

Knobbe Martens

Knobbe Practice Webinar Series: Strategic Considerations for Life Science Claim Drafting

October 12, 2021

Dan Altman, Partner

David Schmidt PhD, Partner

Kenny Masaki, IP Strategist

Part I – Understanding Claims in U.S. Patent Applications

Claiming Basics – U.S. Patent Applications

- Claim structure
 - Each claim is a single sentence
 - Start with a capital letter
 - End with a period
 - Numbered consecutively in ascending order; original numbering preserved throughout prosecution
 - Best Practice: Claim terms/phrases must find clear support in the written description
- Independent claims versus dependent claims
 - Independent claim is standalone claim
 - Dependent claim refers to another earlier claim and further limits that claim
 - Basic US Filing Fee: 3 independent claims/20 total
 - \$480 per additional independent claim (large entity)
 - \$100 per additional total claim (large entity)

Claim Structure

- Preamble
 - Provides context for the claimed invention
 - May or may not limit the claim
 - In “A composition **for treating Moyamoya disease**”, “**for Moyamoya disease**” would typically be non-limiting
- Transitional phrase
 - Determines if the claim is “open” (comprising), “closed” (consisting of), or “partially open” (consisting essentially of)
 - “Comprising” is most common
 - “Consisting essentially of” excludes recited elements other than the recited elements unless they do not materially affect the basic and novel characteristics of the claimed invention
 - Examiners treat as “comprising” unless basic and novel characteristics from specification are pointed out
 - Burden is on applicant to show that prior art elements affect the basic and novel characteristics
 - “Consisting of” means only those recited elements/steps

Claim Structure

- Claim Body
 - Recites the limitations necessary to define the invention
 - Antecedent basis
 - First instance is “a” or “an” and subsequent instances are “the” or “said”
 - No legal difference between “the” and “said”
 - Introduce all of the elements and characterizations of the elements that are necessary for the invention to work and to be different from the prior art
 - Different independent claims can include different combinations of elements or different characterizations of the components
 - Restriction Requirements are common in life science applications—typically each independent claim is found to be a separate invention
- Dependent claim transitions:
 - “Further comprising” when adding a component
 - “Wherein” when further describing previously introduced component
 - Best Practice: No multiple dependent claims.

Claim Structure – Connecting the elements

- A method for treating **Moyamoya disease** in a subject, comprising:
- identifying **narrowed blood vessels** in the subject, thereby determining that the subject is in need of treatment of the **Moyamoya disease**;
 - treating the subject with a **calcium channel blocker** to the subject for a sufficient period to lower blood pressure in the subject;
 - during the period of treating with the **calcium channel blocker**, conducting **pial synangiosis** on the subject so as to reroute healthy scalp blood vessels to bypass the **narrowed blood vessels**; and
 - within 24 hours after completing the **pial synangiosis**, administering a composition comprising an extract of omental tissue to the subject.

Part II – Selecting Subject Matter and Claim Strategy in U.S. Patent Applications

Subject Matter Patentable over the Prior Art – Life Sciences

- Identifying subject matter patentable over the prior art
 - What makes invention more effective, less expensive, faster, fewer side effects, more accurate, etc.
 - What distinguishes the composition or method from earlier compositions and methods
- Examples
 - New way to administer an old pharmaceutical with decreased side effect
 - Increasing the pH of a composition to achieve much longer shelf life
 - Decreasing the concentration of an expensive ingredient without loss of effect
 - Carrying out a diagnostic procedure using a device that eliminates need for trained physicians
 - Using reverse osmosis purification of sample prior to testing to increase accuracy

Types Of Claimed Subject Matter

- Product
 - Apparatus, machine, system, device
 - Composition

- Method or Process to perform function/obtain result
 - Making
 - Using

Examples – Method Claims

- Preamble Examples:
 - A method comprising:
 - A method for treating disease X, comprising:
 - A non-surgical method for treating disease X, comprising:
 - In an outpatient environment including a blood pressure monitor, a non-surgical method for treating disease X, comprising:
- Second Medical Use Claim Example:
 - A method of treating disease X in a patient in need thereof, comprising:
 - administering known drug Y to the patient in an amount effective to treat disease X in said patient.

