శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

Chief Editor: Dr. Sreenivasarao Vepachedu, Esq.

Issue 96 Contents:

Use not Covered by Patent

AstraZeneca markets a cholesterol-lowering drug, rosuvastatin calcium, under the brand name CRESTOR® and holds rights to two method patents, U.S. Patent Nos. 6,858,618 ("the '618 patent") and 7,030,152 ("the '152 patent"), which are at issue in this appeal, and a compound patent which was the

Issue 96	*5113 Kali Era , Khara Year, Phalguna month* *2069 Vikramarka Era, Khara Year, Phalguna month* *1933 Salivahana Era, Khara Year, Phalguna month* *2012 AD, March*

subject of a separate ANDA litigation and appeal. Collectively, the two patents-at-issue claim methods of using rosuvastatin compounds to treat heterozygous familial hypercholesterolemia ("HeFH") and to lower the cardiovascular disease risk for individuals with elevated circulating C-reactive protein ("CRP"). Each patent is listed in the FDA's Orange Book and covers an approved indication for use of CRESTOR®.

In addition to the two treatment indications claimed in the patents-at-issue, rosuvastatin calcium is also approved for uses not claimed by either of these patents, including the treatment of patients with homozygous familial hypercholesterolemia ("HoFH") or hypertriglyceridemia. The defendant generic pharmaceutical companies (collectively "the generic manufacturers") filed ANDAs seeking to market generic rosuvastatin calcium for treating HoFH and hypertriglyceridemia while carving out the patented indications directed toward HeFH and elevated CRP. To do so, the generic manufacturers filed statements under 21 U.S.C. § 355(j)(2)(A)(viii) ("Section viii statement") averring that their ANDAs excluded all uses claimed in the '618 and '152 patents.

The Federal Circuit affirmed the district court's dismissal of AstraZeneca Pharmaceuticals LP, AstraZeneca AB, IPR Pharmaceuticals, Inc., and The Brigham and Women's Hospital, Inc.'s (collectively "AstraZeneca") 35 U.S.C. § 271(e)(2) patent infringement claims for infringement of two method of use patents, in *AstraZeneca Pharmaceuticals LP v. Apotex Corp.*, Nos. 11-1182, -1183, -1184, -1185, -1186, -1187, -1188, -1189, -1190 (Fed. Cir. Feb. 9, 2012).

Prometheus and Laws of Nature

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.

The Andhra Journal of Industrial News

IP and Industry News

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)

.... Claims to Law of Nature Itself Are Not Patent-Eligible The claims in Mayo arc 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:
(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 8x 108 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 8x 108 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.

Issue 96	*5113 Kali Era , Khara Year, Phalguna month* *2069 Vikramarka Era, Khara Year, Phalguna month* *1933 Salivahana Era, Khara Year, Phalguna month* *2012 AD, March*

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 catcgories 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 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. 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.

Another fallout from Prometheus case is that the Supreme Court vacated the Federal Circuit's decision in *AMP v. Myriad Genetics* and has ordered the appellate court to reconsider the case in light of the recent Supreme Court decision in *Mayo v. Prometheus*.

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

http://www.patentlyo.com/patent/2012/03/punishing-prometheus-the-supreme-courts-blunders-in-mayo-v-prometheus.html

http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-ii-what-is-a-claim.html

శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

http://www.patentlyo.com/patent/2012/03/punishing-prometheus-part-iii-conclusions-masquerading-as-analysis-.html

Inventorship

The U.S. Court of Appeals for the Federal Circuit recently considered what activities rise to a contribution to conception that qualify one to be a joint inventor of a chemical compound in its opinion *Falana v. Kent State Univ.*, No. 2011-1198 (Fed. Cir. Jan. 23, 2012).

In general, the inventors listed on a patent include all individuals who made an inventive contribution to at least one claim. The mental act of conception is essential to inventorship. A person may devote long hours to a project, and his or her efforts may be important to its commercial success, but if these efforts do not include the conception of claimed subject matter, the person is not an inventor. For example, reducing to practice or carrying out the idea of another does not qualify one to be an inventor. A person who provides general technical information without contributing to conception is not an inventor. The collaboration of multiple individuals can complicate the determination of inventorship - there must be communication of information relevant to conception between two people for them to be considered joint inventors. Individuals who independently conceive an idea cannot be joint inventors.

