PATENT ANALYSIS AND SEARCHING TECHNIQUES

Project Report Submitted in partial fulfilment of

Bachelor of Technology

in

Biotechnology

By

Simran Gohan (181802)

Under the Supervision of

Dr. Rahul Shrivastava

To

Department of Biotechnology and Bioinformatics,

Jaypee University of Information Technology, Solan

Himachal Pradesh (173234)

CERTIFICATE

This is to certify that the work titled "**PATENT ANALYSIS AND SEARCHING TECHNIQUES**", submitted by **Simran Gohan (181802)** in partial fulfillment for the award of degree of B. Tech in Biotechnology at Jaypee University of Information Technology, Solan has been carried out under the supervision of **Mr. Punit Talwar** (Manager) Talwar and Talwar Consultants and Services Pvt. Ltd., Mohali and **Dr. Rahul Shrivastava** (Associate Professor), Department of Biotechnology and Bioinformatics, JUIT. This work has not been submitted partially or wholly to any other University or Institute for the award of this or any other degree or diploma.

Dr. Rahul Shrivastava
Associate Professor
Department of Biotechnology and Bioinformatics
Jaypee University of Information Technology (JUIT)
Waknaghat, Solan, India - 173234

Date:

TRAINING CERTIFICATE

Corporate Office: Office 413, Tower A, 4th Floor, Bestech Business Tower, Sector- 66, Mohali, Punjab 160055
Phone: +91 172-6459347, +1.347.284.6413
www.ttconsultants.com
hr@ttconsultants.com

Ref. No: HRD/REC/TTC/136/2022

Date: 13 May 2022

TRAINING LETTER

TO WHOMSOEVER IT MAY CONCERN

This is to certify that Simran Gohan (Employee Code: TTC-624) is working with Talwar & Talwar Consultants Pvt. Ltd. since 7 February 2022 as Intern- PRW.

Till now, her performance has been satisfactory.

We wish her all the best for future endeavors.

For Talwar & Talwar Consultants Pvt. Ltd.,

Sna Rikhi
Authenticated through Leegality.com (qdIZVNo)
Sna Rikhi
Date: Fri May 13 15:03:44 IST 2022

Authorized Signatory

DECLARATION

I hereby declare that the work presented in this report entitled "**PATENT ANALYSIS AND SEARCHING TECHNIQUES**" in partial fulfilment of the requirements for the award of the degree of Bachelor of Technology in Biotechnology submitted in the Department of Biotechnology and Bioinformatics, Jaypee University of Information Technology, Waknaghat is an authentic record of my own work carried out over a period from February 2022 to May 2022 under the supervision of **Mr. Punit Talwar** (Manager) Talwar and Talwar Consultants and Services Pvt. Ltd., Mohali and **Dr. Rahul Shrivastava** (Associate Professor), Department of Biotechnology and Bioinformatics, JUIT.

The matter embodied in the report has not been submitted for the award of any other degree or diploma.

Simran Gohan, 181802

This is to certify that the above statement made by the candidate is true to the best of my knowledge.

Dr. Rahul Shrivastava

Associate Professor

Department of Biotechnology and Bioinformatics

Jaypee University of Information Technology (JUIT)

Waknaghat, Solan, India - 173234

Date:

ACKNOWLEDGEMENT

An individual generally needs somebody who inspires them to achieve great feats in life, I would like to offer my gratitude to such amazing individuals who helped me and guided me during my journey.

I would like to thank my supervisor **Mr. Punit Talwar** for his consistent help and direction all through my preparation. He has been a steady support and mentor in these six months of training. Without his assistance it would have been significantly troublesome to understand the idea driving the industrial training.

A very special thanks goes to my mentor and guide during these college years **Dr. Rahul Shrivastava** for his constant support and guidance that will always be a beacon of inspiration in my life. His constant assistances have made me excel in various fields and guided me in difficult times to achieve great success.

I would likewise prefer to extend my gratitude to the Biotechnology Department for their consistent and sacrificial help towards finishing this undertaking to the best of my abilities.

Thank you

Name: Simran Gohan
Date:

Table of Contents

List of figures

List of Tables

List of Abbreviations

IPR: Intellectual property rights

IPC: International Patent Classification

PCT: Patent Corporation Treaty

IP: Intellectual property

CPC: Cooperative Patent Classification

WIPO: World Intellectual Property Organization

KF: Key features

US: United States of America

CA: Canada

EP: Europe

WO: World

HEK: Human embryonic kidney

RPE: retinal pigment epithelium

AAV: Adeno-associated viruses

USPTO: United States Patent and Trademark Office.

USPC: United States Classification

ECLA: The European Classification

EPO: European Patent Office

FTO: Freedom to operate

NPL: Non-Patent Literature

ABSTRACT

This report depicts an elaborate plan on the process of patent analysis and searching. Here, basics of Intellectual Property Rights are elucidated and diverse forms of Intellectual property, Patents, claims, filing applications and searching techniques are also mentioned. The report deep dives into a case study which presents a client who has developed a gene therapy product for Retinal dystrophy. A patentability analysis is done on the invention that is the gene therapy product, to check its novelty. The gene therapy product is a treatment based on adeno-associated virus type 2 (AAV2) in which a proper copy of the RPE65 gene is delivered without disrupting the genome. This concoction is injected directly into the retina to enter the retinal cells. When RPE65 is expressed in those cells, it can do its job and, in essence, stop the progression of the disease. Various searching queries are performed on Orbit and NPLs are performed on google, google scholar or science direct for the analysis. The most relevant patent is found and mapped for the client. Patent analysis helps to increase the scope of scientific innovation. It gives the inventor or creator the alternative of preventing somebody else from assembling, duplicating or selling of the patented merchandise without consent of the patent holder. It motivates the inventor with a form of incentive and thus, helps to keep the flame of innovation alive causing greater revelations for a better future.

Keywords: Patent, Intellectual Property, Retinal dystrophy, Adeno-associated virus, Retinal Pigment Epithelium, Orbit, Patentability Search, Gene Therapy, Claims

CHAPTER 1

PROFILE OF THE COMPANY

TT Consultants is an ISO 27001 and ISO 9001:2008 licensed firm, among the major suppliers of the best quality Intellectual Property along with the support facilities. Through the years, it has been providing patent prosecution and litigation services, Patentability Searches, Invalidity/ Searches, Landscape and Whitespace Analysis, Freedom to Operate Searches etc. With the presence of its offices in five other regions in India, USA and Taiwan it has been delivering services to the clients in more than thirty regions globally.

