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

PGR2019-9999 – Slides for Petitioner

- **Claims 1-4:** are not directed to patent eligible subject matter because they do not overcome the "product of nature" exception

- **Claim 10:** is not directed to patent eligible subject matter because it does not apply a law of nature to treating a disease and preempts the use of the natural substance

- **New Claim 11** is not directed to patentable eligible subject matter because the claimed cells do not represent a permanent structural change from what is found in nature

- **Claims 5-8** do not claim patent eligible subject matter because the product does not represent a permanent structural change and the additional steps

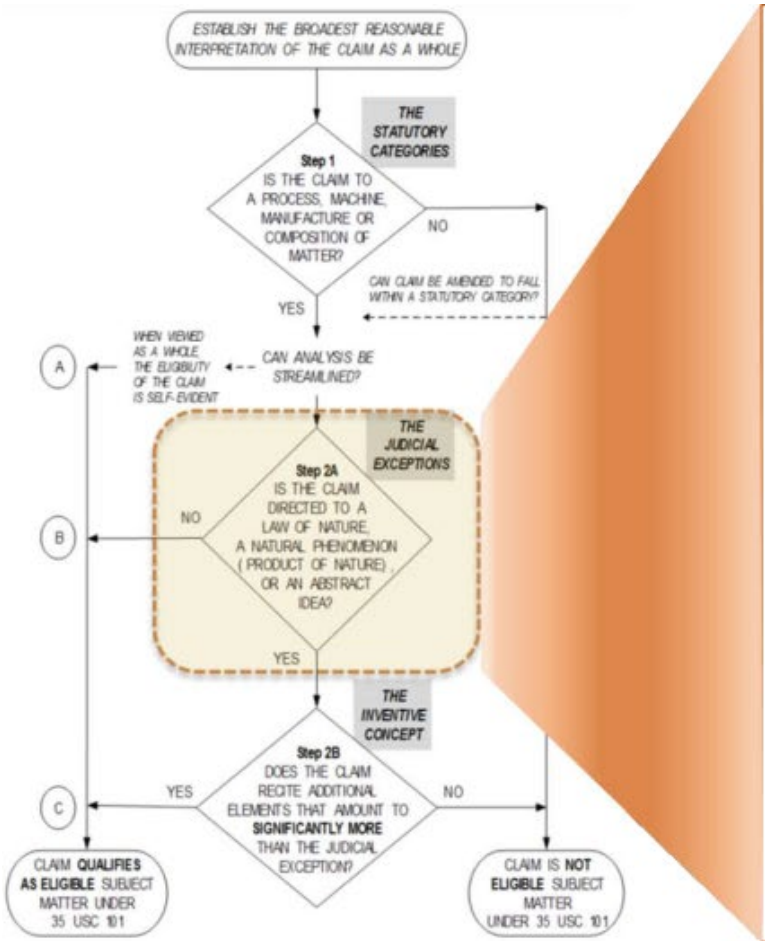
Statutory Subject Matter

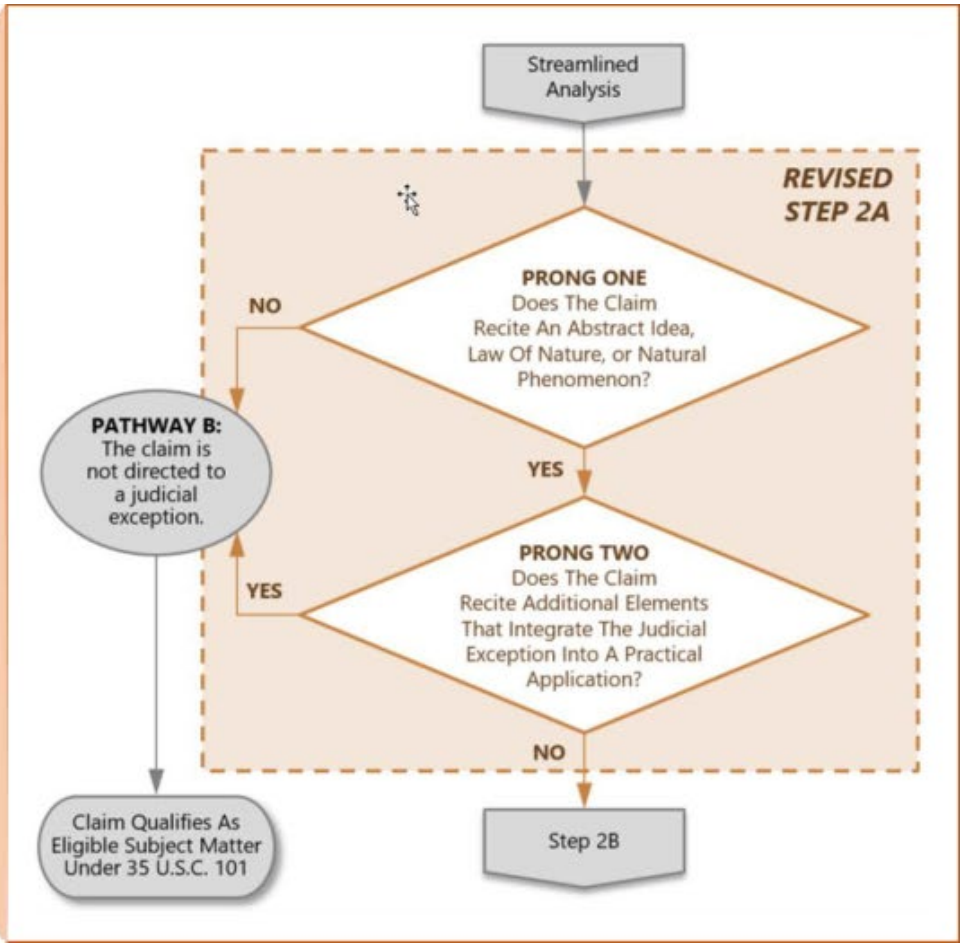
35 U.S.C. 101 – describes what is patentable

- 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.

