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# Office Action Response Workshop – Part 2

**Biotech and Chemical**

AIPLA Prosecution Boot Camp, Washington, DC  
October 26, 2016

- Genus – Species Claims
  - Anticipation
  - Obviousness
- Structural Similarity and Obviousness
- Markush Groups
- Written Description

Visualize Venn Diagrams

Genus – Species Claims

# Generic Claims

- Represent more than a single embodiment (a single species)
- Can include several structures or compositions represented in a generic fashion or as alternatives
- Encompass broadly defined inventions without limitations specific for particular species

# Exemplary Generic Claim

## Claim 1 of US 6,265,055

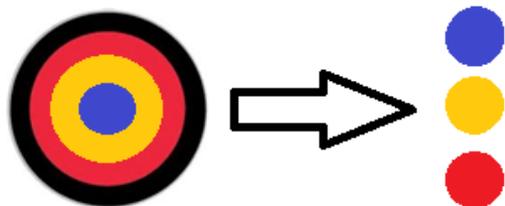
- A multi-layer, thermoplastic stretch wrap film containing seven polymeric layers, comprising:
  - (a) two outer layers, at least one of which having a cling performance of at least 100 grams/inch, said outer layer being selected from the group consisting of linear low density polyethylene, very low density polyethylene, and ultra low density polyethylene resins, said resins being homopolymers, copolymers, or terpolymers, of ethylene and alpha-olefins; and
  - (b) five 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.



## Anticipation

A species always anticipates a genus

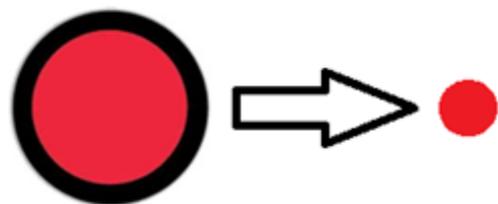
- “A generic claim cannot be allowed to an applicant if the prior art discloses a species falling within the claimed genus.”
  - In re Slayter, 276 F.2d 408, 411 (CCPA 1960)
- If the prior art discloses a species, a genus claim that encompasses the species is anticipated.
- Bullseye!
  - The genus always encompasses, i.e., reads on, the species.
  - When a species is clearly named, a claim to the named species is anticipated no matter how many other species are also disclosed.



## Anticipation

But a genus  
doesn't always  
anticipate a  
species

- Sometimes the scope of a genus claim can be so broad that one would not necessarily select specific portions of the disclosure and combine them in a particular way out of all the other possibilities in order to arrive at the exact same species.
- However, if a PHOSITA is able to “at once envisage” the specific components within the generic chemical formula to arrive at the particular species, the species is anticipated.

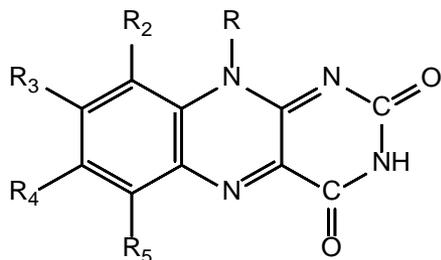


## At once envisage...

- Prior art discloses a definite and limited genus such that a PHOSITA could readily identify each species belonging to the genus.
- Anticipation can only be found if the classes of substituents are sufficiently limited or well delineated.  
Ex parte A, 17 USPQ2d 1718 (BPAI 1990)
- PHOSITA must be able to draw the structural formula or write the name of each of the compounds included in the generic formula before any of the compounds can be "at once envisaged."

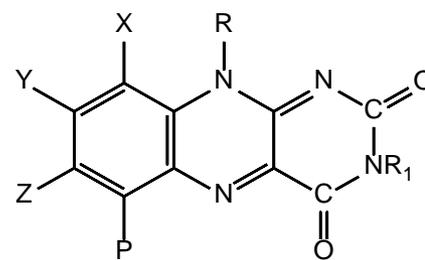
## In re Petering 301 F.2d 676 (CCPA 1962)

- Petering's claims were directed to compounds represented by the formula:



- wherein the R groups encompass lower alkyls

- The prior art reference, Karrer, disclosed compounds represented by the formula:



- where X, Y, Z, P and R' are either hydrogen or alkyl radicals and the R side chain contains an OH group. R was defined as having six groups.
- CCPA found Petering's were anticipated by Karrer