To provide technology proficiency to the clients TT Consultants has specific departments like Life Sciences, Mechanical and Metallurgy, Electronics and Telecommunication, Nanotechnology etc. Its prime aim is to provide robust, innovative and automated solution to the clients. Also, it offers in-house developed Intellectual Property tools that help companies to improve their performance and reduces the cost related to patent prosecution.

TT Consultants is among high scientific discipline corporations that has been delivering patent services to a increasing list of happy clients across the globe. With tremendously proficient and experienced experts who are working 24*7 to deliver quality results and speedy turnarounds it has been providing clients services to increase their business potency.

CHAPTER 2

INTRODUCTION TO INTELLECTUAL PROPERTY RIGHTS

2.1 Intellectual Property

It is the intangible property, produced by creation of the mind that holds the legal rights to be protected by law for its recognition and financial benefits and is said to be the property of the inventor or creator and is called intellectual property. According to intellectual property law the owners of such intellectual property are given special rights over their invention which may include publishing, licensing, manufacturing, distribution and suing in the case of copying or infringement.

2.2 Intellectual Property Rights (IPR)

These refer to the exclusive set of rights that are granted to the owner of the intellectual property for commercial exploitation under provisions of national laws and international agreements. The IP to be protected belongs to domains like scientific, industrial, artistic or literally. These rights can either be assigned or licensed for monetary benefits.

The objective of IPR is to promote progress in the fields of invention so that mankind can reach greater heights. There is an exchange of rights over creative inventions so that the inventors or authors can get incentives over their amazing ideas and implementation. The inventor can benefit from that creation and is motivated to be more inventive.

The advantages of IPR are:

- It encourages innovation and sharing of knowledge
- It also helps to encourage and protect the creator
- It helps the invention to get commercialized and makes new inventions more mainstream

2.3 Types of IPR

It is broadly of two types of industrial property and copyright. Industrial property usually deals with inventions and investment designs used in the industry whereas copyright deals with artistic creations like music paintings sculptures computer programs books and movies

2.3.1 Patent:

It lays down selective legitimate rights permitted by the government to the owner of patent for a limited time period on the terms of revealing of the invention to the society in open space. Patents are offered for an invention which includes a product or innovation/improvement in a product. The validity period of a patent is 20 years.

2.3.2 Copyright:

It includes collection of rights which provide legal means for protecting author's(composers, writers etc.) work and allows him to reproduce the work for a limited time span. When an individual creates an artistic piece of work such as original literary, musical, dramatic, artistic work etc. then the creator is free to decide its use and the destiny of the work. Therefore, by the laws of intellectual property rights their work is protected by copyright. The idea itself is not protected but the way the idea is presented in the form of a product is Scope of copyright includes both (i) moral rights – Right of authorship and Right of Integrity, (ii)economic rights – Right to reproduce work, Right of Distributing and Right of Communication to the Public. The validity of copyrightis life time of author and 50 years after death

2.3.3 Trademark:

A specific sign or marketing logo or graphic that is connected to a specific company or business is called a trademark. Its main purpose is to create a brand value and makes it easy to differentiate between brands. A trademark will have a specific symbol, phrase, logo, picture or a combination of multiple features. It can also have a specific sound shape or colour. It is of three categories unregistered trademark, and registered service mark, registered trademark. It's misuse by others of registered trademark holder without permission will lead to infringement and liable for prosecution. The trademark is registered for 10 years and can be renewed timely on payment of renewal fee.

2.3.4 Trade secret:

Any formula, recipe, pattern, process or information that is a secret or not present in the public domain is called a trade secret. This information being leaked can cause competitors and consumers to take economic advantage over a company therefore it is also referred to as confidential information. It can be any idea, data, experimental results, manufacturing process, recipe, chemical formula etc. which is being kept as a secret by a person or company by signing confidential agreements with business partners. There is restricted entry into the area where trade secret work is done by using protective techniques like digital security tools. In the field of biotechnology trade secrets include production process, microbial strains or cell lines as well as the very infamous secret formula of Coca Cola

2.3.5 Geographical Indication:

The protection rights are provided to a particular community in a geographical area for producing goods/products that hold characteristics of that specific area due to its climatic conditions. Geographical indication. All the specific sign or name that indicates the geographical location of the product. Examples include; Darjeeling tea, Mysore silk, Kullu shawl etc. Geographical Indication is registered for 10 years and can be renewed timelyon payment of renewal fee.

2.3.6 Design layouts of circuits

The layouts of various circuits are also an invention and various types of designs help in increasing the efficiency of circuits. Therefore, in order to stop the copying of these circuit designs they are protected by intellectual property rights.

2.3.7 Industrial designs

Industrial designs are widely applied to various products such as mobile phones, luxury items, watches, housewares as well as buildings and vehicles. Therefore, intellectual property rights also protect the visual design of various objects available in the market by exercising the rights to industrial designs. Designs, in general, add appeal and brand value two any product available in the market therefore protecting it is essential.

2.3.8 Patents

An exclusive right which is provided to the developer of an invention, product or a process is called a patent. This provides protection to the invention for a period of 20 years. The owner of the patent has a right to give permission to use their invention and can also trade or sell the rights of their invention to somebody else. If a patient expires then it enters the public domain and can be commercially exploited by anybody. An invention needs to fulfil certain criteria to be termed patentable. The patent can only be granted in the case of developing a non-obvious process, machine or product that is novel, useful or improves the prior process or product. It restricts others from imitating or manufacturing that particular product.

Advantages:

- Restricts competitors
- Provides monetary benefits
- Product credibility
- Keep others out of the market

Disadvantages:

- High cost for the maintenance of patent.
- Liability

2.4 Different types of patents:

2.4.1 Utility patent

Any useful invention that is not obvious in its field can be called a utility Patent. Utility patents usually can be of five categories which includes a process, machine, manufacturing, composition of matter and improvements in an already existing idea. Examples include computer hardware, cosmetics, chemical formula, computer software, housewares etc.

2.4.2 Design patent

creating a unique design or pattern of a device, or a product can help to get a design patent. Examples include a specific architectural design, design of furniture, wallpaper, devices etc. A design patent only lasts for 14 years after its issue.

2.4.3 Plant patent

A plant is given to an inventor who is able to discovered, invent or asexually produce a new species or variety of plant. It also lasts for 20 years from the date of filing the application and gives the reproducing rights exclusively to the inventor.

