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# VEPACHEDU EDUCATIONAL FOUNDATION

## The Andhra Journal of Industrial News

### IP and Industry News

Chief Editor: Dr. Sreenivasarao Vepachedu, Esq.

#### **Issue 97 Contents:**

Method Patents  
Supplemental Examination  
USPTO's Inconsistency – Luck of the Draw  
Biosimilars  
J&J's Medicaid Fraud

#### **Method Patents**

The U.S. Supreme Court has thrown out two patents held by Prometheus Laboratories involving a blood test that helps doctors determine the best dosage for thiopurine for treating patients with autoimmune disease. Prometheus' method of monitoring a patient and adjusting dosage as needed is based on laws of nature and cannot be patented, the court said.

In a memorandum to the examining corps, Andrew Hirshfeld described the USPTO's approach in the wake of the Supreme Court's decision in Mayo v. Prometheus:

([http://www.uspto.gov/patents/law/exam/mayo\\_prelim\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf))

.... Claims to Law of Nature Itself Are Not Patent-Eligible The claims in Mayo are directed to a process of medical treatment. Claim 1 is representative:

A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:

Issue 97	5114 <i>Kali Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 2070 <i>Vikramarka Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 1934 <i>Salivahana Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 2012 AD, April
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శ్రీ వేపచేదు విద్యా పీఠము

# VEPACHEDU EDUCATIONAL FOUNDATION

## The Andhra Journal of Industrial News

### IP and Industry News

- (a) administering a drug providing 6-thioguanine to a subject having said immune- mediated gastrointestinal disorder; and
- (b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder, wherein the level of 6-thioguanine less than about 230 pmol per  $8 \times 10^8$  red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and wherein the level of 6-thioguanine greater than about 400 pmol per  $8 \times 10^8$  red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject.

The Supreme Court found that because the laws of nature recited by the patent claims - the relationships between concentrations of certain metabolites in the blood and the likelihood that a thiopurine drug dosage will prove ineffective or cause harm - are not themselves patent- eligible, the claimed processes are likewise not patent-eligible unless they have additional features that provide practical assurance that the processes are genuine applications of those laws rather than drafting efforts designed to monopolize the correlations. The additional steps in the claimed processes here are not themselves natural laws, but neither are they sufficient to transform the nature of the claims.

In this case, the claims inform a relevant audience about certain laws of nature. Any additional steps consist of well-understood, routine, conventional activity already engaged in by the scientific community. Those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. The Court has made clear that to transform an unpatentable law of nature into a patent-eligible application of such a law, one must do more than simply state the law of nature while adding the words "apply it." Essentially, 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 patent-eligible.

The decision rested upon an examination of the particular claims in light of the Court's precedents, specifically *Bilski*, *Flook* and *Diehr*. The Court repeated the long standing exceptions (laws of nature, natural phenomena, and abstract ideas) to categories of patent eligibility defined in 35 U.S.c. § 101. In conducting the analysis, the Court addressed the "machine-or-transformation" test explained in *Bilski* with a reminder that the test is an "important and useful clue" to patentability but that it does not trump the "law of nature" exclusion. A claim that recites a law of nature or natural correlation, with

Issue 97	5114 <i>Kali Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 2070 <i>Vikramarka Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 1934 <i>Salivahana Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 2012 AD, April
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

# VEPACHEDU EDUCATIONAL FOUNDATION

## The Andhra Journal of Industrial News

### IP and Industry News

additional steps that involve well-understood, routine, conventional activity previously engaged in by researchers in the field is not patent-eligible, regardless of whether the steps result in a transformation. On the other hand, reaching back to Neilson, the Court pointed to an eligible process that included not only a law of nature (hot air promotes ignition) but also several unconventional steps (involving a blast furnace) that confined the claims to a particular, useful application of the principle.

#### Preliminary Guidance on Examination Procedure

As part of a complete analysis under 35 U.S.c. § 101, examiners should continue to examine patent applications for compliance with section 101 using the existing Interim Bilski Guidance issued July 27, 2010, factoring in the additional considerations below. The Interim Bilski Guidance directs examiners to weigh factors in favor of and against eligibility and reminds examiners that, while the machine~or-transformation test is an investigative tool, it is not the sole or a determinative test for deciding whether an invention is patent~eligible.

Examiners must continue to ensure that claims, particularly process claims, are not directed to an exception to eligibility such that the claim amounts to a monopoly on the law of nature, natural phenomenon, or abstract idea itself. In addition, to be patent-eligible, a claim that includes an exception should include other elements or combination of elements such that, in practice, the claimed product or process amounts to significantly more than a law of nature, a natural phenomenon, or an abstract idea with conventional steps specified at a high level of generality appended thereto.

If a claim is effectively directed to the exception itself (a law of nature, a natural phenomenon, or an abstract idea) and therefore does not meet the eligibility requirements, the examiner should reject the claim under section 101 as being directed to non-statutory subject matter. If a claim is rejected under section 101 on the basis that it is drawn to an exception, the applicant then has the opportunity to explain why the claim is not drawn solely to the exception and point to limitations in the claim that apply the law of nature, natural phenomena or abstract idea.

Issue 97	5114 <u>Kali Era</u> , <u>Nandana Year</u> , <u>Chaitra month</u> 2070 <u>Vikramarka Era</u> , <u>Nandana Year</u> , <u>Chaitra month</u> 1934 <u>Salivahana Era</u> , <u>Nandana Year</u> , <u>Chaitra month</u> 2012 AD, April
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

# VEPACHEDU EDUCATIONAL FOUNDATION

## The Andhra Journal of Industrial News

### IP and Industry News

The USPTO is continuing to study the decision in Mayo and the body of case law that has evolved since Bilski and is developing further detailed guidance on patent subject matter eligibility under 35 U.S.c. § 101.