## CCPA Reasoning

- One skilled in the art would, on reading Karrer, **at once envisage each member of this limited class** even though this skilled person might not at once define in his mind the formal boundaries of the class.
- We wish to point out that is it not the mere number of compounds in this limited class which is significant here but, rather, the **total circumstances involved, including the limited amount of variations.**
- With this in mind, Karrer has **described** to those of ordinary skill in the art each of the various permutations involved as fully **as if he had drawn each structural formula or had written each name.**

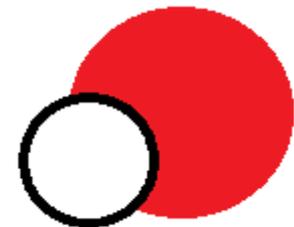
## Anticipation Rejection

Examiner asserts  
the claim is to a  
genus that is  
anticipated by  
species

- Amend the claim to redefine the scope of the genus so that it does not encompass the species.



- Amend an element and flip it around and argue that the claimed genus is really a species and the prior art discloses a genus that does not anticipate the species.



## Anticipation Rejection

Examiner asserts that the prior art discloses a genus such that the claimed species would be "at once envisaged" by a PHOSITA

- Argue that the prior art does not sufficiently define and limit the genus such that a PHOSITA could readily identify the claimed species as belonging to the genus.



- Amend the claim to redefine the species to have a limitation that the genus does not include.



# Genus-Species, Structural Similarity Obviousness

## Obviousness

Of a claimed  
Species belonging  
to a Prior Art Genus

- A species can be unobvious and patentable despite the prior art disclosing a genus that encompasses it.
- Would a PHOSITA have been motivated to select the claimed species or subgenus?
  - Size of the genus
  - Express teachings
  - Structural similarity
  - Similar properties or uses
  - Predictability

## Obviousness

### Structural Similarity and Compositions

- For a chemical compound, a prima facie case of obviousness requires “structural similarity between claimed and prior art subject matter ... where the prior art gives reason or motivation to make the claimed composition. In re Dillon, 919 F.2d 688 (CAFC 1990)
- In addition to structural similarity some TSM is also needed to select claimed species or subgenus. In re Albrecht, 514 F.2d 1389 (CCPA 1975)

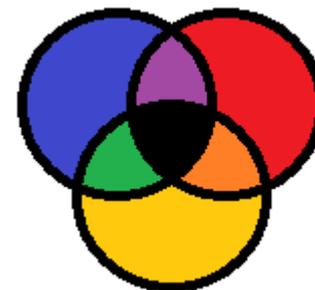
## Structural Similarity and Motivation

- A prima facie case of obviousness of a chemical compound requires
  - Structural Similarity; and
  - Motivation to Make
- Close structural similarity between the claimed compound and the prior art compound can itself be the requisite motivation to make the claimed compound where the structurally similar compounds are expected to have similar properties.
  - Analogs, homologs, and isomers
  - Compounds having the same structural backbone and different substituents, but of the similar type or similar function, e.g., steric hindrance, electron donor/acceptor, etc.

## Obviousness Rejection

Examiner asserts it would have been obvious to select A, B, and C from the listed substituents for the prior art genus with a reasonable expectation of obtaining the claimed species

- Argue unexpected results or properties
- And “superior” if necessary



## Obviousness Rejection

Examiner asserts the claimed compound is obvious because a PHOSITA would have expected it to have properties similar to a structurally similar prior art compound

- Argue the absence of a known or obvious method for making the claim compound.
- Explain why there is no reasonable expectation of similar properties.
- Point out that the prior art compounds have no specific or significant utility or are only useful as intermediates.
- Provide evidence of unexpected or superior results.

## Obviousness Rejection

Examiner asserts that a PHOSITA could take a known lead compound and modify it using known methods in order to obtain the claimed compound

- Point to *Takeda v. Alphapharm* (Fed. Cir. 2007) and argue that there must be:
  - Some TSM to select the particular lead compound out of all the other lead compounds
- Point to *Ortho-McNeil v. Mylan* (Fed. Cir. 2008), and argue that there must be:
  - Some TSM to select the particular synthetic pathway to arrive at the claimed compound
- Point to both cases and argue no reasonable expectation that the resulting compound would likely have the desired properties.

# Markush Groups

Eugene who?

## A Markush Group...

- Is a particular kind of claim limitation that lists various items that can be selected as a given element of the claim.
- Generally follows one of the following formats:
  - a member selected from the group consisting of A, B, and C
  - a member which is A, B, or C
- However, there is no precise language for Markush groups and the above language can be problematic

# Markush Group Examples

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.

