FACT PATTERN FOR MOCK HEARINGS EP OPPOSITION - Part 1

Background of the invention

<u>Inve</u>ntors Samar T. Pantz and Joe K. Stirr have identified what they believe is a novel adult progenitor (stem) cell that is capable of differentiating into at least three different cell lineages.

The cells, isolated from the liver of an anonymous FICPI member, have been termed "FICPI" cells (Frolic-Induced Cells for Progenitor Induction).

When FICPI cells are isolated and expanded under certain conditions, the cellular phenotype of these cells can be argued to have "markedly different characteristics" from their closest naturally-occurring counterpart.

The progenitor cells can be identified by their novel set of cell surface markers. Specifically, *FICPI* cells:

- Do not express the "CET" (cluster of education and training) marker (CET-);
- Do not express the "PEC" (program of excellent communication) marker (PEC⁻); and
- Do express the "BUR" (**b**anter **u**fficiale **R**oberto) marker (BUR⁺).

When exposed to a specially curated "cocktail" of growth factors, as well as late night exposure to nightclub lighting, the CET⁻/PEC⁻/BUR⁺ *FICPI* cells can differentiate into at least the following 3 lineages:

- CET5⁺/PEC⁺/BUR⁻
- CET6⁺/PEC⁺/BUR⁻
- CET7⁺/PEC⁺/BUR⁻

FICPI cells with the CET⁻/PEC⁻/BUR⁺ phenotype do not appear to be naturally occurring in FICPI members' livers. However, other tissues of FICPI members have not been examined.

Examination and Opposition Proceedings

A patent has been granted for this invention by the EPO with the claim set below. The patent has been opposed by an Opponent who has filed the following three prior art references:

D1: Scientific paper disclosing the discovery of CET⁻/PEC⁻/BUR⁺ cells in the bone marrow D2: Abstract disclosing treatment of kidney disease with isolated CET⁻/PEC⁻/BUR⁺ bone marrow cells described in D1

D3: Scientific paper disclosing culture medium for mammalian cells which comprises GNT

Questions addressed in this virtual session

Based on these facts, we pose the following questions:

- 1. Which of the following claims would be subject-matter eligible in Europe?
- 2. Which of the following claims would be novel over D1, D2 and D3?
- 3. What amendments might address the eligibility and novelty issues in Europe?

Granted claims:

- 1. A composition comprising an isolated culture of cells, wherein said cells are essentially free of CET, essentially free of PEC, and BUR⁺.
- 2. The composition of claim 1, wherein at least 80% of the cells are essentially free of CET, essentially free of PEC, and BUR⁺.
- 3. The composition of claim 1, wherein the cells are CET.
- 4. The composition of claim 3, wherein the cells are PEC⁻.
- 5. A method for producing an isolated culture of cells, wherein said cells are CET⁺, PEC⁺ and BUR⁻, wherein said method comprises: (1) isolating liver cells from a FICPI member; (2) exposing said liver cells to a cocktail of growth factors under late night nightclub lighting; and (3) selecting for CET⁺/PEC⁺/BUR⁻ cells.
- 6. The method of claim 5, wherein said cells are CET5⁺.
- 7. The method of claim 5, wherein said cells are CET6⁺.
- 8. The method of claim 5, wherein said cells are CET7⁺.
- 9. A composition for producing an isolated culture of cells, wherein said cells are CET⁺, PEC⁺ and BUR⁻, wherein said composition comprises one or more growth factors selected from GNT, VIN, BIR, MARG, RUM, B52 or MYTY.
- 10. The composition according to claim 1 for use as a medicament.