

Markush Claims in Patent Prosecution and Litigation: Leveraging Federal Court Guidance

Constructing Group Claims, Navigating Comprising and Consisting of, Avoiding Improper Rejections

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Ex Parte Markush
1925 C.D. 126 (Comm'r Pat. 1924)

where no generic expression exists by which a group of alternative elements can be claimed, applicants are permitted to recite the elements in the alternative

“an applicant can properly protect his real invention”

More Markush

“there can be no objection to the use of a true subgeneric term which includes those elements which the applicant has found useful in the combination and excludes those which are not”

The subgeneric term was a group comprising certain substances in the form “material selected from the group consisting of aniline, homologues of aniline, and halogen substitutes of aniline.”

What Markush Groups Mean

- A style of claim drafting by which the applicant may recite different species of a genus
- The members of a Markush group usually have something in common, *i.e.*, a function, a physical attribute, a chemical property., or belong to an art-recognized class.

Simple Markush Examples

- an alcohol selected from the group consisting of methanol, ethanol, and propanol
- an alcohol of the formula R-OH, wherein R is selected from the group consisting of -CH₃, -CH₂CH₃, and -(CH₂)₂CH₃

In re Harnish
631 F.2d 706 (CCPA 1980)

-an applicant has a right to define what he regards as his invention as he chooses, so long as his definition is distinct, as required by the second paragraph of § 112, and supported by enabling disclosure, as required by the first paragraph of § 112.

-in determining the propriety of a Markush grouping, the compounds must be considered as wholes and not broken down into elements or other components

-35 USC §121 not a basis for rejection of a claim but rather deals with restriction practice (*In re Weber*, 580 F.2d 455 (CCPA 1978))

Harnish–Improper Markush Groups?

- the claimed compounds all belong to a subgenus as defined by appellant (Markush), which is not repugnant to scientific classification
- the claimed Markush group had unity of invention because the members of the group shared a common function as dyes and shared a substantial structural feature as being coumarin compounds
- the claimed compounds were part of a single invention so that there is unity of invention and the Markush groupings of claims are therefore proper

MPEP § 803.02

Office must examine that all claims exactly as recited, unless the claim is lacking unity of invention

unity of invention exists where compounds in a Markush group (1) share a common utility, and (2) share a substantial structural feature essential to that utility.

*In re Driscoll 562 F.2d 1245
(C.C.P.A. 1977)*

it is generally understood that by using the Markush group format, the Applicant is asserting that the members of the Markush group are alternatively usable for the purposes of the invention and will exhibit the disclosed utility (see also MPEP § 2173.05(h))

Markush Language

No precise linguistic formula is required to create a Markush claim.

-A Markush group is commonly recited as: “selected from the group consisting of A, B, and C,” but it does not have to be exactly in that format.

-Usually the term “consisting of” is there as well as the word “and.” It is improper to use the term “comprising” instead of “consisting of” in a Markush group. *In re Harnish*, 631 F.2d 716, 723 (C.C.P.A. 1980); *Ex parte Dotter*, 12 USPQ 382 (Bd. App. 1931)

MPEP §2173.05(h)

- “wherein R is A, B, C or D” shall also be considered a proper Markush group.
- ““selected from spirit soluble azo dyes and finely divided pigmenting material,’ sets forth a type of Markush group.” *Metcalfe v. Hampel*, 532 F.2d 1360, 1362 (CCPA 1976)
- “polymer vehicle comprising 0-120 mg of a water-soluble polymer selected from [a list of six polymers]” as being in “Markush form.” *Merck & Co., Inc. v. Mylan Pharm., Inc.*, 190 F.3d 1335, 1339 (Fed. Cir.1999)

MPEP §2173.05(h) (con't)

“[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. *In re Kelly*, 305 F.2d 909, 916, 134 USPQ 397, 402 (CCPA 1962); (MPEP § 2173.05(h))

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’” but there may be a definiteness problem under §112.

“Comprising” Followed by Markush Language

- *Abbott Laboratories and Central Glass Co. v. Baxter Pharmaceutical Products, Inc.*, 334 F.3d 1274 (Fed. Cir. 2003)
 - An anesthetic composition comprising:...a Lewis acid inhibitor ...“said Lewis acid inhibitor selected from the group consisting of water, butylated hydroxytoluene, methylparaben, propylparaben, propofol, and thymol”
 - FC: must be characterized with the transition phrase ‘consisting of,’ rather than ‘comprising’ or ‘including’”

Mixtures and Combinations of Recited List?

- *Abbott Labs. (con't)*:
 - FC: “If a patentee desires mixtures or combinations of the members of the Markush group, the patentee would need to add qualifying language while drafting the claim. ... Thus, without expressly indicating the selection of multiple members of a Markush grouping, a patentee does not claim anything other than the plain reading of the closed claim language.”

