

*Is Method Claim in Biomedical Science  
Patentable?*

*Prometheus Lab., Inc. v Mayo Collaborative Services*



**Jan Wong**

***EAGLE IP LIMITED***

***Hong Kong***

***November 09***

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# Background

- Prometheus Lab's (Prometheus) sued Mayo Collaborative Service (Mayo) for infringement of their US 6,355,623 ('623) and US 6,680,302 ('302) patent.
- '623 and '302 drawn to method claims for calibrating the proper dosage of thiopurine drugs administered to a patient, thus optimizing therapeutic efficacy while minimizing toxic side effects.
- Mayo invalidated the '623 and '302 patent under 35 U.S.C. §101 as non-statutory subject matter in the District Court.
- Prometheus appealed the final judgment of the District Court.
- The US Court of Appeals for the Federal Circuit reversed the District Court's decision.

# The Invention

- Claim 1 of '623 and '302 patents have three steps:
  - a) Administer the drug to a subject;
  - b) Determine metabolite levels; and
  - c) Be warned that an adjustment in dosage may be required.
- DC found that (a) and (b) steps are merely data gathering steps and the (c) step is only a mental step. Thus the patents were invalidated under 101.

# Relevant Case Laws

- In re Bilski, 545 F.3d 943, 88 USPQ 2d 1385 (Fed. Cir. 2008) – the machine-or-transformation test.
- In re Grams, 888 F.2d 835 (Fed. Cir. 1989) – Closest comparison to the instant case.
- In re Abele, 684 F.2d 902 (CCPA 1982) – Similar case which called for use an algorithm.

# Analysis

- Key issue of the present case: whether the claim is drawn to a fundamental principle or an *application* of a fundamental principle
  - Are steps (a) and (b) merely data gathering?
  - Is step (c) merely mental steps?
  - Is the invention a natural phenomenon (non-patent eligible) or an invention that proceeds according to natural laws (patent-eligible)?

# Analysis 1: Transformative Steps

- The Administration Step - Step (a)
  - Transformations operate by natural principles. The instant invention proceed according to natural law.
  - The invention “transform[s] an article into a different state or thing” and it is “central to the purpose of the claimed process”, Bilski.
  - “It is virtually self-evident that a process for a chemical or physical transformation of physical objects or substances is patent-eligible subject matter”, Bilski.
  - Some form of manipulation is needed, such as HPLC as specified in several dependent claims.
- The Determination Step – Step (b)
  - A significant part of the claimed method of treatment.

# Analysis 2: Not merely data-gathering

- Steps (a) and (b) are transformative and are central to the claims rather than “mere insignificant extra-solution activity”, Bilski.
- The court cited *In re Grams*, the situation in *Grams* is similar but the subject matter is not patentable.
  - Claim 1 of *Grams* requires the performance of clinical lab tests on an individual to obtain data for the parameters, the data will then be analyzed to ascertain the existence and identity of an abnormality in subsequent steps.
  - The *Grams* method does not include any transformation.
  - It is not statutory patent subject matter because “it was merely an algorithm combined with a data-gathering step”, Bilski.

# Analysis 3: mental step does not detract from patentability

- The Court agrees that the final “wherein” clauses in Claim 1 are mental steps.
- However, a subsequent mental step does not negate the transformative nature of prior steps.
- In re Abele, the method claim called for use of an algorithm. After removal of the prior step, the method claim is still patentable as it “necessarily involved production, detection, and display with a CAT scan”.
  - Abele discovered a novel way of CAT Scanning using narrower X Ray beam to minimize X Ray exposure and computer calculation time yet producing improved images.
- The presence of the mental steps in the instant case does not detract from the patentability of the administering and determining steps.

# Summary

- For method of treatment/diagnostic:
  - Transformation must be involved and be central to the purpose of the claimed process.
  - Once transformation prong under Bilski has been met, the machine prong need not be essential to consider.
  - Mental step can be part of the claimed invention given that such mental step is not central to the purpose.
  - Compounds used in method claims may be natural or non-natural, as long as transformation is involved.

# Possible Concern

- If a drug/chemical is natural and metabolizes naturally under well known metabolic pathway, would the method claim therefor be non-patent-eligible?
- Examples:
  1. Measuring serum potassium to determine kidney and heart diseases is not patentable.
  2. Measuring the metabolite of a drug to determine the right dosage may be patentable.

# Why method 1 is not patentable but method 2 may be patentable?

- Potassium in blood taken from patients can be measured by conventional titration. Potassium does not go thru any transformation and parameter is read for further studies only (an illustration according to *In re Grams*).
- A drug may be metabolized by natural metabolic pathway in a patient. The drug did transform into some metabolite(s) (it can be new or unknown for its uses previously). The level of the metabolites will be measured for further uses (the instant case).



Questions?