Claim Drafting

Biotech/Pharma/Chemical

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Member

Eckert Seamans Cherin & Mellott, LLC

We will cover the following issues relevant to Biotechnology/Pharma/Chemical claim drafting:

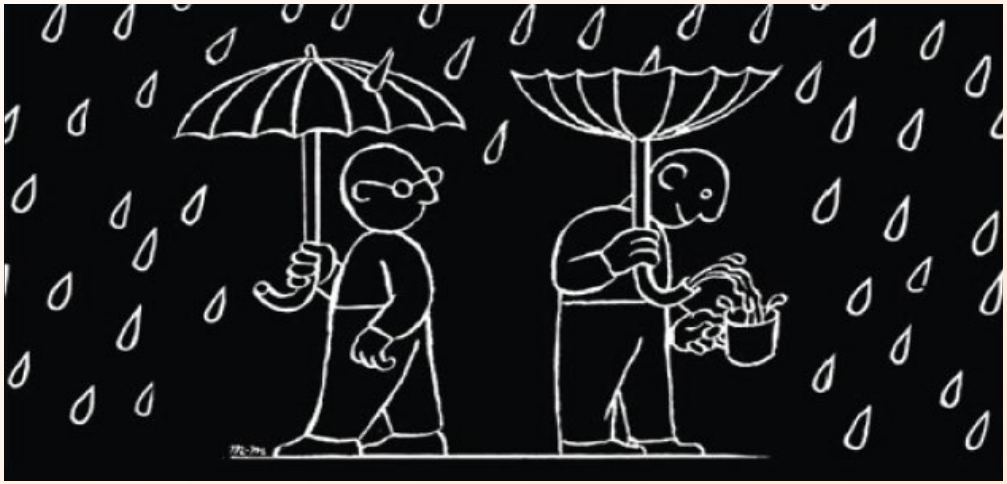
- ✓ Claim Construction
- ✓ Big Picture Claiming Drafting: Know Thy Invention/Client
- ✓ 35 USC 112(a): Written Description
- ✓ 35 USC 112(a): Enablement
- ✓ 35 USC 112(b): Definiteness
- ✓ Markush Groups
- ✓ 35 USC 112(d): Dependent Claims
- ✓ Deeper Dive Claiming Strategies
  - ✓ Product-by-Process Claims
  - ✓ Drafting to a Label
  - ✓ 35 USC 112(f): Means Plus Function
  - ✓ Dosing Regimens
  - ✓ Drafting Claims for Global Filings

Big Picture Claim Drafting
Know Thy Invention

Invention: A Problem/Solution Approach

A Problem: It's raining and my head is getting wet.

The Solution: ?? ***(understand that before you start drafting claims!)***



SOURCE: Innovation is a State of Mind, by James O'Loghlin

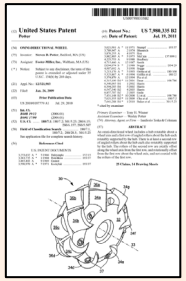
Big Picture Claiming Drafting

Know Thy Invention: Applying Problem-Solution Approach

"Problem"

"Inventive Solution"

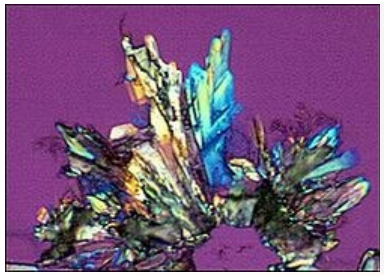
Value

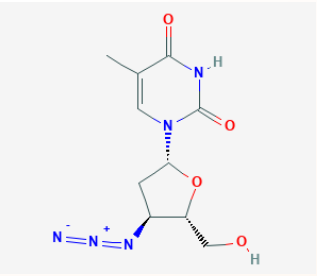


Patent

Big Picture Claiming Drafting

Know Thy Invention: Old Compound, New Use





Old Compound: In 1964, Jerome Horwitz et al. first synthesized azidothymidine (AZT, aka zidovudine), a "fraudulent nucleoside", intended to inhibit duplication of cancer cells. The compound was, however, biologically inert in mice. Dr. Horwitz and colleagues wrote up the poor results and moved on (no patents).

New Use: In 1984, Burroughs-Wellcome (B-W) scientists, seeking to discover drugs that inhibit HIV replication, discovered AZT was active against mouse retroviruses, later confirming AZT could inhibit HIV. B-W filed a patent application for a method to treat AIDS with AZT. ***This drug was a best seller for B-W. Gx entered post-patent expiration in 2005.***

Several Patents Issued to New Use for Old Compound

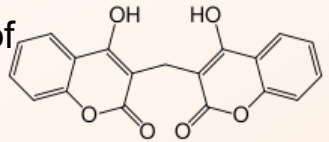
U.S. Patent No. 4,724,232 Claim 1: "A method of treating a human having acquired immunodeficiency syndrome comprising the oral administration of an effective acquired immunodeficiency syndrome treatment amount of 3'-azido-3'-deoxythymidine to said human."