“Comprising” Followed by Markush Language

- *Ecolochem, Inc. v. Southern California Edison Co.*, 1996 U.S. App. LEXIS 13330 (Fed. Cir. 1996) (unpublished)
 - Ecolochem: its Markush grouping could include more than the members recited because the open-ended term "comprising" at the beginning of the claim meant additional elements could be used.
 - Claim 1. a deoxygenation process comprising a first step ..., a second step ..., and a third step of passing said liquid through an ion exchange resin selected from the group consisting of mixed bed resin and cation resin to remove at least said dissolved contaminants.
 - FC: Invalid as anticipated.
 - By using a Markush grouping, "Ecolochem has indicated that, for the purpose of claim validity, the members of the claimed group are functionally equivalent. Thus, if utilizing one element of the group is anticipated or obvious, the patentee is precluded from arguing that the claim is valid."
 - "Placement of 'comprising' before recitation of steps, however, results in a 'comprising' claim that would cover a process that includes additional steps, not one that uses an additional unrecited element for accomplishing a claimed step. . . . In sum, a patentee may not import additional limitations into the steps of a process claim merely by using the word "comprising" in the claim preamble.

“Consisting Of” In Markush Groups

- *Multilayer Stretch Cling Film Holdings, Inc. v. Berry Plastics Corp.*, 831 F.3d 1350 (Fed. Cir. 2016)

Claim 1. A multi-layer, thermoplastic stretch wrap film containing seven separately identifiable polymeric layers, comprising:

- a) two identifiable outer layers, at least one of which having a cling performance of at least 100 grams/inch, said outer layer being selected from the group consisting of linear low density polyethylene, very low density polyethylene, and ultra low density polyethylene resins, said resins being homopolymers, copolymers, or terpolymers, of ethylene and alpha-olefins; and
- b) five identifiable inner layers, with each layer being selected from the group consisting of linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, and metallocene-catalyzed linear low density polyethylene resins; said resins are homopolymers, copolymers, or terpolymers, of ethylene and C3 to C20 alpha-olefins;

wherein each of said two outer layers and each of said five inner layers have different compositional properties when compared to a neighboring layer.

- Claim 10 depends from claim 1 and further requires that “at least one said inner layer comprises low density polyethylene homopolymers.”

“Consisting Of” In Markush Groups

- *Multilayer* (con’t)
 - DC: construed “each of five identifiable inner layers must contained only one class of the following resins and no other resin(s): linear low density polyethylene resins, very low density polyethylene, ultra low density polyethylene, or metallocene-catalyzed linear low density polyethylene resins.”
 - Excluded blends of more than one type of resin and all unlisted resins.
 - Granted Berry’s motion for summary judgment of non-infringement based on its claim construction.
 - Claim 10 invalid under 35 U.S.C. § 112(d) because LDPE is not listed in claim 1 and is chemically distinct from the four resins that are recited, “Claim 10 attempts to improperly broaden the scope of the closed Markush Group in element (b) of Claim 1.”

“Consisting Of” In Markush Groups

- *Multilayer* (con’t)
 - “parties had agreed that ‘at least one of the inner layers of the Accused Films contains blends of resins from the classes of mLLDPE, ULDPE, and LLDPE—all classes of resins separately specified in claims 1 and 28.’...The district court consequently held that, as a matter of law, the accused Berry films could not infringe claims 1 and 28 because those claims had been construed as closed to blends of listed resins within the inner layers of the film. ‘[I]t is apparent that the permissibility of blends of resins within a film’s inner layer was directly considered and rejected during claim construction.’....’At this juncture, to permit blends would impermissibly require the Court to ignore the specific limitations of the ’055 Patent....’”

“Consisting Of” In Markush Groups

- *Multilayer* (con’t)
 - Patent Owner: the listing of other resins in the specification and certain dependent claims were sufficient to overcome the presumptive effect of the term “consisting of.”
 - Claim should be construed as “open” to other resins.
 - Specification describes LDPE as a resin suitable for use in both inner and outer layers.
 - Two of the three embodiments described include an inner layer of LDPE blended with LLDPE.
 - Specification describes several other types of resin as suitable for incorporation into the inner layers not recited in the Markush group of element (b).

“Consisting Of” In Markush Groups

- *Multilayer* (con’t)
 - FC: Affirmed district court’s claim construction in part.
 - “Use of the transitional phrase “consisting of” to set off a patent claim element creates a very strong presumption that that claim element is “closed” and therefore “exclude[s] any elements, steps, or ingredients not specified in the claim.” AFG Indus., Inc. v. Cardinal IG Co., Inc., 239 F.3d 1239, 1245 (Fed. Cir. 2001). “ ‘Consisting of’ is a term of patent convention meaning that the claimed invention contains only what is expressly set forth in the claim.” Norian Corp. v. Stryker Corp., 363 F.3d 1321, 1331 (Fed. Cir. 2004).”
 - “if a patent claim recites ‘a member selected from the group consisting of A, B, and C,’ the ‘member’ is presumed to be closed to alternative ingredients D, E, and F. By contrast, the alternative transitional term “‘comprising” creates a presumption that the recited elements are only a part of the device, that the claim does not exclude additional, unrecited elements.’” ...The presumption that a claim term set off by the transitional phrase “consisting of” is closed to unrecited elements is at least a century old and has been reaffirmed many times by our court and other courts.”

