VENTURE CENTER

DIY PRIMER ON PATENTS

- How Inventors can draft and file Patents on their own

11.08.2026

OBJECTIVES

- Understand what inventions are
- Essentials of Patent Law & procedures (Patentability)
- Anatomy of patent specification
- How to draft a simple patent application
- Step by step guide of patent prosecution in India
- Avoid common mistakes
- After filing a Patent?

INVENTION

An **invention** is a product or a process that provides a new way of doing something or offers a new technical solution to a problem that surpasses trivial solutions#.

Invention Vs Idea

- Idea is thought, concept, may identify or propose solution.
- Do not provide technical solution to a problem

Example

Idea: "I wish there was a pen that could translate languages."

Invention: A pen containing a microphone, processor, translation software, display, and speaker that translates spoken words in real time.

Idea: "Reduce water wastage in agriculture.“

Invention: An automated irrigation system comprising soil moisture sensors, a wireless controller, predictive irrigation software, and electronically actuated valves that irrigate only when soil moisture falls below a defined threshold.

An idea tells you what you want to achieve. An invention tells you how you achieve it

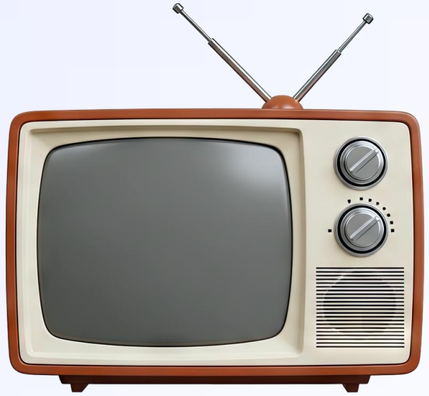
https://www.wipo.int/en/web/patents

NOMENCLATURE

- Invention: Novel solution to a problem
- “Novelty”: Standards are global and not local
- Technical invention: Technical solution to a problem
- Technical inventions that qualify for a patent: Those that the country’s/ region’s patent law allows as patentable
- Patents are enforceable only in the country/ region that issued the patent; It is a territorial property.

INVENTION

- A **new** product or process involving an **inventive step** and capable of **industrial application** *[Sec 2(1)(j)]*
- ***New(Novelty)***:New, unknown, not published ,undisclosed, not in public domain, not discussed, not used, not sold
- ***Inventive step/(non obviousness):*** Involves technical advance as compared to existing knowledge or having economic significance or both which makes it not obvious to the person skilled in the art.*[Sec 2(1)(ja)]*
- ***Industrial Application****:* Is capable of being made or used in any kind of industry.*[Sec 2(1)(ac)]*



WHAT CAN BE AN INVENTION?

Examples include:

- A medical device that reduces surgery time.
- A new pharmaceutical compound.
- Manufacturing Process or Method
- An improved agricultural machine.
- Formulations
- Machine or Apparatus (specialized hockey skates)
- Improvements in any of the above

WHAT IS NOT AN INVENTION?

(Sec. 3 & 4 patents Act, 1970)

- Invention contrary to public order /morality or which causes serious prejudice to human, animal or plant life
- Discovery of any living thing or non-living substance occurring in nature
- Substance obtained by a mere admixture (**Paracetamol(antipyretic) + Brufen(analgesic)= New drug(anti pyretic + analgesic**)
- Plants and animals in whole or any part of them other than genetically modified microorganism (new varieties)
- Method of agriculture or horticulture (***A method for improving productivity of plant by spraying a mixture of plant growth regulators***)
- Process for the medicinal, surgical, curative, diagnostic, therapeutic or other treatment of human beings and animals (***removal of cancer tumor, method of vaccination***)
- Mathematical or business method or algorithm per se
- Inventions related to atomic energy
- Literary, dramatic, artistic work, aesthetic aspects of an article (e.g. **design applied to article**)
- Inventions related to atomic energy

PATENTABILITY

Within a context or a national or multilateral body of law, an invention is patentable if it meets the relevant legal conditions to be granted a patent.

Meaning: *Can I get a patent for my invention?*

Requirements:

- Invention should be Novel (not disclosed to public)
- Invention should involve an invention step (non-obvious to the person skilled in the art)
- Invention should be useful/Utility
- Invention should be a patentable subject matter(as per statutory requirements)

