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# **Stem Cells**

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# Overview

- **Introduction**
  - **Definitions**
- **Types of Stem Cells**
  - **Origin**
- **Examination of Stem Cell Claims**
  - **Statutes**
  - **Sample Claims**



# Introduction: Definitions

## ■ Totipotency

- The ability of a single cell to divide and produce all the differentiated cells in an organism, including extraembryonic tissues.

## ■ Pluripotency

- The potential of a cell to differentiate into any of the three germ layers: endoderm, mesoderm, and ectoderm; any cell except for extraembryonic tissue, such as placenta.



# Introduction: Definitions

## ■ Multipotency

- Cellular potential to become cells from multiple but a limited number of lineages.

## ■ Induced Pluripotency

- Pluripotential of a cell derived from a somatic cell by inducing a “forced” expression of certain genes



# Types of Stem Cells

- **Totipotent Stem Cells**
  - **Oocyte/Sperm**
    - **Zygote**



# Types of Stem Cells (cont.)

## Pluripotent Stem Cells

- **Embryonic Stem Cells**
  - Inner cell mass
- **Embryonic Germ Cells**
  - Develop into eggs and sperm
  - Isolated from the gonad ridge of a fetus
    - Humans > 8<sup>th</sup> embryonic week
- **Embryonic Carcinoma cells**
  - Cells from a germ cell tumor



# Types of Stem Cells (cont.)

- **Multipotent Stem Cells**
  - **Lineage restricted**
  - **Referred to by their tissue of origin**
    - **Hematopoietic stem cell**
    - **Neural stem cell**



# Types of Stem Cells (cont.)

- **Induced Pluripotent Stem Cells**
  - **Somatic cell (fibroblast)**
  - **Pluripotency genes**
    - **Oct3/4, Sox2, c-Myc, and Klf4**
  - **Reprogrammed**
    - **Pluripotent**
    - **Germ-line Chimeras**





# Common Examination Issues in Stem Cells Patents

## 35 USC 101

- Utility
- Statutory Invention

## 35 USC 112, 1<sup>st</sup> paragraph

- Enablement

## 35 USC 103-Obviousness

## 35 USC 102-Novelty



# Examination Issues in Stem Cell Patents-Utility

Section 101 of title 35, United States Code, provides:

- Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



# Examination Issues in Stem Cell Patents-Utility

- **Specific, Substantial, and Credible**
  - Use must be based upon specific (particular) combination of elements
    - **Stem cell + Potential + Marker**
  - **General use such as assaying or culturing would not be considered substantial, unless invention is directed to enhanced assaying or culturing**
  - **Credibility assessed from perspective of skill and knowledge in the art**



# Examination Issues in Stem Cell Patents-Utility (cont.)

## Sample Claim:

**A multipotent stem cell expressing markers A and Z, wherein the stem cell is capable of producing neurons.**



# Examination Issues in Stem Cell Patents-Utility (cont.)

## ■ Considerations:

- What is known about multipotent stem cells?
  - Art and Specification
    - Function/Lineages/Potential?
- Is there a correlation between the disclosed stem cells expressing markers A and Z and neuronal lineage?
  - Art and Specification
- What are the disclosed utilities of the multipotent stem cells?
  - General or Specific?



# Examination Issues in Stem Cell Patents-Utility (cont.)

## ■ Considerations (cont.)

### — Utility Analysis:

- Cellular Markers A and Z are Associated with Neuronal Lineages
- Disclosed Utilities Include Production of Neurons for Transplantation Therapy
  - Treatment of Disease

<http://www.uspto.gov/web/menu/utility.pdf>



# Examination Issues in Stem Cell Patents-Statutory Invention

Section 101 of title 35, United States Code, provides:

- Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.



# Examination Issues in Stem Cell Patents-Statutory Invention (cont.)

- As the Supreme Court has recognized, Congress chose the expansive language of 35 U.S.C. 101 so as to include “anything under the sun that is made by man” as statutory subject matter. **MPEP 2105-2106.**
- *Diamond v. Chakrabarty*, 447 U.S. 303, 308-09, 206 USPQ 193, 197 (1980).





# Examination Issues in Stem Cell Patents-Statutory Invention (cont.)

- **Is The Claimed Invention Statutory?**
  - **Subject Matter Eligible?**
    - **Machine or Transformation?**
      - Interim Guidance for Determining Subject Matter Eligibility for Process Claims in View of *Bilski v. Kappos*. Fed. Reg. 75(143), July 27, 2010.
  - **Product of Nature?**
  - **Hand of Man?**
  - **Humans?**
    - 1077 O.G. 24, April 21, 1987.



