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The Andhra Journal of Industrial News

IP and Industry News

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NIH Support for Drug Trials

More than 95% of medicines that begin human testing do not reach the market. For every drug that is approved there are more than 1,000 candidates that failed, because they are ineffective or unsafe. Drug developers usually test the candidates for many indications before abandoning a promising candidate. If a candidate is abandoned for safety and toxicity reasons, there is no rescue for such candidate, usually. If a candidate fails for efficacy and abandoned in one disease, it might prove useful in another.

Daptomycin, a cyclic lipopeptide antibiotic drug candidate, originally discovered by Eli Lilly & Co, which had discontinued its work on antibiotics and infectious diseases in 1990s. Cubist Pharmaceuticals licensed daptomycin in 1997 and began new clinical trials with the agent in 1999. Daptomycin was approved by the FDA in 2003 as cubicin for the treatment of complicated skin and skin structure infections caused by certain gram-positive organisms.

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Another biotech firm, Aegerion, sells a drug that was abandoned by Bristol-Myers Squibb as a treatment for high cholesterol to treat a rare genetic disease that causes high cholesterol levels. **Bristol-Myers Squibb** originally developed lomitapide as a high cholesterol drug, but gave up on it when a trial had a high patient dropout rate due to liver damage and gastrointestinal side effects. Development of the drug was eventually handed over to Aegerion. Last year, FDA approved lomitapide (Juxtapid) as an adjunct to a low-fat diet and other lipid-lowering treatments in patients with homozygous familial hypercholesterolemia (HoFH). The FDA approval comes with a box warning about the risk of hepatotoxicity and a Risk Evaluation and Mitigation Strategy (REMS) Program which will require certification of health care providers and pharmacies before the drug can be prescribed and dispensed. The drug costs between \$200,000-\$300,000 per year. Research and development expenses were \$25.2 million for the year ended December 31, 2012, compared to \$24.4 million for the same period in 2011. The increase in research and development expenses in the fourth quarter and full year of 2012 over the comparable periods in 2011 was primarily related to increased headcount required to support the Company's regulatory and medical affairs activities, as well as costs for production validation runs, partially offset by decreases in clinical trial expenses related to trials which had been substantially completed in 2011.

In view of such successes. the National Institutes of Health awarded \$12.7 million (compare annual R&D costs above, Peanuts!) to nine academic groups to test potential medicines for diseases including Alzheimer's disease, Duchenne muscular dystrophy, and schizophrenia that drug companies had abandoned because they were viewed as too risky or not lucrative enough.

<http://www.forbes.com/sites/matthewherper/2013/06/18/the-nih-aims-to-develop-drugs-that-big-pharma-discarded/>

Patentable Matter Under Section 101

Consistent with that intent and to fulfill the constitutional mandate "to promote the Progress of Science and the useful Arts,' Congress defined the patentable subject matter under 35 USC § 101 as "[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

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One may only patent something that is a machine, manufacture, composition of matter or a process, and the subject matter sought to be patented should be a novel and useful invention. Accordingly, a complete definition of the scope of 35 U.S.C. §101, reflecting congressional intent, is that any new and useful process, machine, manufacture or composition of matter that is made by a person is the proper subject matter of a patent.

There are two criteria for determining subject matter eligibility. The claimed invention (1) must be directed to one of the four statutory categories, and (2) must not be wholly directed to subject matter encompassing a judicially recognized exception.

1) The Four Statutory Categories of Invention

i. Process – an act, or a series of acts or steps. See *Gottschalk v. Benson*, 409 U.S. 63, 70, 175 USPQ 673, (1972) ("A process is a mode of treatment of certain materials to produce a given result. It is an *act*, or a *series of acts*, performed upon the subject-matter to be transformed and reduced to a different state or thing." (emphasis added) (quoting *Cochrane v. Deener*, 94 U.S. 780, 788, 24 L. Ed. 139, 1877 Dec. Comm'r Pat. 242 (1876)); *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282, 1316, 75 USPQ2d 1763, (Fed. Cir. 2005) ("A process is a series of acts." (quoting *Minton v. Natl. Ass'n. of Securities Dealers*, 336 F.3d 1373, , 336 F.3d 1373, 1378, 67 USPQ2d 1614, (Fed. Cir. 2003))). See also 35 U.S.C. 100(b); *Bilski v. Kappos*, 130 S. Ct. 3218, 95 USPQ2d 1001 (2010).

