

RESEARCH METHODOLOGY & INTELLECTUAL PROPERTY RIGHTS

Course Code: **21RMI56**

Module-3

Text book referred: Dipankar Deb, Rajeeb Dey, Valentina E. Balas “Engineering Research Methodology”, ISSN 1868-4394 ISSN 1868-4408 (electronic), Intelligent Systems Reference Library, ISBN 978-981-13-2946-3 ISBN 978-981-13-2947-0 (eBook), <https://doi.org/10.1007/978-981-13-2947-0>

Other references: Internet; Chatgpt and Bard, <https://www.wipo.int/patents/en/#:~:text=In%20principle%2C%20the%20patent%20owner,without%20the%20patent%20owner's%20consent,https://ipindia.gov.in/writereaddata/Portal/ev/sections-index.html>

Building Intellectual Property Rights, Law of Patents, Fundamentals of Patent Law - Evolution of the patent system, Patentability Requirements; Patentable Subject matter; Industrial Applicability/Utility; Novelty; Anticipation by publication; Anticipation by public knowledge and public use; Anticipation by public display; Anticipation by sale; Inventive Step/Non-Obviousness; Novelty Assessment; Inventive Step Assessment; Specification, Drafting of A Patent Specification - Introduction Patent Specification; Provisional Specification Complete Specification, Parts of the complete specification; Patent Procedure in India - PATENT PROCEDURE; Registration and Renewal fee payment; Patent Infringement -Infringement of a patent; Literal Infringement; Equivalence Infringement; Indirect Infringement; Defenses - Experiment - Research or Education - Bolar Exemption- Government use- Patent Exhaustion Patent Misuse- Inequitable Conduct - Remedies- Injunction- Account of profits- Costs; International Patent Regimes - International Instruments; Paris Convention; TRIPS AGREEMENT; PCT; BUDAPEST TREATY, Patenting Biotechnology Inventions - Unique nature of Biotechnology; Patentability Requirements and Biotechnology Inventions; Patentable Subject Matter- USA- Europe- India; Patentability of Software Inventions - Patentability of Software Inventions in USA; Patentability of software inventions in Europe; Patentability of Software Inventions in India

Building Intellectual Property Rights

Researchers should be aware of intellectual property rights created during research work. This helps develop the maker's mindset. Researchers are required to have basic knowledge of patent law.

Intellectual property (IP) is the term used to refer to non-commercial assets derived from human intelligence, creativity and imagination, but often intangible. A

patent is a special right granted to an invention that is a product or method, usually providing a new way of doing something or a new solution to a problem for that matter.

In order to obtain a patent, the information regarding the invention must be disclosed to the public in the patent application.

The major types of IP are:

1. **Trademarks:** A trademark is a sign that suitably differentiates the owner's goods or services from those of others.

2. **Patents:** A patent is a legal document that gives its owner the exclusive right to manufacture a product or manufacture it in any form in a limited area and for a limited period of time, preventing interested parties from producing, using or selling a product. present invention. Theoretically, applicants (or inventors) can create patent applications, but in practice, patent attorneys and researchers work together to write those applications, providing procedures and complex procedures.

3. **Industrial Designs:** Design protection relates to some specific beautiful images related to products whose work the owner may want to protect.

4. **Copyright:** Copyright is a right vested in the owner or creator of the publication and distribution of text, music, images or other works. Copyright also applies to content such as software, data files and related information.

Copyright does not always require registration with a government agency. The rest of the intellectual property must be approved and registered by government agencies in order to be recognized and managed.

Examples:

Trademarks:

- Brand names: Apple, Nike, Coca-Cola
- Product names: iPhone, Air Jordan, Coke
- Company logos: Golden Arches (McDonald's), Nike swoosh, Apple logo
- Slogans: Just Do It (Nike), Think Different (Apple), I'm Lovin' It (McDonald's)

Patents:

- New inventions: The light bulb, the telephone, the computer
- New processes: The manufacturing process for a new drug, the method for creating a new type of solar cell
- New designs: The design of a new car, the design of a new computer chip

Industrial designs:

- The shape of a product: The shape of a Coca-Cola bottle, the shape of a Samsung Galaxy phone
- The pattern on a product: The pattern on a Tiffany & Co. necklace, the pattern on a Nike sneaker

- The color scheme of a product: The color scheme of a Target store, the color scheme of a Starbucks coffee cup

Copyrights:

- Literary works: Books, poems, scripts, musical pieces
- Artistic works: Paintings, sculptures, photographs, movies
- Software programs: Computer software, video games
- Technical works: Engineering drawings, architectural plans

Law of Patents

The law of patents refers to the legal framework that governs the protection and enforcement of intellectual property rights for inventions. Patents are exclusive rights granted by a government to inventors, allowing them to exclude others from making, using, selling, or importing their patented inventions for a specified period of time. This exclusivity is provided in exchange for the public disclosure of the invention's details, which contributes to the advancement of technology and knowledge.

Key aspects of patent law include:

1. **Eligibility Criteria:** Not all inventions are eligible for patent protection. Generally, an invention must be novel, non-obvious, and useful to qualify for a patent. It should also fall within the scope of patentable subject matter, which typically includes new and useful processes, machines, manufactures, or compositions of matter.
2. **Application Process:** To obtain a patent, an inventor must file a patent application with the relevant government patent office. This application includes a detailed description of the invention, often accompanied by drawings or diagrams. The application is examined by patent examiners to determine whether it meets the patentability criteria.
3. **Granting of Patents:** If the patent office determines that the invention meets the necessary criteria, a patent is granted. This means that the inventor gains exclusive rights to the invention for a specific period, typically around 20 years from the filing date of the patent application.
4. **Enforcement:** Patents provide the owner with the legal right to prevent others from using, making, selling, or importing the patented invention without permission. If someone infringes on a patent owner's rights, the patent owner can take legal action to seek remedies, such as injunctions and damages.
5. **Licensing and Transfer:** Patent owners can license their patents to others, allowing them to use the invention under certain terms and conditions. Patents can also be sold or transferred to other parties, providing the new owner with the rights to enforce the patent.
6. **International Protection:** While patents are typically granted by individual countries, international agreements like the Patent Cooperation Treaty (PCT) facilitate a unified application process across multiple countries. The World Intellectual Property Organization (WIPO) also plays a significant role in harmonizing patent practices globally.

7. **Challenges and Litigation:** Patent disputes can arise if there are questions about the validity of a patent, or if someone believes that their invention is not infringing on a patented invention. Patent litigation involves legal proceedings to resolve these disputes.
8. **Patent Infringement:** Patent infringement occurs when someone uses, manufactures, sells or imports a patented invention without permission. Patent owners can take legal action against infringers to protect their rights.

Fundamentals of Patent Law - Evolution of the patent system

Intellectual property (IP) rights are governed by national laws that comply with the Agreement on Trade in Intellectual Property Rights (TRIPS Agreement)¹ for members of the World Trade Organization (WTO). The TRIPS Agreement defines the purpose of intellectual property in Article 7

. Amended Article 7: Protection and enforcement of intellectual property rights will lead to the development, transfer and dissemination of technology and the promotion of the interests of technology producers and users. Knowledge of health and well-being benefits and equality of rights and obligations.

Challenges India faces under the TRIPS Agreement. The TRIPS Agreement is an international agreement that sets minimum standards for the protection of intellectual property rights. India is a member of the World Trade Organization (WTO), which means it must abide by the TRIPS agreement.

However, India faces some difficulties in implementing the TRIPS agreement as its law does not explicitly recognize intellectual property rights. On the other hand, the constitution in the United States recognized the progress and advancement of science and art, and made special provisions for writers and inventors.

Constitution of India does not explicitly recognize intellectual property rights but guarantees intellectual property rights.

This means that patents are considered "property" and therefore protected by the Constitution. However, the constitution also contains a section on the application of state law, which, although not valid, is an important guide for the government. These principles include improving public health, reducing inequalities, and enabling processes to ensure good ownership and control of resources.

These principles can be considered as limitations of intellectual property rights and can be used to justify laws that limit intellectual property right to public health or well-being. In India, for example, there is a licensing law that allows the government to issue licenses to manufacture patented drugs without the patent owner's consent if necessary to protect public health testing.

The history of the Indian patent system reflects three distinct periods: the colonial period, the post-independence period, and the globalization period.

Colonization. India got its patent from the time of British rule. Following the end of British colonial rule in India, the Indian Patents and Designs Act of 1911 came into effect and established a patent management system in India with the establishment of an administrative office with the Director General of Patents and Designs.

after independence.

India adopted its first constitution in 1950. The Constitution was designed to tackle the problem of creating two committees to make recommendations: the Bakshi Tekchand Committee in 1949 and then Judge Rajagopal Ayyangar. The recommendations of these two groups led to major changes in patent law in response to India's unique economic situation. Some of the major changes relate to food and drug patents, licensing requirements and other requirements. Enacted in 1970, the law was recognized as promoting various industries, including the pharmaceutical industry, which gave India the title of 'Pharmaceutical Center of the World' within two decades as Indian pharmaceutical companies began exporting cheap drugs to many countries. people.

globalization. It renounced Indian trade in 1991 and adhered to the General Agreement on Tariffs and Trade (GATT 1947), which was later implemented by the World Trade Organization and changed accordingly to the TRIPS agreement. These reforms brought significant changes in India allowing product patents for food, pharmaceuticals and agrochemicals. The changes to the TRIPS agreement seek to strike the balance: not forcing the closure of existing trade, but to gradually adjust for reforms. Chemical and pharmaceutical patent laws, patentability and other aspects of change have been repeatedly tested in court and found to be contained in law during the implementation of the TRIPS agreement.

