# The USPTO's May 2016 SME Update

## A practitioner's view

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NOVARTIS

# Beware the (il)logical ramification of *Ariosa v. Sequenom*

## *Claims "encompassing" a natural phenomenon*

- For process claims that *encompass* natural phenomenon, the steps are the additional features.
- New law: "[w]here claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well-understood applications in the art."
  - Assays (e.g., an *Ariosa* claim)?
    - Diagnostics often test for the presence/absence/level of natural phenomenon (e.g., the presence of something in the blood).
  - Dx (e.g., a *Mayo* claim)?
    - Diagnostics often test for the presence/absence/level of natural phenomenon and then subject it to an abstract idea or law of nature (e.g., correlating or predicting).

# Beware the (il)logical ramification of *Ariosa*

## *Claims "encompassing" a natural phenomenon*

- Methods of Tx w/ Dx aspect (e.g., a *Classen* claim)?
  - Compound C, Biomarker B, Disease D and means of administering are known.
  - New? **Natural law** that patients with Disease D + Biomarker B respond better to Compound C.
- Methods of Tx w/o Dx aspect (e.g., a *Merck* claim)?
  - Compound C, Disease D and means of administering are known.
  - New? **Natural law** that patients with Disease D respond to Compound C.
- Compositions (e.g., an *Armour** claim)?
  - trypsin, enteric coating are known.
  - New? **Natural law** that the ileum absorbs trypsin.

* *Armour Pharm. Co. v. Richardson Merrell, Inc.* 396 F.2d 70 (3d Cir. 1968) (citing *Funk Bros.* and holding enterically-coated trypsin ineligible for patenting).

# May 2016 SME Update: 6 Examples; 27 Claims

- two natural product examples (vaccines and dietary sweeteners);
- one law of nature example (diagnosing and treating a disease);
- one abstract idea example (screening for gene alterations); and
- two streamlined analysis examples (paper-making machine (gravity is the JE recited) and fat hydrolysis (no JE recited).

# March 2016 SME Update: Processes with AI

- Eligible: a method of amplifying or hybridizing a newly-identified gene using conventional or unconventional techniques.
  - Wins on step 2A (gene = NBP, but claim is a *process* – no Step 2A [MDC] analysis is required).
  - Not shown, but presumably same outcome if amplify/hybridize a known gene
- Ineligible: a  method of screening for alterations in a particular gene by *comparing* the sequences from different samples...
  - Loses on step 2B
- … unless the sequences are obtained using an unconventional technique in the relevant field.
  - Wins on step 2B

# March 2016 SME Update: Processes with NL

- Eligible: a method of detecting a protein, even using conventional means.
  - Wins on step 2A (protein = NBP, but claim is a process of detecting – no MDC required).
- Ineligible: a method of *diagnosing* a disease based on detection of a protein (yes, even a brand NEW protein)
  - Loses on step 2B
- … unless detection means is unconventional in the relevant field (e.g., a porcine Ab for detecting a human protein or a completely new Ab).
  - Wins on step 2B

# Diagnosing:

## Sequenom's claim 21:

21. A method of performing a prenatal diagnosis, which method comprises the steps of:

(i) providing a maternal blood sample;

(ii) separating the sample into a cellular and a non-cellular fraction;

(iii) detecting the presence of a nucleic acid of foetal origin in the non-cellular fraction according to the method of claim 1;

(iv) providing a diagnosis based on the presence and/or quantity and/or sequence of the foetal nucleic acid.

## USPTO Dx Example Claim 2:

2. A method of diagnosing julitis in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient;
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody; and
   c. diagnosing the patient with julitis when the presence of JUL-1 in the plasma sample is detected.

# Assaying:

## Sequenom's claim 1:

1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises

amplifying a paternally inherited nucleic acid from the serum or plasma sample and

detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

## USPTO Dx Example Claim 1:

Claims

1. A method of detecting JUL-1 in a patient, said method comprising:
   a. obtaining a plasma sample from a human patient; and
   b. detecting whether JUL-1 is present in the plasma sample by contacting the plasma sample with an anti-JUL-1 antibody and detecting binding between JUL-1 and the antibody.