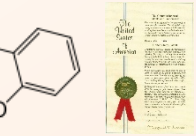
Big Picture Claiming Drafting

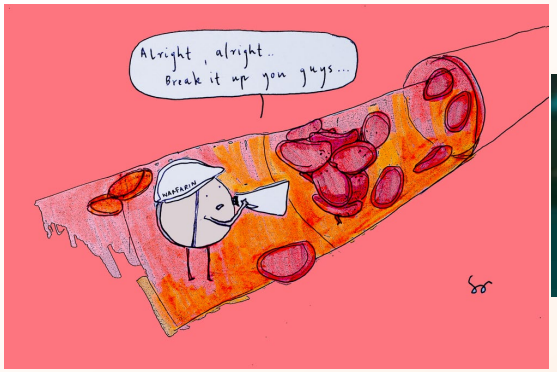
Know Thy Invention: Accidental Discoveries (surprising)

1920's: Mouldy hay from sweet clover crops was identified as responsible for cattle deaths.

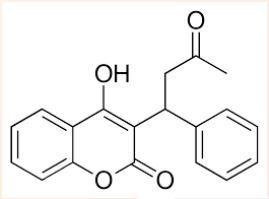
In 1940, scientists in Karl Link's lab at the University of Wisconsin identified the culprit compound, dicoumarol, and patented it in 1941 (therapeutic use as anti-coagulant).







1948: A related compound, coumarin (warfarin), was developed by Link and registered for use as a rat poison. Patented by Wisconsin Alumni Research Foundation (WARF).



1950's: In 1951, an army inductee attempts suicide using warfarin, but fully recovers with vitamin K treatment. Studies show warfarin use as an anticoagulant - superior to dicoumarol. In 1954, warfarin is approved as an anticoagulant for humans. Multi-million $ drug for WARF - patent expired in 1982! Warfarin is one of most widely prescribed medicines worldwide.

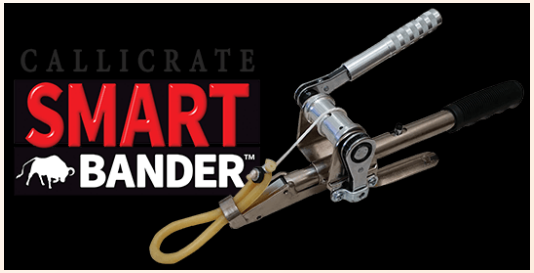
Big Picture Claiming Drafting

Know Thy Invention: Simple Improvements

Since the 1980's, the Wadsworth family had been making devices for bull castration – called the "EZE" castration tools.

Patent Litigation

Callicrate, also in the bull business, developed a simple improvement to change the tightening mechanism for the band.



Big Picture Claiming Drafting
Know Thy Invention: Unmet Need

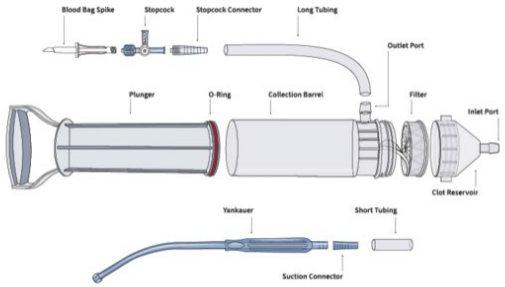
Global Blood Shortage

THERE IS A 100 MILLION UNIT DEFICIT OF DONOR BLOOD AROUND THE WORLD.

This means when clinicians reach for a unit of blood, it is often not there.

Donate Blood to Yourself

HEMAFUSE PROVIDES A SOLUTION TO THE CORE CHALLENGE OF THE GLOBAL DONOR BLOOD SHORTAGE.



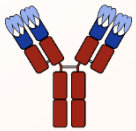
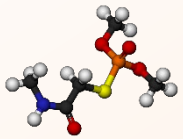
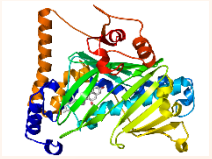
Hemafuse is a simple hand-held device that enables clinicians to salvage, filter, and recycle blood from patients with internal bleeding, introducing an alternative to donor blood.