The Supreme Court's decision in *Novartis v. Union of India* affirmed the need to limit the "always renewal" of patents, while also recognizing the need to provide patent protection for increased innovation. Following *Novartis*, Indian courts have also issued interim orders to protect patent holders' rights in the manufacture of pharmaceuticals and agrochemicals. ¹⁰ The Court has also protected the exemplary patent (SEP) claims by issuing an interim injunction in order to ensure that the right holders can benefit even during the trial. Courts have granted permanent injunction and compensation (amount) in patent infringement cases, and also rejected interim injunctions in appropriate cases.

Each case is considered under certain circumstances based on established law. The current review of the decision shows that there is no bias in favor of or against the patent owner in the patent lawsuit decision.

Note: *Novartis v. Union of India*

Novartis v. The Union of India is an important decision of the Supreme Court of India regarding the patentability of medicines.

The document relates to *Novartis'* patent application for the β -crystal form of imatinib mesylate, the active ingredient of the antiviral drug Gleevec.

Novartis argued that the β -crystal form of imatinib mesylate is a new invention and is patentable under Indian patent law. However, the Indian Patent Office rejected the patent application, arguing that the beta form of imatinib mesylate is not a new invention because it is just a new form of a known product.

Novartis appealed the Indian Patent Office's decision to the Intellectual Property Appeals Board (IPAB), which overturned the Patent Office's decision. The IPAB determined that the beta form of imatinib mesylate is a new invention but cannot be patented because it has no better treatment than the known form of imatinib mesylate.

Novartis appealed the IPAB's decision in the Supreme Court of India. The High Court upheld the IPAB's decision that the β -crystal form of imatinib mesylate cannot be patented under Section 3(d) of the Indian Patent Act. Section 3(d) of the Patent Law states that a new form of a known product cannot be patented unless it "improves performance" over the known product.

Novartis v. The Indian Association is a major victory for public health advocates who argue that patenting incremental changes in medicine can hinder innovation and make essential medicines worthless.

The decision also set an important precedent for the interpretation of Section 3(d) of the Indian Patent Law; this could also have implications for future pharmaceutical patent applications.

This case also highlights the conflict between the need to protect intellectual property and the need to access affordable medicine. The Supreme Court recognized the need for patent protection for further innovation, but also ruled that patenting such innovations should not interfere with the public purpose of processing important medical values.

Novartis v. The Indian Union is an important and important issue that has had a great impact on the Indian patent system and the international drug patent debate.

This case is a reminder of the need to protect intellectual property and balance conflicting public health interests when making policy decisions.

Patentability Requirements

The patentability requirements are the criteria that an invention must meet in order to be eligible for patent protection. These requirements vary slightly from one jurisdiction to another but generally include the following key criteria:

Novelty: An invention must be new and not part of the prior art. This means that the invention cannot have been publicly disclosed, published, or known anywhere in the world before the filing date of the patent application.

Non-Obviousness (Inventive Step): An invention must involve an inventive step or non-obviousness. This means that the invention should not be an obvious development from existing knowledge to a person skilled in the relevant field. If the invention would have been obvious to someone with ordinary skill in the field, it is not considered patentable.

Utility or Industrial Applicability: An invention must have a practical and specific utility. It should serve a useful purpose and be capable of being made or used in some kind of industry.

Enablement (Sufficiency of Disclosure): The patent application must contain sufficient information to allow a person skilled in the relevant field to understand and replicate the invention. The description should provide enough detail for someone to make and use the invention without undue experimentation.

Subject Matter Eligibility: The invention must fall within the scope of patentable subject matter. Most jurisdictions allow for the patenting of processes, machines, manufactures, and compositions of matter. Some jurisdictions have restrictions on abstract ideas, laws of nature, and natural phenomena.

Non-Disclosure: In some jurisdictions, a patent application can be rejected if the invention has been publicly disclosed more than a certain period before the filing date. This is known as the "novelty grace period," during which inventors are allowed to disclose their own invention without jeopardizing its novelty.

No Excluded Categories: Some inventions are explicitly excluded from patent protection, such as mathematical formulas, mental processes, and methods of doing business that lack a technical aspect.

Written Description and Claims: The patent application should include a written description of the invention that is clear, concise, and detailed. The claims section defines the scope of the invention for which patent protection is sought. The claims must be clear and supported by the description.

First-to-File Rule: In many jurisdictions, including the United States, the first person to file a patent application for a given invention is granted the patent, regardless of who first invented it. This emphasizes the importance of prompt filing to secure patent rights.

Patentable Subject Matter

Patentable subject matter refers to the types of inventions or creations that are eligible for patent protection. Not all inventions are considered suitable for patenting, and the criteria for patentable subject matter can vary between jurisdictions. Generally, patentable subject matter includes:

Processes: New and useful methods, techniques, or processes for performing a particular task or achieving a specific result. This category often covers manufacturing processes, industrial methods, and technical procedures.

Machines: Novel and functional devices or apparatuses that perform a specific function or task. This category encompasses a wide range of mechanical and electronic inventions.

Manufactures: Physical objects that are made by humans and have a specific utility. This category includes products, devices, and compositions of matter.

Compositions of Matter: Novel chemical compounds, compositions, or mixtures with specific properties or applications. This includes pharmaceutical compounds, chemical compositions, and new materials.

Articles of Manufacture: Physical objects that are designed or fabricated to perform a particular function or purpose. This category may include products with innovative designs or specific functional features.

Machines and Apparatuses: Mechanical and electronic devices that perform specific tasks or functions. This category encompasses a wide range of technological innovations, from complex machines to simple tools.

Software and Computer-Implemented Inventions: In some jurisdictions, software-related inventions can be patentable if they involve a technical solution to a technical problem. This can include algorithms, software processes, and computer systems that provide a novel and non-obvious technical solution.

Biotechnological Inventions: Inventions related to living organisms, genetic sequences, genetically modified organisms, and methods for manipulating biological materials.

It's important to note that not all countries have the same approach to patentable subject matter. Some jurisdictions, like the United States, have relatively broad criteria for patentable subject matter, allowing for patents on methods, software, and business processes. Other jurisdictions, like some European countries, have stricter requirements and may limit patentability to inventions with a technical character or technical effect.

Additionally, certain subject matter is often excluded from patent protection, regardless of jurisdiction. This can include abstract ideas, laws of nature, natural phenomena, mathematical formulas, and methods of doing business that lack a technical aspect.

Industrial Applicability/Utility in Patents:

Requirement for Patentability: Industrial applicability is one of the key patentability criteria that an invention must meet to be eligible for patent protection. It ensures that the invention has a practical use and can be applied in some form of industry or commerce.

Real-World Application: An invention must demonstrate that it serves a useful purpose and provides a tangible benefit. It should be capable of being manufactured, produced, used, or applied in a way that offers value to society, the economy, or a specific industry.

Preventing Overly Abstract or Theoretical Inventions: The requirement for industrial applicability prevents the patenting of mere abstract ideas, theories, or speculative concepts that lack practical application. It emphasizes the importance of inventions that contribute to technological progress and the advancement of various industries.

Clear and Specific Utility: The utility requirement demands more than just a theoretical or potential use. The invention's utility should be specific, well-defined, and capable of being verified by those skilled in the relevant field.

Examples of Industrial Applicability:

- A new chemical compound that can be used as a drug to treat a specific medical condition.
- A novel manufacturing process that increases efficiency in producing a particular product.
- An innovative software algorithm that improves data processing in a specific application.
- A new type of material with unique properties that can be used in construction or electronics.

Exclusions and Limitations: Some inventions might not be patentable due to lack of industrial applicability. For example, laws of nature, abstract ideas, mental processes, and discoveries are typically excluded from patent protection because they lack practical application.

Balancing Innovation and Public Benefit: The requirement for industrial applicability serves to strike a balance between rewarding inventors with exclusive rights and ensuring that the granted patents contribute to technological advancement and economic growth.

Scope of Protection: The patent's claims define the scope of protection granted to the inventor. The claims should clearly describe the invention's practical application and the specific aspects that are considered inventive.

It's important to note that the concept of industrial applicability may vary between different countries and legal systems. Some jurisdictions may have specific guidelines or case law that further define what constitutes industrial applicability. Additionally, the requirements for utility in other types of intellectual property, such as trademarks and copyrights, are distinct from the utility requirement in patents.

Novelty in patent

[https://www.hkindia.com/news_letter/article/1/Patent%20artile-1.html#:~:text=The%20concept%20of%20novelty%20in%20patent%20law%20embodies%20the%20principle,known%20techniques%2C%20and%20marketed%20products.]

1. Novelty in Patent Law:

Imagine you have a fantastic idea for something new that nobody else has thought of. In patent law, we call this "novelty." It means your idea should be different from anything that's already out there—like things people have written about, known ways of doing things, and stuff that's already being sold.