“Consisting Of” In Markush Groups

- *Multilayer* (con’t)
 - FC: Affirmed district court’s claim construction in part.
 - “We agree with the district court that the Markush group of element (b) must be construed as closed to resins other than LLDPE, VLDPE, ULDPE, and mLLDPE. To construe the inner layers of element (b) as open not only to the four recited resins but also to any other polyolefin resin conceivably suitable for use in a stretchable plastic cling film would be to construe the claims to cover any plastic film with five compositionally different inner layers, each of which contains any amount of one of the four recited resins. Construing element (b) in this manner would render the ’055 patent’s Markush language—...equivalent to the phrase ‘each layer comprising one or more of.’”

“Consisting Of” In Markush Groups

- *Multilayer* (con’t)
 - FC: (con’t)
 - “But to overcome the exceptionally strong presumption that a claim term set off with ‘consisting of’ is closed to unrecited elements, the specification and prosecution history must unmistakably manifest an alternative meaning. ...They do not here.”
 - But the district court erred in closing the Markush group to blends of the four recited resins.
 - “we held in *Abbott [v. Baxter]* that there is a presumption that a Markush group is closed to mixtures of the listed elements.”
 - “Incorporation of additional language—e.g., ‘a member selected from the group consisting of A, B, and C, and mixtures thereof’—expressly opens the Markush group to mixtures of A, B, and C.”

“Consisting Of” In Markush Groups

- *Multilayer* (con’t)
 - FC: (con’t)
 - “The *Abbott* presumption that Markush claims are closed to blends is distinct from, and not as strong as, the presumption that unlisted resins are excluded, which flows from the transitional phrase ‘consisting of.’”
 - “Here, the intrinsic evidence of the ’055 patent is unequivocal that the inner layers described in element (b) of claims 1 and 28 are open, not closed, to blends of the recited resins[.] ... the resins listed in element (b) do not constitute four entirely different species but instead overlap to some extent.”
 - Looked to Abstract and Summary of Invention and Detailed Description for support.
 - Nothing in prosecution history suggested blends excluded.
 - “In the light of this strong intrinsic evidence, the Markush group of element (b) must be read as open to blends of the four listed resins[.]”

The Exception to the Presumption

- *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321 (Fed. Cir. 2004)
 - Claim recited a kit for “preparing a calcium phosphate mineral, said kit consisting of: [specific chemicals].”
 - Stryker’s allegedly infringing kit contained all of the elements recited, plus a spatula.
 - DC: No infringement.
 - The term “consisting of” meant that nothing can be included in the kit beyond what was claimed.
 - FC: Reversed and remanded.
 - The limiting effect of “consisting of” does not apply to aspects unrelated to the invention.
 - “Consisting of” as used in Norian’s claim limited the kit to the claimed chemicals and no other chemicals; a spatula was not part of the invention recited.
 - Stryker did not avoid infringement by including a spatula.
 - Later, on appeal from the remand decision, infringement based on a different claim construction was affirmed. See *Norian Corp. v. Stryker Corp.*, 432 F.3d 1356 (Fed. Cir. 2005).

Application of the Exception

- *Conoco, Inc. v. Energy & Environmental Int'l, L.C.*, 460 F.3d 1349 (Fed. Cir. 2006)
 - Claim 1. A Process for the preparation of a stable nonagglomerating suspension of a solid oil soluble polyolefin friction reducing agent ... which comprises:...(2) combining the coated polymer particles with a water soluble polymeric thickening agent and a suspending material ***selected from the group consisting of water and water-alcohol mixtures***[.]
 - Accused product contained Alfol-2, made up of 8-15% water and 80-82.31% ethanol. The remaining ingredients consisted primarily of a denaturing agent known as methyl isobutyl ketone (“MIBK”).
 - DC: Infringed.
 - The “other non-water and non-alcohol components, such as MIBK, were impurities that were not to be counted against the exclusive ‘consisting of’ language.”

Application of the Exception (con't)

- *Conoco* (con't)
 - FC: Affirmed.
 - “[a]lthough ‘consisting of’ is a term of restriction, the restriction is not absolute.”
 - Cited *Norian Corp. v. Stryker Corp.*, 363 F.3d 1321, 1331-32 (Fed. Cir. 2004) for the principle that “‘consisting of’ does not exclude additional components or steps that are unrelated to the invention.”
 - “Similarly, impurities that a person of ordinary skill in the relevant art would ordinarily associate with a component on the “consisting of” list do not exclude the accused product or process from infringement. EEI contends that MIBK is not an impurity because it was purposely added to the alcohol to denature it. However, the intentional addition of a component does not change its status as an ‘impurity ordinarily associated therewith’...impurities normally associated with the component of a claimed invention are implicitly adopted by the ordinary meaning of the components themselves.”
 - Substantial evidence supported the district court’s conclusion that the MIBK and the other non-alcohol/non-water components were impurities that were not excluded by the “consisting of” language of the claim.

