Biotech/Chem/Pharm Customer Partnership Meeting

August 2, 2017

USPTO, Alexandria, VA

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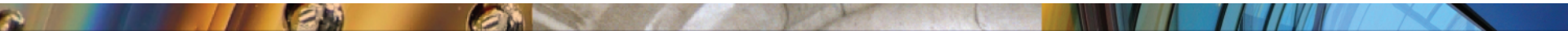

Stakeholders' Perspectives

Subject Matter Eligibility under 35 USC 101

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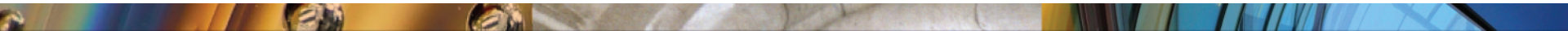
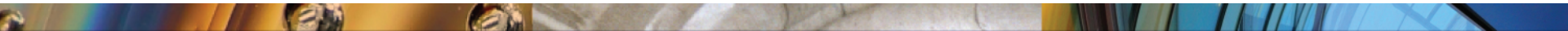


I. May 2016 Updated Guidance to Examiners



Two-Part Eligibility Analysis

- Step 1 determines whether the claim is directed to a process, machine, manufacture, or composition of matter.
- Step 2 is the 'two-part analysis' from Alice Corp. (also called the Mayo test) for claims directed to laws of nature, natural phenomena, and abstract ideas (the judicially recognized exceptions).
  - In **Step 2A**, determine whether the claim is **directed to** a law of nature, a natural phenomenon, or an abstract idea (judicial exceptions). If no, the claim is eligible and examination should continue for patentability. If yes, proceed to Step 2B.
    - "**Directed to**" means the exception is recited in the claim, i.e., **the claim sets forth or describes the exception**.
    - If the claim recites a nature-based product limitation, the 'markedly different characteristics' analysis is used to evaluate whether the claim is directed to a "product of nature" that falls under the law of nature and natural phenomenon exceptions.
  - In **Step 2B**, determine whether any element, or combination of elements, in the claim is sufficient to ensure that **the claim as a whole amounts to significantly more than the judicial exception**.
    - The additional elements should be considered **both individually and as an ordered combination**.

Formulating § 101 Rejections

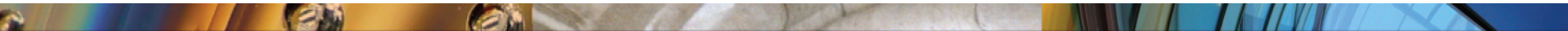
The examiner's rejection must:

- provide an explanation as to why each claim is unpatentable, and
- be sufficiently clear and specific to provide sufficient notice of reasons for ineligibility to enable applicant to effectively reply

Rejection should map to the Two-Part Eligibility analysis:

- Is a claim directed to a judicial exception? (Step 2A)
  - Point to the specific claim limitation and explain why it is a judicial exception
  - Identify the abstract idea, law of nature, natural phenomenon, or product of nature
- Identify additional elements in the claims (if any) and explain why they do not result in the claim as a whole amounting to "significantly more" than the judicial exception (Step 2B)
  - Identify any additional claim elements beyond the judicial exception
  - Consider the additional elements both individually and as a combination

II. Step 2B – More on “Significantly More”



Step 2B – "Significantly More"

Evaluating Applicant's Response (May 4, 2016 Memo, p.5)

Applicant may argue:

- **The claim as a whole** amounts to **significantly more** than the judicial exception when additional elements are considered both individually and in combination.
  - The additional element(s) **meaningfully limits** the judicial exception.
  - The additional element(s) may **not** be **well-understood**, **routine, or conventional** in the **relevant field.**
  - The additional element(s) **improves another technology or technical field.**
  - The additional elements were **not considered in an ordered combination.**

When formulating a 101 rejection (May 4, 2016 Memo, p.2-3):

- *The eligibility of each claim should be evaluated as a whole*
- *Explain why the additional claim elements do not result in the claim as a whole amounting to significantly more than the judicial exception*
- *Should address the additional elements both individually and as a combination when determining whether the claim as a whole recites eligible subject matter*
- *Particularly critical to address the combination of additional elements…those additional elements when viewed in combination may amount to significantly more than the exception by meaningfully limiting the judicial exception*

Step 2B – "Significantly More" cont.