PRIOR ART

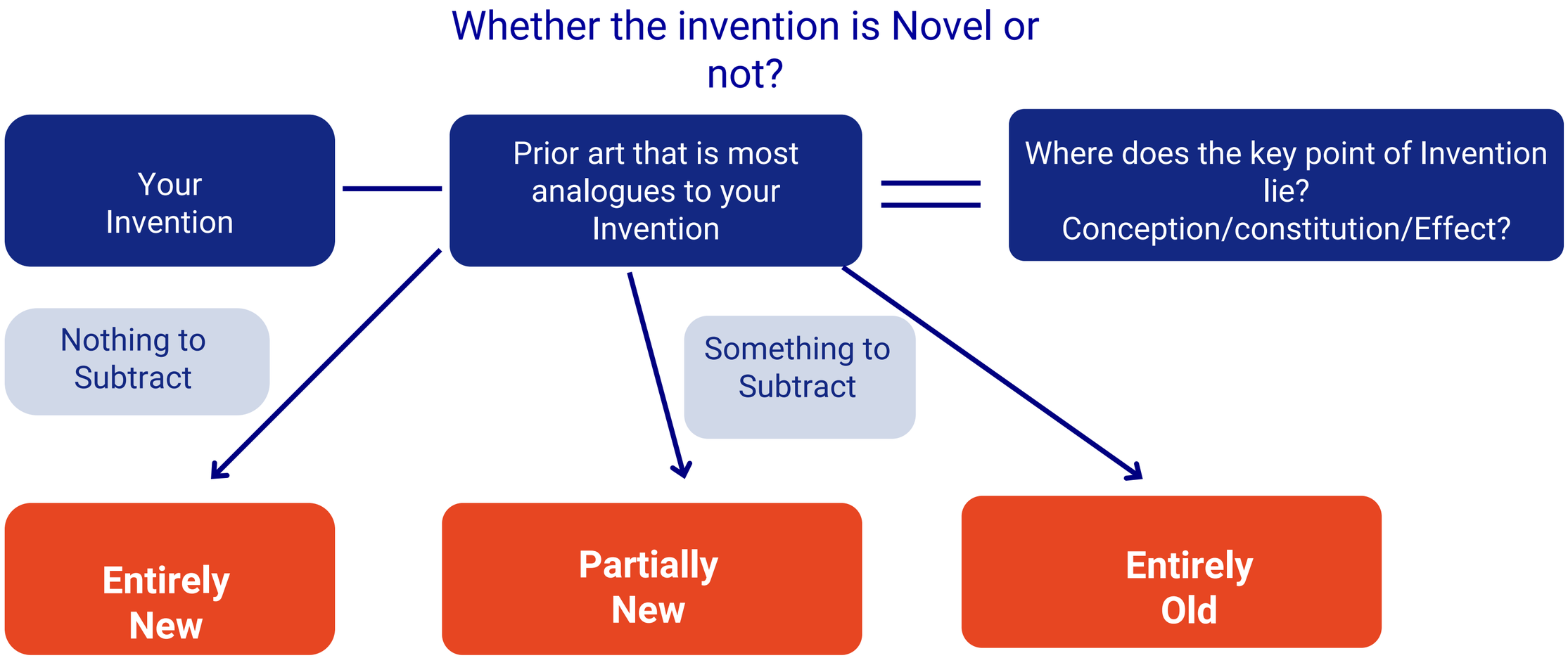
Any invention which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the date of filing of patent application, i.e. the subject matter has not fallen in public domain or that it does not form part of the state of the art#

Meaning: It can be any type of information available to the public

e. g.: Patents, technical publications, conference, papers, marketing brochures, products, devices, equipment, processes and materials