Examples – Apparatus Claims

- Apparatus Examples:
 - An apparatus comprising:
 - A medical device comprising:
 - A wearable defibrillation device comprising:
 - A medical device for providing instantaneous electrode data comprising:
- Claim Examples:
 - A wearable defibrillator comprising:
 - a first set of electrodes for obtaining patient data;
 - a second set of electrodes for providing a therapeutic signal to the patient; and
 - a control unit for processing the patient data
 - A defibrillation device comprising:
 - a first set of electrodes mounted within a garment and having at least a portion of a first surface area in direct contact with a patient, the first of electrodes obtaining patient data;
 - a second set of electrodes separately mounted within the garment and having a portion of a second surface area in direct contact with the patient, the second set of electrodes

Claim Drafting – Terms and Phrases with Special Meaning/Purpose

- Counting/Numbers
 - "Plurality" – Two or more: "A plurality of fasteners"
 - "At least one" - Open ended count with a minimum of one: "At least one processor configured with"
- Associations
 - "Each" - Places a limitation on every member of a group: "wherein each control unit is configured with local ..."
 - "Individual" - Places a limitation on some member of a group: "wherein individual control units are configured with local"
- Combinations or Alternatives
 - "And" - Standard meaning as a conjunctive: "wherein the widget has a first part **and** a second part"
 - "Selected from the group consisting of A, B, and C" – "and" is used in the disjunctive

Claim Drafting – Terms and Phrases with Special Meaning/Purpose

- Potential Problem Terms
 - Relative terminology - "relatively large", "similar", "about", etc.
 - Fails to provide standard for measuring degree
 - Exemplary terminology - "such as", "for example", "preferably"
 - Unclear language
 - Proper manner of achieving this in U.S. practice is to set forth in dependent claim
 - Be careful of "brand names" – "Xiameter antifoam", "GelRed nucleic acid stain"
 - may refer to a number of different compounds
 - may change over time

Top Tips – Avoid Divided Infringement

- Where multiple entities are involved, draft claims that will directly infringed by a single entity
 - Method claims: all steps performed by one entity
 - System claims: all elements operated by single entity
 - Resist temptation to describe a complete system or process
- Particular problem in diagnosis and treatment claims designed to overcome patent eligibility rejections under § 101

Avoiding Divided Infringement – Method Claims

- A method for treating a patient with iloperidone, ..., comprising:
 - determining whether the patient is a CYP2D6 poor metabolizer by:
obtaining or having obtained a biological sample from the patient;
and **performing or having performed** a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype; and
 - **if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less, and**
 - **if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day, ...**

Part III – Avoiding Informalities under 35 U.S.C. 112

Part III – Formal subsections of 35 U.S.C. 112

- **112(b)** - Claims must be definite
- **112(c)** - Claims can be independent, dependent or multiple dependent
- **112(d)** - Dependent claims must incorporate all of the limitations of the claim from which it depends and include at least one more limitation
- **112(e)** - Rules for multiple dependent claims; they must be in the alternative
- **112(f)** - Means plus function claims; they are limited by the specification

Sample claims demonstrating 112 issues requiring corrections in red

1. A microorganism adapted to dissolve arteriosclerotic plaques, said bacteria comprising:
 - a cell nucleus, said nucleus containing additional chromosomes;
 - a **thin** outer membrane;
 - an **ER**, said ER containing additional ribosomes;
 - DNA encoding a **means for dissolving arteriosclerotic plaque.**
2. **The DNA of Claim 1.**

3. The microorganism of Claim 1, wherein said means for dissolving is a protein.
4. A method for dissolving arteriosclerotic plaques in a human patient, comprising administering a plurality of microorganisms according to Claim 1 to said patient.
5. **The dissolved arteriosclerotic plaques produced by the method of Claim 4.**
6. A fungus containing the DNA of **Claim 2.**

7. A method for treating athlete's foot in an affected human patient, comprising administering to said patient an amount of the dissolved plaques of **Claim 4** in conjunction with the microorganisms of **Claim 3** to said patient sufficient to treat said infection.
8. The method of **Claim 7**, wherein the dissolved arteriosclerotic plaques are dissolved in ethanol.
9. The method of either **Claim 7** or Claim 8, wherein the microorganisms are E. coli.

Knobbe Martens

Dan Altman

dan.altman@knobbe.com

949-721-2875

David Schmidt, PhD

david.schmidt@knobbe.com

949-721-6386

Kenny Masaki

Kenny.Masaki@knobbe.com

949-390-1003