Inconsistency among examiners in their interpretation of:

- "**well-understood, routine or conventional**" –
  - "lack of novelty does not necessarily show that an element is well-understood, routine or conventional activity"
  - "even if a particular laboratory technique was discussed in several widely-read scientific journals or used by a few scientists, mere knowledge of the particular laboratory technique or use of the particular laboratory technique by a few scientists us not sufficient to make the use of the particular laboratory technique routine or conventional in the relevant field"
  - "if it is determined that the additional element is widely prevalent and its combination with other additional elements is well-understood, routine or conventional activity…" (Memo p.4)
- "the eligibility of each claim should be evaluated as a whole," "a new combination of steps in a process may be eligible even though all the steps of the combination were individually well known and in common use before the combination was made" (Memo p.2,3)

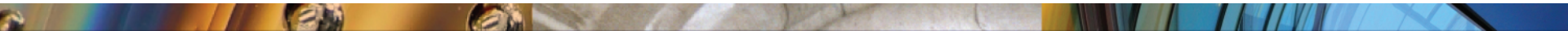
Step 2B – "Significantly More" cont.

Inconsistency among examiners in their interpretation of:

- "**relevant field**" –
  - Not defined in the Memo so open to examiner's definition. Is it the field of biotechnology? cancer screening? disease diagnosis? biological sample identification?
  - Is it the field of treating a specific disease?
  - See Life Science Example 29, claim 6 analysis: "while using anti-TNF antibodies treatment was well understood, routine and conventional in the field for treating julitis, when all the additional elements are viewed as a combination they amount to a claim as a whole that adds meaningful limits on the use of the judicial exception"

- "**improvement** to another technology or a technical field" – not defined in the Memo so open to examiner's interpretation. Higher sensitivity? higher accuracy? a different or new way of doing something? a particular solution to a problem? a particular way of achieving a desired outcome?

III. Overcoming § 101 Rejections



1. Abstract Idea Example A

Rejected claim:

1. **A method for replacing native regulation of a set of genes collectively associated with a function with synthetic regulation**, the method comprising:

providing coding sequences for a set of polypeptides encoded by genes collectively associated with a function;

changing codon identity within at least one coding sequence, thereby removing at least one regulatory sequence within the coding sequence, wherein removing the at least one regulatory sequence comprises replacement of native codons in the coding sequence with non-native synonymous codons and comprises selecting non-native codons having maximal distance from the native codons of the coding sequence;

organizing the coding sequences into one or more synthetic operon(s);

operably linking one or more heterologous transcriptional regulatory sequence to the operon(s), thereby controlling magnitude of gene expression from the operon(s); and

expressing the one or more synthetic operon(s) in a cell under the control of a polypeptide that binds directly or indirectly to the heterologous transcriptional regulatory sequence.

1. Abstract Idea Example A

Examiner's Rejection: the instant claims are directed a method "for replacing native regulation of a set of genes collectively associated with a function with synthetic regulation" where the originally filed disclosure provides that **the methods disclosed encompass the performance of all steps by a computer** (see reproduced paragraph [00115] below; and originally filed claim 71) **and does not include additional elements**, when considered separately and in combination, that are **sufficient to amount to significantly more** than the judicial exception.

1. Abstract Idea Example A

Allowed claim:

1. (Currently Amended) **A method for expressing one or more synthetic operons collectively associated with a function in a cell by** replacing native regulation of a set of genes with synthetic regulation, the method comprising:

providing coding sequences for a set of polypeptides encoded by genes collectively associated with a function;

changing codon identity within at least one coding sequence, thereby removing at least one regulatory sequence within the coding sequence, wherein removing the at least one regulatory sequence comprises replacement of native codons in the coding sequence with non-native synonymous codons and comprises selecting non-native codons having maximal distance from the native codons of the coding sequence;

organizing the coding sequences into one or more synthetic operon(s);

operably linking one or more heterologous transcriptional regulatory sequence to the operon(s), thereby controlling magnitude of gene expression from the operon(s); and

expressing the one or more synthetic operon(s) in a cell under the control of a polypeptide that binds directly or indirectly to the heterologous transcriptional regulatory sequence,

wherein the polypeptide that binds directly or indirectly to the heterologous transcriptional regulatory sequence is expressed from a control expression cassette, the expression cassette comprising a control promoter operably linked to a polynucleotide sequence encoding the polypeptide.

