claims 1 and 3-8 are therefore proper.” (emphasis added)
Questions for Discussion

- If Improper Markush Grouping is an authorized rejection/objection, then how should it be applied?
  - Maybe as stated in *Harnisch*: “Here we are concerned only with the rejection of a single claim on the distinct ground that it is directed to an ‘improper Markush group.’ Reference to the widely recognized concept of ‘unity of invention’ has been made in order to suggest an appropriate term to apply where unrelated inventions are involved – inventions which are truly independent and distinct. This case, we find, does not involve such inventions.” (emphasis in original)

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7 Having recognized the possibility of rejecting a Markush group type of claim on the basis of independent and distinct inventions, the PTO may wish to anticipate and forestall procedural problems by exercising its rulemaking powers under 35 USC 6(a), wherein the views of interested parties may be heard.
Questions for Discussion

- *In re Weber* (CCPA 1978)
  - “Even though the statute allows the applicant to claim his invention as he sees fit, it is recognized that the PTO must have some means for controlling such administrative matters as examiner caseloads and the amount of searching done per filing fee. But, in drawing priorities between the Commissioner as administrator and the applicant as beneficiary of his statutory rights, we conclude that the statutory rights are paramount.” (emphasis added)
  - “We hold that a rejection under § 121 violates the basic right of the applicant to claim his invention as he chooses.”
Suggestions

- Clarify current PTO policy regarding Markush practice
  - Maintain non-controversial aspects
  - Begin conversation regarding unsettled aspects
    - BCP meetings and Roundtables
    - Issue Guidelines
    - Notice and comment
    - Update MPEP
    - Examiner training
- Consider other approaches
  - Focus on searchability?
  - Procedural focus, e.g., election of species + further searching?
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