When you want to protect your idea with a patent, it has to be new and not something people already know about. This rule ensures that only really new and unique things get special legal protection.

2. What's Already Known:

Before you apply for a patent, your idea must not have been made public. That means nobody should have seen it, read about it, or used it before. It should be your own discovery, something that you found out and others haven't.

3. The Patent Monopoly:

When you get a patent, it's like getting a special key that lets you control your new idea for a while. This is like a trade-off—you share your invention's details with the world, and in return, you get the exclusive right to use and profit from it.

4. What's New in India:

In India, for something to be a "new invention," it shouldn't have been made public anywhere before you applied for the patent. It shouldn't be known in India or anywhere else in the world. It should be fresh and not part of what's already known as "the state of art."

5. No Copies from Other Patents:

If someone else tried to patent the same thing before you, that won't count against your invention's novelty. You still have a chance as long as you can show your invention's different from theirs.

6. What Makes an Invention Special:

Just making small changes or mixing known things won't work. Your invention needs to do something new, give new results, or create a better product than before. It should involve real creativity and not just putting things together.

7. Obviousness:

If your invention is just an easy, common-sense idea that anyone could come up with, it's not enough. Your invention needs to be more than just the natural next step—it should be inventive and not something anyone would expect.

8. Keeping Secrets:

Before you apply for a patent, don't tell everyone about your idea. If you do, it might not be considered new anymore, and you could lose your chance to get a patent.

9. Anticipation and Lack of Novelty:

If people already knew about your invention before you applied for a patent, it's called "anticipation." If your invention lacks novelty, it means it's not new anymore.

Anticipation by publication

As per Section 29: Anticipation by previous publication under Chapter 4: Anticipation of the THE PATENTS ACT, 1970:

These are in the case of an invention claimed in a complete specification

(1) Protection for Old Specifications: If someone claims to have invented something and they describe it in a document (like a patent application) filed in India before January 1, 1912, we won't say that someone else's invention is not new just because it's described in that old document. (2) Protection for Self-Disclosure or Unauthorized Publication: If someone says they came up with something and then their description of it gets published without their permission, they can still get a patent if they can prove a few things:

- They or the person they got the idea from didn't want that description published.
- If they found out about the publication before applying for the patent, they applied for the patent as soon as they reasonably could.
- However, if the invention was already being used or sold in India before they applied for the patent (except for just trying it out), then this protection doesn't apply.

(3) Priority for the Real Inventor: If a person who actually invented something or got the idea from them wants to patent it, they can do so even if someone else tried to patent the same thing earlier or used it without their permission later. This is to make sure that the real inventor gets the priority, and they're not prevented from getting a patent just because someone else tried to mess with their rights.

Anticipation by public knowledge and public use after provisional specification

As per Section 23: Anticipation by previous publication under Chapter 4: Anticipation of the THE PATENTS ACT, 1970:

1. Protection for Earlier Filings:

When someone submits a complete description of their invention (we call it a "complete specification") as part of a patent application, there's a rule that can help them. If they initially submitted a simpler description (called a "provisional specification") before, and later on, they provide the complete details, they get special protection.

This rule says that just because some aspects of their invention were used or talked about by others in India or anywhere else after they submitted the provisional specification but before the complete one, the authorities can't reject their patent application or take away their granted patent.

2. Convention Application Protection:

Sometimes, people apply for patents not just in one country but in multiple countries at once. If someone applies for a patent in India based on an application they filed in another country (we call it a "convention application"), they also get special protection. This rule means that even if some parts of their invention were used or shared with others in India or anywhere else after they filed the application in that other country but before their Indian application, it won't stop them from getting a patent or losing the one they got.

In simpler words, these rules make sure that if someone initially shared some information about their invention with others before they completed their patent application, it won't ruin their chances of getting or keeping a patent. This helps

inventors who need time to fully explain their ideas and still keeps their patent rights safe. Remember, when dealing with legal matters, it's always a good idea to consult a legal expert to understand the details clearly.

Anticipation by public display

An invention claimed in a complete specification shall not be deemed to have been anticipated by reason only of

1. Protection for Exhibitions:

Sometimes, inventors want to show off their inventions at big shows or exhibitions, like trade fairs. This law says that just because they've shown their invention to the public at such an event, it doesn't mean their invention isn't new anymore.

2. Permission and Display:

If the true inventor or someone who got the idea from them gives permission to show the invention at an exhibition, it won't count against their patent rights. This means the inventor can still get a patent for the invention even if it was shown to people at the exhibition.

3. Publication from Exhibitions:

Sometimes, when an invention is displayed at an exhibition, people might write about it or describe it in publications. This rule says that even if this happens, it won't stop the inventor from getting a patent.

4. Unapproved Use During Exhibition:

If someone uses the invention without permission while it's being displayed at an exhibition, it's not a problem for the inventor's patent rights as long as they apply for a patent within twelve months after the exhibition starts.

5. Inventor's Presentations:

If the inventor talks about their invention in front of a learned group or society, or if they let someone publish information about it, it won't hurt their chances of getting a patent if they apply within twelve months after the presentation or publication.

In simple terms, this rule ensures that if inventors showcase their creations at exhibitions, give presentations, or let others write about their inventions, they still have a chance to protect their invention with a patent as long as they apply within a year. This gives inventors time to show off their ideas without losing their patent rights. Always remember to consult a legal expert for detailed understanding in legal matters.

Anticipation by public working

1. Protection for Public Testing:

Sometimes, inventors or people who want to get a patent for an invention need to test it out to make sure it works properly. This rule says that even if they test their invention publicly in India within one year before they formally apply for the patent, it won't stop them from getting the patent.

2. Testing by Inventor or Others:

If the person who wants the patent or someone connected to them tests the invention publicly, or if someone else does it with their permission, it's okay as long as it's done for a reasonable trial.

3. Consent and Reasonable Trial:

If the inventor or someone they're associated with, like the person they got the idea from, lets others try out the invention publicly for testing, it's fine as long as it's done for a good reason. This reason should be related to the nature of the invention and it should make sense to do the testing in public.

In simpler terms, this rule makes sure that inventors can test their inventions in public within a year before applying for a patent without ruining their chances of getting the patent. The testing should be reasonable and necessary for understanding how well the invention works. Just remember, it's always a good idea to talk to a legal expert for a clear understanding of legal matters.

Anticipation by sale

In the context of patents, "anticipation by sale" refers to a situation where an invention has been publicly sold or made available to the public before a patent application is filed. This concept is important for determining the novelty of an invention and its eligibility for patent protection. In the Indian patent law context, anticipation by sale means that if an invention has been sold or made available to the public in India before the filing date of a patent application, it could affect the novelty of the invention and potentially prevent the invention from being granted a patent.

In simpler terms:

- If an invention has been sold or made available to the public in India before someone applies for a patent, it might not be considered new anymore.
- This could impact the inventor's ability to get a patent for the invention because patents are usually granted for new and unique ideas.

Inventive step/non-obviousness

"Inventive step" or "non-obviousness" is a key criterion in patent law, including the Indian context. It refers to the requirement that for an invention to be eligible for patent protection, it should not be obvious to a person skilled in the relevant field of technology. In simpler terms, the invention should not be something that someone with average knowledge and skills in that field would easily come up with.

In the Indian jurisdiction, the term "inventive step" is used, and it's defined under Section 2(1)(ja) of the Indian Patents Act, 1970. It states that an invention is considered to involve an inventive step if it's not obvious to a person skilled in the art, having regard to prior art (existing knowledge or technology) at the time of filing the patent application.

It involves:

Prior Art: This refers to existing knowledge, technologies, or solutions that are publicly available before the date of your patent application. It's like all the information that's already out there in your field.

Inventive Step: To have an inventive step means that your invention is more than just a small, logical improvement over what's already known (prior art). It should be something that's not obvious to someone who's knowledgeable and skilled in that area of technology.

Not Obvious to Skilled Person: This means that if someone who's an expert in that field wouldn't naturally and easily think of your invention based on what's already known, then your invention has an inventive step.

Encouraging Real Innovation: The idea behind this requirement is to encourage real innovation. Patents are given to new and creative ideas that push the boundaries, not just small tweaks that anyone could easily figure out.

Novelty Assessment

In the context of Indian Intellectual Property Rights (IPR), specifically patents, the assessment of novelty is a critical step in determining whether an invention is eligible for patent protection. Novelty refers to the requirement that the invention must be new and not part of the existing knowledge or prior art before the date of filing the patent application. The Indian Patents Act, 1970, outlines the criteria for assessing novelty under Section 2(1)(i) and Section 13 of the Act.

Following are the steps taken to assess novelty in the Indian IPR context:

1. **Comparison with Prior Art:** Before granting a patent, the patent office examines whether the invention is already known or disclosed in any form of prior art. Prior art includes everything that was publicly available before the filing date of the patent application, such as existing patents, scientific publications, public knowledge, and publicly accessible databases.
2. **Evaluation of Claims:** The patent office reviews the claims made in the patent application, which are specific descriptions of what the invention is and how it works. These claims are compared with the existing knowledge to determine if any identical or similar inventions have been disclosed previously.
3. **Novelty Criterion:** For an invention to be considered novel, it must not have been anticipated by any prior art. This means that the invention should not be

already known, used, published, or described in any form anywhere in the world before the date of filing the patent application.