ii. Machine – a concrete thing, consisting of parts, or of certain devices and combination of devices. *Burr v. Duryee*, 68 U.S. (1 Wall.) 531, 570, 17 L. Ed. 650 (1863). This includes every mechanical device or combination of mechanical powers and devices to perform some function and produce a certain effect or result. *Corning v. Burden*, 56 U.S. 252, 267, 14 L. Ed. 683 (1854).

iii. Manufacture – an article produced from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by handlabor or by machinery. *Diamond v.*

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Chakrabarty, 447 U.S. 303, 308, 206 USPQ 193, (1980) (emphasis added) (quoting *Am. Fruit Growers, Inc. v. Brogdex Co.*, 283 U.S. 1, 11, 51 S. Ct. 328, 75 L. Ed. 801, 1931 (Dec. Comm'r Pat. 711 (1931))).

iv. Composition of matter – all compositions of two or more substances and all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids, for example. *Chakrabarty*, 447 U.S. at 308.

2) Judicially Recognized Exception

A judicially recognized exception includes laws of nature, physical phenomena, and abstract ideas, or a particular practical application of a judicial exception. See *Bilski v. Kappos*, 561 U.S. 130 S. Ct. 3218, 3225, 95 USPQ2d 1001 (2010), “The Court's precedents provide three specific exceptions to § **101**'s broad patent-eligibility principles: ‘laws of nature, physical phenomena, and abstract ideas.’” quoting *Diamond v. Chakrabarty*, 447 U.S. 303, 309, 206 USPQ 193, (1980); *Diamond v. Diehr*, 450 U.S. 175, 185, 209 USPQ 1, 7 (1981); accord, e.g., *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197; *Parker v. Flook*, 437 U.S. 584, 589, 198 USPQ 193, 197 (1978); *Benson*, 409 U.S. at 67-68, 175 USPQ at 675. “A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.” *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1852). Instead, such “manifestations of laws of nature” are “part of the storehouse of knowledge,” “free to all men and reserved exclusively to none.” *Funk Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130, 76 USPQ 280, 281 (1948).

Consequently, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter under Section **101**. *Chakrabarty*, 447 U.S. at 309, 206 USPQ at 197. “Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity.” *Ibid*. Nor can one patent “a novel and useful mathematical formula,” *Flook*, 437 U.S. at 585, 198 USPQ at 195; electromagnetism or steam power, *O'Reilly v. Morse*, 56 U.S. (15 How.) 62, 113-114 (1853); or “[t]he qualities of ... bacteria, ... the heat of the sun, electricity, or the qualities of metals,” *Funk*, 333 U.S. at 130, 76 USPQ at 281; see *Le Roy*, 55 U.S. (14 How.) at 175.

While abstract ideas, physical phenomena, and laws of nature are not eligible for patenting, methods and products employing abstract ideas, physical phenomena, and laws of nature to perform a real-world function may well be. In evaluating whether a claim meets the requirements of **35 U.S.C. 101**, the claim

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must be considered as a whole to determine whether it is for a particular application of an abstract idea, physical phenomenon, or law of nature, and not for the abstract idea, physical phenomenon, or law of nature itself. *Diehr*, 450 U.S. at 188-178.

In addition to the terms laws of nature, physical phenomena, and abstract ideas, judicially recognized exceptions have been described using various other terms, including natural phenomena, scientific principles, systems that depend on human intelligence alone, disembodied concepts, mental processes and disembodied mathematical algorithms and formulas, for example. The exceptions reflect the courts' view that the basic tools of scientific and technological work are not patentable.

