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Abstract:

Introduction:

A recognised and protected legal right, as well as a violation that is judged "unlawful" and provides the right holder with a remedy. As a result, the term "intellectual property rights" refers to the rights that safeguard intellectual property. A patent is a legal title that gives the holder the exclusive right to create, use, and sell an invention for a set period of time while prohibiting others from doing so without permission.

- **Background**:

  India is fully in compliance with its international obligations under the TRIPs Agreement. The Patents Act 1970 has undergone 3 amendments; 1999. 2002 and 2005. Patents covering food, pharmaceutical, and chemical inventions, as well as the evaluation of "mail box" applications, were included in the 2005 amendment.

- **Rationality**:

  In order for patent applications to be authorized, the invention must meet the basic patentability criteria. Despite the fact that these criteria are subjective, patent requests are typically refused when one of the following conditions is met:

  1. **Novelty issues:**

     If the innovation for which applying for a patent isn't the first of its kind and the examiner can locate a previously patented idea that's quite similar to ours, we will almost certainly be denied.

  2. **Too obvious**:

The patent request for such an innovation may not be successful if the creation is not unique enough to display innovative ingenuity. If our invention lacks any distinguishing and beneficial qualities that set it apart from similar existing ones, we will almost certainly be denied.

3. **When the patent application is not properly written**:

Patent requests might also be denied if the application contains errors. There are two types of them. First, there are the formalities, which deal with the rules/guidelines that must be followed when crafting the application. The second problem is a lack of technical information regarding our invention.

For each innovation, the three requirements for patentability are novelty, non-obviousness, and industrial application. Few ideas met all three patentable criteria but were nonetheless rejected due to morality, public order, or human rights concerns in each country. By taking into account the socio economic wellbeing of the society, Indian patent rights provide mutual benefits to both the patent holder and the consumer of patented medicine. Patentability criteria are described in Section 2 of the Indian Patent Act, while non-patentable inventions are described in Sections 3 and 4.

Statement for Case study:

The main statement for this case study is to perceive the reasons behind why certain patents have been rejected in India and on what grounds has India granted certain patents and America did not. We know there is explicit rationality for rejecting patents in different countries; India embodies similar laws as well.

We will be explaining the observable reasons behind the objections in granting the patents and why different countries possess different inducements in laws for granting patent applications.

Statistical Database of Patent filing in India:

An international legal agreement between all the member nations of the World Trade Organization. It establishes minimum standards for the regulation by national governments of different forms of IP. It introduced intellectual property law into the multilateral agreement on intellectual property to date.

- To defend IPR laws, India has a strict patent system, rules, and enforcement mechanism. Technological advancements are fostered and safeguarded in India as a result of the TRIPs Agreement and revisions to the Indian Patent Act. Section 15 of the Indian Patent Act deals with the controller's ability to refuse.

- According to the WIPO statistical database, 45,379 patent applications were filed in India in September 2018. The applicants withdrawn or abandoned 29,789 applications, resulting in a total of 12,387 applications being granted. About 3203 patents were refused due to the invention's failure to meet patentability criteria, such as novelty, non-obviousness, and industrial application, or non-patentability criteria outlined in Sections 3 and 4 of the Indian Patent Act.

- Between January 2009 and January 2017, the Indian Patent Office rejected 1723 pharmaceutical patent applications.

- Sections 2(1)(j), 2(1)(ja), and Section 3 were used to deny 945, 466, and 1113 patents, respectively. One or more grounds for patent rejection may apply to a single instance. According to the IPR Annual Report 2017–2018 in India, the number of patent applications evaluated, granted patents, and applications disposed of grew by 108.2, 32.5, and 57.6%, respectively, as compared to 2016–2017.

Statistical Database of Patent filing in America:

The Patent Act (35 U.S. Code), which established the United States Patent and Trademark Office, governs patents in the United States (the USPTO). A utility patent is the most prevalent sort of patent. Utility patents last for twenty years from the date of filing, but they are not enforceable until the day they are issued. Ornamental designs are protected by design patents.

To receive protection under US law, the applicant must file a patent application with the USPTO, which will be evaluated by an examiner to decide whether or not the invention is patentable. Patentees in the United States have the legal right to prevent others from creating, using, or selling their innovation.

- Processes, machinery, products of production, and compositions of matter are all patentable under Section 101 of the Patent Act. At first glance, this language looks to embrace every form of invention imaginable. This is true to a significant extent. The United States has one of the widest definitions of patentable subject matter in the world because of this Act. Physical device inventors don't have to worry about their inventions being non-statutory in most cases.