4. **Global Assessment:** The novelty assessment is not limited to just India. It considers prior art from all over the world. If an invention is already disclosed or used in any country, it may affect its novelty even if it's not publicly known in India.
5. **Grace Period:** The Indian Patents Act provides a grace period of one year prior to the filing date of the application. This means that if the inventor or someone else disclosed the invention within one year before filing the application, it won't be considered as destroying the novelty of the invention.
6. **Inventive Step and Novelty:** The assessment of novelty is closely related to the concept of "inventive step" or "non-obviousness," which was explained in the previous response. An invention must not only be new but also involve an inventive step to qualify for a patent.

Inventive Step Assessment

The concept of inventive step focuses on whether the invention involves a non-obvious advancement over existing knowledge in the field. This assessment prevents the granting of patents for trivial modifications or obvious developments.

Here's how the assessment of inventive step works in the Indian IPR context:

1. **Comparison with Existing Knowledge (Prior Art):** The patent office compares the invention's claims with the existing knowledge in the relevant field before the filing date of the patent application. This existing knowledge is known as "prior art," which includes publicly available information like patents, publications, and common knowledge.
2. **Non-Obviousness Requirement:** An invention must exhibit an "inventive step," which means it must not be something that a skilled person in the field would have considered obvious to create based on the prior art. In other words, the invention should involve a level of creativity and innovation that goes beyond the expected.
3. **Person Skilled in the Art:** The assessment takes into account what a person skilled in the relevant field would know and do. If the skilled person would easily come up with the invention using their regular skills and knowledge, then the invention lacks an inventive step.
4. **Combination of Prior Art:** The patent office also evaluates whether combining multiple pieces of prior art could lead to the invention. If the invention is a simple combination of known elements, it might lack the required inventive step.
5. **Unexpected Results:** If the invention produces results that are surprising or unexpected based on the prior art, it's more likely to exhibit an inventive step.

6. **Innovation Beyond Obvious Modifications:** The assessment aims to ensure that patents are granted for innovations that genuinely push the boundaries of knowledge and involve more than just obvious modifications or incremental improvements.
7. **Objective and Subjective Criteria:** The assessment involves both an objective analysis of whether the invention's features were already suggested in the prior art and a subjective analysis of whether a skilled person would have found the invention obvious.

Specification

"specification" refers to a detailed written description of an invention that an applicant submits as part of a patent application. The specification is a critical document that explains what the invention is, how it works, and how it's different from existing technology. It plays a central role in determining the scope and validity of a patent.

Following are the contents of specifications:

1. **Detailed Description:** The specification provides a comprehensive explanation of the invention, including its technical details, components, features, and how it operates. It should be clear and complete, enabling someone skilled in the relevant field to understand and reproduce the invention.
2. **Claims:** Within the specification, there's a section called "claims." Claims are specific statements that define the boundaries of the invention and what the applicant seeks to protect with the patent. They outline the unique aspects of the invention that are new and inventive.
3. **Importance of Clarity:** Clarity and precision are crucial in drafting the specification and claims. Vague or unclear descriptions can lead to ambiguity in the scope of the patent, potentially causing legal disputes.
4. **Determining Patent Scope:** The claims in the specification determine the scope of the patent. The rights granted by the patent will apply to what is described in the claims. Anything outside the scope of the claims may not be protected.
5. **Prior Art Search:** During the patent examination process, the patent office compares the specification and claims with existing knowledge (prior art) to assess novelty and inventive step.
6. **Enablement Requirement:** The specification must enable a person skilled in the relevant field to practice the invention based solely on the information provided. In other words, it should be detailed enough to allow someone to actually make and use the invention without undue experimentation.
7. **Importance for Legal Protection:** The specification is not just a technical document; it's a legal document that defines the invention's boundaries. It's used in patent disputes and litigation to determine whether someone else's product or technology infringes on the patented invention.

8. **Completeness:** The specification should be complete and accurate, describing the invention in sufficient detail to fully capture its unique features and advantages.

Provisional specification

A provisional specification, in the context of patent law, is an initial and preliminary document that provides a basic description of an invention that an applicant intends to patent. It serves as a temporary placeholder that outlines the invention's main features and characteristics. The primary purpose of a provisional specification is to establish a priority date for the invention while giving the applicant additional time to further develop and refine the invention before submitting a complete specification.

Key points about a provisional specification:

1. **Basic Description:** A provisional specification contains a concise and basic description of the invention. It highlights the invention's essential features and concepts without going into extensive technical details.
2. **Priority Date:** By filing a provisional specification, the applicant secures a priority date, which is the date that will be considered for assessing novelty and inventive step in the future. This can be crucial when determining whether the invention is new compared to existing technology.
3. **Temporary Placeholder:** The provisional specification doesn't need to include all the intricate technical details of the invention. It's meant to provide an initial overview, allowing inventors to file quickly while having more time to work on the invention's complete details.
4. **Time Window:** Once a provisional specification is filed, the applicant has a time window (usually twelve months) to submit a complete specification. This allows inventors to refine the invention, conduct further research, and gather additional information to create a comprehensive and detailed complete specification.
5. **Conversion to Complete Specification:** The provisional specification can be converted into a complete specification by adding more detailed information about the invention, including technical drawings, explanations, and claims. The complete specification forms the basis for evaluating the patent application.
6. **Flexibility:** A provisional specification provides flexibility to inventors, allowing them to establish a priority date and secure their invention's place in the patent queue while having the chance to gather more information before finalizing the patent application.

As per the IPR law for the provisional specification:

Provisional Specification:

1. **Filing Complete Specification must be done within 12 Months:**

- If you file an application for a patent along with a provisional specification (a preliminary document outlining your invention), you have to submit a complete specification within twelve months from the application filing date.
- If you don't file the complete specification within this time frame, your application will be considered abandoned. In other words, it won't move forward for further consideration.

2. Combined Patent for Similar Inventions:

- If you, as the same applicant, file multiple patent applications with provisional specifications for related inventions, and the inventions are closely related or one is a modification of another, the Controller (the patent office) can allow you to file just one complete specification for all those provisional specifications.
- This helps if the related inventions together can be considered as a single larger invention.

3. Counting Time from Earliest Provisional Specification:

- The time limit of twelve months (as mentioned in the first point) starts from the date of filing of the earliest provisional specification among the related applications.

Complete specification

It is a comprehensive and detailed document that provides a full and thorough description of an invention. It includes all the technical details, components, functionalities, and specific aspects of the invention that an applicant seeks to protect with a patent. A complete specification is a crucial part of a patent application, as it defines the scope of the invention and outlines the boundaries within which the patent rights will be granted.

Key points about a complete specification:

1. **Comprehensive Description:** Unlike a provisional specification, which offers a basic outline of the invention, a complete specification contains in-depth technical details. It explains the invention thoroughly, including how it works, its components, and any processes or methods involved.
2. **Claims:** One of the most important parts of a complete specification is the claims section. Claims are precise statements that define what aspects of the invention the applicant seeks to protect. They outline the novel and inventive features that distinguish the invention from existing technologies.
3. **Novelty and Inventive Step:** The complete specification must demonstrate how the invention is different from prior art (existing knowledge) and how it involves an inventive step or non-obvious advancement in the relevant field.
4. **Enablement Requirement:** The specification should be detailed enough to enable a person skilled in the relevant field to understand and reproduce the invention without undue experimentation. This ensures that the invention's details are clear and comprehensive.

5. **Best Method:** The complete specification must also disclose the best method known to the applicant for performing the invention. This ensures that the patent office and the public have access to the most effective way to implement the invention.
6. **Abstract:** A complete specification includes an abstract, which is a summary of the invention. The abstract provides a brief overview of what the invention is and its key features.
7. **Single Invention or Group of Inventions:** The claims in a complete specification relate to a single invention or a group of inventions that are linked and share a single inventive concept.
8. **Legal Protection Basis:** The claims in the complete specification define the scope of the invention for which the applicant is seeking patent protection. Any technology or product that falls within the defined scope may be protected by the patent rights.

The deadlines for submitting complete specifications, the possibility of combining related inventions under one patent, and the flexibility to treat a complete specification as provisional under certain circumstances are as follows:

1. Filing Application with Complete Specification:

- If you submit an application for a patent and include a specification that seems complete (contains all the details about your invention), the Controller (patent office) may consider it as a provisional specification if you request this within twelve months from the application filing date.
- Treating it as provisional means you'll have more time to refine and finalize your invention details before it's fully considered for a patent.

2. Canceling Provisional Specification and Post-Dating:

- If you initially filed with a provisional specification and later submitted a complete specification, you can ask the Controller to cancel the provisional specification.
- This can help if your invention evolved significantly between the provisional and complete stages.
- You can also request to post-date your application to the date you filed the complete specification.

Patent Procedure in India

The patent procedure in India involves several steps that an inventor or applicant must follow to secure patent protection for their invention. Here's an overview of the patent procedure in India:

1. **Preparation of Invention:** The process begins with conceptualizing and developing an invention. It's crucial to thoroughly understand the invention's technical details and unique features before proceeding.