The facts in *Falana*: As a post-doctoral researcher at Kent State, plaintiff Dr. Olusegun Falana developed a synthesis protocol for making a novel class of naphthyl-substituted TADDOL (tetraaryl-1,3-dioxolan-4,5-dimethanol) compounds of use in LCDs (liquid crystal displays). Among the compounds synthesized by Falana was Compound 7, which exhibited temperature independence over a range of -20 to +30 °C of the important high helical twisting power property. This range of temperature independence represented significant progress, but was not sufficiently broad to meet the project goals. Falana subsequently resigned from the research group. Another member of the group, Dr. Alexander Seed, then used Falana's synthesis protocol to synthesize a Compound 9 that exhibited temperature independence over a range -20 to +70 °C, meeting the goals of the project. An application was filed, later issuing as U.S. Patent Number 6,830,789 (the "'789 Patent"), which listed Seed and others, but not Falana, as

inventors. The application included a generic claim 1 to a naphthyl-substituted TADDOL. A "generic claim" to a chemical compound encompasses multiple individual compounds, for example, by allowing for the moiety substituted at a position on a molecule to be selected from a list of differing chemical groups. Generic claim 1 did not expressly include a requirement for a temperature independence range of high helical twisting power. Falana then filed the present case in the U.S. District Court of the Northern District of Ohio to be added as an inventor to the '789 Patent. The District Court found for Falana, ruling that he contributed to the conception of the claimed invention and was to be added as an inventor. The defendants, Kent State and Seed, then appealed to the Federal Circuit.

In their appeal, the defendants argued that the claims should have been construed to be limited to a compound "having a substantially temperature independent high helical twisting power," even though this limitation was not expressly recited in the claims, because the specification so described the inventive compounds, and, without such a limitation, the claimed compounds would be commercially worthless. The Federal Circuit disagreed, finding no suggestion in the intrinsic record that the applicant intended to so limit the claims. Therefore, the plain language of the claims governed. The Federal Circuit affirmed the construction of the District Court, in which the claims were not limited to a compound "having a substantially temperature independent high helical twisting power."

The defendants further argued that even if Falana had contributed to the synthesis protocol, he was not a joint inventor, because the claims were all directed to compounds and not methods, invoking the decision in *Bd. of Trs. of Fla. State v. Am. Biosci.*, 333 F.3d 1330, 67 USPQ2d 1252 (Fed. Cir. 2003). The Federal Circuit distinguished *Am. Biosci*. on the facts, because the method of the putative co-inventor in that case was not used to make any of the compounds claimed in the patent at issue. By contrast, in the present case, the method used to make the genus of compounds claimed in the '789 Patent was Falana's synthetic protocol. The Federal Circuit agreed with the conclusion of the District Court that Falana's contribution to developing the synthetic protocol was greater than the exercise of ordinary skill in the art.

In *Falana*, the Federal Circuit held that an individual has contributed to the conception of a genus of chemical compounds and is an inventor of the genus when he or she (i) envisioned the structure of a novel genus and (ii) contributed the method, not already within the scope of public knowledge, of making that genus. On the basis of this conception test, the Federal Circuit affirmed that Falana was an inventor of the '789 Patent.

From a practical perspective, *Falana* highlights the need to address inventorship and the distinct, but related, issue of ownership throughout the entire innovation cycle. At the beginning of employment, individuals should sign an employee agreement that conveys intellectual property developed within the scope of employment to the employer. When two or more companies collaborate on a project, an advance agreement should set forth the allocation of ownership of intellectual property developed. Researchers should be educated about the standards of inventorship and the implications of acknowledging the putative contributions of third parties. They should be encouraged to consult with patent counsel throughout the course of a project. Such communication can help in avoiding missteps and tempering individual expectations. The undesirable situation of having to resolve a dispute or even compete with a disgruntled individual who considers him or herself an incorrectly excluded inventor can be avoided through the early implementation of procedures to assess inventorship before patentable subject matter is perceived as being of substantial value. http://www.martindale.com/intellectual-property-law/article_Venable-LLP_1482372.htm