1. Abstract Idea Example A

Examiner's Reasons for Allowance: 1) the preamble of the claims are amended to clarify that the claims are: a) "directed to **a novel technological process for expressing** one or more synthetic operons collectively associated with a function in a cell by replacing native regulation of a set of genes with synthetic regulation"; and b) "the claimed invention provides a **new and improved technique** for producing a tangible and useful result that falls squarely outside those categories of inventions that are "directed to" patent-ineligible concepts"; and 2) "the claims are patent eligible for at least the reason that they **improve the field of genetic regulation**", where "**there is nothing routine or conventional in the technical field of genetic regulation of expressing synthetic operons**, in which codon identity within at least one coding sequence of the synthetic operon is modified by removing at least one regulatory sequence within the coding sequence that comprises replacement of native codons in the coding sequence with non-native synonymous codons and comprises selecting non-native codons having maximal distance from the native codons of the coding sequence."

2. Abstract Idea Example B

Rejected claim:

1. **A method of measuring a first methylation profile of a first tissue from a first biological sample of an organism**, the method comprising:

obtaining the first biological sample, the first biological sample including cell-free DNA comprising a mixture of cell-free DNA originating from the first tissue and from a second tissue, the first tissue being fetal or placental tissue or tumor tissue, wherein the first biological sample is selected from the group consisting of blood, plasma, serum, urine, saliva, sputum, tears, and stool;

obtaining a second methylation profile corresponding to DNA of the second tissue, the second methylation profile providing a methylation density at each of a plurality of loci in a genome, the methylation density at a particular locus corresponding to a proportion of DNA of the second tissue that are methylated;

determining a cell-free methylation profile of the cell-free DNA of the mixture, wherein the determining the cell-free methylation profile comprises:

performing an assay on the cell-free DNA of the mixture,

detecting methylation statuses of the cell-free DNA from the mixture at the plurality of loci,

determining, by a computer system, a methylation density at each of the plurality of loci using the methylation statuses of the cell-free DNA from the mixture at the plurality of loci;

determining, by the computer system, a percentage of the cell-free DNA in the mixture that are from the first tissue; and

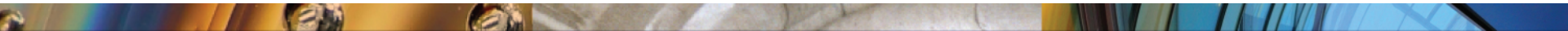
determining, by the computer system, the first methylation profile of the first tissue by:

for each of the plurality of loci:

calculating a differential parameter that includes a difference between the

methylation density of the second methylation profile and the methylation density of the

cell-free methylation profile, the difference being scaled by the percentage.



2. Abstract Idea Example B

Examiner's rejection:

The claimed invention is directed to a judicial exception (i.e. a law of nature, a natural phenomenon, or an abstract idea) without significantly more. Claims 1-11, 13-18, 79, 80 and 101-108 are directed to the abstract idea of determining the methylation profile of a DNA population when present in a mixture of two DNA populations by subtracting the methylation profile contribution of the second population. Based upon an analysis with respect to the claims as a whole, the claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception.

Applicants submit that the "ordered combination of additional limitations is unconventional for determining first methylation profile of first tissue." However, Applicants are mistaken in assuming that the intended result of a process is necessarily limiting of a method step. This is not the case. For example, amplifying and detecting DNA is well-understood, routine and conventional, and thus does not add significantly more to a claim reciting a judicial exception, even if the overall method purpose is, e.g., detecting paternally inherited nucleic acid for prenatal diagnosis, is not a routine intended purpose.

Applicants contend that "The improvement is not that blood can be analyzed to determine a cell-free methylation profile of blood, but it is the use of the cell-free methylation profile of a mixture of cell-free DNA of the first tissue and the second tissue to obtain the first methylation profile of just the first tissue". **This argument was carefully considered but was not found to be persuasive, as it points to the invention as a *different* way of doing something that is known in the field, methylation analysis of blood, but does not point to an improvement to the field.** Different is not necessarily better. The question remains of "how does the practice of the claimed invention necessarily improve a technology or technological field?"