- But -- judicially recognized exceptions:
  - Product of nature
  - Laws of nature/natural phenomena
  - Abstract ideas

Analysis used by USPTO for patent eligibility





Relevant Facts

- "*FICPI*" cells – progenitor cells that have been isolated from a FICPI member and expanded under certain conditions are identified by the following novel set of cell surface markers:

  $CET^{-}/PEC^{-}/BUR^{+}$

- There is no evidence that the isolation and expansion steps involved anything other than routine techniques

- Cells with these surface markers could reside in tissues other than the liver

- The $CET^{-/}PEC^{-/}BUR^{+}$ cells can be further differentiated into the following three lineages (when exposed to known growth factors and dim lighting):

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

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

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

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^-, $PEC^-$and 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.

Judicial Exception: Product of Nature

Claims 1-4 are directed to a "product of nature" and so are not eligible for patenting

- No evidence that isolating and expanding these cells cause them to differ from a naturally occurring cell in a way that influences the characteristics of the cell
  - The claimed $CET^-/PCE^-/BUR^+$ cells differentiate into cell lineages that express the CET and PEC markers, and do not express the BUR marker, showing that the phenotype is naturally occurring, may not be a permanent change and may not influence the cell characteristics
- The claimed cells may well be found in nature
  - Only the liver was tested, it may be in other tissues;
  - Adult stem cells are known to be rare so it is not surprising it may be hard to locate

Case Law Supports Patent Ineligibility

- Supreme Court held that naturally occurring DNA is not patentable even when isolated or purified because it is a product of nature. *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576 (2013)

- Here, there is no evidence to show that the differences in markers are not "nature's handiwork" or whether the differences in the surface markers influence the characteristics of the cells

- These claims are closer to *in re Roslin*, 750 F.3d 1333 (Fed. Cir. 2014), where it wasn't clear that the differences in mitochondrial DNA between the original and cloned sheep were the product of nature and that the differences influenced the characteristics of the cloned sheep and so the cloned sheep was found patent ineligible

Claim 10

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

Claim 10 fails Steps 2A and 2B

Claim 10

- Under **Step 2A**, it is directed to a process of nature
  - Claim 10 depends from claim 1, which is directed to a composition of cells that may be naturally occurring and in any event are not permanently changed from a naturally occurring cell
  - The "method of treating" liver disease is so broad as to be meaningless (October 2019 PEG, page 14 – "treatment … limitation must be 'particular', i.e., specifically identified so that it does not encompass all applications of the judicial exception.")
  - "liver disease" covers everything from hepatitis, to cancer, to enzyme deficiencies, to cirrhosis
  - There is no application of a relationship to teat a disease
- This claim will "tie up" the use of this natural product

Claim 10

- Under **Step 2B**: assessing the remainder of the claim for an "inventive concept"
  - There is nothing in the claim that is not routine or conventional;
  - The "administering" step does not add anything inventive, and there are no specific amounts directed to a specific disease
  - Claim 10 is closer to the claims in *Mayo Collab. Svcs. v. Prometheus Labs.*, 566 U.S. 66 (2012)
    - Claims were directed to a process comprising the steps of "administering" a drug and "determining" the level of a metabolite, which did not transform the nature of the claims.
  - The same is true here – there is no application of a recognized natural law relationship – there is only a recognized (possible) relationship

Proposed New Claim 11

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

- $CET5^+/PEC^+/BUR^-$
- $CET6^+/PEC^+/BUR^-$
- $CET7^+/PEC^+/BUR^-$.

❖Claim 11 is not directed to patent eligible subject matter

- ❖The claimed marker sets in these three lineages have not been shown to be markedly different from the starting material – there may be structural differences but there is no evidence that there is any functional difference from the isolated/expanded cells, and so under Step 2A, are not patent eligible
- ❖Under Step 2B, there is nothing else in the claim to provide "significantly more" or an inventive concept

Method 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;

(b) **exposing** said liver cells to a cocktail of growth factors under late night nightclub lighting; and

(c) **selecting** for $CET^+/PEC^+/BUR^-$ cells.

Method Claims 5-8

Under Step 2A, Claims 5-8 are directed to patent ineligible subject matter ("product of nature")

- The "product of nature" exception includes non-naturally occurring products that lack any **markedly different characteristics** from the naturally occurring cells

- There has been no showing that the characteristics of these differentiated cell lines are markedly different from the CET^-, PEC^- and BUR^+ cells;

Method Claims 5-8

Under Step 2B: The additional claim elements of Claim 5 do not provide an inventive concept or add significantly more

- The step of "isolating" a cell is well known
- The step of "exposing" the liver cells to growth factors is known;
- The poor lighting does not transform the nature of the claims
- "Selecting" cells based on the detection of natural biomarkers is routine and conventional