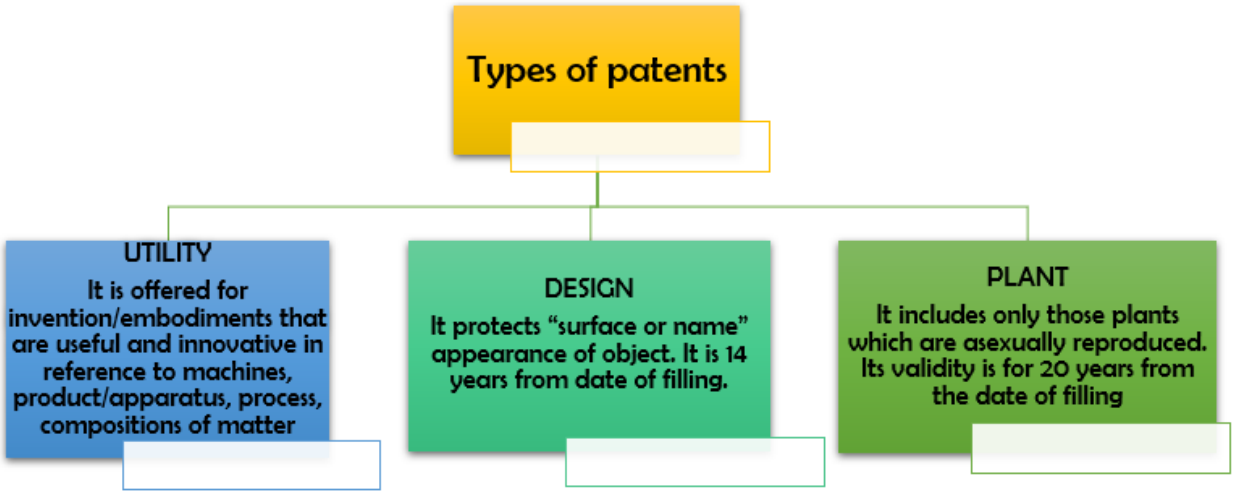

Fig1: Types of Patents

2.5 Criteria for Patentability

2.5.1 Novelty:

Any invention must be a new process or product which means that it should be original and never seen or done before. It must involve nuances that have never been explored and extend the reach of existing knowledge. Novel inventions are a patentability requirement. Novelty specifies that if public disclosure has already been made it is not eligible for patentability. To make sure that the invention is new inventors should do patent searching before filing application.

2.5.2 Non-obviousness and Inventive step:

The invention should be non-obvious which means that it should have a certain level of innovation in order to be patentable. The invention should not appear obvious to a person of the field in which the invention is being done. The obviousness of the invention can be tested by identifying the closest prior art and understanding the technical problem that the invention is trying to solve, then an analysis can be made if the invention is obvious in that particular field of use or not. The examiner in the office of patent will review published application of patent closest to the invention for which patent protection is asked for. If the examiner successfully finds the combination of prior art for the invention, it will be rejected as it would obvious combination of items only.

2.5.3 Utility:

The subject matter of patent should be useful to the society. The patent can only be granted to a specific invention which has applications in the industry not a private or personal ecosystem. If the invention is able to improve a particular process, product or machinery then it is able to put itself in industrial application

2.6 Paris Convention:

An international treaty (1883) that permits the applicants to file a 1st application in his or her own respective country and is considered to as priority document and the respective date on which it is filed is known as priority date. The advantage is that 12 months period is provided to the applicant in which he can seek funding and perform market research for product commercialization. Within that time period a Paris Convention Application can be filed in anyof the respective states claiming same priority date. A delay of 12 months allows the applicant to decide in which country protection is to sought.

2.7 Patent Corporation Treaty (PCT)

The international treaty (1970) which allows an inventor to get patent granted simultaneously inmany nations by registering only one international patent application rather than filling the same in all national patent offices. More than 150 Contracting States are part of this treaty.

Steps in filling:

An international application is filed in single language in the Receiving Office (RO) with PCT formality requirements which is to be done within 12 months of filling local application.

An International Search is executed by "ISA" International Searching Authority within 16 months of filling in home country.

International Publication is done within 18 months from filling in home country.

Supplementary International Search within 22 months and International Preliminary Examination within 28 months of filling are optional.

After the termination of PCT procedure, 30 months from primary filling date of first patent application, priority date can be claimed by the applicant and pursue grant of patent in regional patent offices of countries in that he wants to claim.

2.7.1 Role of World Intellectual Property Organization (WIPO) in PCT

PCT is administered by WIPO. PCT assembly, PCT working Group and meeting of International Authorities is also organized by WIPO. For each application filled for PCT, It plays a major role for accepting and storing all patent application papers, conducting examination, provides coordination of PCT procedure, communication patent documents to patent offices and third party, translation sections of application into French or English wherever it is necessary.

2.8 Non-Patentable Things:

- Inventions contrary to natural laws
- Opposing public command or ethics
- Causing injury to living beings and environment
- Mental Process
- Computer Software
- Abstract ideas
- Basic intermixture resulting only in aggregation of properties of components
- Method of doing business

2.9 Application Sections:

- Claims
- Title
- Abstract
- Summary
- Brief drawing description
- Background
- Drawing
- Field of invention
- Detailed drawing description

CHAPTER 3

DIVERSE METHODS IN THE PROCESS OF PATENT FILING

3.1 Kinds of Patent Applications

3.1.1 Provisional application:

It is a type of temporary filling and is done when the invention is not complete or is still under development. This application includes the specific qualities of the invention along with a description and a diagram of the invention if required. The date of filing a provisional application is not a part of the 20 years lifespan of a patent.

Filing a provisional application comes with its own advantages like:

- It helps in easily getting an official date of filing and helps to preserve the idea of the invention
- It helps to provide a delay of 1 year for the inventor to finalize his or her invention
- It helps to give the inventor an extra year of protection for their patent/invention
- By filing the provisional application, the invention turns into to a practical patentable product

3.1.2 Ordinary application:

It is the principal or 1st application for patent documented inside the Patent and Trademark Office Database. It is a type of application which does not have a Priority application and it does not have a reference application on the process. this type of application has specific qualities of the invention mentioned along with proper claim

3.1.3 Conventional application:

To claim priority in all convention countries conventional application is filed and the priority can be claimed by the applicant if exact application is filed in either of the convention country. The partner degree individual should apply their application in the patent office inside a year from the date of beginning application inside the conventional nation.

3.1.4 PCT-International application:

this type of application can be validated in about 142 Nations and it falls under the patent cooperation treaty there's nothing known as a 'world patent'. The application doesn't offer for the award of a world patent, it simply gives an effective technique to the application strategy in a few nations at consistent time. The countries for the validation can be Chosen up to 30 to 31 months.

3.1.5 PCT-National Phase application:

The national phase of a PCT application is indeed similar to a national filing in a particular country. The decision to get a patent granted in a specific nation completely depends on Patent Office of that particular nation.

3.1.6 Application for patent of addition:

This application is filed when there is any improvement in invention in the patent which is already filed, helps to protect the improvement. It has the same expiry date as the main patent and there are no additional renewal charges for it. It can be granted after the grant of parent patent only.