2. Abstract Idea Example B

Allowed claim:

1. **A method of measuring a first methylation profile of a first tissue from a first biological sample of an organism**, the method comprising:

obtaining the first biological sample, the first biological sample including cell-free DNA comprising a mixture of cell-free DNA originating from the first tissue and from a second tissue, the first tissue being fetal or placental tissue or tumor tissue, wherein the first biological sample is selected from the group consisting of blood, plasma, serum, urine, saliva, sputum, tears, and stool;

purifying the first biological sample for the mixture of cell-free DNA from a cellular portion of the first biological sample;

obtaining a second methylation profile corresponding to DNA of the second tissue, the second methylation profile providing a methylation density at each of a plurality of loci in a genome, the methylation density at a particular locus corresponding to a proportion of DNA of the second tissue that are methylated;

determining a cell-free methylation profile of the cell-free DNA of the mixture, wherein the determining the cell-free methylation profile comprises:

performing an assay on the cell-free DNA of the mixture, **wherein performing the assay on the cell-free DNA of the mixture comprises:**

sequencing the cell-free DNA, wherein the assay is performed at a genome-wide scale; and

detecting methylation statuses of the cell-free DNA from the mixture at the plurality of loci[[,]]; and

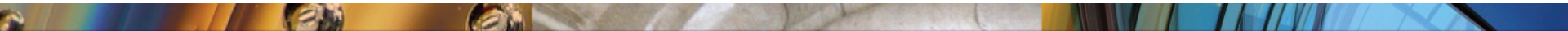
determining, by a computer system, a methylation density at each of the plurality of loci using the methylation statuses of the cell-free DNA from the mixture at the plurality of loci;

determining, by the computer system, a percentage of the cell-free DNA in the mixture that are from the first tissue; and

determining, by the computer system, the first methylation profile of the first tissue by:

for each of the plurality of loci:

calculating a differential parameter that includes a difference between the methylation density of the second methylation profile and the methylation density of the cell-free methylation profile, the difference being scaled by the percentage.



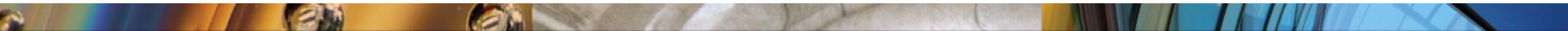
2. Abstract Idea Example B

Examiner's Reasons for Allowance:

Claim 1, as presently amended, **recites steps that are in addition to the judicial exception (abstract idea)** of: purifying the cell-free DNA of the biological sample from the cellular portion of the biological sample, performing genome-wide DNA sequencing of the purified cell-free DNA in an assay that yields methylation status information for the cell-free DNA, and using a computer system to generate a methylation profile. At the time of Applicants' invention, it was well-understood, routine and conventional to purify cell-free DNA, to perform genome-wide sequencing on cell-free DNA, and to assay methylation status on cell-free DNA.

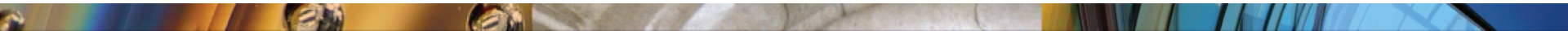
However, **the elements in combination, namely performing DNA sequencing using purified cell-free DNA to yield methylation data on a genome-wide scale, was in limited practice at the time of Applicants' invention**, primarily the Applicants' laboratory (e.g. Lun et al., Clinical Chemistry 59 (11):1583-1594; as cited in the IDS). As **this combination of additional elements was not routine and adds significantly more to the claim**, the U.S.C. 101 rejection is withdrawn.

May 4, 2016 Memo, p. 4: "even if a particular laboratory technique was discussed in several widely-read scientific journals or used by a few scientists, mere knowledge of the particular laboratory technique or use of the particular laboratory technique by a few scientists us not sufficient to make the use of the particular laboratory technique routine or conventional in the relevant field"



2. Abstract Idea Example B

- "**Lack of novelty** (i.e., finding the element in the prior art) does **not** necessarily show that an element is well-understood, routine or conventional activity previously engaged in by those **in the relevant field**." "mere knowledge of the particular laboratory technique or use of the particular laboratory technique by a few scientists is not sufficient to make the use of the particular laboratory technique routine or conventional **in the relevant field**." "If it is determined that the additional element is widely prevalent and its combination with other additional elements is well-understood, routine or conventional activity, the examiner should provide a reasoned explanation that supports that conclusion." May 4, 2016 Memo, p.4.
- "In Step 2B of the USPTO SME guidance, examiners should consider the additional elements in **combination**, as well as individually, when determining whether **a claim as a whole** amounts to significantly more, as this may be found in the **non-conventional and non-generic arrangement of known, conventional elements**." Nov. 2, 2016 Memo, p.3, citing *BASCOM*.
- In other words, "well understood, routine, conventional" is not equivalent to "obvious." Something that is known and arguably would have been obvious (but hasn't been routinely done in that field) is not the same as something routine and conventional in that field.



