AIPLA Patent Prosecution Boot Camp

Responding to Office Actions
Biotech/Pharma/Chemical

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  - Markush Groups
  - Measurements & Methodology
- 101 Subject Matter (In)eligibility

Restriction/Species Requirements

Problems & Pitfalls

- Biotech applications usually receive multiple restrictions because of the types of claims usually involved
- For example, the invention is a novel polypeptide that has activity against a given disease, thus the usual types of claims are directed to:
  - The polypeptide itself
  - A nucleic acid molecule encoding the polypeptide
  - An expression vector comprising the nucleic acid molecule
  - A host cell comprising the nucleic acid molecule or expression vector
  - A method of making the polypeptide
  - A composition comprising the polypeptide
  - Antibodies against the polypeptide
  - A method of treating a subject having the disease by administering the polypeptide or composition to the subject

Requirements for Restriction

- Two or more "independent" or "distinct" inventions are claimed in one application
  - Independent = Unrelated, there is no disclosed relationship between the two or more inventions claimed, that is, they are unconnected in design, operation, and effect
  - Distinct = Can be related inventions, but, as claimed, they are not connected in at least one of design, operation, or effect (e.g., can be made by, or used in, a materially different process) and wherein at least one invention is PATENTABLE (novel & nonobvious) OVER THE OTHER
- Serious burden on the Examiner
  - Shown by separate classification, or separate status in the art, or a different field of search

Distinctness & Independence

- A) Where inventions are independent (i.e., no disclosed relation therebetween), restriction to one thereof is ordinarily proper
- (B) Where inventions are related as disclosed but are distinct as claimed, restriction may be proper
- (C) Where inventions are related as disclosed but are not distinct as claimed, restriction is never proper
- (D) A reasonable number of species may be claimed when there is an allowable claim generic thereto

- AVOID:
- Restriction Requirements (RRs) by understanding the essence of the invention, i.e., the key element that makes the invention so great and distinguishes it from the prior art
  - Draft the claims around the key element
  - Structure the hierarchy of the claims such that the key element is required in all independent claims and their dependent claims
- Having to file a divisional by requesting rejoinder when
  - Amending the unelected claims to depend on the elected claims
  - Selecting product claims and the unelected process claims require the use of the product
  - Never hurts to ask: often can rejoin after allowable claims are identified

Reduce Restrictions

Request rejoinder

- Understand the difference between a Restriction and an Election of Species
  - An Election of Species may turn into a Restriction where the prior art renders a species unpatentable
- Traversal is necessary to preserve the right to petition
  - However, avoid traversing an Election of Species as it requires admitting that the species are not patentably distinct
    - This means if one species is unpatentable over the prior art, the other species are also unpatentable

Traverse Restrictions

Let species slide

- If the Examiner withdraws a RR and related claims are pursued in a continuing application, there may be an obviousness-type double patenting (ODP) issue that requires a Terminal Disclaimer (TD)
  - TDs may reduce patent term by reducing or eliminating any PTA that would otherwise be available
    - So one might actually want a RR
- Filing a continuation or CIP after a RR will lead to a loss of protection against ODP under 35 U.S.C. 121
  - File the subsequent application as a "divisional" if a RR was received in the parent case

Withdrawn Restriction Requirements

Can result in ODP and require TDs

Anticipation

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

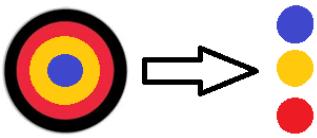
Anticipation

A species always anticipates a genus

- A generic claim cannot be allowed if the prior art discloses a species falling within the claimed genus
  - In re Slayter, 276 F.2d 408
- 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

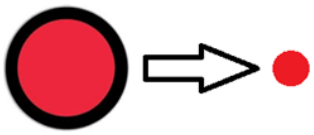
Anticipation

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 the possibilities to arrive at the exact same species
- However, if a PHOSITA is able to "at once envisage" the specific components within the generic formula to arrive at the particular species, the species is anticipated

At once envisage…

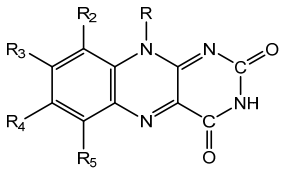


- Prior art discloses a definite and limited genus such that a PHOSITA could readily identify each species belonging to the genus
- Anticipation can only be found if the classes of substituents are sufficiently limited or well delineated
  - Ex parte A, 17 USPQ2d 1718 (BPAI 1990)
- PHOSITA must be able 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