Most Recent Federal Circuit Treatment

- *Shire Development LLC v. Watson Pharms., Inc.*, No. 16-1785, 2017 WL 541013 (Fed. Cir. Feb. 10, 2017)
 - Claim 1. Controlled-release oral pharmaceutical compositions containing as an active ingredient 5-amino-salicylic acid, comprising:
 - a) an ***inner lipophilic matrix*** consisting of ***substances selected from the group consisting of*** unsaturated and/or hydrogenated fatty acid, salts, esters or amides thereof, fatty acid mono-, di- or triglycerids [sic], waxes, ceramides, and cholesterol derivatives with melting points below 90° C., and wherein the active ingredient is dispersed both in said [sic] the lipophilic matrix and in the hydrophilic matrix;
 - b) an ***outer hydrophilic matrix*** wherein the lipophilic matrix is dispersed, and said outer hydrophilic matrix ***consists of compounds selected from the group consisting of*** polymers or copolymers of acrylic or methacrylic acid, alkylvinyl polymers, hydroxyalkyl celluloses, carboxyalkyl celluloses, polysaccharides, dextrans, pectins, starches and derivatives, alginic acid, and natural or synthetic gums;
 - c) optionally other excipients

Most Recent Federal Circuit Treatment

- *Shire* (con't)
 - Watson filed an Abbreviated New Drug Application (ANDA) to market a generic version of Shire's mesalamine drug product, LIALDA®.
 - In an earlier appeal in this case, the Federal Circuit had determined that “the correct construction requires that the inner volume contain substances from the group described for the inner lipophilic matrix (which **are all lipophilic substances**), and that the outer volume separately contain substances from the group described for the outer hydrophilic matrix (which **are all hydrophilic**).
 - DC: Watson's proposed generic product would infringe.
 - “the excipients [in Watson's ANDA product] falling outside the respective Markush groups were ‘unrelated’ to the invention since they did not drive the water-affinity property of their respective matrices,” and therefore, “the lipophilic component in the outer hydrophilic matrix [claim limitation 1(b)] fell within the exception announced in *Norian*.” *Id.* at *2-3.

Most Recent Federal Circuit Treatment

- *Shire* (con't)
 - FC: Reversed.
 - Watson's ANDA product “does not satisfy the claim[ed] . . . Markush limitation[.]”
 - Watson's product included **lipophilic magnesium stearate**, a chemical not within the **hydrophilic closed Markush group** recited in claim limitation 1(b).
 - Claim 1's (a) and (b) limitations use of the phrase “consisting of,” or “consists of,” to characterize the matrix, and “consisting of” to define the groups, “creates a very strong presumption that that claim element is ‘closed’ and therefore ‘exclude[s] any elements, steps, or ingredients not specified in the claim.’”
 - Acknowledged *Norian* exception to the strong presumption, but held that it did not apply:
 - “the magnesium stearate structurally and functionally relates to the invention, and its presence in the outer matrix violates the ‘consisting of’ requirement in claim 1(b).”

Most Recent Federal Circuit Treatment

- *Shire* (con't)
 - FC: Reversed.
 - “Shire argues, and the district court held, that the magnesium stearate in Watson’s product—which Watson includes as a lubricant rather than for its lipophilic properties—is unrelated to the invention because it is not sufficiently lipophilic to render the outer matrix lipophilic. But *Norian* did not restrict “related” components to only those that advance or are intended to advance a Markush group’s allegedly inventive elements. **And we decline to impose such a requirement, which would in effect equate the scope of a Markush group’s “consisting of” language with either “comprising” or “consisting essentially of” language.**”

Most Recent Federal Circuit Treatment

- *Shire* (con't)
 - Federal Circuit applied this “closed” interpretation to the Markush language in *Shire*’s claims even though the patent examples apparently disclosed magnesium stearate in the outer matrix.
 - Also not saved by limitation 1(c), which recites “optionally other excipients.”
 - “Claim 1(c) plainly falls under the preamble’s ‘comprising’ transitional phrase and outside of claim 1’s (a) and (b) Markush groups. Claim 1(c) therefore does not present a permissive catch-all to those closed Markush groups.”

Markush in Claim Construction

- *Biovail Laboratories, Inc. v. Torpharm, Inc.*, 326 F.Supp.2d 605 (E.D. Pa. 2004)
 - Claim language, “wherein the wetting agent is selected from the group consisting of a sugar, ...[.]”
 - DC: “The language thus instructs the reader of the patent to do two things: (1) select a wetting agent, and (2) do so from the list provided. The reader should not understand the patent's language to mean either that a wetting agent should simply be selected, or, ...that one of the items in the Markush group should be selected irregardless of whether it is a wetting agent. Both steps are necessary. Thus, asking the reader to select a wetting agent from a list of chemicals is not the same as defining the term wetting agent. Rather, it is qualifying the term; to treat this usage as a definition would be to severely alter the term's meaning.”
 - Three dictionary definitions of “wetting agent” were submitted by Torpharm.
 - Biovail argued that “wetting agent” be defined as those compounds listed in the Markush group. “

Markush in Claim Construction

(con't)

- *Biovail* (con't)
 - DC: Not all sugars need be defined as wetting agents.
 - “Biovail misinterprets the significance of a Markush group.”
 - “[A]sking the reader to select a wetting agent from a list of chemicals is not the same as defining the term wetting agent. Rather, it is qualifying the term; to treat this usage as a definition would be to severely alter the term's meaning.”
 - Construed the term "wetting agent" as: "any of a group of surface-active agents which, when added to a liquid, reduce the contact angle and cause the liquid to spread more easily over, or penetrate into, a solid surface."