- An invention must be considered innovative or novel in order to be patented. This condition indicates that an invention cannot be patented if it has been disclosed to the public in some way. The statute that defines when a public disclosure has occurred (35 U.S.C. Section 102) is complex, and it frequently necessitates a thorough examination of the facts and the law.

U.S. Patent Statistics Chart
Calendar Years 1963 - 2020

The following table displays the calendar year along with counts of patent applications and grants, by document category (updated 5/2021):

Year of Application or Grant	Utility Patent Applications, U.S. Origin	Utility Patent Applications, Foreign Origin	Utility Patent Applications, Foreign Origin Percent Share	Utility Patent Applications, All Origin Total	Design Patent Applications	Plant Patent Applications	Total Patent Applications *	Utility Patent Grants, U.S. Origin	Utility Patent Grants, Foreign Origin	Utility Patent Grants, Foreign Origin Percent Share	Utility Patent Grants, All Origin Total	Design Patent Grants	Plant Patent Grants	Reissue Patent Grants	Total Patent Grants	Total Patent Grants, Foreign Origin Percent Share *	Year of Application or Grant
2020	n/a**	n/a**	n/a**	597,175	47,838	1,171	646,244	164,575	187,474	53.2	352,049	34,877	1,398	576	388,900	53	2020
2019	285,113	321,449	55.4	621,453	46,847	1,134	669,434	167,115	187,315	52.8	354,430	34,794	1,275	604	391,103	52	2019
2018	285,095	312,046	52.3	597,141	45,083	1,079	643,303	144,413	163,346	53.1	307,759	30,497	1,208	528	339,992	52	2018
2017	293,904	313,052	51.6	606,956	43,340	1,059	651,355	150,952	167,876	52.7	318,828	30,870	1,311	394	351,403	52	2017
2016	295,327	310,244	51.2	605,571	42,571	1,177	649,319	143,725	159,324	52.6	303,049	28,873	1,235	426	333,583	52	2016
2015	288,335	301,075	51.1	589,410	39,097	1,140	629,647	140,969	157,439	52.8	298,408	25,986	1,074	512	325,980	52	2015
2014	285,096	293,706	50.7	578,802	35,378	1,063	615,243	144,621	156,057	51.9	300,677	23,657	1,072	626	326,032	51	2014
2013	287,831	283,781	49.6	571,612	36,034	1,406	609,052	133,593	144,242	51.9	277,835	23,468	847	798	302,948	51	2013
2012	268,782	274,033	50.5	542,815	32,799	1,149	576,763	121,026	132,129	52.2	253,155	21,951	860	822	276,788	52	2012
2011	247,750	255,832	50.8	503,582	30,467	1,139	535,188	108,622	115,883	51.6	224,505	21,356	823	1,029	247,713	51	2011
2010	241,977	248,249	50.6	490,226	29,059	992	520,277	107,791	111,823	50.9	219,614	22,799	981	947	244,341	50	2010
2009	224,912	231,194	50.7	456,106	25,806	959	482,871	82,382	84,967	50.8	167,349	23,116	1,009	453	191,927	50	2009
2008	231,588	224,733	49.2	456,321	27,782	1,209	485,312	77,502	80,270	50.9	157,772	25,565	1,240	647	185,224	50	2008
2007	241,347	214,807	47.1	456,154	27,752	1,049	484,955	79,526	77,756	49.4	157,282	24,062	1,047	508	182,899	49	2007
2006	221,784	204,183	47.9	425,967	25,515	1,151	452,633	89,823	83,949	48.3	173,772	20,965	1,149	519	196,405	48	2006
2005	207,867	182,866	46.8	390,733	25,553	1,222	417,508	74,637	69,169	48.1	143,806	12,951	716	245	157,718	48	2005
2004	189,536	167,407	46.9	356,943	23,975	1,221	382,139	84,270	80,020	48.7	164,290	15,695	1,016	298	181,299	48	2004
2003	188,941	153,500	44.8	342,441	22,602	1,000	366,043	87,893	81,130	48.0	169,023	16,574	994	421	187,012	47	2003
2002	184,245	150,200	44.9	334,445	20,904	1,144	356,493	86,971	80,360	48.0	167,331	15,451	1,133	460	184,375	47	2002
2001	177,511	148,997	45.6	326,508	18,280	944	345,732	87,600	78,435	47.2	166,035	16,871	584	480	183,970	46	2001
2000	164,795	131,131	44.3	295,926	18,292	797	315,015	85,068	72,426	46.0	157,494	17,413	548	524	175,979	45	2000
1999	149,825	120,362	44.5	270,187	17,761	863	288,811	83,906	69,579	45.3	153,485	14,732	420	448	169,085	44	1999

- The subject matter of a patent must be "useful," according to the law. This implies that the invention must have a practical application. In most circumstances, in the context of computer and electrical technology, the usefulness criteria is easily met. When trying to patent a pharmaceutical or chemical compound, the criteria is much more crucial because the new compound must have a practical or specialized utility.