International Trademark Filings

The World Intellectual Property Organization ("WIPO") said March 12 that it received a record number of applications for international protection of trademarks in 2011, with filings from Russia, the European Union, and the United States leading the surge. A total of 42,270 applications were filed through WIPO's Madrid system of international registration, a 6.5 percent increase over the previous year, the United Nations agency said. The Madrid Protocol is an international treaty that allows a trademark owner to seek registration in any of the countries that have joined the Madrid Protocol by filing a *single application*, called an "international application." The International Bureau of the World Intellectual Property

Organization, in Geneva, Switzerland administers the international registration system. The resulting "international registration" serves as a means for seeking protection in member countries, each of which apply their own rules and laws to determine whether or not the mark may be protected in their jurisdiction.

AIA Update: Joinder Provision

The new joinder rules became effective for all patent lawsuits filed on or after September 16, 2011 and limit the ability of a plaintiff to join multiple unrelated defendants in a single action. In addition to potential cost savings of a single-suit, the joining of geographically diverse defendants in a single suit is thought to make it more difficult for one of the defendants to force a transfer of venue. Thus, the idea behind limiting the joinder of unrelated defendants is that it may allow courts to more easily transfer venue and thus shift filing focus away from the Eastern District of Texas.

The preliminary data through December 2011 indicates that (1) post-AIA filings have dropped in the Eastern District of Texas and risen in other districts, namely Delaware; (2) more cases are now being filed in Delaware than any other district; (3) more defendants are being sued in Delaware than any other district. Prior to AIA, E.D. Texas was the clear leader in these categories; and (4) overall the number of defendants being sued has decreased.

http://www.perkinscoie.com/james-pistorino-analyzes-trends-in-patent-case-filings-from-2011-03-16-2012/

Tougher FDA

Notoriously arduous development of new obesity drugs could get tougher. An FDA panel endorsed a plan to have cardiovascular safety studies for obesity drugs even when data on the treatments give no

indication that heart risks exist. If the FDA takes the panel's advice, developers of obesity drugs could face a longer road to approval.

Academia Misleads Industry

The failure to win "the war on cancer" has been blamed on many factors, from the use of mouse models that are irrelevant to human cancers to risk-averse funding agencies. But recently a new culprit has emerged: too many basic scientific discoveries, done in animals or cells growing in lab dishes and meant to show the way to a new drug, are wrong.

Over the last two decades, the most promising route to new cancer drugs has been one pioneered by the discoverers of Gleevec, the Novartis drug that targets a form of leukemia, and Herceptin, Genentech's breast-cancer drug. In each case, scientists discovered a genetic change that turned a normal cell into a malignant one. Those findings allowed them to develop a molecule that blocks the cancer-producing process. This approach led to an explosion of claims of other potential "druggable" targets. Amgen tried to replicate the new papers before launching its own drug-discovery projects. Of 47 cancer projects at Bayer during 2011, less than one-quarter could reproduce previously reported findings, despite the efforts of three or four scientists working full time for up to a year. Bayer dropped the projects. Bayer and Amgen found that the prestige of a journal was no guarantee a paper would be solid. http://www.reuters.com/article/2012/03/28/us-science-cancer-idUSBRE82R12P20120328

AbbVie

When Abbott Laboratories announced some months ago that it was spinning off its pharma business and keeping the Abbott name for itself. Recently, the new company got a name – AbbVie. From the company's perspective, AbbVie (pronounced "Abb-Vee") offered a chance to reference its corporate roots along with the Latin root for "life." "The beginning of the name connects the new company to Abbott and its heritage of pioneering science," said Richard Gonzalez, who will helm the spinout. "The 'vie' calls

attention to the vital work the company will continue to advance to improve the lives of people around the world." With $18 billion in revenue and an appetite for big licensing pacts.