Markush Language In Spec Only

- *Abbott Laboratories v. Andrx Pharmaceuticals, Inc.*, 473 F.3d 1196 (Fed. Cir. 2007)
 - Claim language: “pharmaceutically acceptable polymer.”
 - Specification used Markush language: “a water-soluble hydrophilic polymer selected from the group consisting of polyvinylpyrrolidone, hydroxypropyl cellulose, hydroxypropylmethyl cellulose, methyl cellulose, vinyl acetate/crotonic acid copolymers, methacrylic acids copolymers, maleic anhydride/methyl vinyl ether copolymers and derivatives and mixtures thereof.”
 - Was the glyceryl monostearate (“GMS”) used in the accused’s product equivalent to the claimed polymer?

Markush Language In Spec Only

- Abbott (con't)
 - DC: construed the claimed polymers as limited to those listed.
 - Abbott argued this was in error, since the “Markush group” language occurred in the specification, not in the claims. Instead, the polymers listed should be considered as merely exemplary.
 - FC: Vacated claim construction.
 - A “Markush group” is a form of claim drafting, and therefore “does not have any meaning within the context of a written description of a patent.”
 - The district court erred “at this preliminary stage in limiting the ‘pharmaceutically acceptable polymer’ term to hydrophilic, water-soluble compounds selected from a list given in the written description[.]”

Markush at PTAB

- *Pharmacosmos A/S v. Luitpold Pharms., Inc.*, IPR2015-01493 (P.T.A.B. Dec. 28, 2016)
 - Claim 1. A method of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism resulting in reduced bioavailability of dietary iron, comprising administering to a subject in need thereof an iron carbohydrate complex in a single dosage unit of at least about 0.6 grams of elemental iron, wherein,
 - the iron carbohydrate complex is selected from the group consisting of an iron mannitol complex, and an iron polyisomaltose complex, an iron polymaltose complex, an iron gluconate complex, and an iron sorbitol complex,
 - the iron carbohydrate complex has a substantially non-immunogenic carbohydrate component, and
 - the disease, disorder or condition is not Restless Leg Syndrome.

Markush at PTAB

- *Pharmacosmos* (con't)
 - Reference disclosed “the administration of an iron polymaltose (dextrin) preparation, Ferrimed, for treating chronic hemodialysis patients with iron deficiency anemia[.]”
 - PTAB: Instituted claims unpatentable as anticipated.
 - “iron polymaltose is among the species of iron carbohydrate complexes expressly recited[.]”
 - “disclosure of a specific iron carbohydrate complex is likewise a disclosure of its inherent properties, It is therefore reasonable to conclude that that the iron polymaltose disclosed in van Zyl Smit has a substantially non-immunogenic carbohydrate component in the same manner as the claimed species.”

Markush at PTAB

- *Pharmacosmos* (con't)
 - Reference disclosed
 - “administering an ‘iron oxide complex coated with reduced polysaccharide’”
 - “[t]he pharmacological compositions are of the type employing a polyol or polyether iron oxide complex, which, upon parenteral administration to a subject, are substantially immunosilent [and] provide minimal anaphylaxis.”
 - Patent Owner argued the reference did not disclose any of the recited iron carbohydrate complexes.
 - PTAB: Instituted claims unpatentable as anticipated.
 - Reference disclosed an “iron polyisomaltose complex,” which is recited in the claim, if “polyisomaltose” construed as Patent Owner proposed.
 - Patent Owner’s expert did not specifically address the iron dextran complexes described in the reference.

Markush at PTAB

- *Nanoco Tech. Ltd. v. MIT*, IPR2015-00528 (P.T.A.B. July 5, 2016)
 - Claim 1. A coated nanocrystal capable of light emission, comprising:
 - a core comprising a first semiconductor material, said core being a member of a monodisperse particle population; and
 - an overcoating uniformly deposited on the core comprising a second semiconductor material,
 - wherein the first semiconductor material and the second semiconductor material are the same or different,
 - and wherein the monodisperse particle population is characterized in that when irradiated the population emits light in a spectral range of no greater than about 60 nm full width at half max (FWHM).
 - Claims 32 and 44 require that “the coated nanocrystal emits light in a narrow spectral range selected from blue light, green light, yellow light, orange light, or red light.”

Markush at PTAB

- *Nanoco* (con't)
 - Patent Owner argued:
 - the “spectral range selected from blue light, green light, orange light or red light” recited in claims 32 and 44 is not a Markush grouping “but, rather, ‘a recitation of species that have to be available for selection.’”
 - “claims 32 and 44 are only met ‘if the entire spectral range includ[ing] blue light, green light, orange light or red light are available options.’”
 - Example in specification: “As the size of the CdSe core increased, the color of the luminescence shows a continuous progression from the blue through the green, yellow, orange to red.”
 - Petitioner: “the claim recites a list of alternatives which, if it is not a formal Markush group, has the same meaning as a Markush group.”