## Markush Groups

### Problems of Closed Groups

- Markush groups are closed, i.e., limited to the recited members.
  - Excludes combinations
  - Excludes any elements, steps, or ingredients not specified in the claim
    - These are strong presumptions, which may be rebutted.
- As a closed group, no dependent claim may add a member to the Markush group.
  - A dependent claim cannot change or enlarge the scope of an independent claim.
- A dependent claim that contradicts, rather than narrows, the claim from which it depends is invalid. 35 U.S.C. 112(d)
  - A dependent claim must specify a further limitation of the subject matter claimed.

# Examples of Solutions

- Each layer being selected from the group consisting of linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, metallocene-catalyzed linear low density polyethylene resins, and combinations thereof
- Each layer is made of at least one material of linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, or metallocene-catalyzed linear low density polyethylene resins
- The material of each layer includes a linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, or metallocene-catalyzed linear low density polyethylene resins
- Each layer comprises one or more linear low density polyethylene, very low density polyethylene, ultra low density polyethylene, or metallocene-catalyzed linear low density polyethylene resins
- Use the specification to overcome the strong presumption

## Markush Groups

### Problems of Indefiniteness

- A member of a Markush group may not have subsets that overlap with another member of the Markush group.
  - A member selected from the group consisting of A, B, and C.
  - A = Apples, bananas, oranges
  - B = Carrots, peas, potatoes
  - C = Granny Smith Apples, Gala Apples, Fuji Apples, and McIntosh Apples
- Linear low density polyethylene contains other ethylenes, such as very low density polyethylene, ultra low density polyethylene, and metallocene-catalyzed linear low density polyethylene.
  - Thus, it encompasses a subset of the earlier genus.

## Markush Groups

The problem of  
relying on the  
specification

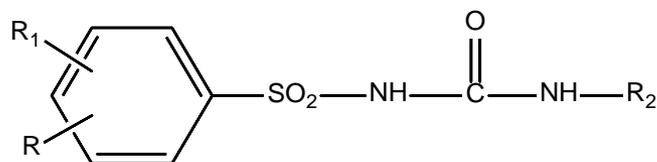
- In an attempt to overcome the strong presumption of a closed group, i.e., it excludes combinations thereof, the patentee attempted to rely upon the specification.
  - The resins used in the film composition include polypropylene (PP), ethylene propylene copolymers, low density polypropylene (LDPE), *linear low density* polypropylene (LLDPE), medium density polyethylene (MDPE), high density polyethylene (HDPE), metallocene-catalyzed polyethylene (mPE), very low density polyethylene (VLDPE), and/or ultra low density polyethylene (ULDPE).
- But the claim recited metallocene-catalyzed linear low density polyethylene.

## Fortunately...

- Overlapping members between the LLDPE and mLLDPE groups suggest that the compositions are open to blending.
- Claim 24: "... wherein at least one layer comprises a blend of at least two of said resins."
- Specification referred to blends
  - "The resins used in the film composition ... may be blended to achieve a desired range of physical or mechanical properties of the final film product."
  - Three embodiments in the description include layers of composition "C" which can contain blended LLDPE within a single layer.

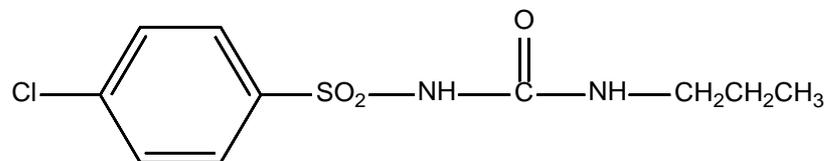
Selection of the Invention

Written Description



- wherein R is selected from the group consisting of H, Cl, Br, methyl, and methoxy;
- R<sub>1</sub> is selected from the group consisting of Cl and Br; and
- R<sub>2</sub> is of 2 to 7 carbon atoms selected from the group consisting of alkyl, alkenyl, cycloalkyl, and cycloalkyl atoms.

## Myriad of Possibilities



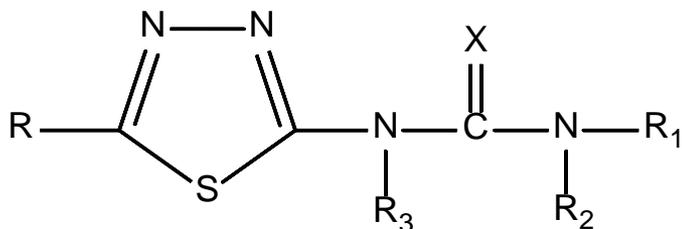
- R must be H
- R<sub>1</sub> must be Cl
- R<sub>2</sub> must be -CH<sub>2</sub>CH<sub>2</sub>CH<sub>3</sub>
- Would a PHOSITA selected these specific substituents over all the other possibilities?