***Ex Parte* Reexamination Stats**

http://www.patentlyo.com/.a/6a00d8341c588553ef0168e8fd5e35970c-pi

MCAT

In 2015, the new MCAT incorporates behavioral and social science concepts in addition to its traditional natural-science focus. These revisions reflect advances in medical technology, as well as a stronger emphasis on external influences on health, which liberal arts and humanities students may better grasp. The addition of the sociological and behavioral sciences will potentially make medical school admissions a little more selective to students who have the capacity to be really great physicians. The MCAT is periodically updated to keep up with medical education and patient needs. This marks the fifth time the test has been revamped since its inception in 1928.

Competition for Epogen

Omontys represents the first new FDA-approved and marketed ESA for anemia since 2001. The approval paves the way to the entry of a rival for Epogen, Amgen's longtime anemia blockbuster, which will offer patients a much easier dosing schedule. Peginesatide's biggest advantage is that patients will only need once-monthly injections, compared to up to 12 times a month for Epogen patients- some 400,000 patients.

Affymax had to battle the cardiovascular risk signals seen in 2010 to win over regulators. Takeda will split the U.S. market with Affymax. Nektar helped on the delivery side of the program and wins a single-

digit royalty stream with the approval. Peginesatide is expected to bring in $700 million a year, with much of that money redirected from the Epogen franchise.

Quetiapine Competition

Quetiapine (long-acting) tablets are used to treat the symptoms of schizophrenia (a mental illness that causes disturbed or unusual thinking, loss of interest in life, and strong or inappropriate emotions). Seroquel is approved for (1) acute depressive episodes in bipolar disorder in adults; (2) acute manic episodes in bipolar disorder in adults when used alone or with lithium or divalproex; (3) acute manic episodes in bipolar disorder in children and adolescents ages 10 to 17 years; (4) long-term treatment of bipolar disorder in adults with lithium or divalproex; (5) schizophrenia in adults and (6) schizophrenia in adolescents ages 13-17 years. The SEROQUEL® brand had U.S. sales of approximately $4.6 billion for the most recent twelve months ending December 2011 according to IMS Health. Dr. Reddy's Laboratories has launched Quetiapine fumarate tablets (25 mg, 50 mg, 100 mg, 200 mg, 300 mg and 400 mg), a bioequivalent generic version of SEROQUEL® tablets in the US market on March 27, 2012 following the approval by the United States Food & Drug Administration (USFDA) of Dr. Reddy's ANDA for Quetiapine fumarate tablets.

NIH and Lilly Collaboration

The National Institutes of Health and Eli Lilly and Company will generate a publicly available resource to profile the effects of thousands of approved and investigational medicines in a variety of sophisticated disease-relevant testing systems, announces NIH. Comprehensive knowledge of the biological profiles of these medicines and molecules may enable biomedical researchers to better predict treatment outcomes, improve drug development, and lead to more specific and effective approaches. Through the collaboration, the NIH's newly established National Center for Advancing Translational Sciences (NCATS) and Lilly Research Laboratories have agreed that NCATS' Pharmaceutical Collection of 3,800 approved and investigational medicines will be screened using Lilly's Phenotypic Drug Discovery (PD2)

panel. This panel features assays (i.e. tests) that are designed to reveal novel mechanisms or pathways of potential medicines and, as part of this collaboration, approved medicines as well. As such, the panel may provide new insights for drug discovery.

The NCATS Pharmaceutical Collection (NPC) is a comprehensive publicly available database (http://tripod.nih.gov/npc) and is a physical sample collection. The PD2 assay panel, part of Lilly's Open Innovation Drug Discovery platform (https://openinnovation.lilly.com), consists of sophisticated human disease pathway-related assays relevant to cardiovascular diseases, cancer and endocrine disorders, among others. These testing systems are designed to reveal novel mechanisms or pathway activities of drugs. http://www.technologynetworks.com/medchem/news.aspx?ID=137624 .

శ్రీ వేపచేదు విద్యా పీఠము

VEPACHEDU EDUCATIONAL FOUNDATION

The Andhra Journal of Industrial News

IP and Industry News

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 96	*5113 Kali Era , Khara Year, Phalguna month* *2069 Vikramarka Era, Khara Year, Phalguna month* *1933 Salivahana Era, Khara Year, Phalguna month* *2012 AD, March*