3.1.7 Divisional application:

If the patent application mentions more than more than invention, then thecandidate/applicant can divide the application depending on the no. of inventions mentioned in it. It can be filed at any time in advance to getting grant of patent application. The divided applications have the same priority date as parent patent application. The term of patent for a divisional application is 20 years from the filing date of parent application.

3.2 Claims

It defines the scope of invention to be protected and is the most important part of the specification of a patent. It specifies the subject matter to be protected by patent. It defines extent of security allowed by the patent therefore it is vital to get claims that encapsulate the peripheral arrangements and details that separate partner inventions. Also, claims play a key role during litigation and prosecution. Any mistake in drafting claims would result in patent that is completely useless.

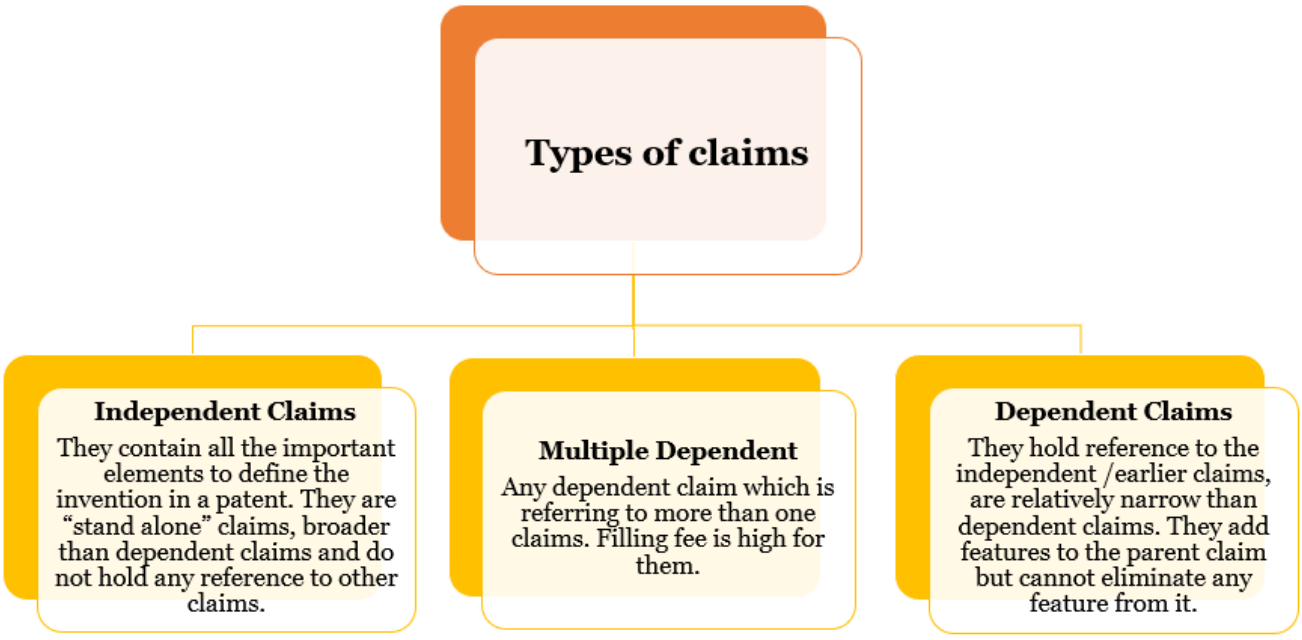

Figure 2 Types of Claims

3.3 Diverse forms of Claims

3.3.1 Jepson Claims:

It states references that link to state of prior art and then it claims some kind of improvement in that prior art. Along with describing prior art before stating an improvement, it also is not employed in domestic application but is received by USPTO. An example describing Jepson claim is “the process of making an instrument with elements A and B (prior art), wherein the improvement comprises (transitional phase) element C (the inventive element).

3.3.2 Markush Claims:

These claims group the elements which can be alternatively used together i.e parallelly in a single claim, the elements share similar a nature and same special properties/characteristics. Inventions in chemistry, metallurgy, refractories, ceramics, pharmacology and biology are usually claimed under the Markush format. Scheme: “selected from the cluster consisting of A, B and C”.

3.3.3 Reach through Claims:

Such claims can be formed to look for protection for things that havenot yet been came across by inventor but may be discovered by making use of them by utilizing the invention. For example: If an inventor files an application for an upstream invention in a particular field, then attempts to claim for downstream invention that have not been actually made, then claims to downstream invention are referred to as reach through claims.

3.3.4 Product by process claims:

Especially used in pharmaceutical and chemical industries wherein the product is defined by the process of its manufacture. The claim might be in this form "Output Z is produced by the procedure X". The expressions like "acquired", "legitimately got" or an equal wording is utilized to guarantee the item by-process, it is coordinated for the item as well as gives total assurance on it.

3.3.5 Swiss type claims:

These claims allow protection for a new subsequent therapeutic use of a known substance (secondary or further medical use). The novelty of such claims is considered to derive from the new medical purpose, not from the manufacture of the medicament. The format of Swiss claims is “The use of (compound A) for the synthesis of a medicament for the prophylactic therapy of (disease B).”

3.3.6 Omnibus claims:

These claims refer to the drawings, description, graphics or photographs and particularly do not point out and clearly claim anything. Some examples of such claims include: “An instrument substantially described”, “the test instrument shown in the drawing”, “process for manufacturing a substance as described” etc. Omnibus claims can offer great advantage, an advantageous tool while drafting patent so as to maximize protection.

3.4 Types of Patent Searching:

S.No.	Types	Definition
3.4.1	**Novelty/Patentability Search**	It helps the inventor to determine if any prior art (patent or non-patent literature) exists that may prevent him/her from patenting the invention. No date restriction exists for this search.
3.4.2	**Freedom to OperateSearch (FTO)**	Before commercializing any product/service in the market, FTO search helps the inventor toknow if he/she is free to operate and commercialize the invention without violating orinfringing the thirty party IP rights
3.4.3	**Infringement Search**	Infringing of patent is the occurrence of a forbidden act in context to a patented invention without getting consent from the owner. According to various jurisdictions the meaning of patent infringement may be different but mainly it includes making or selling a product which is patented already.
3.4.4	**Invalidation Search**	The motive of invalidation search is to either validate the claims made by an applicant in his/her patent or to invalidate one or more claimsof particular patent of competitor. It is a prior artsearch after a patent is issued.
3.4.5	**State of art Search**	It is done to review all of patent or non-patent literature that helps to know state of play in a particular technology which helps the organizations to determine future directions by understanding latest developments.