The claimed subject matter must not be wholly directed to a judicially recognized exception. However, a claim that is limited to a particular practical application of a judicially recognized exception is eligible for patent protection. A "practical application" relates to how a judicially recognized exception is applied in a real world product or a process, and not merely to the result achieved by the invention. When subject matter has been reduced to a particular practical application having a real world use, the claimed practical application is evidence that the subject matter is not abstract (e.g., not purely mental) and does not encompass substantially all uses (preemption) of a law of nature or a physical phenomenon. See, e.g., *Ultramercial v. Hulu*, 657 F.3d 1323, 1329, 100 USPQ2d 1140, 1145 (Fed. Cir. 2011)(stating that the patent "does not claim a mathematical algorithm, a series of purely mental steps, or any similarly abstract concept. It claims a particular method . . . a practical application of the general concept."). Once a practical application has been established, the limited occurrence of preemption must be evaluated to determine whether the claim impermissibly covers substantially all practical applications of the judicially excepted subject matter. If so, the claim is not patent-eligible. If the claim covers only a particular practical application of the judicially excepted subject matter, it is patent eligible.

The Supreme Court in *Bilski v. Kappos*, 561 U.S. 130 S. Ct. 3218, 95 USPQ2d 1001 (2010), clarified the requirements for a claim to be a statutory process. Not every claimed method qualifies as a statutory

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process. A process claim, to be statutory under **35 U.S.C. 101**, must be limited to a particular practical application. This ensures that the process is not simply claiming an abstract idea, or substantially all practical uses of (preempting) a law of nature, or a physical phenomenon. *Bilski* reaffirmed *Diehr*'s holding that "while an abstract idea, law of nature, or mathematical formula could not be patented, 'an application of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection.'" See *Bilski*, 130 S. Ct. at 3230 (quoting *Diamond v. Diehr*, 450 U.S. 175, 187 (1981)) (emphasis in original). The recitation of some structure, such as a machine, or the recitation of some transformative component will in most cases limit the claim to such an application. "The machine-or-transformation test is a useful and important clue, and investigative tool, for determining whether some claimed inventions are processes under § **101**." *Bilski v. Kappos*, 561 U.S. 130 S. Ct. 3218, 3227, 95 USPQ2d 1001, (2010). However, not all such recitations necessarily save the claim: "Flook established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable." See *Bilski*, 130 S. Ct. at 3231. Moreover, the fact that the steps of a claim might occur in the "real world" does not necessarily save it from a **35 U.S.C. 101** rejection. Thus, the *Bilski* claims were said to be drawn to an "abstract idea" despite the fact that they included steps drawn to initiating transactions. The "abstractness" is in the sense that there are no limitations as to the mechanism for entering into the transactions.

Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. 132 S.Ct. 1289, 101 USPQ2d 1961 (2012) (*Mayo*) has provided additional details for the eligibility analysis that the Office developed after *Bilski*. A natural principle is the handiwork of nature and occurs without the hand of man. For example, the disinfecting property of sunlight is a natural principle. The relationship between blood glucose levels and diabetes is a natural principle. A correlation that occurs naturally when a man-made product, such as a drug, interacts with a naturally occurring substance, such as blood, is also considered a natural principle because, while it takes a human action to trigger a manifestation of the correlation, the correlation exists in principle apart from any human action. These are illustrative examples and are not intended to be limiting or exclusive. For this analysis, a claim focuses on a natural principle when the natural principle is a limiting element or step. In that case, the claim must be analyzed (in Inquiry 3) to ensure that the claim is directed to a practical application of the natural principle that amounts to substantially more than the natural principle itself. So, for instance, a claim that recites a correlation used to make a diagnosis focuses on a natural principle and would require further analysis under Inquiry 3. If a natural principle is not a limitation of the claim, the claim does not focus on the use

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of a natural principle and requires no further analysis under this procedure. If the claim focuses on an abstract idea, such as steps that can be performed entirely in one's mind, methods of controlling human activity, or mere plans for performing an action. A claim that focuses on use of a natural principle must also include additional elements or steps to show that the inventor has practically applied, or added something significant to, the natural principle itself. *See Mayo*, 101 USPQ2d at 1966. To show integration, the additional elements or steps must relate to the natural principle in a significant way to impose a meaningful limit on the claim scope. The analysis turns on whether the claim has added enough to show a practical application. *See id.* at 1968. In other words, the claim cannot cover the natural principle itself such that it is effectively standing alone. A bare statement of a naturally occurring correlation, albeit a newly discovered natural correlation or very narrowly confined correlation, would fail this inquiry. *See id.* at 1965, 1971. (See http://www.uspto.gov/patents/law/exam/2012_interim_guidance.pdf).

