

## FACT PATTERN FOR MOCK HEARINGS

Inventors 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 (**F**rolic-Induced **C**ells for **P**rogenitor 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 **e**ducation and **t**raining) marker (CET<sup>-</sup>);
- Do not express the “PEC” (**p**rogram of **e**xcellent **c**ommunication) marker (PEC<sup>-</sup>); and
- Do express the “BUR” (**b**anter **u**fficiale **R**oberto) marker (BUR<sup>+</sup>).

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

- CET5<sup>+</sup>/PEC<sup>+</sup>/BUR<sup>-</sup>
- CET6<sup>+</sup>/PEC<sup>+</sup>/BUR<sup>-</sup>
- CET7<sup>+</sup>/PEC<sup>+</sup>/BUR<sup>-</sup>

*FICPI* cells with the CET<sup>-</sup>/PEC<sup>-</sup>/BUR<sup>+</sup> phenotype do not appear to be naturally occurring in FICPI members’ livers. However, other tissues of FICPI members have not been examined.

Based on these facts, we pose the following questions:

1. Which of the following claims would be subject-matter eligible?
  2. What type of additional evidence might Applicant be required to submit in support of the claims’ eligibility?
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1. A composition comprising an isolated culture of cells, wherein said cells are CET<sup>-</sup>, PEC<sup>-</sup> and BUR<sup>+</sup>.
  2. The composition of Claim 1, wherein the isolated culture comprises at least 80% CET<sup>-</sup>/PEC<sup>-</sup>/BUR<sup>+</sup> cells.
  3. The composition of Claim 1, wherein the isolated culture is essentially free of any CET marker.
  4. The composition of Claim 3, wherein the isolated culture is essentially free of any PEC marker.

5. A method for producing an isolated culture of cells, wherein said cells are CET<sup>+</sup>, PEC<sup>+</sup> and BUR<sup>-</sup>, wherein said method comprises: (a) 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<sup>+</sup>/PEC<sup>+</sup>/BUR<sup>-</sup> cells.
6. The method of Claim 5, wherein said cells are CET5<sup>+</sup>.
7. The method of Claim 5, wherein said cells are CET6<sup>+</sup>.
8. The method of Claim 5, wherein said cells are CET7<sup>+</sup>.
9. A composition for producing an isolated culture of cells, wherein said cells are CET<sup>+</sup>, PEC<sup>+</sup> and BUR<sup>-</sup>, wherein said composition comprises one or more growth factors selected from GNT, VIN, BIR, MARG, RUM, B52 or MYTY.
10. A method for treating liver disease, comprising administering to a FICPI patient in need thereof, an amount of the composition of Claim 1.