# Written Description

## Friend and Foe

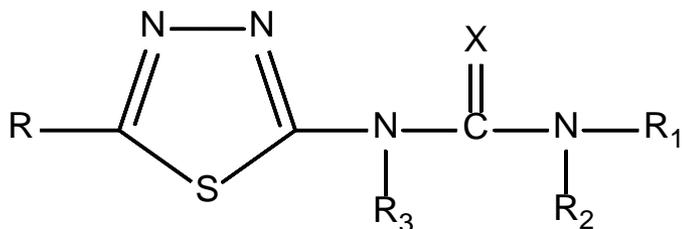
- **FOE** = Lack of written description support in the **original application** for N-(p-chlorobenzenesulfonyl) - N'-propylurea, so **statutory new matter**.
  - In re Ruschig, 379 F.2d 990, 154 USPQ 118 (CCPA 1967)
- **FRIEND** = **Prior art** lacks a (written) description of a specific example of making any compound falling within the broadest claim, so **novel and unobvious**.
  - In re Ruschig, 343 F.2d 965, 145 USPQ 274 (CCPA 1965)

# In re Driscoll 562 F.2d 1245 (CCPA 1977)



- where R is alkylsulfonyl (C<sub>1</sub>-C<sub>6</sub>);
- R<sub>1</sub> is selected from the group consisting of H, alkyl (C<sub>1</sub>-C<sub>4</sub>) and cycloalkyl (C<sub>3</sub>-C<sub>6</sub>);
- R<sub>2</sub> is from the group consisting of H, alkyl (C<sub>1</sub>-C<sub>4</sub>), haloalkyl (C<sub>1</sub>-C<sub>4</sub>), alkoxy (C<sub>1</sub>-C<sub>4</sub>), alkenyl (C<sub>2</sub>-C<sub>4</sub>), aryl, and haloaryl, wherein R<sub>1</sub> and R<sub>2</sub> are alkylene which, together with N, form a ring of at least 3, but not more than 6 members;
- R<sub>3</sub> is H or alkyl (C<sub>1</sub>-C<sub>6</sub>); and
- X is selected from the group consisting of oxygen and sulfur.

## Support for a Subgenus



- Needed written description support in grandparent for priority date for the subgenus claim.
- Grandparent = R is selected from the group consisting of H, alkyl (C1-C6), haloalkyl (C1-C6), cycloalkyl (C3-C6), halocycloalkyl (C3-C6), alkoxy, alkoxyalkyl, alkoxyalkylthio, aryl, substituted aryl, alkenyl (C2-C6), alkylthio (C1-C6), alkylsulfoxide (C1-C6), and alkylsulfonyl (C1-C6)
  - All other substituent groups were the same
- Specification taught: Particularly effective herbicides are thiadiazole ureas which contain an organic substituent in the 5-position of the thiadiazole portion.

## CCPA Reasoning

- Thus, the focus is unquestionably on the substituents at the 5-position of the thiadiazole moiety, and not on the substituents of the urea moiety. Accordingly, one skilled in the art would regard the structural formula of S.N. 782,756 as signifying that no matter which member of the R group is present on the thiadiazole moiety, the urea moiety may be substituted or unsubstituted.
- We thus agree with appellant that a skilled artisan would recognize from the disclosure of S.N. 782,756 fourteen distinct classes of compounds, each class having a single member of the R group at the 5-position of the thiadiazole moiety and variable substituent groups on the urea moiety. This being the case, it follows that S.N. 782,756 describes the subject matter of claim 13 inasmuch as one of the fourteen classes of compounds is the 5-alkylsulfonyl-1, 3, 4-thiadiazole ureas defined therein.
- "Hypertechnical application" of the written description requirement should be avoided.

## Written Description

Representative of  
a Genus

- Adequate written description may be met by a representative number of species. *Regents of the Univ. of Cal. V. Eli Lilly & Co.* 119 F.3d 1559 (Fed. Cir. 1997)
  - Means that the species which are adequately described are representative of the entire genus.
  - When there is substantial variation within the genus, one must describe a sufficient variety of species to reflect the variation within the genus.