Big Picture Claiming Drafting

Know Thy Invention - Categories

Many Kinds of Compositions of Matter

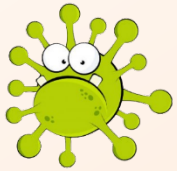
- ✓ **Actives**

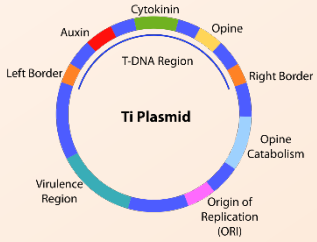




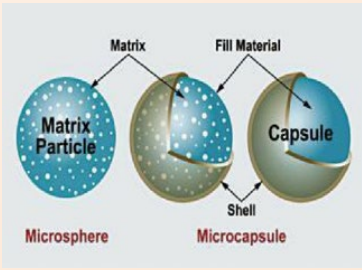

- ✓ **Formulations**



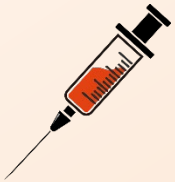

- ✓ **Delivery Systems**

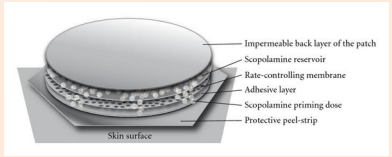






- ✓ **Drug-Device Combos**



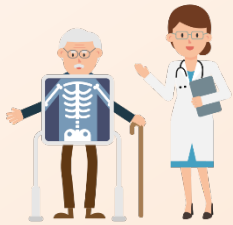



Big Picture Claiming Drafting

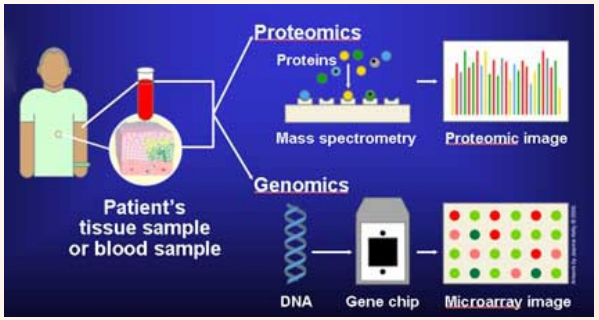
Know Thy Invention – Categories

Many Types of Methods

- ✓ **Methods of Treatment**
  - ✓ Who is the patient?
  - ✓ What is the indication?
  - ✓ How is product administered?
  - ✓ Who administers it?
  - ✓ What is the dosing regimen?



- ✓ **Diagnostic/Personalized Medicine**

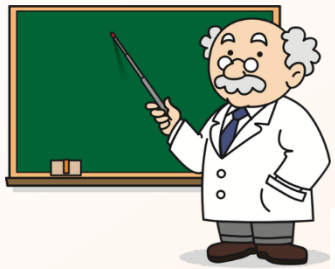


- ✓ **Methods of Manufacture**

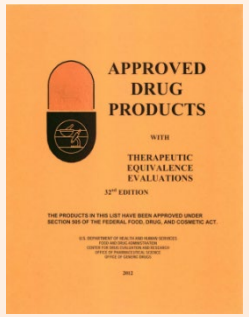
Big Picture Claiming Drafting

Know Thy Client

Who is the Client?



What does the Client want?



Indefiniteness
35 USC 112(b) or 112, 2nd ¶

- Does the claim inform the POSITA with ***reasonable certainty*** about the scope of the claim, based on intrinsic evidence?
  - The standard for indefiniteness is "reasonable certainty" **not** "insolubly ambiguous" *Nautilus, Inc. v. Biosig Instruments, Inc.*, 12-1289 (Fed. Cir. Apr. 27, 2015)
- ***Breadth*** is not indefiniteness
- ***You can be your own lexicographer,*** but clearly define the term!
- ***Terms of degree*** (*e.g.,* "substantially") are not *necessarily* indefinite
- ***You can use approximations*** (*e.g.,* "about", "essentially"), but it must be clear based on the specification that a POSITA would understand the claim boundaries

Indefiniteness
35 USC 112(b) or 112, 2nd ¶

Teva Pharmaceuticals USA v. Sandoz, Inc., No. 2012-1567 (Fed.Cir. 2015)

1. A method of manufacturing copolymer-1, comprising

reacting protected copolymer-1 with hydrobromic acid to form trifluoroacetyl copolymer-1,

treating said trifluoroacetyl copolymer-1 with aqueous piperidine solution to form copolymer-1, and

purifying said copolymer-1, to result in copolymer-1 ***having a molecular weight of about 5 to 9 kilodaltons***.

The term "molecular weight" was not defined in the specification. Is it M_p, M_n or M_w? Would the POSITA know with reasonable certainty?

Indefiniteness
35 USC 112(b) or 112, 2nd ¶

BASF Corp. v. Johnson Matthey Inc. 875 F.3d 1360 (Fed. Cir. Nov. 20, 2017)

1. A catalyst system for treating an exhaust stream containing NOx, the system comprising:

at least one monolithic catalyst substrate having…an undercoat washcoat layer..., and containing a material composition A ***effective for catalyzing*** NH3 oxidation;

an overcoat washcoat layer…., and containing a material composition B ***effective to catalyze*** selective catalytic reduction (SCR) of NOx; and

wherein material composition A and material composition B are maintained as physically separate catalytic compositions.

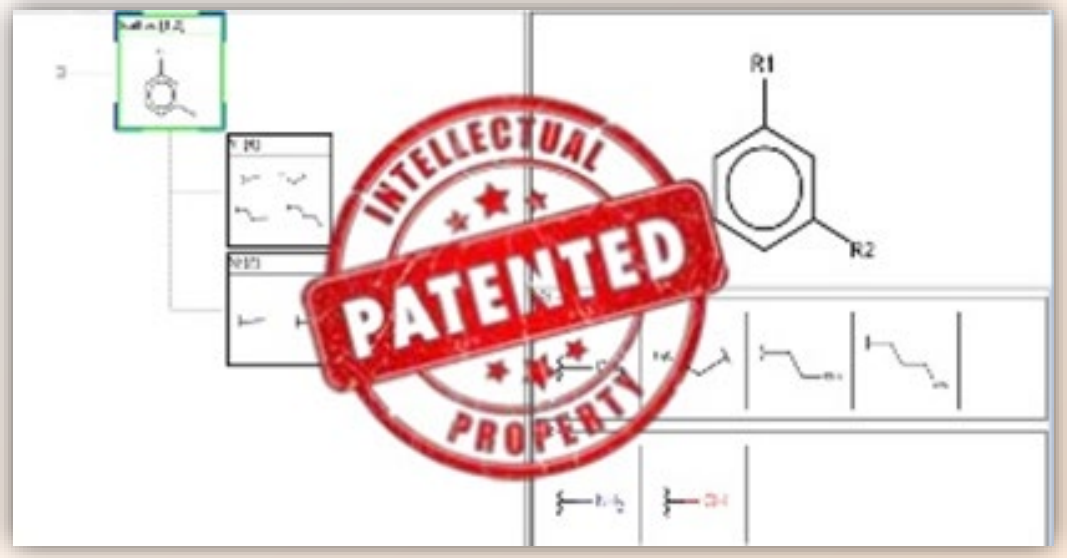
Would the POSITA understand with reasonable certainty the meaning of "effective to catalyze" or "effective for catalyzing"?

