Protecting the Intellectual Property of the Skin Microbiome

In-Cosmetics North America

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Overview

• What is Intellectual Property?
  • Patents
  • Trademarks
  • Trade Secrets

• Approaches for the Skin Microbiome
  • How to leverage these assets?

• Challenges and Strategies Related to Patenting
  • Descriptive and Enabled
  • Novel and Nonobvious
  • Patent Eligible - Natural Products and Natural Processes
• Laws related to obtaining and maintaining property rights for creations of the mind.

• How we reward companies and individuals for coming up with good ideas.

• Treated like other “property”
Patents

- Exclusory Right (20 yrs)
  - Making, Using, Selling, Offering to Sell
  - Stop activity and recover $
- Does NOT give the right to make anything
- Description of the invention
- Claims define the boundary of the property
  - Composition
  - Device
  - Method
  - Design
- Dedicated to the public
• Words, Symbols or Phrases designating the SOURCE of a good or service
• Can also be a sound or color, packaging designs
• Must be “used in commerce”
• No term – just pay $ and you can renew forever
• Value is often in marketing

Trademarks
Trade Secrets

- A formula, practice, process, method, not generally known
- **Provides an economic or business advantage**
- Must designate as “confidential” or “secret”
- Use reasonable efforts to maintain secrecy
- Protection from employees leaving with secrets; or Misappropriation from a competitor
Patents and the Skin Microbiome

• Compositions of Matter or Products/Formulations
  • Strongest patent – Most desirable
  • Greatest protection against Generic Co.
  • Difficult to obtain – microorganisms have been known for a long time

19. A pharmaceutical composition comprising a population of isolated and purified microorganisms, wherein at least one of said microorganisms comprises a microorganism that modulates pH.
Patents and the Skin Microbiome

**Methods of Production/Purification**
- Useful if product was known
- Increased yield
- Good for protection of optimized methods

1. A method of making a topical cosmetic composition, the method comprising:
   (a) **providing a first culture comprising a test agent**, a quantity of a human skin commensal microorganism, and a minimal carbon medium;
   (b) **determining a metabolite level** or a replication level of the human skin commensal microorganism of the first culture;
   (c) **comparing the metabolite level** or the replication level to a first control value, wherein the first control value is the metabolite level or replication level in a culture of the human skin commensal microorganism of the first culture that is grown without the test agent, and wherein the metabolite level correlates with the amount of growth;
   (d) **identifying the test agent as a prebiotic** when the test agent increases the growth of the human skin commensal microorganism and when the metabolite level or replication level of the first culture is greater than the first control value; and
   (e) **combining a safe and effective amount** of the prebiotic with a dermatologically acceptable carrier.
Patents and the Skin Microbiome

• Methods of Treatment/Use/Diagnosis
  • New use for old drug
  • Also valuable against generics
  • Personalized Medicine or Diagnosis – Majority of Skin Microbiome Patents/Applications are Here

1. In vitro method for prognosis and/or diagnosis of atopic dermatitis in an individual, said method comprising the steps consisting in:
   a) measuring the diversity level and/or the diversity profile of the microbiome of a sample from an area suspected to be a lesion area or an area suspected to become a lesion area in said individual,
   b) comparing the diversity level and/or the diversity profile of the microbiome measured in step a) with the diversity level and/or the diversity profile of at least one reference microbiome, and
   c) deducing whether the individual has or is at risk of having atopic dermatitis.
Trademarks and the Skin Microbiome

• Demonstrates to the public that YOU are providing the product or service
• Protection from knock-off products
• Where Patenting may be difficult, Trademarks have increased importance
• Consumers like “cool”
Trademarks and the Skin Microbiome

What's Your Gut Wellness Score? Thryve Launches With New Microbiome Testing Service for Better Health Through Your Stomach

First-of-its-kind monthly testing subscription provides detailed, personalized overview of gut flora paired with probiotic products for improved health
Trade Secrets and the Skin Microbiome

• Tradeoff vs. Patents
  • Keep secret, don’t disclose
  • If easily determined, low value
  • If important method, and otherwise not protectable, viable option

• Often primary use is in production methods

• Protect ideas in “high movement” professions

• Do they have teeth?

Best Buy to pay $27 million in trade secrets case

A company beset by problems now has another: A court ordered Best Buy to pay $27 million for stealing from a California start-up.
Requirements for Patents

- Must be described sufficiently
  35 USC § 112
  - Clear and concise
  - Provide written support for the claims (Written Description)
  - Teach someone of “ordinary skill in the art” how to make and use the invention (Enabled)
    - Fluctuates depending on the field
    - Fictitious person, but very important in the law
Requirements for Patents - Microbiome

• Issues with sufficiently describing or enabling microbiome
  • Still developing technology
  • Can you describe a sufficient “number of representative species?”
  • Are methods universally applicable to different bacteria and different areas of the body?
• New and Nonobvious

35 USC §§ 102 and 103

• Relates to what is in the “prior art”
• Was it already described or sold?
• Would it have been obvious to a “person of ordinary skill in the art” at the time of filing?
• Obviousness = predictability?
• Even if obvious, was it unexpected, copied, did others fail or discount the invention, did it make lots of $$ (can be hard to prove)
Requirements for Patents - Microbiome

• **New and Nonobvious**
  - Issues are similar to other developing technologies (NextGen Sequencing, CRISPR)
  - “Unpredictability” may be easier to argue since newer field
    - But watch double-edged sword of enablement/obviousness
  - Too early to show commercial success?
Requirements for Patents

