FICPI VIRTUAL 19TH OPEN FORUM 2020

Plenary 2 - Arguing subject matter eligibility at the PTAB and in oral proceedings at the EPO

November 5, 2020

IPR2019-9999 Slides for Patent Owner

Background:

"*FICPI*" cells (Frolic-Induced Cells for Progenitor Induction) – progenitor cells that have been isolated and expanded under certain conditions, resulting in a cellular phenotype which is arguably "markedly different" from the closest naturally-occurring counterpart.

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

- Do not express the "CET" (**c**luster of **e**ducation and **t**raining) marker (CET^-);
- Do not express the "PEC" (**p**rogram of **e**xcellent **c**ommunication) marker (PEC^-); and
- Do express the "BUR" (**b**anter **u**fficiale **R**oberto) marker (BUR^+).

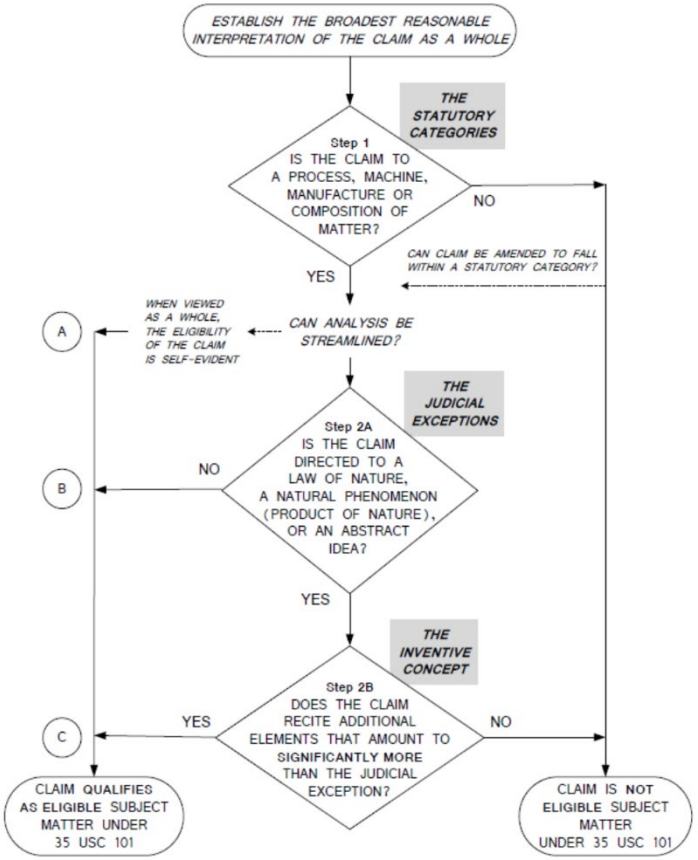
When exposed to a specially curated "cocktail" of growth factors, as well as late night exposure to nightclub lighting, the $CET^-/PEC^-/BUR^+$ *FICPI* cells can differentiate into at least the following 3 lineages:

$CET5^+/PEC^+/BUR^-$

$CET6^+/PEC^+/BUR^-$

$CET7^+/PEC^+/BUR^-$

Analysis used by USPTO for patent eligibility



Patent Owner's Arguments

Claims 1-4:

1. A composition comprising an isolated culture of cells, wherein said cells are CET^-, $PEC^-$and BUR^+.

2. The composition of Claim 1, wherein the isolated culture comprises at least 80% $CET^-/PEC^-/BUR^+$ 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.

- *FICPI* cells do not appear to be naturally occurring in FICPI members' liver
  - Argument – The $CET^-/PEC^-/BUR^+$ phenotype does is not naturally occurring in FICPI members' livers.
  - The marker expression pattern is the result of the isolation and expansion procedures and the cells are not naturally occurring, i.e. are markedly different from naturally occurring cells.
  - Therefore the claims pass Step 2A and are not directed to a natural phenomenon.

Motion to Amend

37 CFR 42.121 Amendment of the patent.

(a) *Motion to amend.* A patent owner may file one motion to amend a patent, but only after conferring with the Board.

(1) *Due date.* Unless a due date is provided in a Board order, a motion to amend must be filed no later than the filing of a patent owner response.

(2) *Scope.* A motion to amend may be denied where:

(i) The amendment does not respond to a ground of unpatentability involved in the trial; or

(ii) The amendment seeks to enlarge the scope of the claims of the patent or introduce new subject matter.

(3) *A reasonable number of substitute claims.* A motion to amend may cancel a challenged claim or propose a reasonable number of substitute claims. The presumption is that only one substitute claim would be needed to replace each challenged claim, and it may be rebutted by a demonstration of need.

Patent Owner Motion to Amend the claims

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.~~

11. (New) A composition comprising an isolated culture of cells, wherein said cells have at one of the following sets of surface markers,

- CET5^{+}/PEC^{+}/BUR^{-}
- CET6^{+}/PEC^{+}/BUR^{-}
- CET7^{+}/PEC^{+}/BUR^{-}.

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

- CET5^{+}/PEC^{+}/BUR^{-}
- CET6^{+}/PEC^{+}/BUR^{-}
- CET7^{+}/PEC^{+}/BUR^{-}

➢ Argument - The marker sets above do not occur in nature and are a structural change to the cells from how they occur naturally.

➢ Therefore proposed claim 11 passes Step 2A and is not directed to a natural phenomenon.

- Claim 10.

10. A method for treating liver disease, comprising administering to a FICPI patient in need thereof, an amount of the composition of Claim 1.

➢ Argument: Claim 10, directed to a method of treatment, is patent eligible under the holding of *Vanda Pharmaceuticals Inc. v. West-Ward Pharmaceuticals*, 887 F.3d 1117 (Fed. Cir. 2018) and the subsequently issue USPTO guidance, which states,

"(1) "method of treatment" claims that practically apply natural relationships should be considered patent eligible under Step 2A of the USPTO's subject matter eligibility guidance; and (2) it is not necessary for "method of treatment" claims that practically apply natural relationships to include nonroutine or unconventional steps to be considered patent eligible under 35 U.S.C. § 101." USPTO Memorandum issued June 7, 2018.

➢ Therefore claim 10 is patent eligible.

Claims 5-8

5. A method for producing an isolated culture of cells, wherein said cells are CET^+, PEC^+ and BUR^-, 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 $CET^+/PEC^+/BUR^-$ 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 $CET7^+$.

Arguments:

- There is no evidence presented that cells naturally occur which are $CET^+/PEC^+/BUR^-$.
- $CET^+/PEC^+/BUR^-$ cells only occur through exposure to cocktail of growth factors under late night nightclub lighting, which one skilled in the art knows does not occur in nature.
- The step of exposure to a cocktail of growth factors under late night nightclub lighting is not conventionally done.

- Therefore, the method of claims 5-8 are not directed to a judicial exception and are patent eligible under Step 2A.
- Alternatively, the method recites additional elements that amount to more than the judicial exception under Step 2B with the recitation of the nonconventional step of exposure to a cocktail of growth factors under late night nightclub lighting.