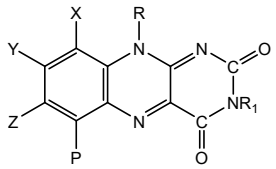
301 F.2d 676

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



- wherein the R groups encompass lower alkyls

- The prior art, 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

Anticipation

By Inherency

Inventors tell us all the time

- I discovered a new property of this compound
- We didn't even know that it had this feature until we conducted further studies
- But the prior art doesn't mention anything about this characteristic

Anticipation by Inherency

- Discovery of an inherent property of an old composition does not make the old composition patentable
  - Atlas Powder v. Ireco, 190 F.3d 1342
- But the lack of appreciation of the inherent property may help make a new use of the old composition patentable
- Inherent anticipation does not require recognition by a PHOSITA at the critical date
  - Schering v. Geneva, 339 F.3d 1373
- Actual creation or reduction to practice is not necessary as need only an enabling disclosure
  - Schering v. Geneva, 339 F.3d 1373
- Trace amounts of a by-product and contaminant that *might* be present inherently anticipate claims to the by-product or contaminant
  - Smithkline v. Apotex, 403 F.3d 1331

Schering v. Geneva

339 F.3d 1373

- First patent was directed to loratadine (API in Claritin®)
  - Disclosed administering loratine to patients
- Second patent (>1 year) was directed to a metabolite of loratadine
- Since administration of loratine to patients necessarily results in the metabolite being formed, the first patent was found to inherently anticipate the metabolite claimed in the second patent
  - Even though it was not actually previously administered because all that is required is an enabling disclosure, not an actual reduction to practice

Smithkline v. Apotex

403 F.3d 1331

- SKB had a patent claiming paroxetine HCl hemihydrate ("H", API in Paxil®)
- Apotex filed an ANDA for the anhydrous form ("A")
- SKB submitted evidence that producing A will necessarily result in trace amounts of H and
  - Therefore Apotex's production of A will infringe its patent claims covering H
- Seems SKB forgot about its really old patent covering A
  - SKB's own arguments and evidence backfired
  - Resulted in their subsequent claims to H being invalid as being inherently anticipated

- Burden
  - Anticipation requires each and every element
  - Examiners must provide reason why an inherent feature necessarily flows from the prior art
    - In re Oelrich, 666 F.2d 578
    - Ex parte Levy, 17 USPQ2d 1461 (BPAI 1990)
- Rebuttal
  - Use "If-Then" logic to explain the asserted inherent feature does not necessarily result
    - Apples are fruits, but all fruits are not apples; Dropping an apple does not always result in the apple being bruised
  - Each and Every Limitation - Point out limitations that are neither inherently nor expressly taught
  - Add limitations to avoid inherency

Burden & Rebuttal

Necessarily Flows

- HYPOTHETICAL
- Prior art: Antiviral A is a known therapeutic that has been used to treat hemorrhagic fever
  - A subject who was administered Antiviral A also had cancer
- Discovery: Antiviral A has an inherent property—prevents abnormal cell proliferation when administered in a therapeutically effective amount
- Claimed Invention: A method of treating cancer in a subject, which comprises administering to the subject Antiviral A
- Inherent anticipation? What if:
  - The subject is "in need thereof"?
  - A "therapeutically effective amount" is administered?
  - Limited to a specific type of cancer?

Inherency can be your FRIEND

- A specification describing undisclosed yet inherent properties of an invention can be sufficient written description for an explicit recitation of the inherent properties
  - Kennecott v. Kyocera, 835 F.2d 1419
  - Yeda Research v. Abbott, 837 F.3d 1341
- In Yeda Research:
  - Claimed Invention: A purified and isolated protein having a MW of about 42 kDa and at the N terminus the sequence Xaa Thr Pro Tyr Ala Pro Glu Pro Gly Set Thr Cys Arg Leu Arg Glu …
  - Priority document (PD) did not disclose the full sequence, instead it disclose a partial sequence, a protocol for obtaining, MW, biological activity, and other characteristics
  - Caution: Undisputed that the claimed protein is exactly the same as that of the PD
    - Thus, distinguished from Hyatt v. Boone, 146 F.3d 1348 and In re Wallach, 378 F.3d 1330