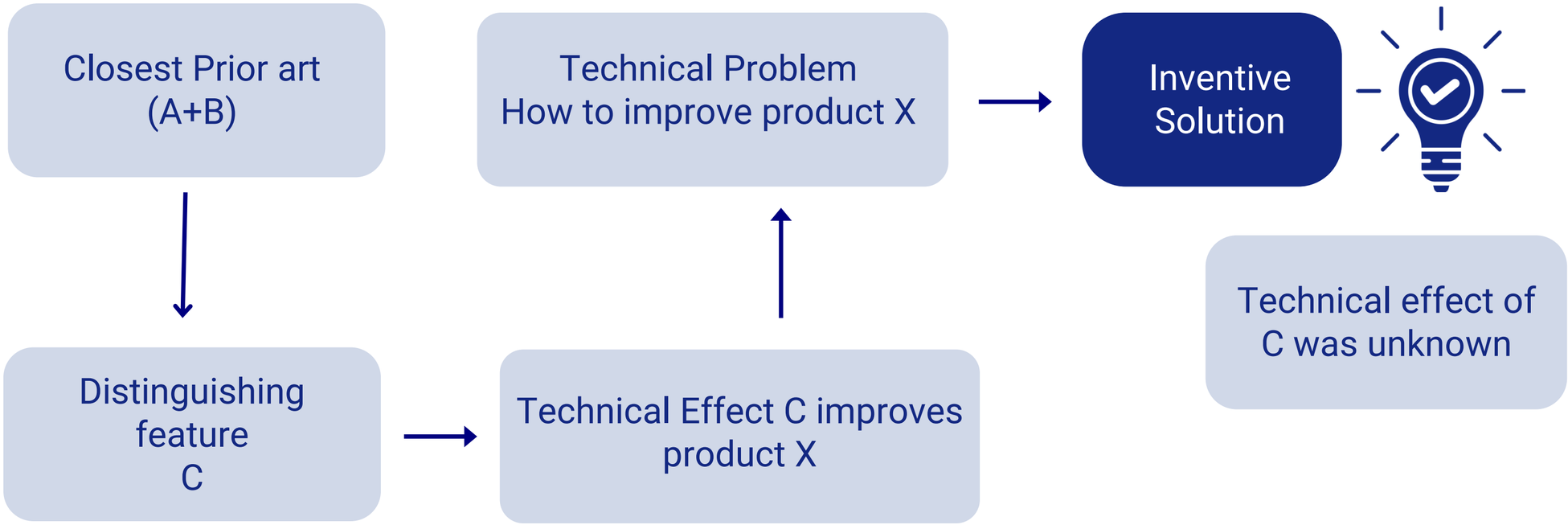
Section 2(1)(l) refers to new invention

PATENTABILITY: SUBTRACTIVE RULE



INVENTIVE STEP

- Claim of present invention states that
- Product X comprising A+B+C



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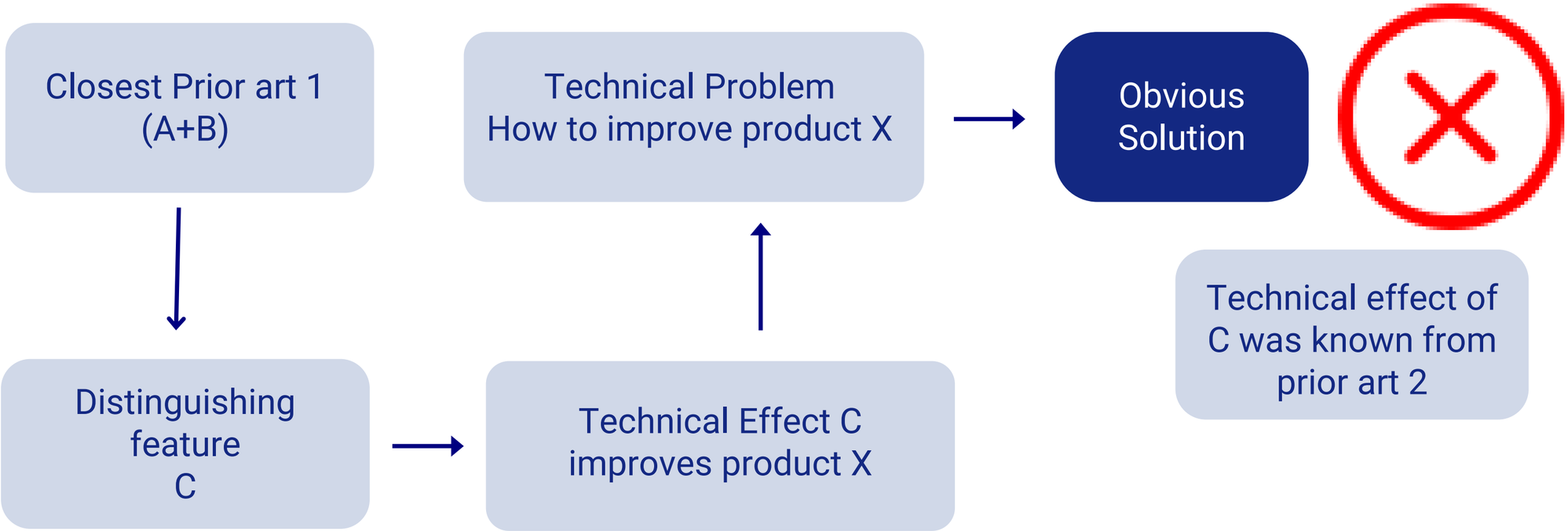
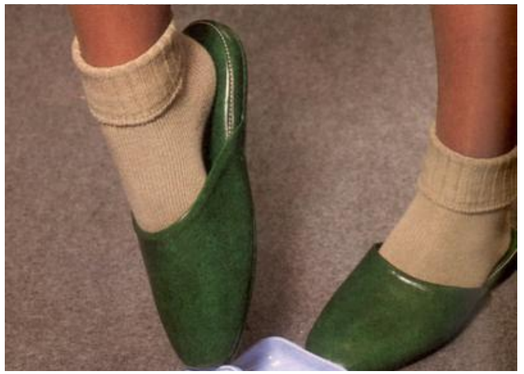


INDUSTRIAL APPLICATION

Refers to the condition that the subject matter has a useful purpose and also includes operativeness