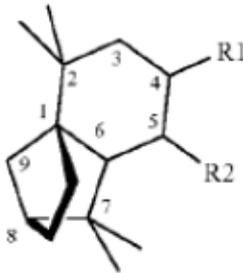
Markush at PTAB

- *Nanoco* (con't)
 - PTAB: Instituted claims unpatentable as anticipated.
 - Agree with Petitioner that “the plain meaning of the claim language ...is a list of alternatively useable species.”
 - “Patent Owner concedes that the claim is to a single nanocrystal, not to a population of nanocrystals.”
 - “consistent with the Specification, the claimed single nanocrystal can only emit light in one color spectrum.”
 - We are not persuaded that the claims require the recited “monodisperse particle population,” of which the single nanocrystal is a member, to possess the capability of emitting light in each of the spectral ranges listed in the claim. The claim language that precedes the list of spectral ranges specifies that it is the coated nanocrystal that emits light in the selected range, not the population of nanocrystals. We also are not persuaded that the word “or” should be construed as “and/or” and that such a construction would mean “the spectral range is for the population of nanocrystals” as Patent Owner argues.”

Markush at PTAB

- *Int'l Flavors & Fragrances Inc. v. U.S.*, IPR2013-00124, Paper 12 (P.T.A.B. May 20, 2014)

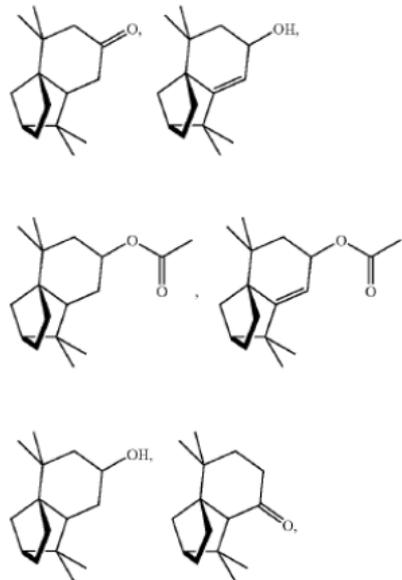
Original claim 1: A method for repelling arthropods, said method comprising treating an object or area with an arthropod repelling effective amount of at least one isolongifolenone analog and optionally a carrier or carrier material; wherein said at least one isolongifolenone analog has the following formula:



wherein R1 is hydrogen, an oxygen, a C1-10 alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a C1-10 saturated or unsaturated, straight or branched acid and R2 is hydrogen, an oxygen, a C1-10 alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a C1-10 saturated or unsaturated, straight or branched acid; optionally there is a double bond between carbons 5 and 6 and R2 is hydrogen.

Markush at PTAB

- *Int'l Flavors* (con't)
 - Original claim 8: The method according to claim 1, wherein said at least one isolongifolenone analog is **selected from the group consisting of:**



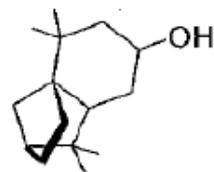
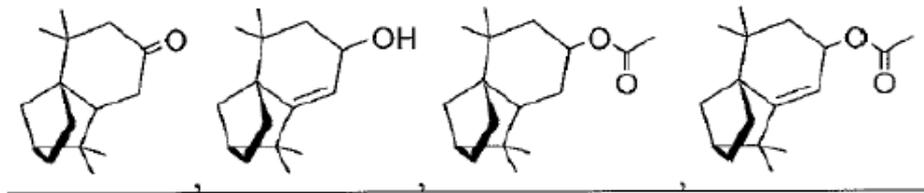
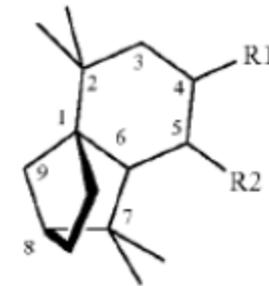
and mixtures thereof.

Markush at PTAB

Proposed substitute 27. A method for repelling arthropods, said method comprising treating an object or area with an arthropod repelling effective amount of at least one isolongifolenone analog and optionally a carrier or carrier material; wherein said at least one isolongifolenone analog has the following formula:

wherein R₁ is hydrogen, an oxygen, a C₁₋₁₀ alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a C₁₋₁₀ saturated or unsaturated, straight or branched acid and R₂ is hydrogen, an oxygen, a C₁₋₁₀ alcohol, aldehyde, alkyl, ether, or esters of said alcohol with a C₁₋₁₀ saturated or unsaturated, straight or branched acid; optionally there is a double bond between

carbons 5 and 6 and R₂ is hydrogen; wherein said at least one isolongifolenone analog is selected from the group consisting of



, and mixtures thereof.

Notes:

- Proposed claim 27 corresponds to original claim 1, but limits the isolongifolenone analogs to the first five compounds of the Markush group in original claim 8, and mixtures of those compounds.
- “and mixtures thereof” is strange in juxtaposition with “at least one” in context of this case.

Markush at PTAB

- *Int'l Flavors* (con't)

- PTAB:

- No broadening of scope.

- Patent Owner showed written description support for amended claims.

- Patent Owner demonstrated the level of ordinary skill in the art, as well as the unobviousness of features being relied upon to demonstrate patentability of the proposed claims.

- “Because the prior art does not provide a reason to modify isolongifolanone to arrive at the modified isolongifolanone compounds of proposed claim 27, nor does it provide a reasonable expectation that such modifications would result in a compound having the desired insect repellent activity, we conclude that the preponderance of the evidence supports the patentability of claim 27.