Inherency & Obviousness

- Inherency can be used to render claims obvious, but it is a high burden
  - Par Pharm v. TWI, 773 F.3d 1186
- However, later discovered inherent properties cannot be used to prove non-obviousness
  - BMS v. Teva, 769 F.3d 1339

Obviousness

Reasonableness & Reason (aka Motivation)

Obviousness

- Basic structure of an obviousness rejection:
  - A PHOSITA would have done X because Y in order to obtain Z with a reasonable expectation of success
- A *prima facie* case of obviousness requires:
  - PHOSITA
    - What is the art?
    - What is the level of one of ordinary skill?
  - Reason Why (Y)
  - To do What (X)
  - To obtain Z, the claimed invention
    - "As a Whole"
  - Reasonable Expectation of Success
    - Predictability
    - At the time of the invention (pre-AIA) or effective filing date (FITF)

- Attack the Motivation:
  - Proposed modification cannot render the prior art invention being modified unsatisfactory for its intended purpose
  - Proposed modification cannot change the principle mode of operation of the prior art invention being modified
- Attack the Result:
  - Even if modified or combined as proposed, the modification or combination does not result in the claimed invention "as a whole"

Reasonableness

- A reasonable expectation of success is required for obviousness
  - Determined at the time of the invention (pre-AIA) or effective filing date (FITF)
  - About obtaining the claimed invention not the intended operation of the combined references.
    - Intelligent Bio-Systems v. Illumina, 821 F.3d 1359
- 103 rejections typical for treatment claims
  - Using a drug having properties similar to another drug for the same indication
  - Using a drug for a new indication that is similar to a known indication for the same drug

- Attack the Reasonableness: Use the high level of unpredictability in the biotech arts to your advantage and support with evidence
  - Similar drug for same indication
    - Provide evidence, e.g., scientific article, showing claimed drug and prior art drug do not both work for a different indication
  - Same drug for similar indication
    - Provide evidence that another drug does not work for both the claimed indication and the prior art indication
- Be careful as arguments and evidence of unpredictability may make the case for lack of enablement

Overcoming Predictability

High level of unpredictability in biotech arts

- European “Problem-Solution Approach”
  - Those skilled in the art would not have solved the given problem in the same manner
- But we have KSR and the problem can be the reason for the solution as claimed
  - Obvious to apply a solution to a similar problem in a completely unrelated field
    - In re ICON, 496 F.3d 1374
  - Obvious where known problem was the motivation
    - Dome v. Lee, 799 F.3d 1372
  - Unobvious where unrecognized problem
    - Leo v. Rea, 726 F.3d 1346

Avoid making the problem the motivation

The problem can be the reason

Obviousness

Broadest (UN)Reasonable Interpretation

Broadest Reasonable Interpretation

- Often, an Examiner's Broadest Reasonable Interpretation (BRI) of a claim term can render a claim obvious
- Most times, an Examiner does not explicitly point out that BRI is being applied
- If you don't know if BRI is being applied, walk backward in the Examiner's shoes
  - Determine how the Examiner would need to interpret the claim terms in order to apply the prior art to render the claim obvious

- Determine whether the Examiner's application of BRI is proper
- Use of BRI is improper where
  - A special definition applies, or
  - An ordinary & customary meaning applies

Argue improper use of BRI

If a special definition or an ordinary & customary meaning

BRI is Unreasonable if it

- Conflicts with the plain meaning of terminology used in the specification
  - Perfect Surgical Tech. v. Olympus, 841 F.3d 1004
- Is illogical and fails to meet other claim limitations
  - D'Agostino v. Mastercard, 844 F.3d 945
- Results in a meaning that is redundant to another claim term
  - Home Semiconductor v. Samsung, July 25, 2017 (nonprecedential)
- Read limitations out of the claim or makes the claim inoperable for its asserted purpose
  - L.A. Biomedical v. Eli Lily, 849 F.3d 1049
- Is based on some unrelated disclosure or context
  - In re NuVasive, May 31, 2017 (nonprecedential)

- Ignores the special definition in specification or the ordinary & customary meaning
- Is inconsistent with the plain meaning of terms used in the specification
- Is illogical and inconsistent with other claim terms
- Leads to redundant claim limitations
- Reads other limitations out of the claims
- Renders the claim inoperable
- Is inapplicable to the given context