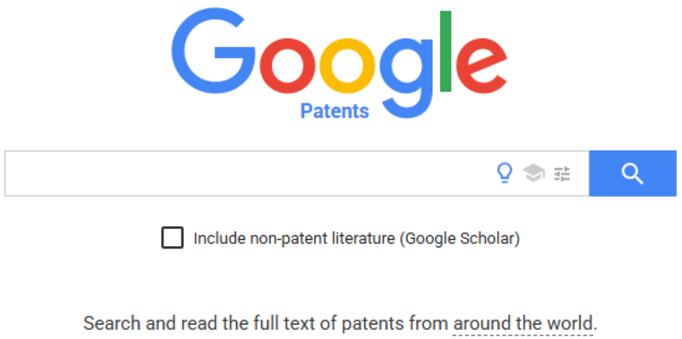
Example

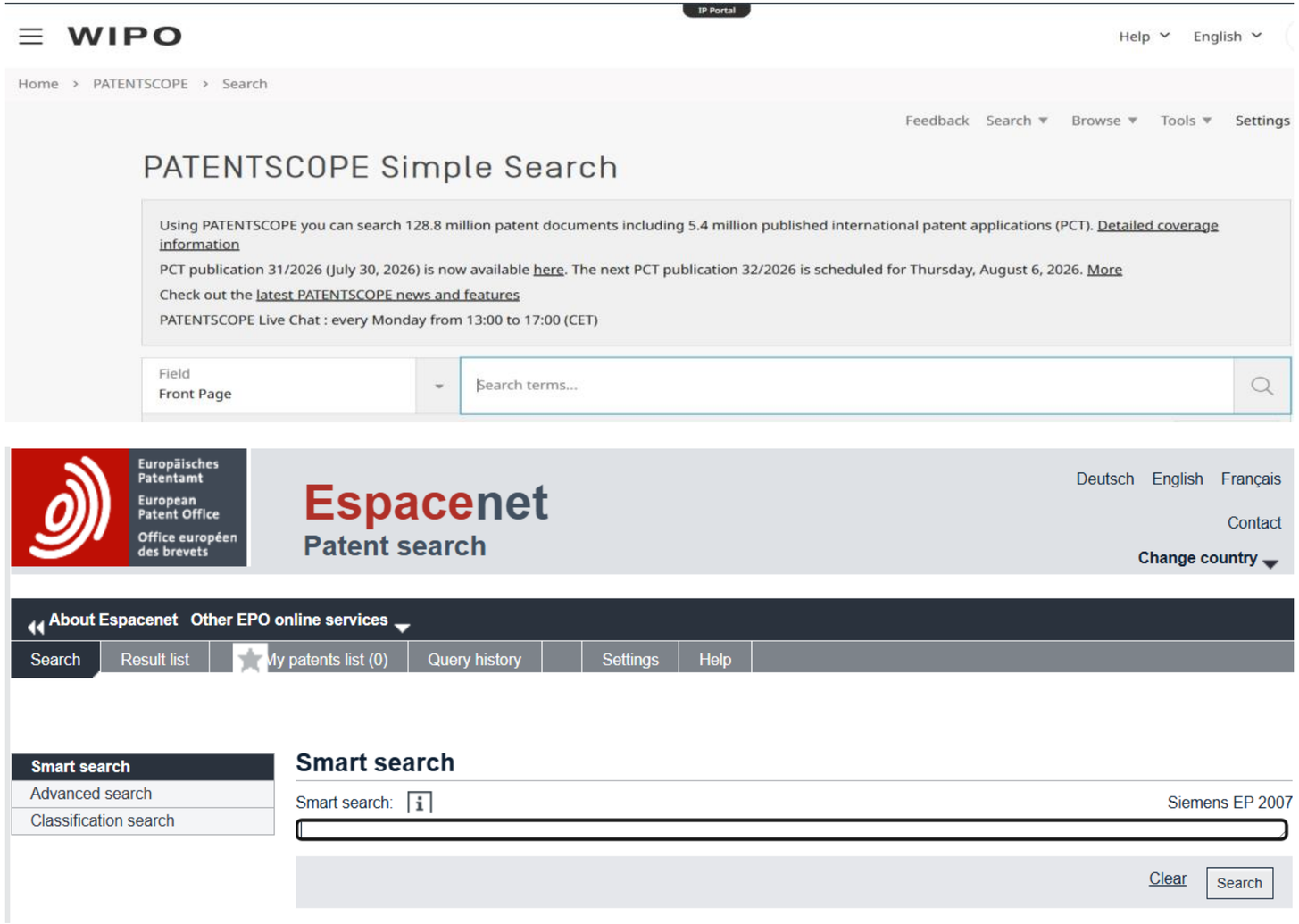
- A utensil that regulates the number of bites consumed during a specified period of time for dietary purposes.



FREE DATABASES FOR PATENT SEARCH

VENTURE CENTER

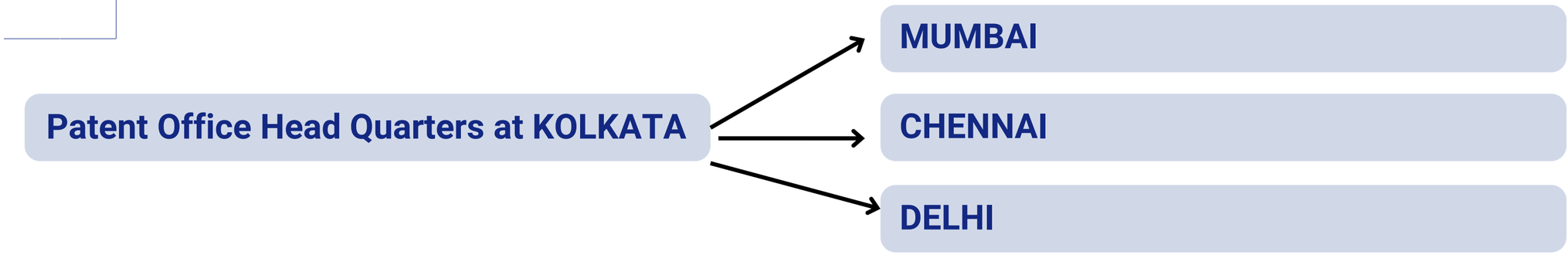




WHO CAN FILE?

- Who can make an application (Sec. 6)
- Either alone or Jointly
  - Any person claiming to be true and first inventor
  - Assignee of the person claiming to be true and first inventor
  - The legal representative of the deceased person who immediately before his death was entitled to make the application

INDIAN PATENT OFFICE



Patent Office	Territorial jurisdiction
Mumbai	Gujarat, Maharashtra, Madhya Pradesh, Goa, Chhattisgarh, Diu, Daman, Dadra & Nagar Haveli
Delhi	Haryana, Himachal Pradesh, J & K, Punjab, Rajasthan, U.P., Uttaranchal, Delhi, Chandigarh
Chennai	Andhra Pradesh, Karnataka, Kerala, Tamil Nadu, Pondicherry and Lakshadweep
Kolkata	Rest of India

HOW TO DRAFT A PATENT APPLICATION?

ANATOMY OF PATENT

(12) **United States Patent**
Kariko et al.

(10) **Patent No.: US 8,278,036 B2**
(45) **Date of Patent: Oct. 2, 2012**

(54) **RNA CONTAINING MODIFIED NUCLEOSIDES AND METHODS OF USE THEREOF**

(75) Inventors: **Katalin Kariko**, Rydal, PA (US); **Drew Weissman**, Wynnewood, PA (US)

(73) Assignee: **The Trustees of the University of Pennsylvania**, Philadelphia, PA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 276 days.