- It is considered novel when an innovation differs significantly from past items or processes (known as "prior art"). The patent statute, however, stipulates that an invention must be a non-obvious improvement over prior art in order to be patentable (35 U.S.C. Section 103). This is determined by determining whether the claimed invention would have been evident "to a person of ordinary competence in the art to which the claimed invention pertains." In other words, the invention is compared to the previous art, and it is determined whether the differences in the new invention would have been obvious to a person of ordinary competence in the field.

Comparative Study between Indian Patent Law and American Patent Law:

While all patent laws have the same goal, the methods for implementing them and the laws themselves differ. What all patents have in common is that they hand over all of a product's rights to the patentee, allowing him or her to profit from their device or product for a certain length of time.

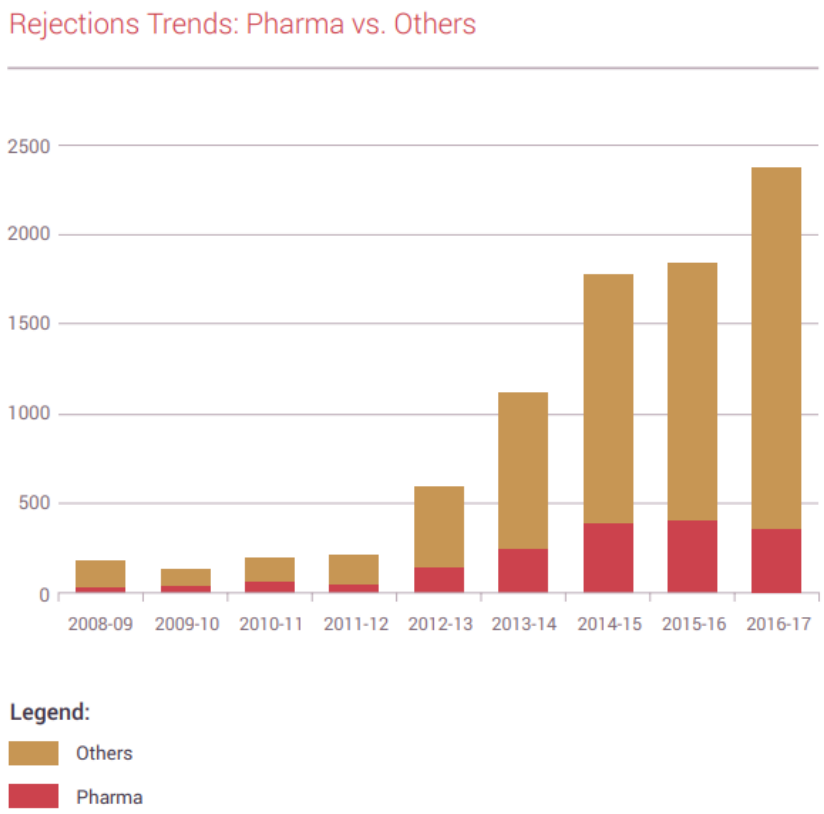
➔ The biggest distinction between the two countries' legal systems stems from the manner the laws are expressed. The United States adopts a more demonstrative approach, stating what can be patented. On the other hand, India's patent regulations specify what cannot be patented.

Minor adjustments or extensions to patents that have already been awarded are not permitted under Indian law. The patent laws in the United States, on the other hand, provide for this flexibility. The Utility patent is a type of patent used in the United States. This provides for the patenting of a process or machine discovery as long as it is unique, valuable, and unobvious. In India, however, this is not the case. The mere discovery of a process, machine, or product is not patentable under Indian law.

Case 01:

We studied a set of orders issued by the Indian Patent Office (also known as the Intellectual Property Office or IPO for short) when rejecting patent applications to better understand how it had examined patent applications concerning pharmaceuticals.