Explain why BRI is unreasonable

And point to support and evidence

Obviousness

Genus-Species, Structural Similarity

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 & 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
- In addition to structural similarity some TSM is also needed to select claimed species or subgenus
  - In re Albrecht, 514 F.2d 1389

Structural Similarity & 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 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

Enablement

Can be your FOE or FRIEND

The Enablement Requirement

- TEST: Whether a PHOSITA could make or use the invention based on the specification coupled with information known in the art without undue experimentation
- Wands Factors:
  - Claim breadth
  - Nature of the invention
  - State of the prior art
  - Level of one of ordinary skill
  - Level of predictability in the art
  - Amount of direction provided by the inventor
  - Existence of working examples
  - Quantity of experimentation needed to make or use based on the content of the disclosure

Lack of Enablement

- Usually the result of overly broad claims, i.e., full scope of the claim is not supported by the disclosure
  - Only experiments provided relate to Parkinson's, but claim is to treating *all* neurodegenerative diseases including Alzheimer's
  - But if experiments relate to a shared biochemical pathway, might get a method of treating a ND which comprises, e.g., inhibiting the biochemical pathway by…
- Inability to prove a negative, e.g., impossible to prove that an animal model will not develop cancer as a result of treatment
  - Can't get claims to "preventing" cancer
  - Can get claims to "treating" cancer
- Lack of an accepted animal model
  - Multiple Sclerosis and EAE animal model

Enablement as a FRIEND

- To be an anticipatory, a prior art reference must be enabling
  - In re Hoeksema, 399 F.2d 269
    - XOM™, custom reagent, not publicly available, not a sale, no disclosure of ingredients = non-enabling = no 102
- But a reference that lacks an enabling disclosure may qualify as prior art for an obviousness rejection for all that it discloses
  - Beckman v. LKB, 892 F.2d 1547
    - The combination with other references does not enable one to make and use the claimed invention if one does not have XOM™ or know its ingredients = no 103

- The "Biotech Squeeze" is where a claim is rejected under both 112 and 103 as lacking enablement and also being obvious
  - Means the claimed invention is not enabled, yet a PHOSITA would have obtained the invention with a reasonable likelihood of success
- Scream when you get this rejection… Then breathe
  - Imho, there is never a "proper" squeeze… if a decently drafted claim
- Evaluate the claim scope and specification objectively, and amend if needed
  - If prior art teaches or suggests the claimed invention "as a whole", i.e., claimed invention lacks something special = 103
  - If prior art lacks something special then ≠ 103, and
    - If spec provides something special ≠ 112
    - If spec doesn't provide something special = 112

- Exercise extreme caution, especially when attempting to overcome with arguments without amendments
  - Can be a damned if you do, damned if you don't situation
  - Interview the examiner – The examiner can be your friend
    - Sometimes the fix is a simple amendment that doesn't impact the client's desired claim scope
- Emphasize the key limitation the prior art doesn't teach or suggest and explain why it is sufficiently enabled

Responding to

The 112/103 Biotech Squeeze

- HYPOTHETICAL
- Prior art: Family of peptides having 95% homology to each other are active against Disease D
  - Peptide P is particularly effective at Dose D.
  - Peptides <95% homology = inactive
- Discovery: The same peptides having a C9 substitution have in vitro activity at half the dose of Peptide P
- Specification: Exemplifies Peptide N = Peptide P with C9
  - No in vivo data
- Claimed Invention: A method of treating Disease D in a subject, which comprises administering a peptide having 90% homology to Peptide P to the subject.
- 103 and/or 112?
  - 90% homology to Peptide N with C9?
  - 95% homology to Peptide N?
  - Therapeutically effective amount?
  - What if the in vitro test is not an accepted model for in vivo activity?

Written Description

Friend, Foe, & Functional Language

Written Description – Friend or Foe

- 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
- 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

Functional Language

- Can *seemingly* broaden the scope of biotech claims
- Can help provide enablement for biotech claims by, e.g., narrowing the claim scope to biomolecules having a particular function that requires only routine screening methods to identity
- Unfortunately, functional language often leads to invalidity for lack of written description support

No Actual Compounds

- Claim 1 of US 6,048,850:
  - 1. A method for *selectively inhibiting PGHS-2 activity* in a human host, comprising administering a non-steroidal compound *that selectively inhibits activity of the PGHS-2 gene product* to a human host in need of such treatment.
- Specification:
  - No actual compounds that performed the claimed function were disclosed
- Thus, no written description support
  - Univ. of Rochester v. Searle, 358 F.3d 916
  - See also Ariad v. Eli Lilly, 598 F.3d 1336