(21) Appl. No.: **11/990,646**

(22) PCT Filed: **Aug. 21, 2006**

(86) PCT No.: **PCT/US2006/032372**
§ 371 (c)(1),
(2), (4) Date: **Mar. 27, 2009**

(87) PCT Pub. No.: **WO2007/024708**
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(65) **Prior Publication Data**

US 2009/0286852 A1 Nov. 19, 2009

Related U.S. Application Data

(60) Provisional application No. 60/710,164, filed on Aug. 23, 2005.

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Patent No. US 8278036 B2
Date of Grant: Oct. 2, 2012

Title:
RNA Containing modified nucleosides and methods of use thereof

- *Not more than 15 words*
- *Suggesting the area of the invention*

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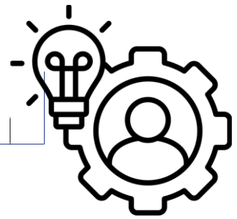
Inventors

Katalin Kariko, Rydal, PA (US);
Drew Weissman, Wynnewood, PA (US)

Katalin Karikó and Drew Weissman: 2023 Nobel Prize in Medicine For developing mRNA based COVID-19 vaccine

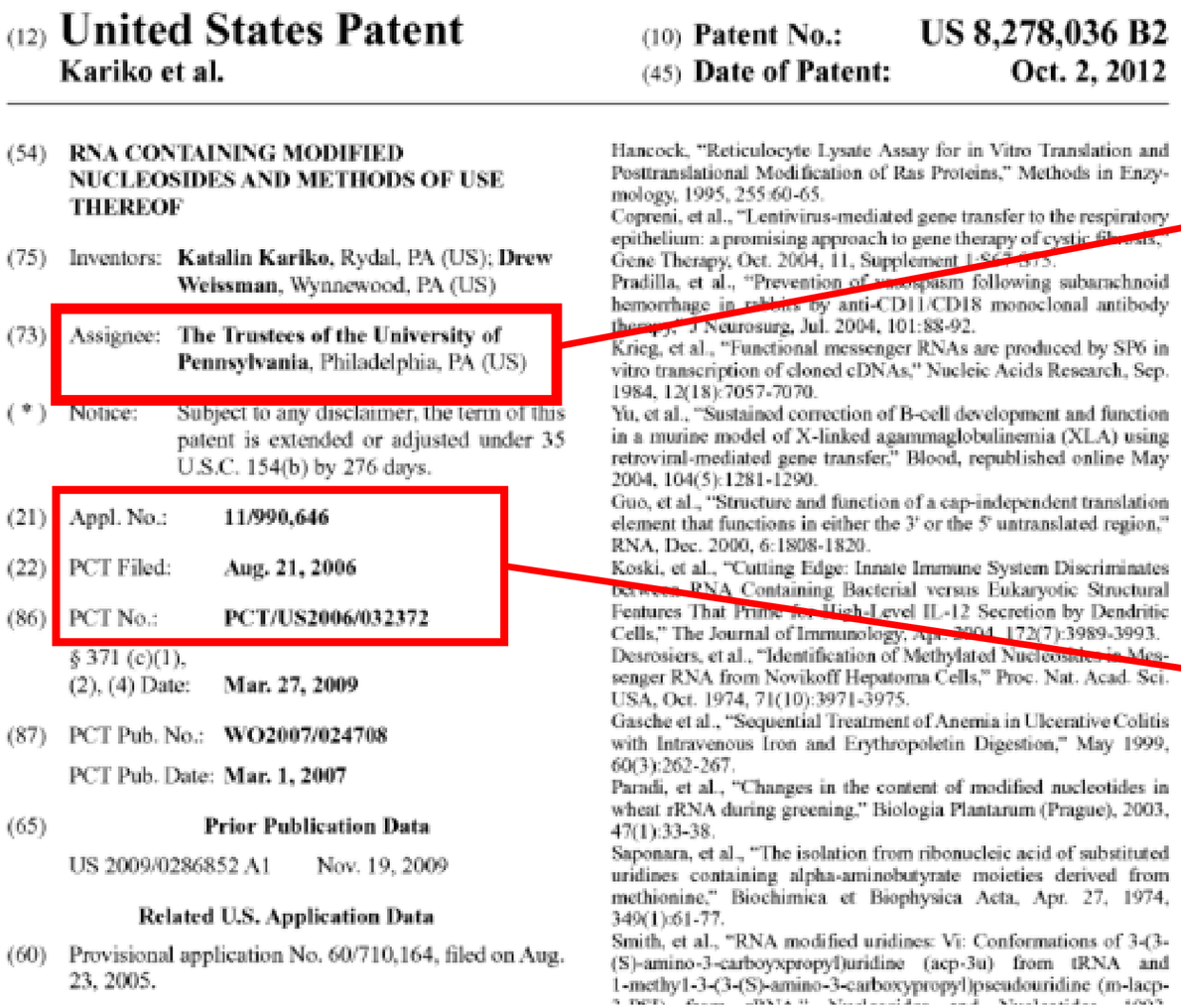


INVENTOR

- Someone who helped to conceive the specific features listed in at least one patent claim
- Someone who has directly contributed to the creation of an invention through their own skill, ingenuity, and labor#
- Colleagues, students, research assistants, technicians, mechanists, or their Supervisors [including those who gather essential data or construct a practical embodiment of the invention]aren’t inventors unless they have made an inventive contribution
- Always an Individual

#V.B. Mohammed Ibrahim v. Alfred Schafraneck and Ors, the Karnataka High Court defined an Inventor

ANATOMY OF PATENT



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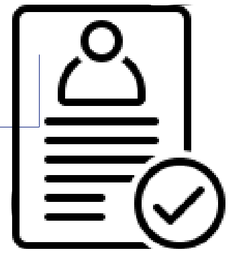

APPLICANT/ASSIGNEE/PATENTEE

- Can be individual/entity
- Either alone or Jointly
- Organization employing the inventor of the technology
- Can also change at a later date
- Has all the rights to exploit the invention commercially
- It has given that person all the rights to deal with the Patent

ANATOMY OF PATENT

U.S. PATENT DOCUMENTS

2005/0089913 A1 4/2005 Williams
2005/0137155 A1 6/2005 McSwiggen et al.