Indefiniteness – Practice Points

- Review all of your claim terms before filing, and consider:
  - Would a POSITA, *in light of the specification*, be reasonably certain about the scope of the claim?
  - Do you need to add, or revise, a definition of the claim term?
  - Do you have terms with more than one "ordinary" meeting, which might be confusing to the POSITA?
  - Have you been your own lexicographer? Is the meaning clear?
- If you have used approximations or subjective terms, consider whether they are adequately defined or clear
- Consider whether you have correctly used and defined numerical ranges and "amount" limitations
- Think about the difference between BRI and POM, particularly if litigation is anticipated. Does this change how/whether you use a term, or how you define it?

Markush Groups

Claim Construction – District Court

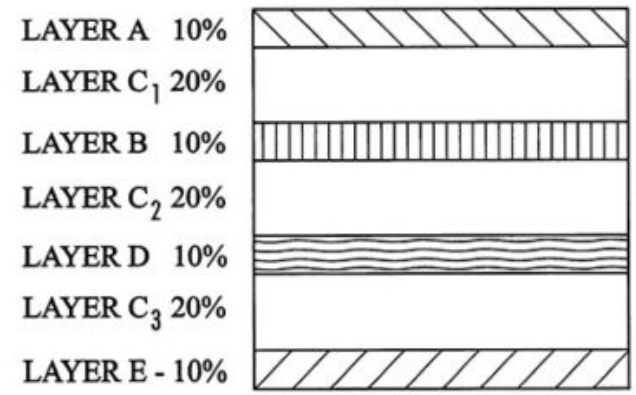


Multilayer v Berry Plastics (Fed. Cir. Aug. 4, 2016)

Facts

Background

- Multilayer Stretch Cling Film Holdings, Inc. (“Multilayer”) brought suit against Berry Plastics Corp. (“Berry”), alleging infringement of at least claim 1 of US Patent No. 6,265,055.
- The ‘055 patent relates to multilayered plastic cling wrap films.
- The District Court granted Berry’s motion for summary judgment of non-infringement based on its claim construction.



Claims at issue

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

Claims at issue

(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.

Claims at issue

Claim 28

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

Claims at issue

(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;

wherein at least one of said inner layers comprises a metallocene catalyzed linear low density polyethylene resin with a melt index of 0.5 to 3 dg/min and a melt index ratio of 16 to 80; and wherein each of said two outer layers and each of said five inner layers have different compositional properties when compared to a neighboring layer.

District Court Claim Construction

Disputed part of element (b) of claims 1 and 28:	District court's construction:
five [identifiable][1] inner layers, with each layer being selected from the group consisting of linear low density polyethylene [(LLDPE)], very low density polyethylene [(VLDPE)], ultra low density polyethylene [(ULDPE)], and metallocene-catalyzed linear low density polyethylene [(mLLDPE)] resins	each of five identifiable inner layers must contain only one class of the following resins, and no other resin(s): linear low density polyethylene [(LLDPE)] resins, very low density polyethylene [(VLDPE)] resins, ultra low density polyethylene [(ULDPE)] resins, or metallocene-catalyzed linear low density polyethylene [(mLLDPE)] resins

District Court Claim Construction

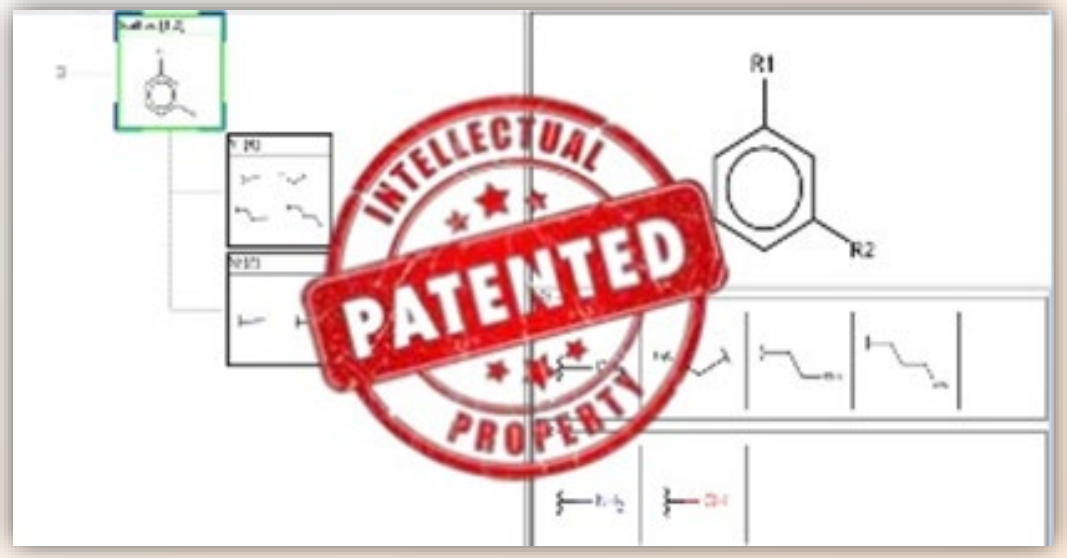
- The Markush group in Claim 1 (b) was construed by the District Court to be ***closed***.
- Only one of the resins ***listed*** in Claim 1(b) could be used to construct each of the five inner layers.
- ***Blends*** of the listed resins were also ***excluded***.
- Dependent claim 10 was held ***invalid*** under 35 USC 112(d) because it recited “low density polyethylene homopolymers” which was not recited in the Markush group of claim 1, from which it depends.

