

# Practitioner's Perspective on 101 as Applied to Biotech Applications

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**March 4, 2014 Procedure for Subject Matter Eligibility Analysis of Claims Reciting or Involving Laws of Nature/Natural Principles, Natural Phenomena and/or Natural Products**

**According to the guidelines, a natural product must be “markedly different” from how it appears in nature to rise to the level of patent-eligible subject matter. It was revealed during the USPTO forum on May 9, 2014 that the USPTO’s definition of “markedly different” required a difference in structure and that a difference in function will not suffice.**



## **December 15, 2014 Interim Guidance on Patent Subject Matter Eligibility (“Interim Eligibility Guidance”) and Examples**

**In contrast to the previous position that a marked difference requires a structural difference, the Interim Eligibility Guidance makes it clear that a marked difference may be the result of a structural or functional difference. If the product is markedly different, then the claim does not recite a product of nature exception, therefore the subject matter is patent-eligible and it is not necessary to proceed to Step 2B.**



## **December 15, 2014 Interim Guidance on Patent Subject Matter Eligibility (“Interim Eligibility Guidance”) and Examples**

**In another departure from the previous procedures, claims that recite a judicial exception, but clearly do not seek to monopolize the judicial exception, are subject to a streamlined eligibility analysis, in which the markedly different characteristics analysis is not necessary.**



## **December 15, 2014 Interim Guidance on Patent Subject Matter Eligibility (“Interim Eligibility Guidance”) and Examples**

**Many of the new examples involve claims that were discussed in the March materials, but the analysis and conclusion is different, resulting in far more patent-eligible claims under the new procedures. Although isolated DNA, and other naturally occurring products, remain(s) ineligible patent subject matter, the new Guidance is substantially more permissive than the March 4, 2014 procedures.**



**December 15, 2014 Interim Guidance on Patent Subject Matter Eligibility (“Interim Eligibility Guidance”) and Examples**

**Examples and discussion regarding diagnostic claims and personalized medicine are limited, thus it is not as clear how the new procedures will change the analysis with respect to such discoveries.**



## **Biomarker/diagnostic industry**

**Press Release**

**June 3, 2014, 4:30 p.m. EDT**

**NanoString Technologies Enters into Biomarker Companion Diagnostic Collaboration with Celgene Corporation to Support Development of REVLIMID as Treatment for Patients with Diffuse Large B-Cell Lymphoma**

**NanoString Eligible to Receive up to \$45 million for Upfront, Developmental and Regulatory Milestones, and Commercial Payments from Celgene**

**“Biomarker-driven clinical trials are the future of clinical oncology.”**

<http://tinyurl.com/nyhrefh>



## Biomarker/diagnostic industry

The U.K.'s Cytox attracts \$2.5M in new investment to pursue Alzheimer's biomarker work

April 3, 2014

U.K. diagnostics developer Cytox raised nearly \$2.5 million in new funding to help expand work on the development of a viable Alzheimer's biomarker.

Report: Biomarkers market to grow 18.5% by 2018

October 2, 2013

Biomarkers are becoming increasingly useful to doctors as a tool to help diagnose patients earlier, predict the course of disease and tailor more individualized treatment regimens.

Fluidigm is acquiring DVS in a \$208M single-cell technology buyout

January 29, 2014

Fluidigm and DVS Sciences announced Wednesday they're merging in a tie-up for which Fluidigm will pay \$207.5 million in stock and cash to buy out its San Francisco Bay-area neighbor.



## **July 3, 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature**

### **EXAMPLE 2: Facts**

**There is a naturally occurring correlation (natural principle/law of nature) between a patient having rheumatoid arthritis and their level of rheumatoid factor IgM. Increased levels of rheumatoid factor IgM shown by increased binding of an anti-IgM antibody indicate a higher likelihood of a patient being diagnosed with rheumatoid arthritis. For purposes of the following example, anti-IgM antibody XYZ does not occur in nature and is novel and non-obvious. Assays M and N can be used for comparing the anti-IgM antibody to a control sample, but are not routinely used together.**



**July 3, 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature**

**EXAMPLE 2: Claims**

- 1. A method of determining the increased likelihood of having or developing rheumatoid arthritis in a patient, comprising the steps of:
  - obtaining a serum sample from a patient;**
  - contacting the serum sample with an anti-IgM antibody; and**
  - determining that the patient has rheumatoid arthritis or an increased likelihood of developing rheumatoid arthritis based upon the increased binding of the anti-IgM antibody to IgM rheumatoid factor in the serum sample.****