FOREIGN PATENT DOCUMENTS

WO WO 00/27340 5/2000

OTHER PUBLICATIONS

Charette et al. (Life 2000; vol. 49:341-351).*
Wilkie et al. (Trends in Biochemical Sciences 2003, vol. 28: 182-188).*
Lian et al. (J. Pharmaceutical Science 2001, vol. 90:667-680.*
Shingo et al. (J. Neuroscience 2001: 9733-9743).*
Baker et al., "RNA-Guided RNA modification: functional organization of the archaeal H/ACA RNP," Genes & Dev., published online May 3, 2005, 19:1238-1248.
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Zimmerman, et al., "Electrolyte- and pH-stabilities of aqueous solid lipid nanoparticle (SLN) dispersions in artificial gastrointestinal media," Eur J Pharmaceutics and Biopharmaceutics, Sep. 2001,
Biochemistry and Molecular Biology Inc. US, Mar. 26, 2004, 279(13):12542-12550.
Bloch, et al., "Sequence-Dependence of the Conformational Changes Induces by the 5 Methylcytosine in Synthetic RNA Oligomers," FEBS Letters, 1987, 219(2):464-468.

(Continued)

Primary Examiner — Kimberly Chong
(74) *Attorney, Agent, or Firm* — Riverside Law LLP

(57) **ABSTRACT**

This invention provides RNA, oligoribonucleotide, and polyribonucleotide molecules comprising pseudouridine or a modified nucleoside, gene therapy vectors comprising same, methods of synthesizing same, and methods for gene replacement, gene therapy, gene transcription silencing, and the delivery of therapeutic proteins to tissue in vivo, comprising the molecules. The present invention also provides methods of reducing the immunogenicity of RNA, oligoribonucleotide, and polyribonucleotide molecules.

ANATOMY OF PATENT

may have certain rights in this invention.

FIELD OF INVENTION

This invention provides RNA, oligoribonucleotide, and polyribonucleotide molecules comprising pseudouridine or a modified nucleoside, gene therapy vectors comprising same, methods of synthesizing same, and methods for gene replacement, gene therapy, gene transcription silencing, and the delivery of therapeutic proteins to tissue in vivo, comprising the molecules. The present invention also provides methods of reducing the immunogenicity of RNA, oligoribonucleotide, and polyribonucleotide molecules.

BACKGROUND OF THE INVENTION

All naturally occurring RNA is synthesized from four basic ribonucleotides ATP, CTP, UTP and GTP, but some of the incorporated nucleosides are modified post-transcriptionally in almost all types of RNA. Nearly one hundred different nucleoside modifications have been identified in RNA (Rozenski, J, Crain, P, and McCloskey, J. (1999). The RNA Modification Database: 1999 update. Nucl Acids Res 27: 196-197). The extent and nature of modifications vary and depend on the RNA type as well as the evolutionary level of the organism from where the RNA is derived. Ribosomal RNA, the major constituent of cellular RNA, contains significantly more nucleoside modifications in mammalian cells than bacteria. Human rRNA, for example, has 10-times more pseudouridine (Ψ) and 25-times more 2'-O-methylated nucleosides than bacterial rRNA, while rRNA from mitochondria has very few modifications. Transfer RNA (tRNA) is the most heavily

nucleoside.

In another embodiment, the present invention provides a double-stranded RNA (dsRNA) molecule containing, as part of its sequence, a pseudouridine or a modified nucleoside and further comprising an siRNA or shRNA. In another embodiment, the dsRNA molecule is greater than 50 nucleotides in length. Each possibility represents a separate embodiment of the present invention.

In another embodiment, the present invention provides a method for inducing a mammalian cell to produce a recombinant protein, comprising contacting the mammalian cell with an in vitro-synthesized RNA molecule encoding the recombinant protein, the in vitro-synthesized RNA molecule comprising a pseudouridine or a modified nucleoside, thereby inducing a mammalian cell to produce a recombinant protein.

In another embodiment, the present invention provides a method for treating anemia in a subject, comprising contacting a cell of the subject with an in vitro-synthesized RNA molecule, the in vitro-synthesized RNA molecule encoding erythropoietin, thereby treating anemia in a subject.

In another embodiment, the present invention provides a method for treating a vasospasm in a subject, comprising contacting a cell of the subject with an in vitro-synthesized RNA molecule, the in vitro-synthesized RNA molecule encoding inducible nitric oxide synthase (iNOS), thereby treating a vasospasm in a subject.