Table 1: Different types of Patent Searching

3.5 Patent Classification System

Patent Classification System provides an effective way of organizing patent in patent offices by technology subject which helps to retrieve document quickly and efficiently. It is an approach where patent documents are curated and kept in a patent office so that discovery of a similar innovation or any infringement can be checked with ease.

3.5.1 Searching based on Classification

Advantages

Does not include grammatical language.

Changes in phrasing is not required

Ideas Searching

Available for patent reports where no full content of claims/description is accessible.

Disadvantages

Structure of classifications is very complex.

Classification rules learning is required.

3.6 Types of Patent Classification Systems

3.6.1 International Patent Classification (IPC)

A widely used patent classification system which symmetrically arranges the patent documents, applicable in more than 100 countries. The Strasbourg Agreement was established it in the year 1971. It makes a different leveled progressive course of action of sans language images for the portrayal of licenses and utility models according to the various particular fields to which they have a place. All specialized information for the field of inventions is separated into sections, classes, subclasses, main groups and subgroups, indiving request of progression. Symbols are organized in a various leveled, tree-like structure:

at the most elevated level are the eight sections relating to wide specialized fields (e.g.,Section B manages Biomedical and life sciences);

areas are additionally partitioned into classes (e.g., Class B21 deals with viralinfections);

classes are divided into in more than 500 subclasses (e.g., Subclass B21A deals withinfections caused by Retroviruses).

Cooperative Patent Classification (CPC)

It is the augmentation of the International Patent Classification and is mutually carried on by

the EPO and the USPTO. It is divided into 9 parts, A-H and Y, that are sub-divided in classes, sub-classes, groups, further into sub-groups. About 250,000 classification entries are currently present.

Objectives to launch CPC

Helps to increase patents exploring efficiency.

Resources distribution.

CPC to a greater extent is founded on the past European order framework (ECLA), which itself was a progressively explicit and point by point variant of the International Patent Classification framework.

3.6.2 European Patent Classification (ECLA)

Basically, an expansion of the International Patent Classification (IPC) framework carried on by European Patent Office (EPO). Both ECLA and IPC are separated into eight areas which are additionally partitioned into classes, sub-classes, groups and sub groups. Around 135,000 classification section are present in ECLA. ECLA classes are issued many months after classification. It can't be utilized to recover as of late distributed/gave patent reports.

Features

Extremely gifted work force: ECLA classes are just relegated by the EPO analyzing corps for example a little assemblage of profoundly prepared people keeps up the importance of the framework.

Narrow class definition: The sub groups are additionally further classifications.

Accelerated modification plans: It is amended even before 5 years' time of update of International patent classification.

non-patent literature is included in the sub group

Disadvantages

ECLA classes are given a while after grouping. It cannot be used to recover recently issuing documents.

3.6.3 US Patent Classification

The United States Patent Classification is an official patent order framework being used and kept up by the United States Patent and Trademark Office (USPTO). Class is three-digit number and subclasses a six-digit number in which last three-digits are decimal places. Classes and subclasses are separated by a slash.

For instance: bbb/NNN.nnn

Advantages

There is a better arrangement of patents in US as compared to IPC. USPC can without much of a stretch adjust to the advances which are changing since it is overhauled more often in comparison to IPC.

3.7 Main Dates in Application of Patent

- **Invention date**: The date on which an invention is completed**.**

- **Publication date:** The date on which information of respective patent is accessible to the society, 18 months later than date of priority.

- **Issue date:** The date on which the patent is issued from the office of patent.

- **Priority date:** The 1st date of filling application of patent in any country.

- **Filling date:** The date on which application is registered with full information.

- **Expiration date:** Particular Date on which patent validity term terminates.

3.8 Citations: Data used in patent to refer earlier prior art.

1. **Backward Citation:** It is reference of patents that includes prior art
2. **Forward citation**: It is reference of invention completed in a particular field after issuing of patents.

.

3.9 Important US laws:

3.1.1 USC35§112 - It specifies that invention/patent has to be fully disclosed.

3.1.2 USC35§101 – It is related to utility of present invention.

3.1.3 USC35§102 - It is related with the newness of the present invention.

3.1.4 USC35§103 - It relates with non-obviousness of invention.

CHAPTER 4

PROJECT UNDERTAKEN

4.1 Patentability Search:

Search for patentability includes looking the prior art, which has printed patent applications, gave licenses, and the other printed records, with view of determinative whether documenting patent document/application is reasonable. A brisk patentability search in the specialized space can help settle on powerful business choices and spare a few dollars associated with patent documenting and upkeep. The reason for existing is to decide if there are any past patents or non-patents that may keep the creator from protecting their thought. A patentability search will help inside the status of partner degree application. The chase can empower plot partner degree palatable extensiveness for the instances of a futureapplication besides as go about as partner degree help to find that pieces of the development to focus partner degree application on.

Patentability search must be done before the documenting of a patent on the grounds that an innovation consumes a ton of endeavors and costs, so before recording, an innovator must be certain whether others have just had a special interest in that development.

Notwithstanding above,

- The patentability scan additionally gives a thought for an innovator about the extent ofthe development;
- Help the patent drafter to draft the case by better comprehension of the innovation over the earlier art;
- Candidate can be prepared ahead of time to offer response to the assessment dismissal which may come during its assessment stage.

4.2 Searching patent documents

A patentability search will typically include searching of significant patent assortments - United states, European, Japanese, patent cooperation treaty assortments. Albeit any prior published record can be utilized against a patent application, most patent examiners from significant patent workplaces will go directly to these assortments, so it bodes well to remember them for any patentability search, regardless of how superficial. The patent search instrument ought to be chosen in order to increase fundamental essential inclusion, however valuing is typically a limitation with shorter patentability examinations.

4.3 How Non-Patent literature searching is done

A patentability search will likewise incorporate searching of non-patent literature. Crucial sources of non-patent literature incorporating numerous specialized branches of knowledge incorporate, yet are not constrained to:

Engineering village (membership), google, Scopus(membership), Google scholar

4.4 Specific Search Strategies

These search systems are instances of explicit accepted procedures that can be applied over the span of a patentability search.

- always be a discuss with the client if the search is tough and there is a need to find documents that can describe alternative form or types or is the task feasible and demands only the relevant result.
- The person conducting the search should discuss with client if the search needs to be on all the claims just like the examiner will do in the patent office during filing.
- You should always search on the innovator name to know about in depth about their research interests.

At extremely starting stage, our customer will give us just smidgen data with respect to their development. They never unveil their complete innovation, yet they manage us to accomplish the relevant citation while searching through different databases.

Presently let us assume, the client has given us this much data with respect to their invention.