**July 3, 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature**

**EXAMPLE 2: Claims**

- 2. The method of claim 1 further comprising:  
providing a positive control sample; and  
contacting the positive control sample with  
an anti-IgM antibody,  
wherein the step of determining that the patient  
has rheumatoid arthritis or increased  
likelihood of developing rheumatoid arthritis  
comprises a step of comparing the anti-IgM  
antibody in the serum sample to the positive  
control sample.**



**July 3, 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature**

**EXAMPLE 2: Claims**

**3. The method of claim 1 or 2, wherein the anti-IgM antibody is antibody XYZ.**

**4. The method of claim 2, wherein the step of comparing the anti-IgM antibody to the positive control sample includes performing assay M and then performing assay N.**



## **July 3, 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature**

### **EXAMPLE 2: Analysis**

**Claim 3: The additional step of using a particular anti-IgM antibody, and especially an antibody that is not known in the field, integrates the law of nature as it is used to express the principle and is also sufficient to limit the application of the law of nature. While it is not necessary that the particular antibody be novel or non-obvious to render the claim eligible, in this case use of the particularly claimed antibody does transform the claim to a patent-eligible practical application as it does not cover substantially all practical applications of the correlation because it is limited to those applications that use the antibody XYZ.**



## **July 3, 2012 Interim Procedure for Subject Matter Eligibility Analysis of Process Claims Involving Laws of Nature**

### **EXAMPLE 2: Analysis**

**Claim 4: The additional step of comparing the anti-IgM antibody to the positive control sample includes performing assay M and then performing assay N, which integrates the correlation into the process because use of the control sample facilitates testing for the correlation. This step additionally uses assays M and N, which are not routinely used together. Thus, the claim is limited to a process that involves particular assays M and N and uses those assays in a particular combination. So, the claim does not cover substantially all practical applications of testing for the correlation. For purposes of this example, use of these assays together is not well-known, routine or conventional, but at this stage of examination it has not been determined whether such use is novel or non-obvious. While claim 4 is eligible, further examination would be required to determine whether the claim 4 is patentable.**



***Ariosa Diagnostics, Inc. v. Sequenom, Inc.***

**The Federal Circuit held the following claim, and others, to be to patent ineligible subject matter.**

- 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.**



***Ariosa Diagnostics, Inc. v. Sequenom, Inc.***

**Sequenom has petitioned for reconsideration en banc.**

**Twelve amicus briefs have been filed in support of Sequenom's petition for reconsideration en banc.**



## **Uncertainty – Considerations**

- **Investment – internal**
- **Investment – external**
- **Licensing**



## **Uncertainty – Response**

- **Innovation ceases**
- **Development moves overseas**
- **Information maintained as proprietary**
- **Pending claims amended**



**Exemplary biomarker claim:**

**A method of treating a patient having a disease characterized by one or more PI3K-expressing cells, comprising:**

- a. detecting PI3K protein expression in a biological sample obtained from the patient by contacting the biological sample with antibody XYZ and determining if said antibody molecule binds to said PI3K molecule; and**
- b. administering a PI3K-targeted therapeutic agent to the patient if the biological sample expresses PI3K.**



***Limelight Networks, Inc. v. Akamai Technologies, Inc.***

**The U.S. Supreme Court held that a defendant is not liable for inducing infringement under §271(b) when no one has directly infringed under §271(a) or any other statutory provision.**

**Thus, there can be no inducement absent direct infringement.**



## **Uncertainty – Retroactive Impact of Changing Law**

- **Applications that have been filed become public, this trade secret protection is no longer an option.**
- **Granted claims no longer enforceable.**
- **Claims amended through examination are potentially not enforceable.**



## **Conclusions**

**The revised examination procedures are a huge step in the right direction, but there are still very important issues remaining to be resolved.**

**There is a need for settled law in this area and the lack of it has a detrimental impact of both patent owners and potential infringers or licensees.**

**Ultimately, legislative action may be necessary to provide clarity regarding § 101 and possibly even § 271 in the wake of the Supreme Court decisions of the last several years.**