Accused Films

- The parties had agreed that at least one layer of the Accused Films made by Berry contained ***blends*** of resins: mLLDPE, ULDPE and LLDPE.
- These are all classes of resins that were separately listed in the Markush groups of claims 1 and 28.
- Thus, under the District Court's claim construction there was ***no infringement***.
- Multilayer appealed to the Federal Circuit.

Markush Groups

Claim Construction – Federal Circuit



Federal Circuit Decision - Judge Dyk

Markush Groups

"[a] Markush group lists specified alternatives in a patent claim, typically in the form: a member selected from the group consisting of A, B, and C," where "[i]t is generally understood that . . . the members of the Markush group . . . are alternatively usable for the purposes of the invention"

Federal Circuit Decision - Judge Dyk

Holding:

1. whether the Markush group of element (b) is closed to resins other than the listed four--YES

2. whether the Markush group is closed to blends of the four listed resins--NO

Federal Circuit Claim Construction

- The Markush group in Claim 1 (b) was construed by the Federal Circuit to be ***closed***. Agreed with District Court.
- Only one of the resins ***listed*** in Claim 1(b) could be used to construct each of the five inner layers.

Federal Circuit looked at specification in *Multilayer* for claim construction

- Specification repeatedly and consistently references blends in describing any and all resins, including the four resins in element (b)
- Specification discusses blending the resins in order to achieve a desired range of physical or mechanical properties
- Court concluded ***blends were included in Markush group***
- Thus, under Fed. Cir. claim construction there was infringement

Amgen v Amneal Pharmaceuticals (Fed. Cir. Jan. 7, 2020)

- Amgen sued Amneal for infringing claims 1, 2-4, 6, 8-12, and 14-18 of Amgen's U.S. Patent No. 9,375,405 (the '405 patent)
- District Court found that Amneal did not infringe
- Fed. Cir. ***reversed*** and remanded because it found that the District Court interpreted Amneal's claims incorrectly

Amgen v Amneal Pharmaceuticals

A pharmaceutical composition comprising:

(a) from about 10% to about 40% by weight of cinacalcet HCl in an amount of from about 20 mg to about 100 mg;

(b) from about 45% to about 85% by weight of a diluent selected from the group consisting of microcrystalline cellulose, starch, dicalcium phosphate, lactose, sorbitol, mannitol, sucrose, methyl dextrins, and mixtures thereof,

(c) from about 1% to about 5% by weight of **at least one** binder selected from the group consisting of povidone, hydroxypropyl methylcellulose, hydroxypropyl cellulose, sodium carboxymethylcellulose, and mixtures thereof; and

(d) from about 1% to 10% by weight of **at least one** disintegrant selected from the group consisting of crospovid[o]ne, sodium starch glycolate, croscarmellose sodium, and mixtures thereof,

wherein the percentage by weight is relative to the total weight of the composition, and wherein the composition is for the treatment of at least one of hyperparathyroidism, hyperphosphonia, hypercalcemia, and elevated calcium phosphorus product.

Amgen v Amneal Pharmaceuticals

- Amneal's ANDA states that its product uses "Opadry" as a binder
- It was undisputed that Opadry is a composite product comprised of HPMC, polyethylene glycol ("PEG") 400, and PEG 8000
- HPMC is listed in the binder Markush group of claim 1
- The Markush was construed as being **open** due to the 'at least one' claim language
- "Because the district court erred in its analysis of the binder in Amneal's formulation, we vacate its finding that Amneal does not infringe the asserted claims because of the identity of Opadry. On remand, the court should consider whether Amneal's formulation contains "from about 1% to about 5% by weight" of HPMC, irrespective of the HPMC's pairing with PEG"

35 USC 112(d) Dependent Claim Invalidation

Federal Circuit

35 USC 112(d)

(d) REFERENCE IN DEPENDENT FORMS.—Subject to subsection (e), a claim in dependent form shall contain a reference to a claim previously set forth and then ***specify a further limitation*** of the subject matter claimed. A claim in dependent form shall be construed to incorporate by reference all the limitations of the claim to which it refers.