3. Diagnostic Method Example

Rejected claim:

1. **A method of assessing a colorectal cancer risk status** in an individual, comprising the steps of

obtaining a circulating blood sample from the individual;

obtaining a biomarker panel level for a biomarker panel comprising a list of proteins in the sample comprising AACT, CO3, C09, MIF, and PSGL to comprise panel information from said individual;

comparing said panel information from said individual to a reference panel information set corresponding to a known colorectal cancer status; and

categorizing said individual as having said colorectal cancer risk status if said individual's reference panel information does not differ significantly from said reference panel information set.

3. Diagnostic Method Example

Examiner's rejection:

The "abstract ideas" include "**comparing**" and "**categorizing**" steps. The "natural phenomenon" is: information such as biomarker levels correlate with colorectal cancer status and efficacy of treatment. The claims do not include additional elements that are sufficient to amount to significantly more than the judicial exception because the additional elements (when considered both individually and as an ordered combination) are limited to well-understood, routine and conventional steps of "obtaining" biological samples, "contacting" samples with antibodies, and "administering" colorectal cancer treatments.

3. Diagnostic Method Example

Allowed claims:

1. A method comprising:

obtaining a circulating blood sample from an individual; and

detecting protein levels for each member of a list of proteins in the sample, said list comprising AACT, CO3, C09, MIF, and PSGL.

- May 2016 Life Sciences Example 29 (JUL-1) Claim 1: Eligible under Step 2A – "the steps do not recite or describe any recognized exception" "recited steps of administering a drug…and determining the resultant level of…are not themselves natural law"(citing Mayo)

2. The method of claim 1, further comprising diagnosing said individual as having a colorectal cancer risk status when said protein levels from said individual do not differ significantly from a reference panel information set corresponding to a known colorectal cancer risk status; and performing a polypectomy on said individual.

- May 2016 Life Sciences Example 29 (JUL-1) Claim 6: Eligible under Step 2B – "while using anti-TNF antibodies treatment was well understood, routine and conventional in the field for treating julitis, when all the additional elements are viewed as a combination they amount to a claim as a whole that adds meaningful limits on the use of the judicial exception" "new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use"(citing Diehr)

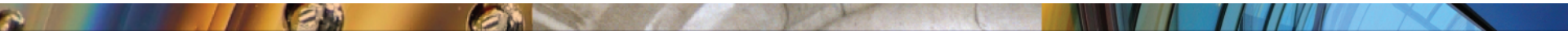
4. Natural Phenomenon Example

Rejected claim:

1. A method to perform a genetic or proteomic analysis on a plurality of cells, the method comprising:

incubating the plurality of cells under both a positive pressure and hypoxic condition **to allow enrichment of a target cell subpopulation**, wherein the genetic or proteomic analysis is performed on the target cell subpopulation, wherein the genetic or proteomic analysis comprises **measuring biomarker expression** in the target cell subpopulation and **comparing to biomarker expression** in cells not subjected to the positive pressure and hypoxic conditions.

- We argued that because the claim required enrichment of a target cell subpopulation, the claim did not merely recite a natural law. Rather, the claim is directed to an application of a natural law.



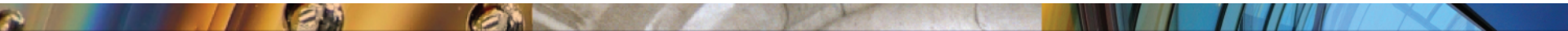
4. Natural Phenomenon Example

Examiner's Rejection on 2/29/2016 (before May 4, 2016 updated guidance):

The unpatentability of laws of nature was confirmed by the U.S. Supreme Court in Mayo Collaborative Services v. Prometheus Laboratories, Inc., No. 10-1150 (March 20, 2012). Based upon consideration of all of the relevant factors with respect to the claims as a whole, claims 1, 2, 5, 9, 32-43 are held to claim a law of nature, and is therefore rejected as ineligible subject matter under 35 U.S.C. 101. The practice of the method claims does not result in an inventive concept that transforms the natural phenomenon into a patentable invention.