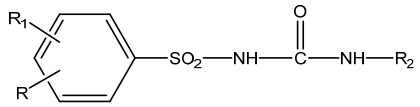
No Example Having All Limitations

- Claim 1 of US 7,713,723:
  - 1. An isolated variant of a parent alpha-amylase, wherein:
  - (a) the variant *has at least 90% sequence identity* to SEQ ID NO: 6 [ ],
  - (b) the variant comprises a *substitution of serine at position 239* [ ], and
  - (c) the variant has *increased thermostability relative to the parent alpha-amylase, wherein thermostability is determined at pH 4.5, 90°C and 5 ppm calcium and has alpha-amylase activity*.
- Specification:
  - 2 working examples had < 90% identity
  - The only specifically described substitution at position 239 *does not* result in increased thermostability
- Thus, no written description support
  - Novozymes v. DuPont, 723 F.3d 1336

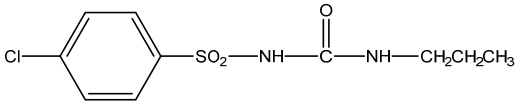
Written Description

Selection of a Species (or Subgenus)

Myriad of Possibilities



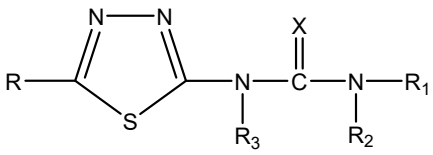
- wherein R is selected from the group consisting of H, Cl, Br, methyl, and methoxy;
- R1 is selected from the group consisting of Cl and Br; and
- R2 is of 2 to 7 carbon atoms selected from the group consisting of alkyl, alkenyl, cycloalkyl, and cycloalkyl atoms.



- R must be H
- R1 must be Cl
- R2 must be –$CH_2CH_2CH_3$
- Would a PHOSITA selected these specific substituents over all the other possibilities?

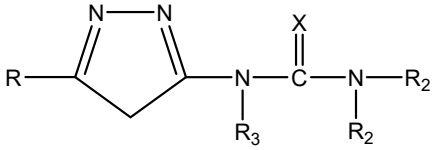
In re Driscoll

562 F.2d 1245



- where R is alkylsulfonyl (C1-C6);
- R1 is selected from the group consisting of H, alkyl (C1-C4) and cycloalkyl (C3-C6);
- R2 is from the group consisting of H, alkyl (C1-C4), haloalkyl (C1-C4), alkoxyl (C1-C4), alkenyl (C2-C4), aryl, and haloaryl, wherein R1 and R2 are alkylene which, together with N, form a ring of at least 3, but not more than 6 members;
- R3 is H or alkyl (C1-C6); 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 disclosed:
  - 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 disclosed:
  - 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 Genus

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, 119 F.3d 1559
  - 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

One Example

- In re Lukach, 442 F.2d 967
- 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 but only of one sub-genus

- AbbVie v. Janssen, 759 F.3d 1285
- Claim to an Ab that binds to human IL-12 and dissociates from human IL-12 with a k_{off} rate constant of $1x10^{-2}$ 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

Not Representative of a Genus

- Claim 1 of US 4,767,708:
  - 1. A recombinant plasmid containing *a cloned complete structural gene coding region isolated from a bacterial source for the expression of DNA polymerase I*, under operable control of a conditionally controllable foreign promoter functionally linked to said structural gene coding region, said foreign promoter *being functional to express said DNA polymerase I in a suitable bacterial or yeast host system*.
- Claim broadly encompasses coding sequences originating from *any* bacteria and expressing in *any* bacterial or yeast host system
- Specification:
  - Disclosed only E. coli DNA polymerase I and E. coli host strain
- Thus, no written description
  - Carnegie Mellon v. Hoffman-La Roche, 541 F.3d 1115

- HYPOTHETICAL
- Claim: A recombinant plasmid containing a nucleic acid molecule that encodes a Bacillus spp. DNA polymerase functionally linked to a foreign promoter.
- Specification: Exemplifies a handful of DNA polymerases from a variety of gram-negative bacteria
  - No DNA polymerases from Bacillus spp.
- Written description support?
- What if:
  - Some examples of DNA polymerase from gram-positive bacteria, e.g., Staphylococcus and Streptococcus (but not Bacillus spp.)?
  - Some examples of DNA polymerases from a few species of Bacillus, but one does not work with a given foreign promoter?

