

Protecting Inventions in the Microbiome Space: Challenges and Strategies

Olga Partington, Ph.D., J.D.

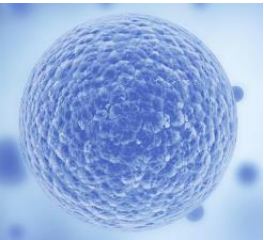
October 29, 2018

Technical Minds. Legal Muscle.

General Perspectives



Protection



Freedom-to-operate



Enforcement



Regulatory

Patenting Your Invention—Basic Requirements

- The invention must be useful (35 U.S.C. § 101)
- The invention must constitute patent eligible subject matter (35 U.S.C. § 101 and judicial law)
- The invention must be novel (35 U.S.C. § 102)
- The invention must be non-obvious (35 U.S.C. § 103)
- Patent must describe the invention with enough particularity such that those skilled in the art will be able to make, use and understand the invention that was made by the inventor (35 U.S.C. § 112)

Written Description and Enablement Requirements (35 U.S.C. §112)

- Difficulty in adequately describing replicable ways for obtaining a unique strain
- New field – uncertainty what data will convincingly show written description and enablement
- Law may be changing

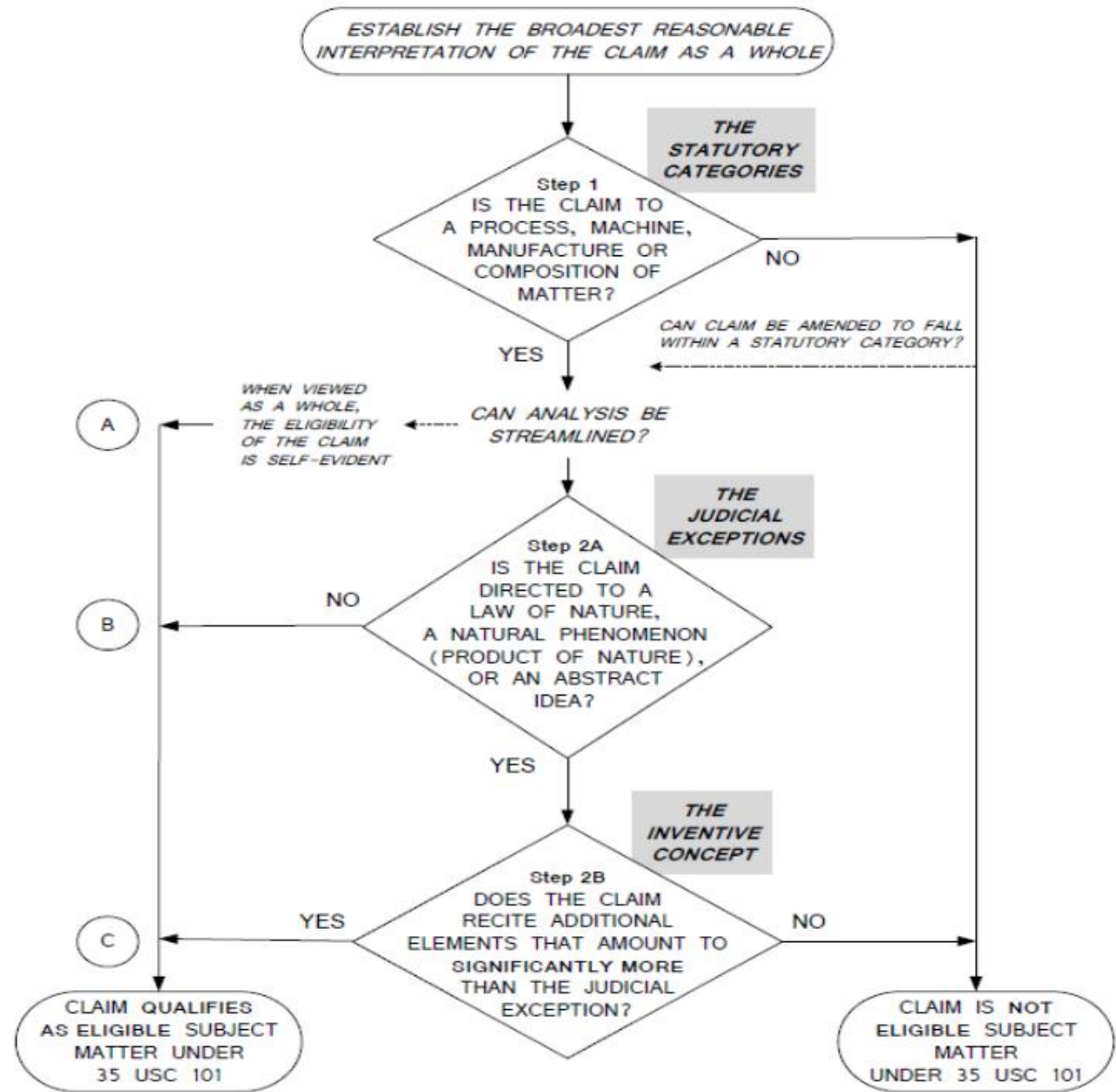
Strategies for Meeting §112 Requirements

- Depositing a sample of the organism with, e.g., American Type Culture Collection (ATCC)
- Describe a strain so that a skilled artisan can make and isolate without undue experimentation
 - Gene sequences
 - Synthetic plasmids
 - Metabolic features
 - Methods of isolation
- Evaluate timing for filing

Subject Matter Eligibility (35 U.S.C. §101 and Judicial Law)—Products of Nature

- 1931: a citrus fruit whose skin is covered in borax—**NOT ELIGIBLE**
- 1948: combining two different species of naturally-occurring bacteria into an inoculant—**NOT ELIGIBLE**
- 1980: a recombinant microbe—**ELIGIBLE**
- 2013: isolated genes—**NOT ELIGIBLE**
- 2014: Dolly the sheep—**NOT ELIGIBLE**
- 2014: a pair of single-stranded DNA primers—**NOT ELIGIBLE**

Eligibility Test



A B C → THE PATHWAYS TO ELIGIBILITY

Step 2A vs. 2B

- “a probiotic composition comprising a mixture of *Lactobacillus* and milk” —2A, entire composition
- “a yogurt starter kit comprising *Lactobacillus* in a container with instructions for culturing *Lactobacillus* with milk to produce yogurt” —2A, *Lactobacillus*; 2B, container
- “a method of producing a desired preparation of multi-cryopreserved hepatocytes”—2B, entire method

Strategies for Claim Drafting

- A genetically-modified bacterium (man-made)
- A mixture of bacteria that normally infects different organisms
- A composition comprising a bacterium and an additive that substantially changes property (e.g., an anti-oxidant, a preservative)
- A bacterial sample that has been altered (e.g., lyophilized, homogenized)
- A purified bacteria having a specific activity (“pharmaceutically-commercially” new)
- A method of transforming bacteria (e.g., cryoprotection)
- A method of treatment using bacteria
- A method of treatment using symbiotic/antagonistic properties of different bacterial strains

Strategies for Patenting in the Microbiome Space

- Creative patent and claim drafting—“markedly different”
- Tell the examiners that what’s routine or conventional is an issue of fact!
- On-point arguments
- Interview examiners early
- Close collaboration between patent counsel, technical teams, and commercial team
- Life-cycle management—different claims
- Other IP—trademark, copyright

Questions?



Olga A. Partington, Ph.D., J.D.
opartington@sternekessler.com
+1.202.772.8626