In this case, **the claims inform a relevant audience about certain laws of nature**. The additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community. The additional steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately.

The claims are directed to a method to perform a genetic or proteomic analysis on a plurality of cells comprising **incubating the plurality of cells** under both positive pressure and hypoxic condition, **measuring and comparing the expression of biomarkers**. The claims set forth laws of nature- namely relationships between incubating the plurality of cells under both positive pressure and hypoxic condition and expression of biomarker. The relation is a consequence of the way in which an indicator i.e. biomarker expression increases or decreases as the result of incubation of the cells under both positive pressure and hypoxic condition and thus simply **describes a relation set forth by a natural law**.



4. Natural Phenomenon Example

Examiner dropped 101 rejection of amended claim:

1. **A method for isolating a target cell subpopulation** from a plurality of cells, the method comprising:

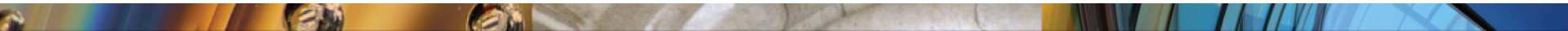
a) **incubating** the plurality of cells under both a positive pressure and hypoxic condition in an enclosed environment chamber, wherein the enclosed environment chamber is configured to produce the positive pressure and hypoxic condition;

b) **performing** an assay to determine size, morphology, a physical property, a biological property, or a kinetic property of the target cell subpopulation;

c) **isolating** the target cell subpopulation based on the size, morphology, a physical property, a biological property, or a kinetic property of the target cell subpopulation based on the results of the assay.

- We argued that, like the claims in *Rapid Lit. Mgmt. v. CellzDirect*, amended claim 1 is directed to an **application** of a law of nature. That is, it **applies** the discovery that growth of a target cell subpopulation can be enhanced by incubation under positive pressure and hypoxic condition.

IV. Recommendations



Recommendations

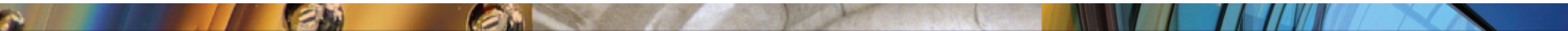
- **More consistency among examiners in their interpretation and application of USPTO's Subject Matter Eligibility ("SME") guidance.**
- **More training examples, e.g., bioinformatics inventions (see following slides).**
- **Continue to issue guidance memos to examiners on new court decisions.**
- **We depend on the USPTO to strive to develop more comprehensive (rather than reactive) policy in addressing SME.**
  - 35 USC 3(a)(2)(A):The Director shall be responsible for providing policy direction and management supervision for the Office and for the issuance of patents and the registration of trademarks. The Director shall perform these duties in a fair, impartial, and equitable manner.
- **Any guidance issued by the UPSTO should represent unified/consolidated views of business units within the agency (see following slide).**
- **More clarification on the role of "preemption" in determining SME of claims (see following slide).**

Bioinformatics Inventions

- What is "**computer-related**" technology?
- Is bioinformatics a "**computer-related**" technology? Below are some common definitions of "bioinformatics":
  - "the collection, classification, storage, and analysis of biochemical and biological information **using computers *especially as applied to molecular genetics and genomics***" (Merriam-Webster dictionary)
  - "Bioinformatics involves the **application of computer technology** to manage volumes of biological information. **Computers are used** to not only store, but also gather, analyze and integrate biological and genetic data that can then be applied for such uses as gene-based drug discovery and development." https://www.usfhealthonline.com/resources/key-concepts/what-is-bioinformatics/)
  - "The discipline grew out of the massive amounts of information accumulated by the Human Genome Project, which has **required advanced computer technology** to help sequence the entire human genome, which amounts to some 3 billion base pairs." (USF, https://www.usfhealthonline.com/resources/key-concepts/what-is-bioinformatics/)

