Knobbe Martens

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

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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
  - For example: “A composition for treating X disease” or “for X 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 of” means only those recited elements/steps
    - “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

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, costs can multiply

Claim Structure – Connecting the elements

A method for treating Moyamoya disease in a subject, comprising:

- identifying a narrowed blood vessel 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 vessel; 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

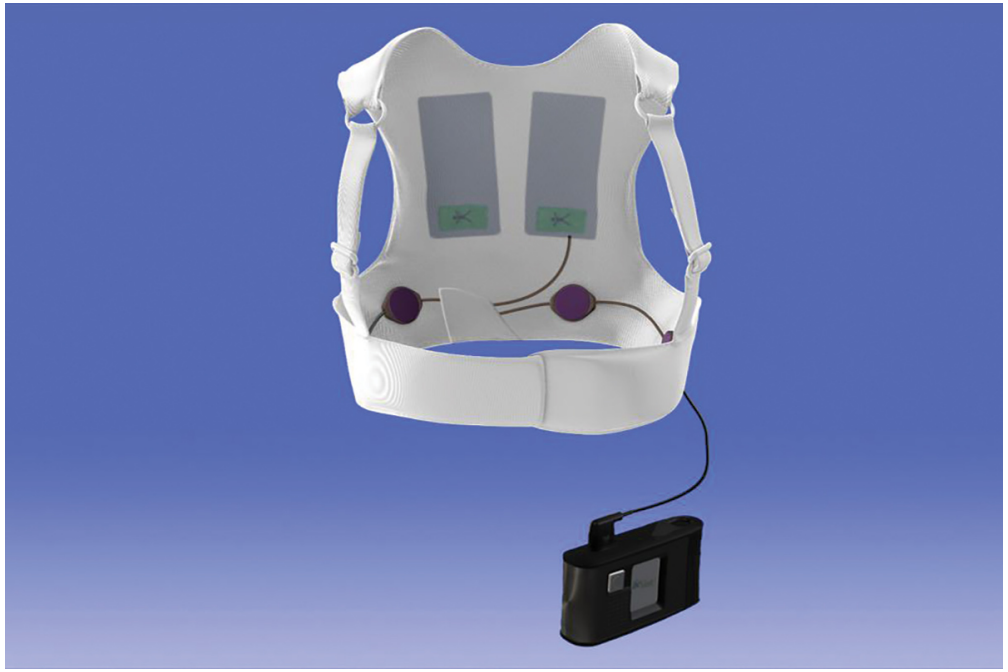
Examples – Method Claims

- 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

- Preamble Examples:
  - An apparatus comprising:
  - A medical device comprising:
  - A wearable defibrillation device comprising:
  - A medical device for providing instantaneous electrode data comprising:



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 (Markush Group)

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
    - Meaning 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.

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