Multilayer v. Berry Plastics

- Dependent claim 10 was held ***invalid*** under 35 USC 112(d) because it recited “low density polyethylene homopolymers” which was not recited in the Markush group of claim 1, from which it depends.
- Claim 1 recited “***linear*** low density polyethylene homopolymers”
- Federal Circuit agreed with the District Court.

Pfizer v. Ranbaxy

Pfizer, Inc. v. Ranbaxy Laboratories Ltd., 457 F.3d 1284 (Fed. Cir. 2006) (Lipitor® case):

- Dependent salt claim 6 was held to be invalid for failing to further limit its base claim; the base claim was not open to salts:
  - 1. Compound A or Compound B; or pharmaceutically acceptable salt thereof.
  - 2. Compound A.
  - 6. The hemicalcium salt of the compound of claim 2.
- Base claim 2 was not open to salts, and therefore dependent claim 6 was an improper dependent claim since it referred to a "salt"

Pfizer v. Ranbaxy

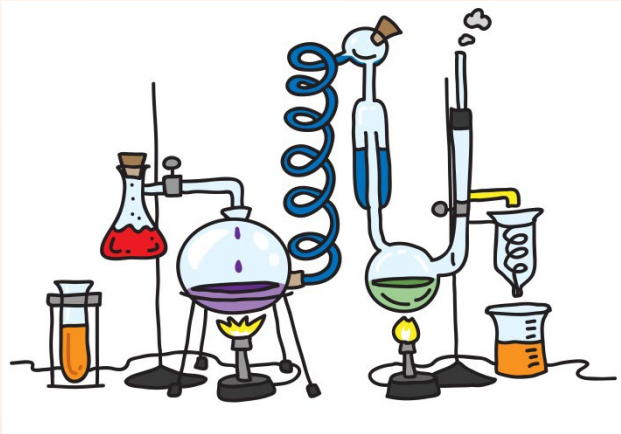
- Thus, Section 112, 4th paragraph is an independent ground for holding a patent claim invalid.

Markush Groups & 35 USC 112(d) Practice Points

- Take care to include all desired compounds in a Markush group
- Make sure that any compound recited in a dependent claim is also listed in the Markush group of the independent claim
- Instead of traditional Markush language consider using language such as “wherein the compound is A, B, C, or D”
- Consider using “comprising a compound selected from the group consisting of A, B, C, and D” – *not recommended*
- To cover blends or combinations in a Markush group, consider adding qualifying language such as:
  - “and mixtures thereof”
  - “and combinations thereof”
  - “at least one member of the group”
  - “wherein X is at least one of A, B or C”
  - “with at least one X chosen from A, B or C”

Deeper Dive Claiming Strategies
Product-by-Process Claims

- MPEP 2113
- Product-by-process claims are not limited to the manipulation of the recited steps
- Product-by-process claims are only limited by the structure implied by the steps



Deeper Dive Claiming Strategies
Product-by-Process Claims

***In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985)**

"[E]ven though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process."

Deeper Dive Claiming Strategies
Product-by-Process Claims

Validity versus Infringement

Amgen Inc. v. F. Hoffman-La Roche Ltd., 580 F.3d 1340 (Fed. Cir. 2009)

Claim 1 ('422 patent): A pharmaceutical composition comprising a therapeutically effective amount of human erythropoietin and a pharmaceutically acceptable diluent, adjuvant or carrier, ***wherein said erythropoietin is purified from mammalian cells grown in culture***.

Note: Claim 1 was valid because recombinant EPO was shown to be *structurally different* than EPO isolated from a natural source. However, this case illustrated that:

(1) Validity of the claim rests on whether a prior art product, ***even if made by a different process***, is the same (invalid) or different (valid); while in contrast

(2) Infringement of the claim is ***limited to*** only those products ***made by the claimed process***.

Product-by-Process Claims Practice Points

When drafting product-by-process claims:

- Make sure that the recited steps are sufficient to result in a novel and non-obvious product
- Limit steps that do not result in a structural and functional difference between the product and the prior art
- Don’t list more steps than are necessary to arrive at the desired product—to make it harder for a competitor to design around the process and avoid infringement

Negative Claim Limitations

Negative claim limitations are sometimes introduced during prosecution to try to avoid prior art. In a recent Federal Circuit decision (*Novartis Pharmaceuticals v. Accord Healthcare Inc*. Fed. Cir. 2022), the court held that the negative limitation "absent an immediately preceding loading dose" added during prosecution to overcome prior art failed to satisfy the written description requirement of 35 U.S.C. §112(a). Claim 1 of the patent at issue (U.S. Pat. No. 9,187,405) recites:

> **Claim 1.** A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis in a subject in need thereof, comprising orally administering to said subject 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol, in free form or in a pharmaceutically acceptable salt form, at a daily dosage of 0.5 mg, *absent an immediately preceding loading dose regimen*.

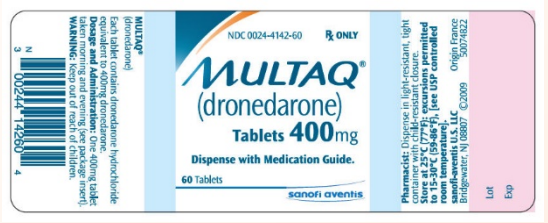
There was no mention of an immediately preceding loading dose regimen in the specification.