Markush at PTAB

- *Pruvit Ventures, Inc. v. VND Butyrate LLC*, IPR2015-01798, Paper 11 (P.T.A.B. March 10, 2016)
 - Claim 1. A process for causing weight loss, or avoidance of weight gain, in mammals, comprising oral administration to said mammals of butyric acid or one or more pharmaceutically effective and acceptable salts or derivatives of butyric acid **selected from the group consisting of/butyric acid, sodium butyrate, calcium butyrate, potassium butyrate, magnesium butyrate, alphahydroxybutyric acid, sodium alphahydroxybutyrate, calcium alphahydroxybutyrate, potassium alphahydroxybutyrate, magnesium alphahydroxybutyrate, betahydroxybutyric acid, sodium betahydroxybutyrate, calcium betahydroxybutyrate, potassium betahydroxybutyrate, magnesium betahydroxybutyrate, isobutyric acid, sodium isobutyrate, calcium isobutyrate, potassium isobutyrate, and magnesium isobutyrate.**

Markush at PTAB

- *Pruvit Ventures* (con't)
 - Petitioner argued that the list of compounds recites “C4 Carboxylic Compounds.”
 - Patent Owner argued that “C4 Carboxylic Compounds” is overly broad because it includes oligomeric and ester forms of the compounds that are not recited in the claims.
- PTAB: Construed claims and instituted IPR.
 - As a Markush group, the claim is “closed” and limited to the specific salts and derivatives identified.
 - Reference discloses a preferred composition that includes 3-hydroxybutyric acid—also known as betahydroxybutyrate—which is one of the Markush compounds identified in claim 1.

Markush at PTAB

- *Captioncall, LLC v. UltraTec, Inc.*, IPR2013-00543, Paper 6 (P.T.A.B. March 5, 2014)
 - Claim 1. A relay system using a call assistant for facilitating communication between a hearing user and an assisted user, the system comprising
 - [A, B]; and
 - communication connections between the hearing user and the relay and between the assisted user and the relay, **the communication connections independently selected from the group consisting of wired telephone connection, wireless telephone connection, PCS connection and [I]nternet connection;**
 - the system connected such that if the call assistant repeats the words spoken by the hearing user, the digital text stream created by the relay causes the words spoken by the hearing user to appear on the display of the captioned telephone device.

Markush at PTAB

- *Captionalcall* (con't)
 - PTAB: Instituted IPR.
 - Limitation written as a Markush group, therefore “**the prior art discloses the limitation if one alternative is in the prior art**. See *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1298 (Fed. Cir. 2009).”
 - Reference described “standard telephone lines, fiber-optic cables, and radio waves” (i.e., wired and wireless telephone connections) as examples of telecommunications links.
 - Another reference described that communication links between users and the relay may use LAN, WAN, or Internet communications over analog or digital lines conforming to a known protocol, such as TCP/IP (Transmission Control Protocol/Internet Protocol).

Combating Improper Markush Rejections

- An example of avoiding the closed “consisting of” language can be seen in the following response:
 - First, Applicants wish to point out that several claims have been added that contain claim language with the phrase “wherein [X] is selected from A, B, and C.” Support for this alternative claim language can be found in several places, e.g., Appendix AI (PCT) of the MPEP (Specifically, Example 20, p. AI-44 of the July 1998 edition). Training Materials For Examining Patent Applications with Respect to 35 U.S.C. Section 112, First Paragraph - Enablement Chemical/Biotechnical Applications, released August, 1996. (Specifically, Examples H and J.) These examples make it clear that the phrase “X selected from A, B, and C” is proper claim language, and therefore, new claims 17 and 21-25 should not be rejected under 35 U.S.C. §112, second paragraph, for improper claim language.

Markush Claiming

- Offers financial benefits, but certain issues to consider:
 - Indefiniteness
 - Double inclusion
 - Combination vs. compound claims
 - Generic claims
 - Improper Markush grouping

Indefiniteness and Double Inclusion

- *Eli Lilly and Company v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357 (Fed. Cir. 2017)
 - Claim 1. A method of administering pemetrexed disodium to a patient in need thereof comprising administering an effective amount of folic acid and an effective amount of a methylmalonic acid lowering agent followed by administering an effective amount of pemetrexed disodium, wherein the methylmalonic acid lowering agent **is selected from the group consisting of vitamin B12, hydroxycobalamin, cyano-10-chlorocobalamin, aquocobalamin perchlorate, aquo-10-cobalamin perchlorate, azidocobalamin, cobalamin, cyanocobalamin, or chlorocobalamin.**
 - Claim 2 further requires that “the methylmalonic acid lowering agent is vitamin B12.”
 - Accused product: generic drug with folic acid and vitaminB12 pretreatment.

Indefiniteness and Double Inclusion (con't)

- *Lilly* (con't)
 - Issue: was claim limitation “vitamin B12” indefinite?
 - DC: construed as cyanocobalamin; not indefinite.
 - Parties agreed that “vitamin B12” can be used in the art to refer either to cyanocobalamin specifically or, more broadly, to a class of compounds including pharmaceutical derivatives of cyanocobalamin.”
 - Teva argued that “if ‘vitamin B12’ means ‘cyanocobalamin,’ then claim 1 recites a Markush group of ‘methylmalonic acid lowering agents’ **that lists the same compound twice.**”

Indefiniteness and Double Inclusion (con't)

- *Lilly (con't)*

- FC: Affirmed.