[http://www.uspto.gov/patents/law/exam/mayo\\_prelim\\_guidance.pdf](http://www.uspto.gov/patents/law/exam/mayo_prelim_guidance.pdf)

<http://www.patentdocs.org/2012/03/mayo-collaborative-services-v-prometheus-laboratories-what-the-courts-decision-means.html>

### Supplemental Examination

The supplemental examination procedure was designed to provide patentees with a quick and decisive examination of items that were overlooked during the patent's original prosecution. The AIA set a three-month period for the USPTO to conduct and conclude a supplemental examination after a request is filed. In order to meet this timeframe, there is a limit of 10 items of information that a patent owner can submit to the USPTO for consideration in each request. The purpose of this limit is to strike a balance between the needs of the patent owner and the ability of the Office to timely conclude the proceeding.

[http://www.uspto.gov/blog/director/entry/the\\_role\\_of\\_submission\\_limits](http://www.uspto.gov/blog/director/entry/the_role_of_submission_limits)

### USPTO's Inconsistency – Luck of the Draw

The USPTO comprises of two kinds of examiners: low allowance rate examiners consisting mainly of secondary examiners (junior examiner usually with less than 5 years of experience and no signatory authority), on average, issue a very small number of patents per year (less than 5 patents per year), and high allowance rate examiners consist mainly of primary examiners (senior examiners usually with more than 5 years of experience and full signatory authority), on average issue a high number of patents per year (more than 50 patents per year), according to a report by Dr. Tu. Examiners should be consistent in the way they apply patentability rules at the USPTO. This study suggests that examiners even within the same art unit may be applying the rules of patentability in an inconsistent manner.

Issue 97	5114 <u>Kali Era</u> , <u>Nandana Year</u> , <u>Chaitra month</u> 2070 <u>Vikramarka Era</u> , <u>Nandana Year</u> , <u>Chaitra month</u> 1934 <u>Salivahana Era</u> , <u>Nandana Year</u> , <u>Chaitra month</u> 2012 AD, April
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

# VEPACHEDU EDUCATIONAL FOUNDATION

## The Andhra Journal of Industrial News

### IP and Industry News

[http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1939508](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1939508)

#### **Biosimilars**

In February, the U.S. Food and Drug Administration published three draft guidance documents on biosimilars and the abbreviated biosimilar approval pathway created by the Biologics Price Competition and Innovation Act of 2009 ("ABLA pathway") (see "[FDA Publishes Draft Guidelines for Biosimilar Product Development](#)"). The FDA provided a 60 day period for stakeholders to provide comments on the guidances, opening a docket for the each of the three draft guidance documents, FDA-2011-D-0602 (Quality Considerations), FDA-2011-D-0605 (Scientific Considerations), and FDA-2011-D-0611 (Questions and Answers). The FDA received submissions from a wide array of stakeholders, including the Biotechnology Industry Organization (BIO), which [published its comments](#) (<http://www.bio.org/media/press-release/bio-submits-comments-fda-draft-guidances-biosimilars>)

In a [Citizen Petition](#) filed with the U.S. Food and Drug Administration on April 2, Abbott Laboratories requested that the FDA refrain from accepting biosimilar applications under the Biologics Price Competition and Innovation Act (BPCIA) that cite reference products (biologics) for which a biologics license application (BLA) was submitted to the FDA prior to March 23, 2010.

#### **J&J's Medicaid Fraud**

Johnson & Johnson was fined more than \$1.1 billion for Medicaid fraud. An Arkansas Circuit Court jury found that Johnson & Johnson deceived the Medicaid program about risks of a schizophrenia drug. The drug, Risperdal, is marketed by J&J subsidiary Janssen Pharmaceuticals Inc. The fine was equal to \$5,000 times 240,000 prescriptions of Risperdal issued to state Medicaid patients. Added to this was another \$11 million fine. This was for 4,500 violations of the state's deceptive practices act. Risperdal and similar

Issue 97	5114 <i>Kali Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 2070 <i>Vikramarka Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 1934 <i>Salivahana Era</i> , <i>Nandana Year</i> , <i>Chaitra month</i> 2012 AD, April
----------	---



శ్రీ వేపచేదు విద్యా పీఠము

# VEPACHEDU EDUCATIONAL FOUNDATION

## The Andhra Journal of Industrial News

IP and Industry News

drugs have been linked to increased risk of strokes and death in elderly dementia patients. They also have been linked to a greater risk of seizures, weight gain and diabetes.

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*Source: The primary sources cited above, New York Times (NYT), Washington Post (WP), Mercury News, Bayarea.com, Chicago Tribune, USA Today, Intellihealthnews, Deccan Chronicle (DC), the Hindu, Hindustan Times, Times of India, AP, Reuters, AFP, womenfitness.net, about.com, mondaq.com, etc.*

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**Om! Asatoma Sadgamaya, Tamasoma Jyotirgamaya, Mrityorma Amritamgamaya, Om Shantih, Shantih, Shantih!**

**(Aum! Lead the world from wrong path to the right path, from ignorance to knowledge, from mortality to immortality, and peace!)**

Issue 97

5114 Kali Era, Nandana Year, Chaitra month  
2070 Vikramarka Era, Nandana Year, Chaitra month  
1934 Salivahana Era, Nandana Year, Chaitra month  
2012 AD, April

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