# March 2016 SME Update: Processes with NL + treat

- Eligible: a method of treating a disease, based on biomarker detection, using a drug previously known or unknown for the disease.
  - Wins on step 2B: integrates the JE (claim as a whole) or unconventional
- The USPTO states that a basic, run-of-the-mill, method of treatment claim **does not require analysis** because it does not recite a JE.

# May 2016 SME Update: Improvements...

## General

- It is "**critical**" to address the combination of additional elements in the claim beyond the JE (good example shown in Ex. 29, claim 6);
- well-understood, routine, conventional activity (part of step 2B) must be
  - widely prevalent activity engaged in by scientists
  - in the relevant field
  - at the time of filing, **and**
  - its combination with any other additional elements in the claim must also have been well-understood, routine, conventional in the relevant field at the time of filing.
- if the JE identified is an AI, the examiner must explain how it corresponds to a concept the courts have already identified as an AI.

# May 2016 SME Update: Improvements...

## Products

- Lots of “wins” on Step 2A.
- A new example of a product winning on Step 2B, i.e., vaccine on microneedle (prior example also had similar step 2B winner – cells + biocompatible matrix).
- Subjective properties (feel, taste) considered as MDC (but not preference? Ex. 30, claim 2).
- If a claim recites several NBPs, during step 2B each NBP is considered as an additional element to the other NBPs in the claim.
  - Not used by the CAFC.
  - *U. Utah v. Ambry*.
    - **PAIR** of primers. No step 2B analysis, i.e., each primer not considered as AE to each other.
    - Decision indicates that AEs only include non-JEs.*
  - No Step 2B mentioned in *Roslin*.

* “That is, we next ask whether the remaining elements, either in isolation or combination **with the other non-patent-ineligible elements**, are sufficient to “‘transform the nature of the claim’ into a patent-eligible application.” *U. Utah.*

# May 2016 SME Update: Opportunities ...

## Products

- Virtually impossible to compare isolated X to X in native environment. Tendency:
  - To assume X native is the same as X isolated and then use X isolated for comparative purposes.
  - To create fictional comparisons.*
- Process tests in step 2B for product claims not supported by 101 case law. Other 101 tests for products should be included in step 2B:
  - *Hartranft* test (name, character, or use)
  - *Funk Brothers* test (expansion in the range of utility)
- Be careful with B**R**I – e.g., pharmaceutically acceptable carrier.
- In several claims, the property relied upon to establish compliance with step 2A (MDC) is described as "relevant to the nature of the invention" and *Roslin* is cited.

* For example, sap doesn't have discreet pockets of texiol + water. Only when one removes the multitude of other chemicals from sap would one have texiol + water. Thus, the claimed invention is compared to something that simply does not exist in nature

# May 2016 SME Update: Opportunities ...

## Products

- In claims reciting NBP + non-NBP:
  - Streamlined analysis if the claim "clearly does not seek to tie up" the NBP, e.g., mineral coated onto artificial hip, firework.
  - Streamlined analysis if the NBP is "ancillary" to the invention, e.g., plastic chair with wood trim.
  - Regular analysis if the NBP is 'central' to the invention, e.g., pacemaker cells in dish or a peptide coated on miconeedle.
    - If central, and 2A not satisfied, the non-NBP analyzed f[illegible]entionality, specificity, required for use of NBP.

Central vs. ancillary will cause difficulties

# May 2016 SME Update: Improvements...

## Processes

- MDC analysis not triggered for a process claim that simply recites a NBP. Must be another JE in the process claim (abstract idea, law nature, etc.).
  - Tension with *Ariosa*?
- Pure assay/detect claims are not directed to a JE (wins on step 2A). Step of "determining" is not itself a natural law (citing *Mayo*).
  - Tension with *Ariosa?*
- Pure MoT (use) claim employing a NBP is focused on the process, not the product. Step of "administering" is not itself a natural law (citing *Mayo*).