- Avoid trying to get claims that have a claim scope that is broader than the written description provided by the specification
- Avoid arguments that result in a claim interpretation that is not supported by the specification

Basically, don't be greedy

When drafting claims

Ensure the specification provides adequate support

Indefiniteness

Markush Groups

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
- There is no precise language for Markush groups and the above language can be problematic

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 enlarge the scope of an independent claim
- A dependent claim that contradicts, rather than narrows, the claim from which it depends is invalid
  - A dependent claim must specify a further limitation of the subject matter claimed

Markush Group Example

Multilayer v. Berry Plastics, 831 F.3d 1350

- Claim 1 of US 6,265,055 (as amended by reexam):
- 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 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

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

Indefiniteness

Measurements & Methodology

Measurements can be Indefinite

- Often patent claims to biotech, chemical, and pharmaceutical inventions include a measurement limitation, e.g., a molecular weight, affinity range, etc.
- Even though a claimed measurement may be a precise number/amount, it can be indefinite if the method of measuring is not specified
- For example, indefiniteness found where
  - Different measurement methods give different "measured" results, and the claims, specification, and prosecution history fail to specify the particular method
    - Teva Pharm v. Sandoz, 789 F.3d 1335
  - No guidance provided as to the physical stage/state of a composition when the measurement was taken
    - Dow Chem v. Nova, 803 F.3d 620

- Consider the influence and impact of different:
  - Methodologies
  - Standards, Controls, and Reagents
  - Temperature, Time, and Pressure
  - Subjects and Population Pools
  - Etc.

- If specification discloses multiple methodologies, add specific method to the measurement limitation, e.g., "as measured by…"
- Similarly, if a comparative measurement, add "as compared to…"

Make sure Measurements have Meaning

Before adding to claims and arguing

(IN)Eligibility

BARF – Bogus Arbitrary Rejection Forever

Well-Understood, Routine, & Conventional

- Analysis is a watered-down subjective version of an obviousness analysis
  - Doesn't require a person of "ordinary skill"
  - Unclear as to the scope of the art
  - So-called "as a whole" analysis considers limitations *apart from* those involving the asserted judicial exception (JE).
    - GTL v. Merial, 818 F.3d 1369
  - Discovery of unknown property can be the reason why a novel combination of steps is conventional.
    - Ariosa v. Sequenom, 788 F.3d 1371
- Consequently, a claimed invention can be unobvious under 103, but lack inventiveness under 101

Step One

- Is it directed to law of nature, natural phenomenon, or abstract idea?
  - Argue and/or amend to stay out of Mayo/Alice Two-Step!
  - Direct claim to method of performing an assay
  - Claim the kit used to perform the assay
  - Avoid mentioning the natural principle
  - Study and follow the USPTO Guidelines & Examples

Step Two

- Is it REALLY routine & conventional?
  - Has the exact same assay been performed on the same samples using the same reagents in the same sequence?
  - If the context (selection of subject, sample, etc.) differs, you may be able to argue that it's not routine & conventional as claimed
  - Consider narrowing limitations that won't hurt the client's objectives

Step Two

- Give it "something more"!
  - Consider whether a feature that relates to the inventive concept can be added to the claim
  - Add a treatment step that would not have been used in combination with "routine & conventional" assay
  - Direct the claim to treatment that is contingent on assay results
  - May be difficult to enforce, but could be better than nothing in some cases

- Remember the Examiner has the initial burden, so push back when no evidence that, e.g., a product naturally exists
- Present the claimed invention as a technological improvement to the functioning of a thing itself
- Argue the ordered combination is unconventional if the individual elements are known
- Push back when an Examiner asserts that a given step can be performed solely in the mind when it can't
  - If a given step can be performed solely in the mind, add limitations so it can't

Recommendations

- AVOID:
- Conceding that a claim is "directed to" a judicial exception
- Indicating that certain elements are well-known, conventional, or routine
- Relying on intended use
- Relying on structural limitations that are well-understood, routine, or conventional
- Functional limitations
  - Consider it lucky if functional limitations are ignored as non-limiting (i.e., insufficient to make generic structure a specific and unconventional device) as functional limitations may likely result in invalidity under 112

Avoid

HIT THE ROAD

Roll Over And Die

THANK YOU!

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