Negative Claim Limitations Practice Points

When drafting negative claim limitations:

- Ensure that there is written description in the specification for the negative claim limitation
- Consider including reasons to exclude the element
- Consider adding a list of alternative elements

Claim Strategies:
Drafting Claims to a Label



How?

- Do you have access to pivotal clinical trial data?
- Draft ***narrow claims*** that capture what will be ***in the drug product label***, *e.g.,* specific indication, specified target patient population, contraindicated symptoms, warnings and risk factors.

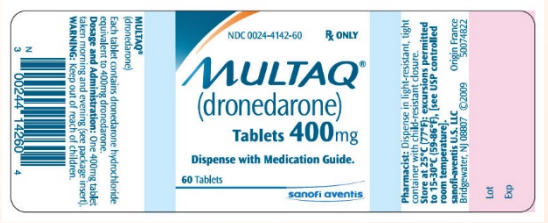
Why draft a very narrow claim?

- Generic or biosimilar manufacturers need to propose the same or highly similar labeling and could be captured on the basis of inducement to infringe.
- In other words, the generic label, by directing doctors and patients on the use of the drug product, intentionally encourages infringement of the branded drug maker's patent claims!

Okay, show me a real world example!

Credit for, and detailed coverage of, this strategy: "Combine the Label with Phase III Clinical Results and a Carefully Crafted, Mirroring US Patent Application to Achieve Longer Patent Exclusivity for US Bio/Pharm Patents: Strategic Considerations and Opportunities Raised by Sanofi v. Watson" by Tom Irving, Michele Bosch, and Stacy Lewis, *2019 Newsletter of the AIPLA Chemical Practice Committee, Vol. 6, Issue 3*

Claim Strategies:
Drafting Claims to a Label



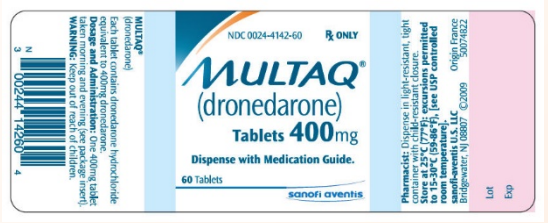
Sanofi v. Watson, 875 F.3d 636 (Fed. Cir. 2017)

Dronedarone, sold as Multaq® in the U.S., is an antiarrhythmic agent to reduce the risk of hospitalization of patients with atrial fibrillation.

Original Patent Claim:

> *A method of decreasing the risk of mortality, cardiac hospitalizations, or the combination thereof in a patient*, said method comprising **administering** to said patient an effective amount of **dronedarone** or a pharmaceutically acceptable salt thereof, **with food**.

Claim Strategies:
Drafting Claims to a Label



From the MULTAQ Drug Product Label:

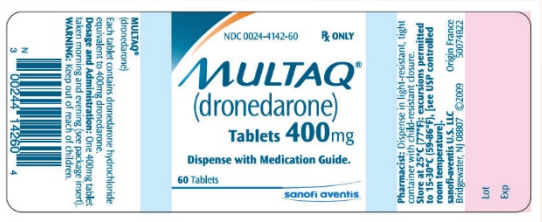
----------INDICATIONS AND USAGE----------

MULTAQ is an antiarrhythmic drug indicated to reduce the risk of cardiovascular hospitalization in patients with paroxysmal or persistent atrial fibrillation (AF) or atrial flutter (AFL), with a recent episode of AF/AFL and associated cardiovascular risk factors (i.e., age >70, hypertension, diabetes, prior cerebrovascular accident, left atrial diameter ≥50 mm or left ventricular ejection fraction [LVEF]

----------DOSAGE AND ADMINISTRATION----------

One tablet of 400 mg twice a day with morning and evening meals (2)

Claim Strategies:
Drafting Claims to a Label



Issued Claim (*Generics induced infringement via their labels*):

A method of decreasing a risk of cardiovascular hospitalization in a patient, said method comprising **administering** to said patient an effective amount of **dronedarone** or a pharmaceutically acceptable salt thereof, ***twice a day with a morning and an evening meal***, wherein said patient does not have severe heart failure, (i) wherein severe heart failure is indicated by: a) NYHA Class IV heart failure or b) hospitalization for heart failure within the last month; and (ii) wherein said patient has a history of, or current, paroxysmal or persistent nonpermanent atrial fibrillation or flutter; and (iii) wherein the patient has at least one cardiovascular risk factor selected from the group consisting of:

I. an age greater than or equal to 75;

II. hypertension;

III. diabetes;

IV. a history of cerebral stroke or of systemic embolism;

V. a left atrial diameter greater than or equal to 50mm; and

VI. a left ventricular ejection fraction less than 40%.

Practice Points
Drafting Claims to a Label

- If you have pivotal clinical trial results, consider drafting patent claims that may, or will, capture salient portions of the drug product label, such as the Indications and Usage; Dosage and Administration; Contraindications, Warnings and Precautions
- Keep in mind that the claim should be practiced by the physician and/or patient who is following the label (inducement to infringe by the Generic/Biosimilar)
- Make sure the specification provides adequate written description support for the claim and includes the results of the clinical study
- *Client communication is required for this strategy to be successful*: Make sure the drug product label actually includes the results of the clinical trial, and that features you want to claim are actually present on the label, particularly the Indications and Usage section
- What does a label look like? Take a look at the FDA website

Claim Strategies:
Dosing Regimens

Gilenya® (fingolimod) – Novartis blockbuster - $2.3B

- 24 Generic Applicants (ANDA)
- U.S. Patent No. 9,187,405, expires December 2027
  - *Fingolimod* patent expired; *Formulation* patent invalid
  - '405 Patent upheld at PTAB, District Ct, and Federal Circuit!