In *Assn. for Molecular Pathology v. Myriad Genetics, Inc. (Myriad)*, the Federal Circuit correctly ruled that claims to isolated DNA molecules were patent eligible because they were not found in nature. A policy basis supporting that determination was that the Patent Office had been granting patents on DNA molecules for 30 years, and Court's should leave the issue to Congress before disturbing long-settled expectations of what is patentable. Also, the Federal Circuit ruled that method claims directed to performing known steps to "transformed cells" were patent eligible because the "transformed cells" limitation concerned things that are "a product of man, not of nature."

But, for the nine Justices of the Supreme Court, who are not well-versed in organic chemistry and biochemistry, it was natural to talk about how a baseball bat gets created, how the sap of a plant in a forest in the Amazon might be analyzed for its powers to cure human disease, kidneys taken out of the body, metals isolated from streams, leaves plucked from trees etc. Though the Justices understood very well that the nucleotide sequences are chemical molecules, failed to use the right analogies. Unfortunately, those very wrong analogies strongly suggested the wrong conclusion that an inventor should not get a

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patent for taking something out of the human body and manipulating it. The analogies were wrong because, for example, if you take out a kidney from the body and implant it in another body, it is expected to function as the kidney would in the new body, unless organ rejection kicks in. These examples fail to cover the hydrolyzed and isolated DNA fragment, for three reasons, 1) the kidney taken out of the owner's body is a complete organ, not a fragment of the kidney, 2) the whole organ implanted in a new body performs the same kidney function, and 3) a fragment of kidney is useless for a transplant. The proper example would be isolated nephrons from the kidney, manipulated to perform a new job, which is not kidney function, such as a test for some disease in the body, which is similar to one specific gene cut out from a human genome chain of 30,000 genes. Neither an individual nephron nor an individual gene exists in a human body in isolation, or function individually outside of the human body.

In *Assn. for Molecular Pathology v. Myriad Genetics, Inc.*, 106 U.S.P.Q.2d 1972 (U.S. 2013), the Supreme Court unanimously determined that a piece of isolated oligomer of chemical nucleotides was unpatentable under section 101, e.g., the human *BRCA1* gene comprising 80000 base pairs (Myriad identified the exact location of the *BRCA1* and *BRCA2* genes on chromosomes 17 and 13; the *BRCA1* and *BRCA2* genes are each about 80,000 nucleotides long. If just exons are counted, the *BRCA1* gene is only about 5,500 nucleotides long; for the *BRCA2* gene, that number is about 10,200), hydrolyzed and isolated from human DNA comprising about 30,000 genes and about 3,164,700,000 chemical nucleotide bases, wherein single-base DNA differences (SNPs) occur at about 1.4 million locations, is unpatentable under section 101. It should be noted that the oligomeric fragment of 81,188 base pairs does not exist as floating piece that could be filtered out using a filter paper or a gel from the blood or serum. In addition, the Court significantly departed from the well-settled examination of claims directed to nucleic acid sequences in 30 years of the USPTO practice and judicial precedent. The Court stated: "If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the *BRCA1* or *BRCA2* gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad."

However, the Court held that oligomer of complementary chemical nucleotides is patent eligible under § 101, because complementary oligomer of chemical nucleotide pairs is allegedly not naturally-occurring, even though the sequence of cDNA is dictated by nature. The complementary base pairing is standard and well defined - the complementary nucleotide pairing of thymine (T) with adenine (A) and cytosine (C)

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with guanine (G). Complementary DNA (cDNA) is the DNA obtained from a messenger RNA (mRNA) template in a reaction catalyzed by reverse transcriptase and DNA polymerase, and occurs naturally by retroviruses (such as HIV-1, HIV-2, Simian Immunodeficiency Virus, etc.), and contains only exons that code the specific protein of interest. When scientists transfer a gene from one cell into another cell in order to express the new genetic material as a protein in the recipient cell, the cDNA will be added to the recipient (rather than the entire gene containing both introns and exons), because 1) the introns do not code for the protein, and b) introns make the DNA fragment too large to be introduced into a plasmid. In essence, according to the Supreme Court, the BRCA1 and BRCA2 oligomers of about 80,000 nucleotides each, hydrolyzed and isolated from 3 billion base polymer is not patentable under section 101, but if you isolate cDNA, that is the same BRCA1 gene oligomer, but the introns removed through known and naturally occurring processes, it is patentable under section 101.