2. **Prior Art Search:** Before filing a patent application, it's advisable to conduct a prior art search to ensure that the invention is novel and not already patented or published.
3. **Drafting Provisional Specification:** If the invention is in a relatively early stage of development, the applicant can file a provisional specification. This provides a basic description of the invention and establishes a priority date.
4. **Filing Patent Application:** The formal patent application is filed with the Indian Patent Office. It includes a complete specification that thoroughly describes the invention, including technical details, drawings, claims, and other necessary information.
5. **Examination Request:** After filing the application, the applicant can choose to file a request for examination. The patent office will not automatically examine the application unless a request is made.
6. **Publication:** Once the application is in order and accepted, it is published in the official patent journal. This publication provides public notice of the invention.
7. **Examination:** If a request for examination was filed, the patent office examines the application for compliance with patent laws, including novelty, inventive step, and industrial applicability. The patent office may issue examination reports, and the applicant needs to address any objections or provide clarifications.
8. **Amendments and Responses:** The applicant can amend the application or respond to the examination report within the stipulated time frame to overcome objections raised by the patent office.
9. **Grant or Refusal:** If the patent office is satisfied with the application's compliance with patent laws, the patent is granted. If not, the application may be refused. In case of a refusal, the applicant can appeal the decision.
10. **Post-Grant Opposition:** After the grant, third parties have a window to file oppositions against the granted patent if they believe it doesn't meet patentability criteria.
11. **Term and Renewals:** A patent is typically granted for a specific term (usually 20 years from the filing date). Annual renewal fees must be paid to keep the patent in force.

Registration and Renewal fee payment [<https://ipindia.gov.in/form-and-fees.htm>]

In India, the registration and renewal of patents involve fees that applicants and patent holders need to pay to the Indian Patent Office to secure and maintain their patent rights. An overview of the registration and renewal fee payment process for patents in India:

Registration Fees:

1. **Filing Fee:** The filing fee is the initial fee paid at the time of submitting the patent application. The fee varies depending on factors such as the applicant's category (individual, small entity, or other), the type of application (physical or e-filing), and the number of claims. Different fee structures apply for individuals, small entities, and other entities.
2. **Examination Request Fee:** If an applicant chooses to request an examination of their patent application, a separate fee must be paid. This fee is payable after the application is filed and before the patent office initiates the examination process.
3. **Additional Claims Fee:** If the patent application contains more than ten claims, an additional fee is applicable for each claim beyond the tenth one.
4. **Request for Expedited Examination:** If an applicant wishes to expedite the examination process, an additional fee can be paid to request expedited examination.

Renewal Fees: After a patent is granted, the patent holder (applicant/owner) needs to pay renewal fees to maintain the patent's validity over its term. These fees are paid annually, starting from the third year after the patent's grant date. The renewal fees increase with each subsequent year until the patent's term expires.

Renewal fee rates are different for individual inventors, small entities, and other entities. In general, renewal fees are higher for entities other than individual inventors and small entities.

It's important to note that renewal fees must be paid on time; failure to pay them can result in the patent's expiration and loss of patent rights. If the patent holder misses the payment deadline, there's usually a grace period during which the fees can be paid with a late fee.

Renewal fees are paid annually and progressively increase as the patent ages. It's crucial to keep track of the due dates for renewal fee payments and to budget for these fees over the patent's lifespan.

The specific fee amounts, payment methods, and deadlines can change over time due to updates in patent regulations

Infringement of a patent

In the context of patent law, infringement refers to the unauthorized use, making, selling, or importing of a patented invention by someone other than the patent holder. There are different types of patent infringement, including literal infringement, equivalence infringement, and indirect infringement. Let's break down each type:

1. Literal Infringement:

Literal infringement occurs when someone directly uses the patented invention without any modifications or variations that might change the core features described in the patent claims. In other words, if someone copies the exact elements and

characteristics of the patented invention as described in the patent claims, it can be considered literal infringement.

Example: If a patented device has specific components and functions, and another party makes, uses, or sells an identical device with the same components and functions, it might be a case of literal infringement.

2. Equivalence Infringement:

Equivalence infringement refers to situations where an accused product or process does not exactly match the language of the patent claims but performs substantially the same function in a similar way and achieves similar results. In other words, it's about determining whether a variation is equivalent to the claimed invention.

This type of infringement accounts for minor modifications that do not change the essential functionality or purpose of the invention. Courts analyze factors like the overall function, differences in structure or method, and whether the variation was obvious to determine equivalence infringement.

Example: If a patented process involves heating a substance to a certain temperature and another party uses a different method to achieve the same temperature, it might be considered equivalence infringement if the overall purpose and effect are similar.

3. Indirect Infringement:

Indirect infringement occurs when a party contributes to or induces another party to infringe a patent. There are two types of indirect infringement:

Contributory Infringement: This happens when someone supplies or sells a component, material, or product that is specially designed for use in an infringing manner. To prove contributory infringement, it's necessary to establish that the supplied component is a key part of the infringing process.

Induced Infringement: This occurs when someone intentionally encourages or induces another party to infringe a patent. The inducer knows or should know that their actions will lead to infringement.

Example of Contributory Infringement: If a company sells a part that is specifically designed to be used in an infringing product, they might be held liable for contributory infringement.

Example of Induced Infringement: If someone actively encourages others to use a patented process in a way that infringes the patent, they might be held liable for induced infringement.

Defenses: Defenses in patent law are legal arguments that a defendant can present to counter claims of patent infringement. Some common defenses include:

- **Invalidity:** Challenging the validity of the patent by showing that it does not meet the criteria for novelty, inventive step, or other requirements.

- **Non-Infringement:** Asserting that the accused activity does not fall within the scope of the patent claims, meaning it does not use, make, or sell the patented invention.
- **Prior Use:** Demonstrating that the defendant was already using the invention before the patent's filing or priority date.
- **Experimental Use:** Showing that the accused activity is for research, experimentation, or educational purposes and not for commercial gain.
- **Exhaustion:** Arguing that the patent rights have been exhausted when the patented product was sold to the defendant or others in the distribution chain.

Experiment, Research, or Education: This defense allows individuals or entities to use patented inventions for experimentation, research, or educational purposes without facing infringement claims. It acknowledges the importance of advancing scientific knowledge and learning.

Bolar Exemption: The Bolar exemption allows generic drug manufacturers to perform tests and studies necessary for regulatory approvals of generic drugs before the expiration of the original drug's patent. It ensures that the regulatory process is not hindered by patent rights.

Government Use: Governments can use patented inventions without the patent holder's consent for public interest or national security reasons. However, governments are typically required to provide reasonable compensation to the patent holder.

Patent Exhaustion: The doctrine of patent exhaustion states that once a patent holder sells a patented product, they no longer have control over what the buyer does with that specific product. The buyer can use, sell, or dispose of it without infringing the patent.

Patent Misuse: Patent misuse occurs when a patent holder improperly uses their patent rights to extend control beyond what's granted by the patent. It can include practices that create an anticompetitive effect or tie unrelated products together.

Inequitable Conduct: Inequitable conduct refers to deceptive behavior by the patent applicant or holder during the patent application process. If the applicant intentionally withholds relevant information from the patent office, the patent may be rendered unenforceable.

Remedies: Remedies are legal solutions to address patent infringement and compensate the patent holder for harm caused by the infringement.

Injunction: An injunction is a court order that prohibits the infringing party from continuing the infringing activity. Injunctions can be preliminary (temporary) or permanent and can have significant impact on the infringing party's business.

Account of Profits: The account of profits remedy requires the infringing party to hand over the profits they earned from the infringing activity. This remedy aims to provide monetary compensation to the patent holder.

Costs: In a patent infringement case, the losing party may be ordered to pay the prevailing party's legal costs. This is a way to compensate the successful party for the expenses they incurred while defending their patent rights.

International Instruments

In the realm of intellectual property, several international instruments and agreements have been established to provide a framework for protecting various forms of intellectual property rights, including patents. These instruments promote harmonization of laws and procedures across different countries, facilitating global trade and innovation. Here are some key international instruments related to intellectual property and patents:

1. Paris Convention for the Protection of Industrial Property (1883)
2. Patent Cooperation Treaty (PCT) (1970)
3. World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994)
4. Berne Convention for the Protection of Literary and Artistic Works (1886)
5. Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977)
6. Nairobi Treaty on the Protection of the Olympic Symbol (1981)
7. WIPO Copyright Treaty (WCT) and WIPO Performances and Phonograms Treaty (WPPT) (1996)

Paris Convention for the Protection of Industrial Property (1883)

The Paris Convention, established in 1883, is the oldest international agreement focused on protecting intellectual property (IP) rights. It covers various aspects of industrial property, including patents, trademarks, industrial designs, and more. It was updated in 1967.

Guiding Principles:

The Convention is built on three main principles:

National Treatment: Every country that's part of the Convention must give foreign inventors and creators the same level of protection as it gives to its own citizens.

Right of Priority: If someone applies for a patent or design in one Convention country, they get a certain time period (usually 6 or 12 months) to apply for protection in other Convention countries. This way, they don't have to apply everywhere at once, making the process more flexible.

Uniform Rules: The Convention sets common rules that all member countries have to follow. For example, patents granted in different countries for the same invention are considered separate, and the person who invented the thing gets credit in the patent. Also, designs must be protected in each country, even if the products aren't made there.