# Examination Issues in Stem Cell Patents-Statutory Invention (cont.)

## Sample Claim

- A hematopoietic stem cell.



# Examination Issues in Stem Cell Patents-Statutory Invention (cont.)

- **Considerations**
  - **Product of Nature?**
    - **Hand of Man**
  - **Prior Art**
    - **Invention known**
  - **Does the Claim Embrace Humans?**



# Examination Issues in Stem Cell Patents-35 USC 112, 1<sup>st</sup> paragraph

The first paragraph of 35 U.S.C. 112 provides:

- **The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.**



# Examination Issues in Stem Cell Patents-Enablement

- **How to “make” the stem cells**
  - **Isolating from tissue**
  - **Culturing**
  - **Characterizing**
    - **Marker Expression**
    - **Potential**
  - **Consider reproducibility and scope of claims**



# Examination Issues in Stem Cell Patents-Enablement (cont.)

- What is the “use” of the stem cell?
  - Is it based upon the marker expression?
  - Is it based upon potential?



# Examination Issues in Stem Cell Patents-Enablement (cont.)

- Consider *Wands* factors-MPEP 2164.01(a)
  - Breadth of the Claims
  - Nature of the Invention
  - The state of the Prior Art
  - The Level of One of Ordinary Skill
  - The Level of Predictability in the Art
  - The Amount of Direction Provided by the Inventor
  - The Existence of Working Examples
  - The Quantity of Experimentation Needed to Make or Use the Invention Based on the Content of the Disclosure

*In re Wands*, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988)



# Examination Issues in Stem Cell Patents-Enablement (cont.)

## ■ Sample Claim

**A method of producing liver cells, comprising culturing a pluripotent stem cell in the presence of factors for at least a week to produce liver cells.**





# Examination Issues in Stem Cell Patents-Enablement (cont.)

## ■ Considerations

- Are liver cells predictably produced from pluripotent stem cells?
  - Breadth of claims
  - Working Examples
  - State of Art Regarding Culturing of Pluripotent Stem Cells and Liver Cells
    - Factors Required
    - Liver Biology/Markers
  - Guidance/Teachings Provided by the Specification



# Examination Issues in Stem Cell Patents-35 USC 103

*35 U.S.C. 103. Conditions for patentability; non-obvious subject matter:*

- **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**



# Examination Issues in Stem Cell Patents-35 USC 103

- **What's in a Claim?**
  - **Broad limitation to a stem cell?**
  - **Specific limitation to markers, characteristics, or outcomes?**
    - **Outcome “expected”?**
    - **Are markers, characteristics or outcomes required?**



# Examination Issues in Stem Cell Patents-35 USC 103 (cont.)

- **Sample Claim:**
- **A method of transplanting liver cells, comprising culturing a pluripotent stem cell in the presence of factors for at least a week to produce liver cells; and transplanting the produced liver cells into the liver of a subject in need thereof.**



# Examination Issues in Stem Cell Patents-35 USC 103 (cont.)

## ■ Considerations

- Culturing of pluripotent stem cells to produce liver cells known?
  - Specification
  - Prior art
- Routine to transplant liver cells?
  - Specification
  - Prior art



# Examination Issues in Stem Cell Patents-35 USC 102

*35 U.S.C. 102. Conditions for patentability; novelty and loss of right to patent.*

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent, or
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States,



# Examination Issues in Stem Cell Patents-35 USC 102

- (e) the invention was described in — (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for the purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language;



# Examination Issues in Stem Cell Patents-35 USC 102

- **What's in a claim?**
  - **Broadest Reasonable Interpretation of Claimed Invention Consistent with the Teachings of the Specification**
  
- **Prior Art**
  - **Invention Known?**
  - **All Claimed Embodiments Taught?**
  - **Inherent Properties?**
    - **Same stem cell-different properties**
    - **Claimed and prior art stem cells appear structurally the same**





# Examination Issues in Stem Cell Patents-35 USC 102 (cont.)

- Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a *prima facie* case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977).
- MPEP 2112.01



# Examination Issues in Stem Cell Patents-35 USC 102 (cont.)

- [Therefore,] the *prima facie* case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433.



# Questions

**Thank You!**

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