We sought to learn how the IPO had rejected patent applications for pharmaceuticals in order to better appreciate the role of the Patent Office in protecting the public's interests by rejecting applications for medicines and therapies that did not meet the patentability requirements.



1. Powder Formulation for Valganciclovir:

As per Section 2, Rejected Patents;

A contract which ceases to be enforceable by law becomes void when it ceases to be enforceable.

Section 2(1)(ac),"capable of industrial application", in relation to an invention, means that the invention is capable of being made or used in an industry

Section 2(j), Inventions means a new product or process which involves an inventing step and having industrial applicability;

Section 2(ja). Inventive step means invention should show technical advancement in comparison with the existing knowledge or having economic significance or

both and invention must not be obvious to a person skilled in the art;

Patent application entitled "Powder Formulation for Valganciclovir" :

1. When maintained under ambient circumstances, the solid-state of valganciclovir hydrochloride demonstrates acceptable physical, chemical, and light stability. For pediatric patients as well as those that demand flexibility, the applicant produced a liquid dosing form of valganciclovir hydrochloride. Short-term stability studies, on the other hand, revealed that a liquid dosage form would be unstable over the product's expected shelf life.

2. As a result, the applicants concentrated on powder dosage forms that could be reconstituted with water later to give valganciclovir hydrochloride and the resulting (constituted) liquid dosage form a reasonable shelf life. The dry mix granulation procedure was replaced with a wet mix granulation procedure. Because valganciclovir hydrochloride is easily soluble in acidic environments, a solid pharmaceutical dosage form must contain an organic acid in an amount sufficient to solubilize and stabilize the valganciclovir hydrochloride in a predetermined amount of water for the shelf life of the resulting (constituted) liquid dosage form.

3. They claimed a non-hygroscopic organic acid from the fumaric acid, succinic acid, and adipic acid group, and the amount of that acid was chosen to reduce the pH of the formed valganciclovir hydrochloride solution to 3.8 or below.

4. The patent examiner claimed that stability of valganciclovir below pH 3.8 was already described in the prior art when utilizing an organic acid, such as citric acid. As a result, the present innovation provides no technical progress. The patent was rejected under Section 15 on the grounds of Section 2(1)(ja) of the Patent Act [17] because it did not constitute any innovative step. The case's examination report may be seen at Dynamic Patent Utilities: The Controller's Decision on the Indian Patent Office's website.

Case 02:

Gene Family (LBFL313) Associated with Pancreatic Cancer :

As per Section 3, Rejected Patents;

Section 3 of the Indian Patent Act describes non-patentable inventions.

Section 3(a). An invention which is frivolous or which claims anything obviously contrary to well-established natural laws.

3(c) The mere discovery of a scientific principle or the formulation of an abstract theory [or discovery of any living thing or non-living substances occurring in nature]

3[d] the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant. Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

3(j), plants and animals in whole or any part thereof other than micro-organisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals;

Gene Family (LBFL313) Associated with Pancreatic Cancer :

The invention is concerned with gene expression variations in human pancreatic adenocarcinoma in general. The innovation is particular to a human

gene family that is expressed differently in malignant and non-cancerous pancreatic tissues. The hearing was held on April 10th, 2014, and the following objections were raised :

1. In the prior art, 764 base pairs were used, whereas the applicant used 777 base pairs. Although the claimed sequence ID has an additional 13 base pairs, the applicant does not demonstrate any benefit from these additional 13 nucleotide base pairs. Furthermore, it's possible that the 764 base pairs will keep their natural property.

2. The modified claim 6 (Production of Polyclonal Anti-LBFL313 Antibody) is directed at a host cell, which is not permissible under Section 3 (j) of the Act.