A form of gene therapy is used in patients with a defective type such as retinal dystrophy. Retinal dystrophy is an umbrella term for progressive eye infections. ‘Retinal’ means that this condition is related to the retina, which is the back layer of the eye that converts light into a clear message to the brain. ‘Dystrophy’ is a deteriorating condition. Retinal dystrophy causes progressive degeneration or visual impairment that can eventually lead to complete blindness. This gene therapy product can be used in patients with RPE65 gene mutations. The gene therapy is a treatment based on adeno-associated virus type 2 (AAV2) in which a proper copy of the RPE65 gene is delivered without disrupting the genome. This concoction is injected directly into the retina to enter the retinal cells. When RPE65 is expressed in those cells, it can do its job and, in essence, stop the progression of the disease. AAV2 vector contains the human RPE65 cDNA with modified Kozak sequence the virus is grown in HEK 293 cells and purified for administration.

4.5 Search begins:

The search starts with understanding the novelty of the exposure. Patent analyst needs to comprehend the novelty by perusing the background and description of the exposure. In the event that he/she can't get it, at that point he/she should examine the novelty with the innovator in any case the search won't be toward the path where the creator needs it to be. So, understanding of the disclosure is must. After this the genuine search starts.

As indicated by our divulgence the novelty part is that the client sends the retransmission solicitation to the framework and the error in the message is additionally featured which as per the inventor was absent in the prior art.

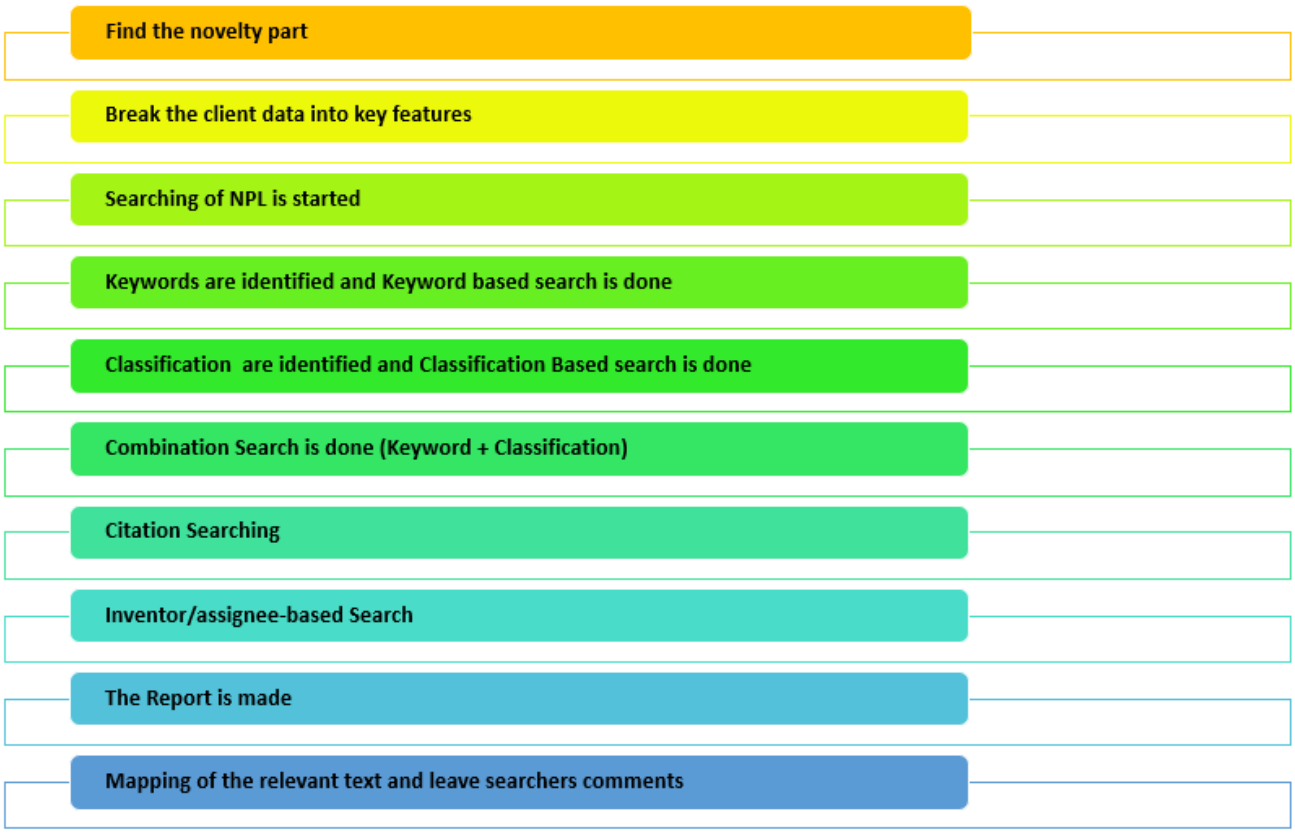

Figure 3 Steps of searching strategy

NOTE: We break the client data into key features, with the goal that it will assist us with breaking the entire innovation into parts. The parting of divulgence make innovation much clearer to comprehend

4.6 Case Study:

Mentioned below are the key features defined by the inventor according to the disclosure of the patent.

4.6.1 Key features (Table 2)

KF 1.	Gene therapy can be used in patients with RPE65 gene mutations to treat Retinal dystrophy.
KF 1.1	Treatment based on adeno-associated virus type 2 (AAV2) encoded with a proper copy of the RPE65 cDNA and is delivered without disrupting the genome.
KF1.2	AAv2- RPE65 cDNA also has a modified Kozak sequence
KF 1.3	The virus is grown in HEK 293 cells and purified for administration
KF 2	Concoction injected directly into the retina to enter the retinal cells.
KF 3	When RPE65 protein is expressed in those cells, it can do its job and, in essence, stop the progression of the disease

Relevant Citations: US9433688B2 **(Mapped according to key features)**

4.6.2 Mapped Patent details (Table 3)

Application/Patent no.	**US9433688B2**
Title	**Method of treating or retarding the development of blindness**
Assignee	Cornell Research Foundation Inc University of Florida Research Foundation Inc University of Pennsylvania Penn
Inventor	Gregory M. Acland Gustavo D. Aguirre Jean Bennett William W. Hauswirth Samuel G. Jacobson Albert M. Maguire
Priority Date	2001-04-13
Filing Date	2014-06-20
Family Members	**CA2442670A1 | WO2002082904A2 | EP1381276A4**

Abstract

A method for treating an ocular disorder characterized by the defect or absence of a normal gene in the ocular cells of a human or animal subject involves administering to the subject by subretinal injection an effective amount of a recombinant adeno-associated virus carrying a nucleic acid sequence encoding the normal gene under the control of a promoter sequence which expresses the product of the gene in the ocular cells. The ocular cells are preferably retinal pigment epithelial (RPE) cells, and the gene is preferably an RPE-specific gene, e.g., RPE65. The promoter is one that can express the gene product in the RPE cells. Compositions for subretinal administration are useful in this method.