Bioinformatics Inventions

- Examiner: Bioinformatics is not a technology; it is a technical field.
- We urged the examiner to consider and apply computer-related precedent in bioinformatcs cases.
- "An improvement in computer-related technology is not limited to improvements in the operations of a computer or computer network *per se*, but may also be claimed as **a set of rules (basically mathematical relationships**) that improve computer-related technology by allowing computer performance of a function not previously performable by a computer" (Nov. 2, 2016 Memo, citing McRO)
- "An indication that a claim is directed to an improvement in computer-related technology may include – (1) teaching in the specification about how the claimed invention improves a computer **or other technology**…" (Nov. 2, 2016 Memo)
- "Nor do we think that claims directed to **software**, as opposed to hardware, are inherently abstract and therefore only properly analyzed at the second step of the Alice analysis." Enfish, Slip Op at 11.



Bioinformatics Inventions

- **Examiners should not have a *per se* rule against applying computer-related precedent to life science cases. Not only do many life-science cases involve information processing similar to the computer precedent, but other aspects such as the structure of the claim or the use of specific words can be relevant even if the technology is different.**

- **The *per se* rule hobbles a full discussion of the issues because to date, much of the developing precedent is on the computer side. There is no reason to believe that the PTAB or the Federal Circuit would adopt the *per se* rule as a basis for their analyses.**

Impact of PTAB Decisions?

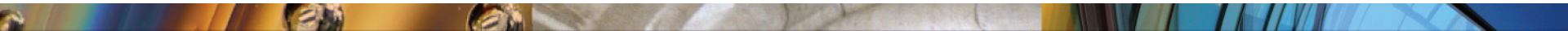
Ex Parte Chamberlain

- Appeal 2014-009849, decided Jan. 20, 2017
- Claim 1. A method of treating a human individual having a bone disorder, the method comprising:

  determining in a nucleic acid sample obtained from the individual, the presence of a TT genotype at a single nucleotide polymorphism rs2297480 (SNP rs2297480) in the farnesyl diphosphate synthase (FDPS) gene, the presence of the TT genotype at SNP rs2297480 being indicative that the individual is responsive to bisphosphonates; and

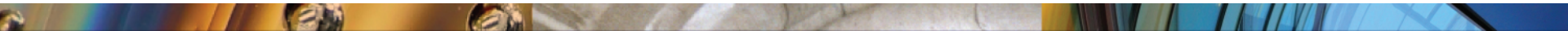
  administering a bisphosphonate to the individual if the TT genotype is present.

- PTAB found the claim ineligible under 101 stating that: "the step of administering a bisphosphonate recited in Appellants' claim 1 was a well-known and routine treatment or individuals suffering from bone disorders" "the genotype determining step in claim 1's process is performed using conventional techniques" Decision at 7.
- In conflict with May 2016 Life Sciences Example 29 (JUL-1) Claim 6 analysis: "Eligible per Step 2B, while using anti-TNF antibodies treatment was well understood, routine and conventional in the field for treating julitis, when all the additional elements are viewed as a combination they amount to a claim as a whole that adds meaningful limits on the use of the judicial exception."



Preemption

- **Supreme Court clearly identified preemption as a key concern:**
  - ***Mayo Collaborative Services v. Prometheus Laboratories Inc.*, 132 S. Ct. 1289 (2012).**
  - ***Alice Corp. v. CLS Bank International*, 134 S. Ct. 2347 (2014).**
- **Federal Circuit:**
  - ***Rapid Litigation Management Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042 (Fed. Cir. 2016).**
  - ***McRO, Inc. dba Planet Blue v. Bandai Namco Games America Inc.*, 837 F.3d 1299 (Fed. Cir. 2016).**
- **USPTO:**
  - **"Questions of preemption are inherent in and resolved by the two-part framework from *Alice Corp.* and *Mayo*, as explained by the Federal Circuit in *OIP* and *Sequenom*." May 4, 2016 Memo at 7.**
  - **"Several recent decisions discuss the role of preemption in the eligibility analysis, and the Office will be addressing preemption in more detail in its forthcoming update to its SME guidance. Specifically, some recent decisions discuss the absence of preemption as confirming the analysis that the claimed invention is not directed to a judicial exception (*CellzDirect*) or included an inventive step (*BASCOM*). The *McRO* court discusses the absence of preemption in determining that the claimed invention was not "directed to" a judicial exception." Nov. 2, 2016 Memo at 3.**



Thank You