Myriad significantly changes the USPTO's examination policy regarding nucleic acid-related technology. The USPTO's Office of the Deputy Commission for Patent Examination Policy issued a memorandum to the examining corps advising the corps that claims to isolated DNA are not patent eligible under 35 U.S.C. § 101. Fragments of naturally occurring nucleic acids are not patent eligible even if they have been isolated by hydrolysis, under 35 U.S.C. § 101. Claims clearly limited to non-naturally-occurring nucleic acids, such as a cDNA or a nucleic acid in which the order of the naturally occurring nucleotides has been altered (e.g., a man-made variant sequence), remain eligible. Other claims, including method claims, that involve naturally occurring nucleic acids may give rise to eligibility issues and will be examined under the existing guidance in MPEP 2106, Patent Subject Matter Eligibility.

It is touted that the ruling would give medical and scientific researchers and doctors greater opportunity to help women patients discover their potential vulnerability to those types of cancer. Hopefully, this procedure will be available for all poor women at a cheaper rate to help them to make the very important and intimate decision about removing their breasts; while *Myriad* continues to help rich people like Angelina Jolie to voluntarily have breasts removed. It is not clear how this helps poor, because doctors

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need reliable diagnostic kits to identify the breast cancer mutation before they confidently disfigure the woman due to suspicion of breast cancer vulnerability; unless women are willing to take chances with their breasts with quacks and untested kits.

The Court states, “It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA.” But strangely there was no breast cancer kit until Myriad came along, which was founded about 20 years ago in 1991, while ACLU began its journey about a century ago, in 1920. It should also be noted that the breast cancer and human genes existed since the dawn of humanity, and nobody came up with the Myriad’s diagnostic kit for the past several millennia to help women vulnerable to breast cancer. It is nothing but blatant stealing of years of hard work and millions of dollars of investment, in the name of justice for the poor, the Robin Hood Way.

Luckily, the Court did not rule on any right to a patent on methods of manipulating the genes, any applications of what Myriad had learned about the two cancer-suggesting genes, BRCA1 and BRCA2, and the patentability of altering the genetic code in specific DNA forms. Hopefully, Myriad will recover over \$500 million investment and 17 years in the research, development and ensuing commercialization and operational support of the BRCA*Analysis* test, and profits to fund new ventures and keep the scientists who worked hard for the company in the employ.

Thus, in spite of the apparent drastic change and reversal of 30-year judicial precedents in the patentability of an enzymatically hydrolyzed and isolated specific oligomeric fragments obtained from a large polymeric nucleotide molecule, it appears that biotech industry will survive, and disease diagnostic kits and methods continue to be patentable under section 101. As a result, the unanimous Supreme Court opinion is “much ado about nothing,” especially when the entire genome is in the public domain for everyone to use it.

Fortunately, we have clarity at last, thanks to the unanimous Supreme Court that created yet another judicial exception to section 101 regarding publicly available human genome, so that we can avoid worrying about sections 102 or 103.

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Now that any gene mutations to diagnose or predict any diseases are not patentable; the myopic patients, ACLU, the doctors, AMA, and the Supreme Court have effectively killed a golden goose and the opportunity for laying a golden egg.

***“We merely hold that genes and the information they encode are not patent eligible under §101...,”
The Supreme Court of the United States. June 13, 2013***

See also: <http://www.uspto.gov/web/offices/pac/mpep/s2106.html>
http://www.uspto.gov/aia_implementation/gene-comment-myrriad-gen.pdf
<http://supreme.justia.com/cases/federal/us/569/12-398/>

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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!)

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