1. A method for reducing or preventing or alleviating relapses in Relapsing-Remitting multiple sclerosis *in a subject in need thereof*, comprising

orally administering to **said subject** 2-amino-2-[2-(4-octylphenyl)ethyl]propane-1,3-diol, in free form or in a pharmaceutically acceptable salt form,

at **a daily dosage of 0.5 mg**,

absent an immediately preceding loading dose regimen.

Practice Points
Dosing Regimens

- Dosing regimens can be a powerful way to claim methods of treatment for a more advanced product (*e.g.,* one that is about to, or is in, the clinic).
- Consider dosing regimen claims if your invention includes treatment method with a dosing protocol that involves: two or more different time points for administration, different amounts of a product administered in different doses, varying routes of administration, or even a target physiological result (*e.g.,* a pK profile).
- *Beware* of prior art issues if the formulation, general methods of treatment, and/or clinical trial study design are published prior to filing such claims.
- Consider that not all non-U.S. jurisdictions accept this type of claim, if you have a global filing strategy.

Bonus Section Big Picture: Drafting Claims for Global Filings

Biotech/Pharma/Chemical patents are often filed globally, but patent laws and regulations can make efficient and effective claim drafting tricky!

In this section, we will hit a few highlights of global claim drafting:

- ✓ **Methods of Treatment/Diagnostics**
- ✓ **Written Description and Support Issues**
- ✓ **Multiple Dependent Claim Use**

Global Claim Drafting:
Methods of Treatment

- ✓ Method of treatment (U.S., Australia, Russia):

  A method to treat Disease Y by administering Compound X.

- ✓ First Medical Use (Europe, Compound X never used as a medicine):

  Compound X for use as a medicament.

- ✓ Second Medical Use (Europe, Australia, Canada, Japan, Mexico, South Korea, Compound X used in medicine, but inventive for use in Disease Y):

  Compound X for use in the treatment of Disease Y.

- ✓ Swiss-Style Claims (Brazil, China, Israel, Japan, New Zealand):

Use of Compound X in the preparation of a medicament for the treatment of Disease Y.

Global Claim Drafting:
Methods Practiced on the Human Body

- ***Tip:*** Some countries do not allow **any** of the claim formats for treatment of the human body (India, some LATAM countries). ***If this is your only possible claim type, consider this before filing in these countries.***

- ***Tip:*** Include the alternative types of method of treatment, medical use, and Swiss-style claims when filing globally (*i.e.,* avoid support issues and write them in the specification too).

- ***Tip:*** While medical use or Swiss-style claims are allowed in many countries, ***dosing regimens*** may not be acceptable or may be difficult to obtain.

- ***Tip:*** Diagnostic methods involving surgical steps or collection of human samples can be even more problematic than treatment methods in many jurisdictions. ***Think about whether you can draft these claims to recite an in vitro method and avoid reciting the body or bodily samples.***

Global Claim Drafting:
Written Description & Support Issues

- Many countries are very strict about providing *literal support* for claims in the specification.
  - ***Tip:*** Provide literal support in the specification for **any and all claim combinations** you claim or might want to claim.
  - ***Tip:*** Consider whether you have provided **adequate working examples**; your claims might be limited to what is demonstrated in the Examples (Asian countries, Latin American countries).
  - ***Tip:*** If you have **Markush groups or lists of alternate embodiments** in your claims, the EPO may only search the *first* listed embodiment; you will have to pay for other embodiments, and/or file a divisional (expensive!!!). ***List your most preferred embodiment first!***

Global Claim Drafting:
Multiple Dependent Claims

Many countries allow multiple dependent claims, and even multiple dependents of multiple dependent claims, **without payment of extra fees**

- ***Tip:*** Use multiple dependent claims in provisional or PCT applications, but…
  - Be prepared to amend the claims to remove multiple dependencies when entering the national stage in some countries;
  - Beware of support issues due to the multiple dependent claim structure, i.e., does your specification provide literal support for all of the combinations you have just encompassed with this claiming style?

Global Claim Drafting:
Special Technical Features

Can you define a **single general inventive concept** in your claims?

- To avoid a Lack of Unity rejection in an international application (and in many national jurisdictions), if there is more than one invention, all inventions should be linked as to form a single general inventive concept:
  - What **special technical features** define a **contribution** which each of the claimed inventions, considered as a whole, makes over the prior art?
- ***Tip:*** Consider the budget, and that the client may not want to file divisionals/continuations in all jurisdictions (or that it may be difficult to do so in some countries). One comprehensive patent is some jurisdictions may be sufficient.
- ***Tip:*** Use your categories, and make sure that the **special technical feature(s)** clearly flows through each claim type.

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