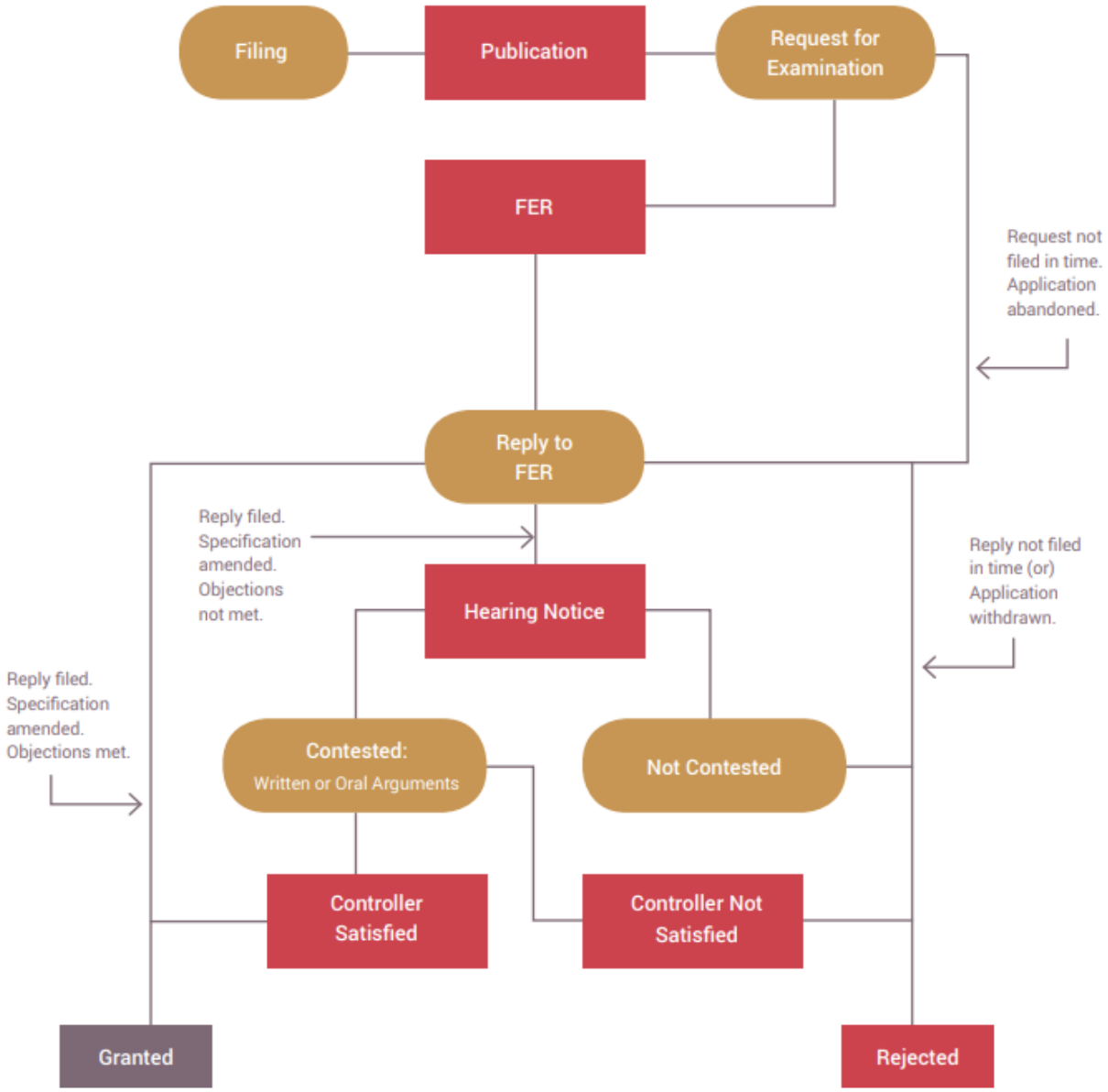
3. The amended claims 1–4 & 7–8 are not patentable because the subject matter of claim 1–4 is directed to isolated nucleic acid/PP sequence from human genomic DNA, which is considered to be an isolated nonliving substance occurring in nature, and is not allowable to be patented under the provision of Section 3(c) of the Act in the absence of any clear cut recombination in these molecules. The subject matter of claims 7-8, which encodes polypeptides from the isolated nucleic acid of claims 1, i.e. sequence ID No-2, makes the same finding. It has previously been mentioned that the nucleotide sequence was obtained from nature and that the polypeptide encoded by them is available in the source from which the nucleic acid was recovered. As a result, the subject matter of claims 7–8 is likewise covered by Section 3 (c) of the Act. 3.

4. Since modified claims 7 and 8 do not completely define the invention, claims should include all significant properties of the polypeptide, which is recognized by its amino acid sequence ID rather than its nucleotide sequence ID. The asserted claim must be characterized by its essential technical qualities, if any, as previously stated, or it will be rejected in its existing form.

5. The applicant should also bring the description into compliance with the modified claims when filing amended claims. During the revision process, be careful not to add topic matter that goes beyond the original application's content.

6. The Applicant's agent responded to the hearing notice with a faxed letter dated April 9, 2014, stating: "We have been informed by our client that they are not interested in pursuing this application further, and as a result, we will not be attending the hearing scheduled for April 10, 2014. Given the Applicant's desire not to continue the current application, it is accordingly concluded that the conditions stated in the hearing notice remain unmet, and the application for a patent is thus denied.