• Patent Eligibility - 35 USC § 101
  • Any new and useful process, machine, manufacture or composition of matter, or improvement thereof
  • For decades, could patent “natural products” and use of “natural processes”
    • “Isolated” nucleic acids, proteins, cells
    • Methods of utilizing information for diagnosis or treatment
      • Genetic characteristics, reactions to treatments, “personalized medicine”
Requirements for Patents

• Patent Eligibility - 35 USC § 101
  • “Natural Products” no longer patentable
  • Assoc. for Molecular Pathology v. Myriad Genetics (SC 2013)
    • Isolated nucleic acids (specifically DNA) - cancer marker genes BRCA1 and BRCA2
    • “may have found an important and useful gene . . . [but] separating that gene from its surrounding genetic material is not an act of invention.”
  • Must be something “markedly different” from that found in nature
  • Extended to proteins, peptides, minerals, bacteria, plant extracts, other substances found in nature
Requirements for Patents

- **Patent Eligibility - 35 USC § 101**
  - *Application of, or Correlations* based on, “Natural Process” no longer patentable
    - **Diagnosing a condition or disease** based on a naturally occurring relationship or correlation - **NO**.
    - **Identifying a preferred patient population** using a naturally occurring relationship or correlation - **NO**.
    - Claim needs something “significantly different” or not “routine or conventional”
    - Or **ACTIVE** treatment steps
Requirements for Patents - Microbiome

• Patent Eligibility - 35 USC § 101
  • What is/is not “markedly different” as it relates to the microbiome?
  • Isolated?
  • Collection of bacteria?
  • Formulation?
    • Mutation or modification in the bacteria or sequence?
  • Change in properties or characteristics of the natural product
Requirements for Patents - Microbiome

• Patent Eligibility - 35 USC § 101

20. A composition, comprising: a population of non-pathogenic bacteria from the skin microbiome, at least a portion of the population of bacteria transformed to express a compound of interest, the composition formulated for topical application to a subject.

• Eligible for patenting
• Faces other issues (obviousness, enabled)
Requirements for Patents - Microbiome

• Patent Eligible - 35 USC § 101
  • Personalized Medicine – Significant use of Microbiome “Information”
  • How to add “significant difference” or something “not routine”
  • Must be more than just “apply” the correlation
  • Method of “detection” vs. Method of “diagnosis”
  • Method of treatment
Requirements for Patents - Microbiome

• Patent Eligibility - 35 USC § 101

33. A method of diagnosing a disease or disorder in a subject comprising:
   a) obtaining a sample comprising a plurality of microorganisms from the skin or
      subcutaneous tissue of the subject;
   b) analyzing and classifying the plurality of microorganisms of (a) to identify a
      microbiome of the subject; and
   c) comparing the microbiome of the subject to a reference microbiome representative
      of a microbiome of a subject having or at risk of the disease or disorder, wherein a
      similarity between the microbiome of the subject and the reference microbiome is
      indicative of the subject being at risk of, or having the disease or disorder, thereby
      diagnosing a disease or disorder in the subject.

• Not eligible for patenting

• “Classic” personalized medicine claim that is no longer OK
Requirements for Patents - Microbiome

• Patent Eligibility - 35 USC § 101

• 1. A method for aiding in the diagnosis of irritable bowel syndrome (IBS) and a clinical subtype thereof in a subject by generating a series of at least three biomarker scores (a) through (f) from a sample, said method comprising (a) detecting in a sample obtained from said subject the level of at least one bacterial antigen antibody marker to obtain a microbiome score; (b) detecting in said sample the level of at least one mast cell marker to obtain a mast cell score; (c) detecting in said sample the level of at least one inflammatory cell marker to obtain an inflammatory score; (d) detecting in said sample the level of at least one bile acid malabsorption (BAM) marker to obtain a BAM score; (e) detecting in said sample the level of at least one kynurenine marker to obtain an oxidative stress score; (f) detecting in said sample the level of at least one serotonin marker to obtain a serotonin score; and (g) applying a statistical algorithm to said at least three scores, wherein the at least three scores include the bile acid malabsorption score, the serotonin score, and the oxidative stress score, wherein the sample is from a subject with IBS or is suspected of having IBS.

• Eligible for patenting – “Detecting” is key

• “Generating” a series of three biomarker scores using a statistical algorithm

• Not a correlation, thus not the application of a “natural process”
Requirements for Patents - Microbiome

• Patent Eligibility - 35 USC § 101

16. A method for the personalized treatment of acne comprising determining the strains of *P. acnes* affecting a subject and treating said subject with an active ingredient directed to at least one detected strain of *P. acnes*, wherein the active ingredient comprises a drug targeting specific strains of *P. acnes*, wherein the targeting drug comprises small molecules, antisense molecules, siRNA, biologics, antibodies, and combinations thereof targeting genomic elements specific for strains of *P. acnes* associated with acne.

• Eligible for patenting – “Treatment step”

• Problem though is who infringes this claim?
  • The company that makes the kit – doesn’t administer
  • The doctor – doesn’t run the test
  • The lab that runs the test – maybe? If they direct the doctor, or all are associated together
IP and the Skin Microbiome

• Protection of ideas, brands, secrets are critical for:
  • Getting funding or start-up money
  • Finding development partners
  • Delivering a product to the market
  • Recovering sales from that product

• The Skin Microbiome has unique challenges in:
  • Description and enablement of methods
  • Evidence of non-obviousness
  • Eligibility of natural compounds and methods for personalized medicine
Thank You

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