# May 2016 SME Update: Opportunities ...

## Processes

- Process claim case law asks whether a JE is meaningfully *applied*.
  - Too much focus on conventionality overlooks *application*.
  - Drinking coffee + E=mc2 (conventionality of coffee drinking is relevant because JE not applied); *Enfish* (conventionality of a computer irrelevant, because JE applied).
- If a biomarker (e.g., JUL-1) is novel, then <u>any</u> probe to that marker (e.g., mAb to JUL-1) must be unconventional (step 2b win).
  - Only by ignoring the substrate is probe conventional: "mAb ~~to JUL-1~~" vs "mAb to JUL-1".
  - *Mayo*: AEs cannot be conventional **and** highly general.* *Mayo* corollary: AEs can be general if they are unconventional.
  - But, Office seems to equate "high level of generality" with conventionality.#

* "appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable." *Mayo*

# "When recited at this high level of generality (generic anti-JUL-1 antibody), there is no meaningful limitation … in this step that distinguishes it from well-understood, routine, and conventional data gathering activity engaged in by scientists prior to applicant's invention …" See, eg., Ex 29, claim 2.

# May 2016 SME Update: Opportunities ...

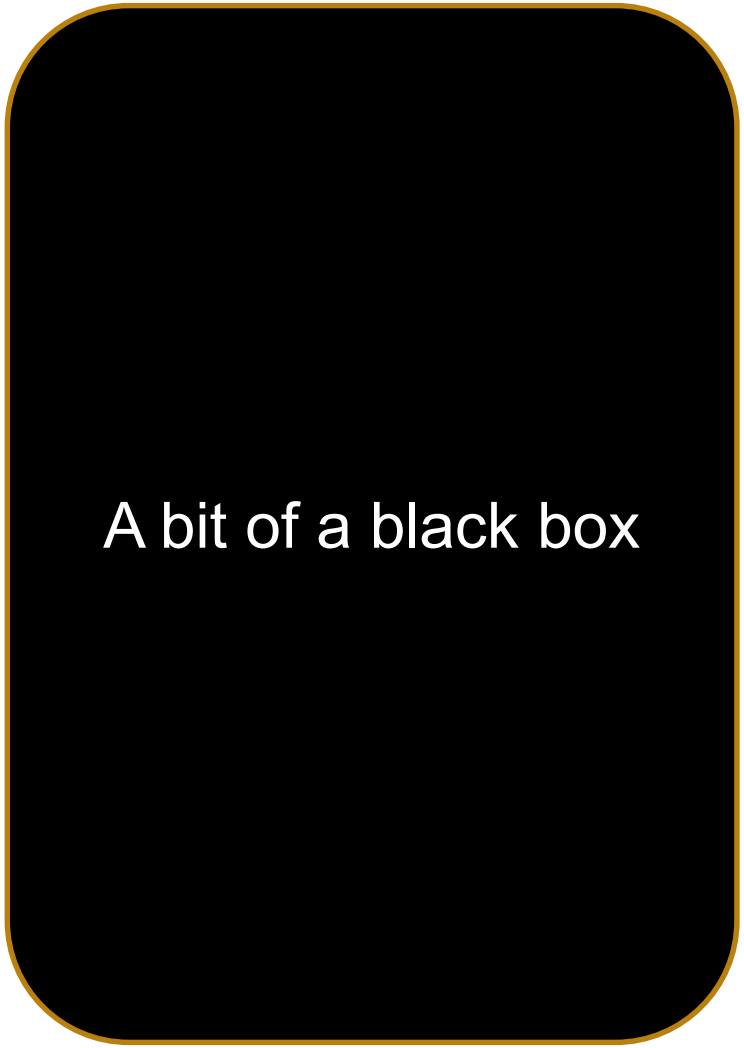
## Processes

- The Eligible Assay Needs Further Explanation.
  - At June 21 Patent Quality Chat, USPTO states no conflict between *Ariosa* and the new examples.
  - USPTO examples and guidance should refer to, interpret, and synthesize *Ariosa* and *U. Utah.*
- The Eligible Assay Only Goes So Far.
  - Conventional assay claims suffer from 102/103 issues (unless novel biomarker).
  - Dx + MoT claims employ multi-actors, meaning assertion is often impossible.
  - MoT claims, while helpful to Pharma, don't help Dx company.