# Not Representative

## Example of One Species

- In re Lukach, 442 F.2d 967 (CCPA 1971)
- Claim to a solid elastomeric copolymer of ethylene and propylene having a Mw/Mn ratio of at least 2.0 and less than about 3.0.
- Specification:
  - Exemplified Mw/Mn ratio of 2.6, which is between 2.0 and 3.0
  - But no express mention of the specific range, just simply that the range is “narrow”

## Multiple Examples of Species

- AbbVie v. Janssen (Fed. Cir. 2014)
- Claim to an Ab that binds to human IL-12 and dissociates from human IL-12 with a  $k_{off}$  rate constant of  $1 \times 10^{-2} \text{ s}^{-1}$  or less.
- Specification:
  - Provided over 300 examples of one species of antibody
  - No disclosure of structural features common to the members of the claimed genus

# Thank You!

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Craig's experience includes counseling on freedom to operate, patentability, and invalidity opinions; ANDA paragraph IV certifications; due diligence analysis of patent portfolios; and patent procurement, both domestic and foreign. His domestic patent experience includes interviewing cases at the USPTO, drafting appeal briefs, and arguing cases before the Board of Patent Appeals and Interferences.

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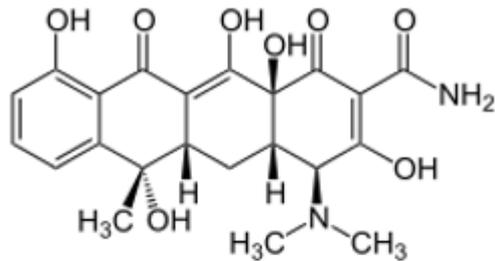
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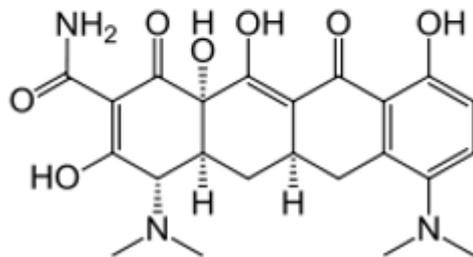
Suzannah practices all aspects of intellectual property law including patent preparation, and prosecution, licensing, opinion work, strategic planning, and client counseling relating to diverse technologies including biochemistry, molecular biology, pharmaceuticals, industrial chemicals, microfluidics, diagnostics, medical devices, and nanotechnology

# Apotex v. Wyeth (Fed. Cir. August 16, 2016)

Prior Art Compounds

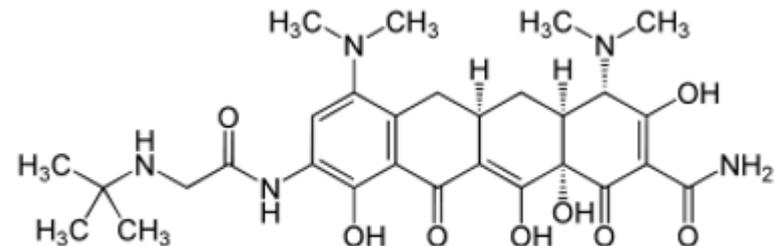


**Tetracycline**



**Minocycline**

Claimed Compound

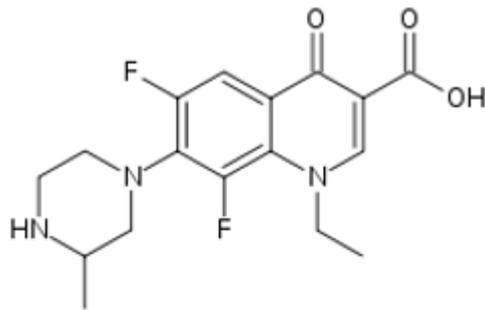


**Tigercycline**

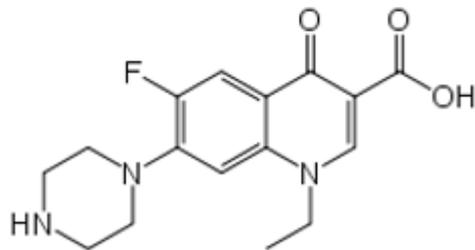
Unobvious

# Senju v. Lupin 780 F.3d 1337 (Fed. Cir. 2015)

## Prior Art Compounds

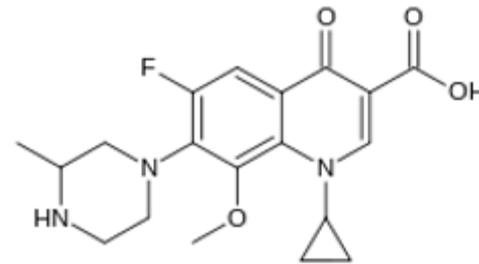


**Lomefloxacin**



**Norfloxacin**

## Claimed Compound



**Gatifloxacin**

Obvious