Right of Priority in Detail:

Imagine you come up with a new invention, and you apply for a patent in your home country. The Paris Convention says that for a certain time after that (6 or 12 months), you can apply for patents in other countries and still be treated like you applied on the same day you applied at home. This gives you time to decide where else you want protection.

National Treatment:

This means that a person from one Convention country should be treated the same as a person from another country when it comes to IP protection. If your country is part of the Convention, you can't treat foreign inventors or creators unfairly.

Uniform Rules:

The Convention makes sure that certain things are the same across all countries that are part of it. For example, if you get a patent for your invention in one country, it's not automatically protected in another. But the Paris Convention says that's okay. It also says that trade names (business names) should be protected in every country without needing extra paperwork.

World Trade Organization (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) (1994)

The TRIPS Agreement (Trade-Related Aspects of Intellectual Property Rights) is a significant international treaty that sets out the minimum standards for the protection of various forms of intellectual property (IP) rights. It was negotiated under the auspices of the World Trade Organization (WTO) and came into effect on January 1, 1995. The TRIPS Agreement aims to strike a balance between protecting IP rights and promoting global trade and innovation. Here's an overview of the key aspects of the TRIPS Agreement:

1. **Scope and Coverage:** The TRIPS Agreement covers a wide range of intellectual property rights, including patents, trademarks, copyrights, trade secrets, geographical indications, and industrial designs. It sets out the standards for the protection and enforcement of these rights.
2. **Minimum Standards:** TRIPS establishes minimum standards that member countries must follow to protect and enforce IP rights. This ensures that all WTO member countries provide a certain level of IP protection, which promotes consistency and fair treatment for creators and innovators across different jurisdictions.
3. **National Treatment and Most-Favored-Nation Treatment:** The TRIPS Agreement requires member countries to treat foreign IP holders the same way they treat their own citizens or entities (national treatment). Additionally, member countries must provide the same level of protection to IP holders from all other member countries (most-favored-nation treatment).
4. **Patents and Pharmaceuticals:** TRIPS requires member countries to provide patent protection for inventions in all fields of technology, including pharmaceuticals. However, there was a debate about the implications of patent protection on access to affordable medicines, particularly in developing

countries. The Doha Declaration on TRIPS and Public Health reaffirmed the flexibilities available to member countries to take measures to protect public health and ensure access to essential medicines.

5. **Enforcement:** TRIPS sets out rules for the enforcement of IP rights, including civil and criminal procedures, remedies, and border measures to prevent the import and export of counterfeit or pirated goods.
6. **Transitional Periods for Developing Countries:** Developing countries were given flexibility to implement the TRIPS Agreement gradually, allowing them time to adjust their laws and systems to comply with the standards.
7. **Dispute Settlement:** The WTO's Dispute Settlement Understanding provides mechanisms for resolving disputes related to TRIPS. This ensures that member countries uphold their obligations under the Agreement.
8. **Technology Transfer:** TRIPS recognizes the importance of technology transfer between developed and developing countries to promote technological development and economic growth.
9. **Public Policy and Flexibilities:** The Agreement acknowledges the importance of striking a balance between IP protection and other public policy objectives, such as public health, nutrition, and the promotion of cultural diversity.

The TRIPS Agreement represents a significant step in international IP law, aiming to create a level playing field for intellectual property protection while addressing concerns related to access to essential goods and technology. It has played a crucial role in shaping global IP standards and fostering cooperation among WTO member countries.

Patent Cooperation Treaty (PCT) (1970)

The Patent Cooperation Treaty (PCT) is an international treaty that simplifies and streamlines the process of seeking patent protection in multiple countries. It provides a unified framework for filing a single international patent application that can be used to seek patent rights in multiple countries or regions. The PCT is administered by the World Intellectual Property Organization (WIPO) and offers several key benefits for inventors and applicants. Here's a closer look at the main features of the PCT:

1. **Unified Application Process:** With the PCT, inventors can file a single international patent application instead of filing separate applications in each country where they want protection. This reduces paperwork, administrative burden, and costs associated with filing multiple national applications.
2. **International Search:** After filing a PCT application, an international search is conducted by a recognized international search authority. This search identifies existing inventions (prior art) related to the claimed invention. The search report provides valuable information for evaluating the patentability of the invention.

3. **International Publication:** The PCT application is published by WIPO approximately 18 months from the priority date (usually the filing date). This publication makes the technical details of the invention publicly available, promoting transparency and knowledge sharing.
4. **International Preliminary Examination (Optional):** Applicants have the option to request an international preliminary examination. This is a more in-depth examination of the claimed invention's patentability. While not mandatory, it helps applicants assess the strengths and weaknesses of their application before entering the national phase.
5. **National/Regional Phase:** At the end of the PCT process, applicants choose the countries or regions where they want to pursue patent protection. This is known as the national or regional phase. Each selected country or region conducts its own examination and grants or denies the patent based on its national laws.
6. **Benefits of the PCT:**
 - **Time Flexibility:** The PCT provides an extended period (usually 30 months from the priority date) for applicants to decide where to seek patent protection, allowing them more time to assess commercial potential and secure funding.
 - **Cost Efficiency:** Filing a single PCT application is more cost-effective than filing separate national applications. This allows applicants to defer costs until they have a clearer idea of where they want protection.
 - **Improved Patent Strategy:** The international search report and preliminary examination report (if requested) provide insights into patentability, helping applicants refine their patent strategy before entering the national phase.
7. **National Laws Apply:** While the PCT simplifies the filing process, patent rights are granted and enforced based on the laws of individual countries or regions. Applicants need to meet the requirements of each country's patent office to secure patent protection.

In summary, the Patent Cooperation Treaty offers a streamlined and efficient route for inventors and applicants to seek patent protection on a global scale. It simplifies the process of filing, searching, and assessing the patentability of an invention, ultimately contributing to a more effective and strategic approach to international patent protection.

Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure (1977)

The Budapest Treaty on the International Recognition of the Deposit of Microorganisms for the Purposes of Patent Procedure, commonly known as the Budapest Treaty, is an international treaty that addresses the deposit of microorganisms for patent purposes.

It was adopted in Budapest, Hungary, in 1977 and is administered by the World Intellectual Property Organization (WIPO). The treaty aims to facilitate the patenting of inventions that involve microorganisms by providing a mechanism for the deposit and access to these microorganisms. Here's an overview of the key aspects of the Budapest Treaty:

1. **Microorganism Deposits:** Many inventions, particularly in biotechnology and genetic engineering, involve the use of microorganisms such as bacteria, yeast, and fungi. These microorganisms play a crucial role in the development and implementation of various inventions. The Budapest Treaty addresses the need to deposit these microorganisms to ensure reproducibility and proper examination of patent applications.
2. **Depositary Authorities:** The treaty establishes a network of depositary authorities, which are specialized institutions that accept and store microorganism deposits. These authorities ensure the safekeeping of the deposited microorganisms and provide access to them for examination and research purposes.
3. **Accession to the Treaty:** Countries that are members of the Budapest Treaty ("Contracting Parties") agree to adhere to its provisions and provide access to microorganism deposits in their territory. This encourages the harmonization of procedures for microorganism deposits and access across different countries.
4. **Benefits of the Budapest Treaty:**
 - **Facilitates Patenting:** The treaty provides a way to satisfy the requirement of disclosing the biological material necessary for the invention's implementation.
 - **Promotes Reproducibility:** Microorganism deposits ensure that other researchers can reproduce the invention's results and verify its accuracy.
 - **Supports Patent Examination:** Patent examiners can access deposited microorganisms to assess the validity and novelty of the invention.
 - **Saves Time and Resources:** Applicants can focus on their patent applications without the need to provide samples to patent offices or potential infringers.
5. **Designation of Deposits in Patent Applications:** Applicants who use microorganisms in their inventions can fulfill the disclosure requirement by including information about the deposited microorganisms in their patent applications. This allows patent examiners and the public to access the deposited microorganisms to confirm the accuracy of the patent application.
6. **Availability of Samples:** The treaty requires depositary authorities to furnish samples of the deposited microorganisms to anyone who requests them for research and development purposes. This promotes further innovation and collaboration in the field of biotechnology.

In summary, the Budapest Treaty addresses the challenges of patenting inventions involving microorganisms by providing a standardized and organized way to deposit and access these essential biological materials. It facilitates patent examination, supports transparency, and contributes to the advancement of biotechnological research and innovation on a global scale.