In another embodiment, the present invention provides a method for improving a survival rate of a cell in a subject, comprising contacting the cell with an in vitro-synthesized RNA molecule, the in vitro-synthesized RNA molecule

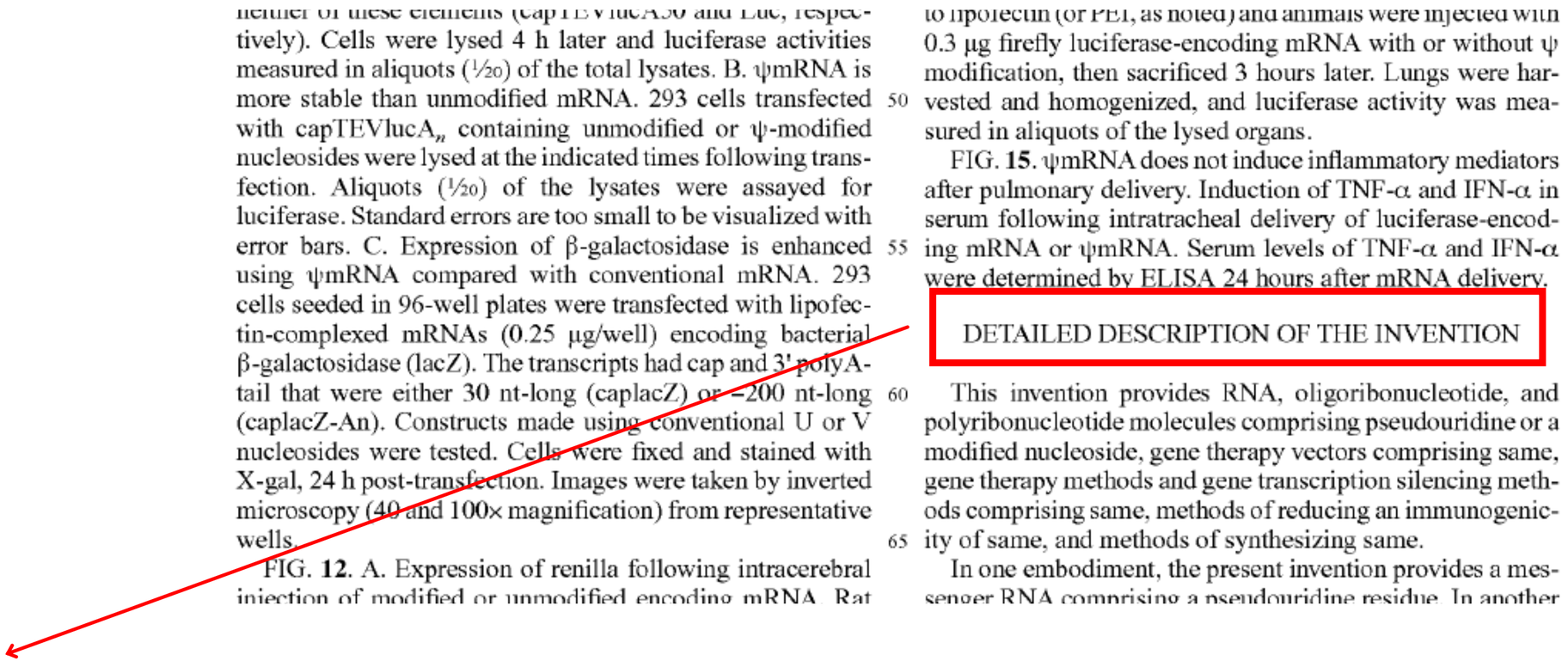
Field of Invention:

- Brief, 1-2 sentences,
- Used by patent office to determine examiner to be assigned to and to classify the application

Background of Invention:

- Explain where technology stands as of today with help of patents and published docs
- Bring out problems/issues/lacuna in prior art

ANATOMY OF PATENT



neither of these elements (capTEVlucA50 and Luc, respectively). Cells were lysed 4 h later and luciferase activities measured in aliquots (1/20) of the total lysates. B. ψmRNA is more stable than unmodified mRNA. 293 cells transfected with capTEVlucA$_n$ containing unmodified or ψ-modified nucleosides were lysed at the indicated times following transfection. Aliquots (1/20) of the lysates were assayed for luciferase. Standard errors are too small to be visualized with error bars. C. Expression of β-galactosidase is enhanced using ψmRNA compared with conventional mRNA. 293 cells seeded in 96-well plates were transfected with lipofectin-complexed mRNAs (0.25 μg/well) encoding bacterial β-galactosidase (lacZ). The transcripts had cap and 3' polyA-tail that were either 30 nt-long (caplacZ) or ~200 nt-long (caplacZ-An). Constructs made using conventional U or V nucleosides were tested. Cells were fixed and stained with X-gal, 24 h post-transfection. Images were taken by inverted microscopy (40 and 100× magnification) from representative wells.

FIG. **12**. A. Expression of renilla following intracerebral injection of modified or unmodified encoding mRNA. Rat

to lipofectin (or PEI, as noted) and animals were injected with 0.3 μg firefly luciferase-encoding mRNA with or without ψ modification, then sacrificed 3 hours later. Lungs were harvested and homogenized, and luciferase activity was measured in aliquots of the lysed organs.

FIG. **15**. ψmRNA does not induce inflammatory mediators after pulmonary delivery. Induction of TNF-α and IFN-α in serum following intratracheal delivery of luciferase-encoding mRNA or ψmRNA. Serum levels of TNF-α and IFN-α were determined by ELISA 24 hours after mRNA delivery.

DETAILED DESCRIPTION OF THE INVENTION

This invention provides RNA, oligoribonucleotide, and polyribonucleotide molecules comprising pseudouridine or a modified nucleoside, gene therapy vectors comprising same, gene therapy methods and gene transcription silencing methods comprising same, methods of reducing an immunogenicity of same, and methods of synthesizing same.