An overview of the Rejection Process:



Some Patent Infringement Cases that changed US Patent Law:

The patent system that exists in the United States today is the consequence of numerous rulings and verdicts that have affected the history of patent laws. Some cases had a little impact, while others had a substantial impact and impacted rules on patentability and how patents were viewed. Every decision altered some part of patent law in some way. Others revised the criteria for determining patent eligibility, while others shaped the regulations governing the patentability of genetically modified organisms.

The patentability of software inventions, whether in the form of claims or an intermediate step in the process, or perhaps the patent eligibility of subject matter in the form of software, even if the claims cover an abstract idea in the first place, were among the most notable decisions on the list.

Case 03: Patentability Case

Diamond vs. Chakrabarty:

Ananda Mohan Chakrabarty worked at General Electric as a genetic engineer. He had developed a bacterium from the Pseudomonas genus, which is today known as Pseudomonas putida. He offered to employ this bacterium in the treatment of oil spills because it was capable of breaking down crude oil.

Commissioner of Patents and Trademarks Sidney A. Diamond filed an appeal with the Supreme Court to overturn the decision. The case was heard in front of the Supreme Court on March 17, 1980, and resolved on June 16, 1980.

The final verdict on the issue:

The court ruled in Chakrabarty's favor, 5–4, affirming that "a live, human-made micro-organism" is patentable subject matter under 35 USC 101. Within that statute, the respondent's microorganism is a "manufacture" or

"composition of substance."

In regard to the original legislation's breadth, he noted, "Congress evidently expected that the patent statutes would be given extensive scope by using such vast phrases as "manufacturing" and "composition of matter" modified by the comprehensive "any." "Judged in this perspective, respondent's micro-organism manifestly meet the standards as patentable subject matter," he said, noting that Congress had intended patentable subject matter to "cover everything under the sun that is made by man." His claim is to a non naturally occurring production or composition of matter — a product of human ingenuity with a distinct name, character, and function — rather than to a previously unknown natural phenomena."

Case 04: Software Patent Case

Alice vs. CLS Bank:

In this case, the question was whether certain claims involving a computer-implemented, electronic escrow service for facilitating financial transactions were patentable abstract concepts. The patents were declared invalid because the claims were drawn to an abstract idea, and putting those claims into practice on a computer did not transform that idea into patentable subject matter.

Despite the fact that the Alice decision did not specifically address software, the case was largely regarded as a judgment on software patents or software patents for business practices.

- Alice Corporation ("Alice") owned four patents on electronic methods and computer programmes for financial-trading systems in which trades between two parties who are to swap payment are settled by a third party in ways that reduce "settlement risk"—the risk that one party will carry out while the other does not.

- CLS Bank International and CLS Services Ltd. (collectively "CLS Bank") allegedly began using identical technology in 2002, according to Alice. CLS Bank accused Alice of infringing on her patents, and when the parties couldn't come to an agreement, CLS Bank sued Alice in 2007, seeking a declaratory ruling that the claims at issue were invalid. In response, Alice filed a countersuit, alleging infringement.

- The district court ruled that each of Alice's patents was invalid because the claims involved abstract notions, which are not patentable under 35 U.S.C. 101.

- Seven separate judgments were delivered by a panel of ten Federal Circuit judges, with no single opinion being backed by a majority on all points. Seven of the ten judges agreed with the district court that Alice's method and computer-readable medium claims were patent-ineligible, albeit for different reasons. The panel could not agree on a single criterion for determining whether a computer-implemented invention is a patent-ineligible abstract notion.

The final verdict on the issue:

Relying on Mayo v. Prometheus, the court found that an abstract idea could not be patented just because it is implemented on a computer. In Alice, a software implementation of an escrow arrangement is not patent-eligible because it is an implementation of an abstract idea. Escrow is not a patentable invention, and merely using a computer system to manage escrow debts does not rise to the level needed for a patent. Under Alice, the “Mayo framework” should be used in all cases in which the Court has to decide whether a claim is patent-eligible.

The ruling concluded with the following suggestions:

1. A simple computer programme to implement an abstract idea "cannot provide patent eligibility."
2. A patent-ineligible abstract notion cannot be transformed into a patent-eligible invention simply by reciting the generic computer.

3. Patent eligibility requires more than stating an abstract notion and adding the words "apply it."
4. Limiting the application of an abstract concept to a certain technological setting is also ineffective.