- Expert testimony supported conclusion that “vitamin B12” in a medical context refers to cyanocobalamin.
 - “Although we have in some instances interpreted claim terms to avoid redundancy, “the rule is not inflexible.” ... Here, the redundancy is supported by the prosecution history, during which the examiner stated that vitamin B12 and cyanocobalamin “are the same” agents. J.A. 4239. Therefore, faced with an interpretation that would read redundancy into claim 1 and another that would violate the doctrine of claim differentiation, we hold that the claims here support the former result over the latter.

Indefiniteness and Double Inclusion (con't)

- *Lilly* (con't)
 - FC: Affirmed.
 - During prosecution, Examiner noted that “vitamin B12” and “cyanocobalamin” are synonymous, and Lilly initially removed the term “cyanocobalamin.” Later during prosecution, Lilly added “cyanocobalamin” back into the claim that eventually issued as claim 1.
 - No evidence that a POSITA would understand including “cyanocobalamin” in the claim language as changing understanding that “vitamin B12” and “cyanocobalamin” refer to the same compound.

Mixtures of Components Included in Markush Language?

- *Amgen v. Hospira*, 2017 WL 129992 (D. Del. Jan. 12, 2017)
 - Claim 24. A method of preparing erythropoietin molecules having a predetermined number of sialic acids per molecule said number **selected from the group consisting of 1-14**, comprising applying material containing erythropoietin to an ion exchange column and selectively eluting said molecules from the column.
 - Hospira: Claim 24 requires one and only one isoform because of Markush language.

Mixtures of Components Included in Markush Language? (con't)

- *Amgen v. Hospira* (con't)
 - DC: Construed as a method of preparing an isoform.
 - No clear intent manifested to claim a method of preparing one and only one isoform.
 - The Markush language did not necessarily prohibit mixtures of such isoforms.
 - Construed to include methods of preparing one or more “isoforms.”

Mixtures of Components Included in Markush Language? (con't)

- *Amgen v. Hospira* (con't)
 - DC:
 - “*Multilayer* ...is inapposite because that case dealt with whether a component could contain combinations of Markush members. Here, the component is the isoform which, by my definition, can only have one member of the Markush group. If the isoform had more than one member of the Markush group, it would no longer appear as a single band on an isoelectric focusing gel and it would no longer be an ‘isoform’ by definition. Thus, *Multilayer* is not on point. **The real issue is whether mixtures of isoforms, where each isoform has one member of the Markush group, are allowed, not whether an isoform could be comprised of more than one member of the Markush group.** *Multilayer* does not speak to this.”

Mixtures of Components Included in Markush Language? (con't)

- *Amgen v. Hospira*, (con't)
 - DC:
 - “Furthermore, the prosecution history does not evince a clear disclaimer of mixtures of isoforms from claim 24.”
 - Hospira: “the present language does not encompass mixtures because the original claim language, which expressly provided for mixtures, was eliminated.”
 - Amgen: “the elimination of the original mixture language was not intended to disclaim all mixtures, just mixtures generated by techniques of the prior art.”
 - **DC: “The drafting history shows that the patentee intended to disclaim only mixtures derived by prior art techniques and not of mixtures derived from, for example, the [claimed process].”**

Take Aways

- Lessons from recent Federal Circuit decisions
 - Be on guard to easy design-arounds from merely adding an extra component not included in the Markush groupings recited in the claims.
 - If there is no reason to close the scope of the claim with respect to particular embodiments to overcome prior art, then practitioners may want to consider claiming such embodiments in the alternative without “closed” language, or with an open-ended transitional term such as “comprising,” rather than using Markush “consisting of” language to close the group.
 - Consider “at least one molecule chosen from a, b, and c.” Is that “equivalent” to “selected from the group consisting of a, b, and c”?
- Consider steps to take to avoid indefiniteness, double inclusion and other issues that arise with Markush claims.

Take Aways

- Strategies to employ to reduce the likelihood of an improper Markush rejection.
 - Avoid “selected from the group consisting of A, B, and C.”
 - Consider
 - “a member selected from a, b, and c”
 - “a member chosen from a, b, and c.”
 - “a member chosen from at least one of a, b, and c.”
 - Consider reciting Markush language "selected from the group consisting of" in dependent claims rather than in an independent claim.
 - Does “a member selected from a, b, and c” broaden a claim that was directed to “a member selected from the group consisting of a, b, and c”?
- Consider a functionally-defined genus in accord with 35 U.S.C. § 112(f) in an independent claim divorced from any need for “consisting of” Markush language.

Take Aways

- Avoid the trap of *Superguide Corp. v. DirecTV Enterprises, Inc.*, 358 F.3d 870 (Fed. Cir. 2004).
 - Claim: “at least one of a W, a X, a Y, and a Z.”
 - Does the phrase mean at least one W and at least one X and at least one Y and at least one Z?
 - Likely, yes.
 - “at least one of” modifies each category in the criteria list
 - “and” connotes a conjunctive list
 - claim required at least one of all of W, X, Y, and Z to be present, resulting in a finding of non-infringement.

May have avoided with “at least one material chosen from W, X, Y, and Z.”

Thank You

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