Relevant Text

Claims

1. A method for treating a human subject having Leber Congenital Amaurosis, the method comprising: administering to said human subject by subretinal injection a recombinant adeno-associated virus (rAAV) vector comprising a nucleic acid sequence encoding a normal retinal pigment specific epithelial 65 (RPE65) gene operably linked to a chicken beta actin promoter/CMV enhancer, wherein said rAAV vector is administered in a dosage of from 1×10^{9} to 2×10^{12} rAAV vector in a volume of at least 150 microliters, thereby restoring visual function in said human subject.

12. A method for treating a human subject having a mutation in the retinal pigment specific epithelial 65 (RPE65) gene, said method comprising: administering to said human subject by subretinal injection a pharmaceutical composition comprising a physiologically acceptable vehicle and a recombinant adeno-associated virus (rAAV) vector having a nucleic acid sequence encoding a normal RPE65 gene operably linked to a chicken beta actin promoter/CMV enhancer, wherein said rAAV vector is administered at a dosage in the range of 1×10^{9} infectious units to 2×10^{12} infectious units at a volume of at least 150 microliters, and wherein said mutation in the RPE65 gene results in an ocular disease or disorder in said human subject and wherein administration of said pharmaceutical composition to said human subject results in an improvement to said human subject's visual function.

15. A method for treating a human subject having an ocular disease or disorder resulting from a mutation in the retinal pigment specific epithelial 65 (RPE65) gene, said method comprising: administering to said human subject by subretinal injection a pharmaceutical composition comprising a physiologically acceptable vehicle and recombinant adeno-associated virus (rAAV) vector having a nucleic acid sequence encoding a normal RPE65 gene operably linked to a chicken beta actin promoter/CMV enhancer, said pharmaceutical composition having a volume of at least 150 microliters and said rAAV vector being present in said pharmaceutical composition in an amount of about 1.5×10^{11} infectious units; wherein administration of said pharmaceutical composition results in an improvement in said human subject's visual function.

16. A method for treating a human subject having Leber Congenital Amaurosis, the method comprising: administering to said human subject by subretinal injection a recombinant adeno-associated virus (rAAV) vector comprising a nucleic acid sequence encoding a normal retinal pigment specific epithelial 65 (RPE65) gene operably linked to a chicken beta actin promoter/CMV enhancer, wherein said rAAV vector is administered in a dosage of from 1×10^{9} to 2×10^{12} rAAV vector in a volume of at least 150 microliters, thereby improving said human subject's visual function.

Description

In one aspect, the invention provides a method for treating an ocular disorder in a human or animal subject characterized by the defect or absence of a normal gene in the ocular cells. The method includes administering to the subject by subretinal injection an effective amount of a recombinant adeno-associated virus carrying a nucleic acid sequence encoding the normal gene under the control of a promoter sequence which expresses the product of the gene in the ocular cells.In another aspect, the invention provides a method for treating an ocular disorder in a human or animal subject characterized by the defect or absence of a normal gene in the retinal pigment epithelial (RPE) cells of the subject. The method involves administering to the subject by subretinal injection an effective amount of a recombinant virus carrying a nucleic acid sequence encoding a normal retinal pigment epithelial (RPE) cell-specific gene under the control of a promoter sequence which expresses the product of the gene in RPE cells. In one embodiment, the gene is the RPE65 gene.

In another aspect, the invention provides a method for treating Leber congenital amaurosis in a subject by administering to the subject by subretinal injection an effective amount of a recombinant virus carrying a nucleic acid sequence encoding a normal gene under the control of a promoter sequence which expresses the product of the gene in ocular cells, wherein the cells contain a mutated version of the gene. Expression of the normal gene provides to the cells the product necessary to restore or maintain vision in the subject. In one embodiment, the cells are RPE or photoreceptor cells, and the promoters are cell-specific promoters. In still another embodiment, the invention provides a composition for treatment of an ocular disorder characterized by the defect or absence of a normal gene in the ocular cells of the subject. Such compositions comprise effective amounts of a recombinant adeno-associated virus carrying a nucleic acid sequence encoding the normal gene under the control of a promoter sequence which expresses the product of the gene in the ocular cells, formulated with a carrier and additional components suitable for subretinal injection. In one embodiment, the normal gene is RPE65.Other aspects and advantages of the present invention are described further in the following detailed description of the preferred embodiments thereof. The invention provides a method for treating an ocular disorder in a human, other mammalian or other animal subject. In particular, the ocular disorder is one which involves a mutated or absent gene in a retinal pigment epithelial cell or a photoreceptor cell. The method of this invention comprises the step of administering to the subject by subretinal injection an effective amount of a recombinant virus carrying a nucleic acid sequence encoding an ocular cell-specific normal gene operably linked to, or under the control of, a promoter sequence which directs the expression of the product of the gene in the ocular cells and replaces the lack of expression or incorrect expression of the mutated or absent gene.

4.6.3 Queries (Table 4)

	Queries	Database	No. of Hits
1.	((((GENE+ 2d THERAP+) p ((RETINA+) 2d (DYSTROPH+ or DEGENERAT+))))/TI/AB/CLMS/DESC/ODES/TX AND (("AAV2" or (ADENO+ 2d ASSOCIATED 2d VIRUS+)))/TI/AB/CLMS/DESC/ODES/TX AND ((RETINAL 2d PIGMENT 2d EPITHELIUM) or ("RPE"))/TI/AB/CLMS/DESC/ODES/TX)	ORBIT	370/2623
2.	(((((GENE+ 2D THERAP+) P ((RETINA+) 2D (DYSTROPH+ OR DEGENERAT+)))))/TI/AB/CLMS/DESC/ODES/TX AND (("AAV2" OR (ADENO+ 2D ASSOCIATED 2D VIRUS+)))/TI/AB/CLMS/DESC/ODES/TX AND ((RETINAL 2D PIGMENT 2D EPITHELIUM) OR ("RPE"))/TI/AB/CLMS/DESC/ODES/TX AND	ORBIT	98/835