# Critical to practitioners

- Do not recite a JE if it is not necessary, thereby avoiding 101 scrutiny.
  - "comparing" is an AI (*U. Utah v. Ambry*; Example 31, claim 1)
  - A method of selectively treating disease, comprising selectively administering drug to patient on the basis of patient having previously been determined to have biomarker B.
- Conventionality – be prepared to define the relevant field.
- Do not designate things in your spec. as known generic functions, components, activities, etc.
- If evidence of conventionality is not provided, use MPEP 2144.03 – official notice procedure.
- Subjective properties can satisfy MDC.
  - Push back on "relevant to the nature of the invention"
- Appeal good facts.

# The Uncertain Future




**Process:**

Court*: Enfish* (the "directed to" inquiry of Alice does not ask whether a claim "involves a patent-ineligible concept", but asks whether a claim, based on its "character as a whole is directed to excluded subject matter.")

USPTO:

- Input to a Govt. *Ariosa* brief?

**Product:**

Court: No assistance on the horizon.

USPTO:

- *critical* to consider the claim as a whole, and
- subjective characteristics are important (e.g., mouth feel, smoothness, etc.), although these may have to be "relevant to the nature of the invention."

# Backup

# USPTO Examples: Products/Compositions

*Winners and ...* *Losers*

Vaccine:

- live attenuated pigeon flu virus or inactivated pigeon flu virus (virus Δ **structure and prop.**)
- pep F, cream, emulsion, gel, liposome, nanoparticle or ointment (*mixture* Δ **structure and charac.;** c.f. mix. to pep F, oil, and water)
- pep F, aluminum salt adjuvant (w or w/o carrier) (*mixture* Δ **property;** c.f. mix. to pep F, adjuvant (+/water))
- pep F on delivery device: microneedle array coated with vaccine comprising peptide. (**Step 2B** – microneedles, although known, **not conventional**)

Vaccine:

- peptide and pharmaceutically acceptable carrier (BRI covers peptide in water) (c.f. mix. to pep F, and water)

# USPTO Examples: Products/Compositions

*Winners and ...* *Losers*

Sweetner:

- 1-5% texiol and at least 90% water and 1-2% cpd. N (*mixture* has **Δ charac. – taste**; c.f. complete mixture to cpd. N, mixture of texiol + water in sap)
- 5% texiol; water or juice (or combination); and pectin sufficient to form a gel (*texiol* has **Δ charac.– spreadable; mouth feel**; c.f. complete mixture to mixture of pectin + water (e.g., in apples), mixture of texiol + water in sap)
- granular texiol with a diameter X (*formulation* has **Δ charac. - dissolution rate;** c.f. granulated texiol to irregular crystals of texiol on broken leaves).
- texiol in a controlled release formulation (*formulation* has **Δ charac. – altered time release**; c.f. complete mixture to naturally-occurring texiol [in leaf?])
  - Hypo tells us that texiol in its natural state releases all of its sweetness at one time. How can anyone know what happens in the leaf? For this comparison, the Office appears to compare isolated texiol (which is NOT natural) to the claimed formulation.

Sweetner:

- texiol and water (BRI covers natural sap)
- 1-5% texiol and at least 90% water (retains sweetness and bitterness of sap) (c.f. complete mixture to mixture of texiol + water in sap)

– This seems wrong. Hypo. says this mixture is *preferred* over mixtures with higher [texiol] (which would include sap). Obviously, claimed composition has some difference creating taster preference.

- Also, sap doesn't have discreet pockets of texiol + water (nor do apples have discreet pockets of water and pectin). Only when one removes the multitude of other chemicals from sap would one have texiol + water. Thus, the comparison is made to something that simply does not exist.

# BACKUP: What was working before the May 2016 USPTO SME update:

- In in assay/diagnostic claims:
  - Particular type of assay format in in, e.g., ELISA (a la suggestion from Mayo regarding general vs. specific limits [also found in dicta in U. Utah re: claim 21)
  - Device/structure limitations (plates, dipsticks, chips, etc.)
  - Narrow ranges of reagents
  - Specific subset of diseases/afflictions
  - Unconventional reagents
  - Treatment and other “active” steps
- In product/composition claims:
  - Specific types of antibodies in kits (monoclonal)
  - Conjugating otherwise NBP (e.g., detectable labels)
  - Additional components in a composition having NBP (e.g., aluminum adjuvant)