Patenting Biotechnology Inventions

Unique nature of Biotechnology

Patenting biotechnology inventions involves a unique set of challenges and considerations due to the distinctive nature of biotechnology. Biotechnology inventions often involve living organisms, genetic materials, and complex processes that have a significant impact on various industries, including medicine, agriculture, and environmental science. Here are some key aspects that highlight the unique nature of biotechnology and its implications for patenting:

1. *Living Organisms and Genetic Information*: Biotechnology inventions often relate to living organisms such as microorganisms, plants, animals, and even human cells. These inventions may involve genetic modifications, gene sequences, and genetic engineering techniques. Unlike traditional mechanical or chemical inventions, biotechnology innovations are closely tied to the genetic makeup and functioning of living organisms.
2. *Complexity and Interdisciplinarity*: Biotechnology inventions combine knowledge from various scientific fields, including biology, chemistry, genetics, and engineering. The interdisciplinary nature of biotechnology inventions makes them inherently complex and challenging to understand and assess, both for inventors and patent examiners.
3. *Ethical and Moral Considerations*: Biotechnology raises ethical and moral questions, especially when it comes to the manipulation of genetic material and the potential for unintended consequences. Patenting biotechnology inventions may involve addressing ethical concerns related to genetic modification, cloning, and potential misuse of technology.
4. *Regulatory Oversight*: Many biotechnology inventions are subject to regulatory oversight due to concerns about safety, environmental impact, and public health. Obtaining a patent does not guarantee the right to commercialize an invention without adhering to regulatory requirements.
5. *Disclosure and Enabling Requirements*: Patents require clear and complete disclosure of the invention's details to enable others skilled in the field to replicate and use the invention. In biotechnology, this can be challenging, as the intricate details of genetic sequences, molecular interactions, and cellular processes must be described accurately.
6. *Biological Materials and Deposits*: Biotechnology inventions often involve the use of biological materials, such as cell lines, microorganisms, and genetic sequences. The availability and deposit of these materials play a crucial role in ensuring the reproducibility and validity of the invention.

7. *Overlap with Other Intellectual Property:* Biotechnology inventions may also be eligible for other forms of intellectual property protection, such as plant variety protection, data exclusivity, and regulatory exclusivities in the pharmaceutical and agrochemical industries.
8. *Global Nature and Cooperation:* Biotechnology is a global field with international collaboration and knowledge sharing. Patents granted in one country can impact research and development efforts in other countries, necessitating coordination and cooperation among patent offices.

Given these unique characteristics, patenting biotechnology inventions requires careful navigation of legal, scientific, ethical, and regulatory landscapes. Inventors and applicants must work closely with patent professionals who understand the nuances of biotechnology and can effectively communicate the technical and legal aspects of the invention to patent examiners and regulatory authorities. Additionally, they must consider the broader implications of their inventions on society, ethics, and the environment.

Patentability Requirements and Biotechnology Inventions

Patentability requirements for biotechnology inventions, like all other types of inventions, are designed to ensure that the granted patents contribute to innovation, promote progress, and strike a balance between rewarding inventors and fostering public access to knowledge. However, due to the unique nature of biotechnology, there are specific considerations and challenges related to each of the patentability requirements. Here's how the standard patentability requirements apply to biotechnology inventions:

1. **Novelty:** Biotechnology inventions involve complex genetic sequences, molecular interactions, and cellular processes. To meet the novelty requirement, a biotechnology invention must be new and not previously disclosed or made available to the public. The intricacies of genetic information and molecular structures make it crucial to provide clear and comprehensive descriptions of the invention's unique features that distinguish it from prior art.
2. **Non-Obviousness (Inventive Step):** The non-obviousness requirement poses challenges for biotechnology due to the interdisciplinary nature of the field and the rapid advancement of genetic engineering techniques. Biotechnology inventions often combine knowledge from biology, genetics, chemistry, and engineering. Inventors must demonstrate that their invention involves an inventive step, meaning it is not obvious to someone skilled in the relevant field. This requires showing that the invention's innovation goes beyond conventional practices and combines elements in a non-obvious manner.
3. **Industrial Applicability:** Biotechnology inventions must have a practical and credible utility or application to be considered industrially applicable. In the context of biotechnology, this requirement is often met by demonstrating how the invention can be used for medical treatments, agricultural improvements, environmental solutions, or other practical purposes. The

application must be more than theoretical; it should show that the invention can be applied in a real-world context.

4. **Adequate Description (Enablement):** The enablement requirement necessitates that the patent application provides enough information for someone skilled in the field to replicate and use the invention without undue experimentation. In biotechnology, this can be challenging due to the complexity of genetic sequences and cellular processes. The application should include detailed descriptions of methods, materials, and experimental data that enable others to practice the invention.
5. **Best Mode:** The best mode requirement obliges inventors to disclose the best method known to them for carrying out the invention. In biotechnology, this includes disclosing the most effective techniques for modifying genetic sequences, conducting experiments, or achieving desired outcomes. Failure to disclose the best mode could lead to challenges during patent enforcement.
6. **Unity of Invention:** Unity of invention requires that a patent application covers a single invention or a group of inventions that share a single inventive concept. In biotechnology, this can apply to multiple aspects of a genetic sequence, a therapeutic method, or an industrial application. The challenge is to define the common inventive concept among related elements.

Biotechnology inventions often involve cutting-edge research and innovative applications of genetic information. To meet patentability requirements, biotechnology inventors must carefully document their work, provide comprehensive explanations, and illustrate how their inventions contribute to technical progress and practical applications. Consulting with experts in both biotechnology and patent law can help navigate the complexities and challenges of patenting in this field.

Patentable Subject Matter- USA

In the United States, the patent system grants protection to various types of inventions, provided they meet certain criteria. The patentable subject matter in the U.S. is defined by the U.S. Patent and Trademark Office (USPTO) and is outlined in Section 101 of the U.S. Patent Act. This section defines the types of inventions that are eligible for patent protection. Here's an overview of the patentable subject matter in the U.S.:

Utility Patents:

Utility patents are the most common type of patents granted in the U.S. They cover new and useful processes, machines, manufactures, or compositions of matter, or any new and useful improvements thereof. This category includes a wide range of inventions, from mechanical devices and chemical compounds to software algorithms and methods of doing business.

Plant Patents:

Plant patents are granted for distinct and new varieties of plants that have been asexually reproduced (other than by seed). This category includes plants that are unique and have not been found in nature or previously cultivated.

Design Patents:

Design patents protect the ornamental design or appearance of an article of manufacture. Unlike utility patents, design patents focus on the visual aesthetics of an object rather than its functional aspects.

Examples of patentable subject matter within each category include:

Utility Patents: Software algorithms, pharmaceutical compounds, manufacturing processes, medical devices, electronic circuits, chemical compositions, and methods of doing business (if they have a practical, tangible application).

Plant Patents: New and distinct varieties of plants that have been asexually reproduced, such as hybrid roses or fruit trees.

Design Patents: Unique and ornamental designs applied to everyday objects, such as the shape of a bottle, the design of a smartphone casing, or the pattern on a fabric.

It's important to note that not all inventions are eligible for patent protection. The U.S. patent law excludes certain subject matters from patentability, such as laws of nature, natural phenomena, abstract ideas, and purely mental processes. Additionally, inventions must meet the criteria of novelty, non-obviousness, and utility to be eligible for a patent.

In recent years, the interpretation of patentable subject matter has been subject to legal debates and court decisions. For example, determining whether software-related inventions or medical diagnostic methods are eligible for patents has been a topic of discussion. The U.S. Supreme Court case of *Alice Corp. v. CLS Bank International* (2014) clarified the standards for patent eligibility for abstract ideas implemented on a computer.

Overall, patentable subject matter in the U.S. covers a wide array of inventions, reflecting the country's commitment to encouraging innovation and technological progress across various industries.

Patentable Subject Matter- Europe

In Europe, patentable subject matter is defined by the European Patent Convention (EPC) and the interpretation of the Convention by the European Patent Office (EPO). The EPC provides guidelines on the types of inventions that are eligible for patent protection within the member states of the European Patent Organisation. Here's an overview of patentable subject matter in Europe:

1. **Technical Character:** One of the key criteria for patentability in Europe is that the invention must have a "technical character." This means that the invention must relate to a technical field of knowledge and have a technical effect. Purely abstract or non-technical ideas, mathematical methods, and

business methods are generally excluded from patent protection if they lack technical character.

2. **Novelty and Inventive Step:** Inventions must also meet the criteria of novelty and inventive step (non-obviousness) to be patentable. They must be new and involve an inventive step that is not obvious to a person skilled in the relevant technical field.
3. **Exclusions from Patentability:** The EPC lists certain subject matters that are explicitly excluded from patent protection. These include:
 - Discoveries, scientific theories, and mathematical methods.
 - Aesthetic creations, plans, rules, and methods for performing mental acts.
 - Computer programs as such (although technical applications of software can be patentable).
 - Methods of medical treatment of humans or animals.
 - Plant or animal varieties or essentially biological processes for the production of plants or animals (however, biotechnological inventions can be patented if they meet certain criteria).
4. **Biotechnological Inventions:** Biotechnological inventions are subject to specific rules and guidelines. They can be patented if they involve a technical process for producing, modifying, or using a biological material, and if the invention is new, involves an inventive step, and is capable of industrial application. Inventions related to genetic engineering, recombinant DNA technology, and specific applications of biotechnology may be patentable.
5. **Software-Related Inventions:** The patentability of software-related inventions in Europe is assessed based on their technical character and technical effects. If a software invention provides a technical solution to a technical problem, it may be patentable. However, pure software algorithms or computer programs as such are excluded from patent protection.
6. **Business Methods:** Business methods are generally not patentable in Europe if they are purely abstract or do not involve a technical character or effect. However, if a business method involves a technical solution to a technical problem, it may be eligible for patent protection.