	(("KOZAK" 2D (SEQUENCE OR CONSENSUS)))/TI/AB/CLMS/TX/DESC/ODES)		
3.	(((((GENE+ 2D THERAP+) P ((RETINA+) 2D (DYSTROPH+ OR DEGENERAT+)))))/TI/AB/CLMS/DESC/ODES/TX AND (("AAV2" OR (ADENO+ 2D ASSOCIATED 2D VIRUS+)))/TI/AB/CLMS/DESC/ODES/TX AND ((RETINAL 2D PIGMENT 2D EPITHELIUM) OR ("RPE"))/TI/AB/CLMS/DESC/ODES/TX AND (("KOZAK" 2D (SEQUENCE OR CONSENSUS)))/TI/AB/CLMS/DESC/ODES/TX AND (((HUMAN 2D EMBRYONIC 2D KIDNEY 2D CELLS 2D "293") OR ("HEK" OR "HEK293")))/TI/AB/CLMS/DESC/ODES/TX)	ORBIT	67/635

4.6.4 Queries of the NPL (Table 5)

S. no.	Queries	Database
1	(“gene therapy”) AND ((“AAV2”) OR (“Adeno associated virus”)) AND ((“retinopathy”) OR (“retinal dystrophy”) OR (“retinal degeneration”)) AND ((“RPE65” OR (“Retinal pigment epithelium”))	GOOGLE, GOOGLE SCHOLAR, IEEE EXPLORE, SCIENCE DIRECT
2	(“gene therapy”) AND ((“AAV2”) OR (“Adeno associated virus”)) AND ((“retinopathy”) OR (“retinal dystrophy”) OR (“retinal degeneration”)) AND (“RPE65”) AND ("HEK293") AND ("Kozak")	GOOGLE, GOOGLE SCHOLAR, IEEE EXPLORE, SCIENCE DIRECT

4.6.5 Top Assignees (Table 6)

Top Assignees
INSERM - INSTITUT NATIONAL DE LA SANTE & DE LA RECHERCHE MEDICALE
UNIVERSITY OF PENNSYLVANIA
UNIVERSITY OF FLORIDA
UNIVERSITY OF FLORIDA RESEARCH FOUNDATION
UNIVERSITY OF CALIFORNIA
CNRS - CENTRE NATIONAL DE LA RECHERCHE SCIENTIFIQUE

4.6.6 Top IPC classifications (Table 7)

Classification	Definition
A61K-048/00	Medicinal preparations containing genetic material which is inserted into cells of the living body to treat genetic diseases; Gene therapy
A61P-027/02	Drug disorders of the senses; Ophthalmic agents
C12N-015/86	Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; Use of hosts therefor (mutants or genetically engineered microorganisms; Viral vectors
A61K-035/76	Medicinal preparations containing materials or reaction products thereof with undetermined constitution Viruses; Subviral particles; Bacteriophages
A61K-038/17	Medicinal preparations containing peptides from animals; from humans (enzyme inhibitors A61K38/005)
A61K-031/7088	Medicinal preparations containing organic active ingredients; Compounds having three or more nucleosides or nucleotides
C12N-015/113	Mutation or genetic engineering; DNA or RNA concerning genetic engineering, vectors, e.g. plasmids, or their isolation, preparation or purification; Use of hosts therefor (mutants or genetically engineered microorganisms; Non-coding nucleic acids modulating the expression of genes, e.g. antisense oligonucleotides; Antisense DNA or RNA; Triplex- forming oligonucleotides; Catalytic nucleic acids, e.g. ribozymes; Nucleic acids used in co-suppression or gene silencing
C07K-014/47	Peptides having more than 20 amino acids; Gastrin; Somatostatins; Melanotropins; Derivatives; thereof from mammals

4.6.7 Keywords (Table 8)

AAV2	**consensus**	**expression**	**modify**	**retinal**
adeno	cultured	eye	mutation	retinopathy
administer	degeneration	gene	pigment	RPE
advancement	development	genetic	progression	RPE cDNA
associated	directly	grown	progressive	RPE65
blind	disease	HEK	protein	sequence
blindness	dystrophy	HEK293	purified	straight
cDNA	encoded	inject	released	therapy
cell	encrypted	Kozak	retina	viral
clean	epithelium	modified	retina	virus

CHAPTER 5

PRACTICAL APPLICATION

- A patent gives the designer the alternative of preventing somebody else from assembling, duplicating, selling or bringing in the patented merchandise without consent of the patent holder.
- The patent bearer is having exclusive business rights to utilize the invention.
- The patent bearer can easily make use of invention for his/her own motivation.
- The patent bearer older can permit the patent to others for use that is Licensing of the patent which generates revenue by royalties from the users.
- The patent holder has a right to sell the patent any value they accept to be reasonable.
- The patent gives assurance to a foreordained period of twenty years keeping your rivals under control.
- Patents are in part answerable for headways in clinical science, biotechnology, sedate science, PCs and so forth.
- A patent motivates the inventor with a form of incentive and thus, helps to keep the flame of innovation alive causing greater and better revelations.

CHAPTER 6

CONCLUSION

In the wake of completing the training, I was acknowledged with the significance of the patents inside the mechanical world. Piles of cash are spent by the associations for intellectual property. It's the sole procedure that is used to shield the benefits of the people's property. To instigate a patent, you need a powerful arrangement that should be novel, non-evident and useful in the industries inside the lifetime of the creator. The inventor receives the security over the cases that are included inside the patent. The date models are crucial for the examination and analysis of patents since its adjustments depends upon the type or kind of search. For patentability search I will in general provide the licenses and NPL until date. In separation I will in general give patents and NPL required for the need or viable documenting date of subject patent. If there should arisean occurrence of encroachment, the item is provided, that are presented inside the market once the need or successful documenting date of parent patent. Patents may likewise operate if the client requests it.

In the training I got the knowledge of most recent advancements in the field of biological sciences and also got to cross-collaborate with other terms of marketing and open database artificial intelligence projects. I was able to get insights on nit only biotechnology projects but also projects related to biochemistry, mechanical sciences, biomedical engineering and nanobiotechnology.

REFERENCES

1. Worldwide.espacenet.com, '*espacenet'*, 2022. [online] Available at: <https://worldwide.espacenet.com/> [Accessed 30 May 2022].
2. Whitman, K., '*Intellogist: An online community dedicated to comparing major patent search systems'*, 2022.
3. Static.orbit.com, '*Tutorials and User guides'*, 2022. [online] Available at: <https://static.orbit.com/orbit/help/1.9.8/en/Documents/tutorialsanduserguides.htm> [Accessed 30 May 2022].
4. Patents.google.com, '*Google Patents'*, 2022. [online] Available at: <https://patents.google.com/> [Accessed 30 May 2022].
5. Wipo.int, 2022. [online] Available at: <https://www.wipo.int/edocs/pubdocs/en/patents/434/wipo_pub_l434_11.pdf> [Accessed 30 May 2022].
6. Patents.google.com, '*Google Patents'*, 2022. [online] Available at: <https://patents.google.com/patent/US9433688B2> [Accessed 30 May 2022].