Overall, patentable subject matter in Europe is determined by a combination of technical character, novelty, inventive step, and industrial applicability. The European Patent Office plays a crucial role in examining patent applications and ensuring that they meet the established criteria for patentability. Legal decisions and case law further shape the interpretation of patentable subject matter in the European context.

Patentable Subject Matter- India

In India, the patentable subject matter is governed by the Indian Patents Act, 1970. The Act outlines the types of inventions that are eligible for patent protection in the country. Here's an overview of the patentable subject matter in India:

1. **Novelty and Inventive Step:** To be eligible for a patent in India, an invention must be new (novel) and involve an inventive step. It should not be anticipated by prior knowledge or prior art, and it should not be obvious to a person skilled in the relevant field. The invention must contribute something new and non-obvious to the existing body of knowledge.
2. **Industrial Applicability:** The invention must be capable of industrial application, meaning it should be capable of being made or used in an industry. It should have a practical utility and a clear purpose that can be realized through its application.
3. **Exclusions from Patentability:** The Indian Patents Act excludes certain subject matters from patent protection. These include:
 - Inventions that are frivolous or contrary to well-established natural laws.
 - Inventions that would cause harm to humans, animals, or the environment.
 - Methods of agriculture or horticulture.
 - Processes for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic, or other treatment of humans or animals.
 - Computer programs as such (although technical applications of software can be patentable).
 - Traditional knowledge and biological resources obtained from Indian biodiversity.
4. **Biotechnological Inventions:** Biotechnological inventions can be patented in India if they meet the criteria of novelty, inventive step, and industrial applicability. This includes inventions related to microorganisms, recombinant DNA technology, genetically modified organisms, and other biotechnological processes. However, the Indian Patents Act prohibits the patenting of traditional knowledge and biological resources obtained from Indian biodiversity.
5. **Software-Related Inventions:** Similar to many other countries, the patentability of software-related inventions in India is determined by their technical character and technical effects. If a software invention provides a technical solution to a technical problem, it may be eligible for patent protection. However, algorithms and computer programs as such are excluded from patentability.
6. **Business Methods:** Business methods are not explicitly mentioned in the list of excluded subject matters in the Indian Patents Act. However, to be

patentable, a business method must meet the criteria of novelty, inventive step, and industrial applicability. If a business method involves a novel and non-obvious technical solution to a technical problem, it may be eligible for patent protection.

Overall, the patentable subject matter in India is defined by a combination of novelty, inventive step, industrial applicability, and exclusions from patentability. The interpretation of these criteria is shaped by legal decisions and case law in the Indian patent system.

Patentability of Software Inventions in USA

The patentability of software inventions in the United States is a nuanced and evolving area of patent law. The U.S. Patent and Trademark Office (USPTO) and the courts have developed guidelines and principles to determine whether software-related inventions are eligible for patent protection. Here's a closer look at the factors influencing the patentability of software inventions in the USA:

Statutory Basis:

The U.S. patent law is governed by 35 U.S.C. §101, which states that "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof" can be patented. Software inventions are often categorized as processes.

Alice Corp. v. CLS Bank International (2014):

The U.S. Supreme Court's Alice decision established a two-part framework, known as the Alice/Mayo test, for evaluating whether an invention is eligible for patent protection. The test helps determine if an invention claims an abstract idea or natural phenomenon without providing significantly more.

Alice/Mayo Test:

The Alice/Mayo test involves two steps:

- a. Determine whether the claims are directed to a patent-ineligible concept, such as an abstract idea, natural law, or mathematical formula.
- b. If the claims are directed to a patent-ineligible concept, assess whether the claims include an inventive concept that adds significantly more than the patent-ineligible concept, making the claims something more than just an abstract idea.

Technical Improvement and Practical Application: For software inventions to be eligible for patent protection, they must offer a technical solution to a technical problem. Demonstrating how the invention involves a practical application and provides a tangible benefit in a technical field can enhance its patentability.

Specific Implementation and Novelty: Software inventions that are tied to a specific implementation or novel technical solution are more likely to be considered

patentable. Describing how the software functions in a unique and innovative way can strengthen the case for patent eligibility.

Tangible Outcomes and Concrete Steps: When seeking patent protection for software inventions, it can be helpful to highlight how the invention produces a tangible outcome or involves concrete steps beyond just implementing an abstract concept.

Integration with Hardware: Linking software inventions to specific hardware components or physical systems can increase the likelihood of patent eligibility. The integration of software with hardware can demonstrate a technical application that goes beyond a mere abstract idea.

Dependence on Precedent and Case Law: The patentability of software inventions is often influenced by legal decisions and precedents set by court rulings. Evaluating similar patents and case law can provide insights into the likelihood of obtaining patent protection.

Expert Legal Guidance: Given the evolving nature of patent law, especially in relation to software inventions, seeking advice from experienced patent attorneys who specialize in software-related patents is crucial. They can help navigate the complex legal landscape, craft effective patent claims, and increase the chances of successful patent prosecution.

Patentability of software inventions in Europe

The patentability of software inventions in Europe is governed by the European Patent Convention (EPC) and the interpretation of the Convention by the European Patent Office (EPO). While Europe shares some common principles with the United States regarding the patentability of software, there are certain distinct factors to consider. Here's an overview of the patentability of software inventions in Europe:

Technical Character:

Similar to the U.S., software inventions in Europe must have a technical character to be eligible for patent protection. This means that the invention should involve a technical solution to a technical problem and go beyond abstract or non-technical ideas.

Aerotel/Macrossan Test:

The European Patent Office has adopted a test known as the Aerotel/Macrossan test, which is used to assess the patentability of computer-implemented inventions, including software. The test involves several steps:

- a. Identify the contribution of the invention to the known art.
- b. Determine whether the contribution has technical character.
- c. Assess whether the technical contribution is novel and inventive.

Technical Effect and Technical Contribution:

For a software invention to be patentable in Europe, it should demonstrate a technical effect or a technical contribution to a technical field. The software should solve a technical problem or improve a technical process.

Tangible Results and Interaction with Hardware:

Emphasizing the tangible results achieved by the software and its interaction with hardware components can enhance the case for patentability. Demonstrating how the software affects the operation of a computer or a technical system can be advantageous.

Programs "as such":

The EPC excludes "programs for computers" from patentability if they are considered as such. This means that pure software programs, algorithms, and mathematical methods are generally not eligible for patent protection unless they have a technical character and provide a technical solution.

Technical Steps in the Claims:

When drafting patent claims for software inventions, it's essential to include technical steps that describe the interaction with hardware or the technical problem solved. Claims that are narrowly focused on specific technical aspects are more likely to be deemed patentable.

Avoiding Business Methods and Pure Business Concepts:

Europe tends to be more cautious regarding the patentability of business methods and pure business concepts. If a software invention involves a technical solution applied to a business problem, it may have a higher chance of being considered patentable.

Expert Legal Advice:

Given the complexity and evolving nature of software patentability in Europe, consulting with experienced patent attorneys who are well-versed in European patent law is crucial. They can provide guidance on drafting patent applications that emphasize technical contributions and navigate the intricacies of patent prosecution.

Patentability of Software Inventions in India

The patentability of software inventions in India is determined by the Indian Patents Act, 1970, and its interpretation by the Indian Patent Office and the judiciary. While software inventions can be patented in India, certain criteria must be met to ensure eligibility. Here's an overview of the patentability of software inventions in India:

1. **Technical Contribution and Novelty:** To be eligible for patent protection, a software invention in India must provide a technical contribution and be novel. The invention should go beyond abstract ideas or algorithms and offer a tangible technical solution to a technical problem.
2. **Usefulness and Industrial Applicability:** The software invention must demonstrate a practical application and industrial utility. It should be capable of being used in an industry and provide a practical benefit.

3. **Computer Programs "as such":** The Indian Patents Act excludes "computer programs per se" from patentability. This means that mere computer programs or algorithms without a technical effect are not eligible for patents. However, if the software is combined with hardware elements or solves a technical problem, it may overcome this exclusion.
4. **Technical Effect and Concrete Implementation:** Emphasizing the technical effect of the software and its concrete implementation can enhance its patentability. Describing how the software interacts with hardware components or how it improves a technical process strengthens the case for patent eligibility.
5. **Non-Obviousness (Inventive Step):** A software invention must involve an inventive step, meaning it should not be obvious to a person skilled in the relevant technical field. It should provide an innovative solution that goes beyond what is already known.
6. **Section 3(k) Exclusion:** Section 3(k) of the Indian Patents Act explicitly excludes mathematical methods, business methods, computer programs "per se," and algorithms from patentability. However, software inventions that have a technical effect or technical application are not automatically excluded under this section.
7. **Drafting Patent Claims:** When drafting patent claims for software inventions in India, it's important to include technical features and specify how the software interacts with hardware or provides a technical solution. Claims that focus on specific technical aspects are more likely to be considered patentable.
8. **Practical Application and Demonstrable Outcome:** Highlighting the practical application and demonstrable outcomes of the software can strengthen its patentability. Showing how the software improves efficiency, solves a technical challenge, or enhances a technical process can support the case for patent protection.
9. **Expert Legal Guidance:** Given the complexities and evolving nature of software patentability in India, consulting with experienced patent attorneys who are well-versed in Indian patent law is essential. They can assist in drafting patent applications that align with the legal requirements and navigate the patent examination process effectively.