In one embodiment, the present invention provides a messenger RNA comprising a pseudouridine residue. In another

Detailed Description of The Invention:

- Describe the invention in detail.
- Give all variables, embodiments, ranges, concentrations, possibilities
- What is not described cannot be claimed, claim all that is disclosed
- Examples

ANATOMY OF PATENT

What is claimed is:

1. A method for inducing a mammalian cell to produce a protein of interest comprising: contacting said mammalian cell with in vitro-synthesized modified RNA encoding a protein of interest, wherein said in vitro-synthesized modified RNA comprises the modified nucleoside pseudouridine.

2. The method of claim **1**, wherein said in vitro-synthesized modified RNA further comprises a poly-A tail.

3. The method of claim **1**, wherein said in vitro-synthesized modified RNA further comprises a m7GpppG cap or 3'-O-methyl-m7GpppG cap.

4. The method of claim **1**, wherein said in vitro-synthesized modified RNA further comprises a cap-independent translational enhancer.

5. The method of claim **1**, wherein said in vitro-synthesized modified RNA further comprises 5' and 3' untranslated regions that enhance translation.

6. The method of claim **1**, wherein said in vitro-synthesized modified RNA induces a detectably lower innate immune response than the same quantity of in vitro-synthesized unmodified RNA that exhibits the same sequence except with uridine in place of said pseudouridine modified nucleoside.

7. The method of claim **1**, wherein said in vitro-synthesized modified RNA exhibits enhanced ability to produce said

14. The method of claim **6**, wherein said detectably lower innate immune response is detected by at least one method selected from the group consisting of:

(i) detecting that repeatedly contacting the mammalian cell with an amount of the modified RNA that results in detectable expression of the encoded protein after a single contacting does not detectably reduce expression of the protein, whereas repeatedly contacting the mammalian cell with the same quantity of the unmodified RNA does detectably reduce expression of the encoded protein;

(ii) detecting that the modified RNA results in a lower level of self-phosphorylation of RNA-activated protein kinase (PKR) or phosphorylation of the eukaryotic translation initiation factor (eIF2α) compared to the same quantity of the unmodified RNA counterpart based on in vitro phosphorylation assays;

(iii) detecting that the quantity of at least one cytokine induced by the mammalian cell in response to unmodified RNA is higher than the quantity of said at least one cytokine induced by the mammalian cell in response to said modified RNA counterpart;

(iv) detecting a difference in the level of expression of at least one dendritic cell (DC) activation marker in response to the unmodified RNA compared to the level

Claims:

- Defines the scope or borders of the invention
- Protects the inventor from infringers
- Independent claims and dependent claims
- Language style-legal

A method for inducing a mammalian cell to produce a protein of interest comprising: contacting said mammalian cell with in vitro-synthesized modified RNA encoding a protein of interest, wherein said in vitro-synthesized modified RNA comprises the modified nucleoside pseudo uridine.

PATENT FILING PROCESS
Step by Step Guide

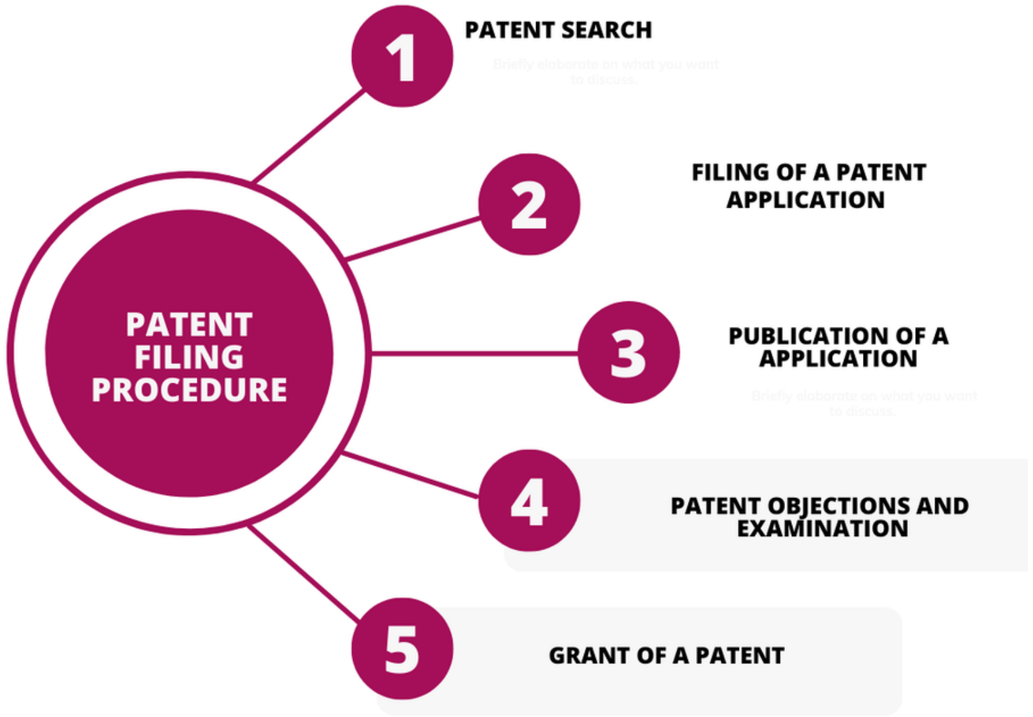
PATENT FILING STEPS

1. **Documentation**:
   - Keep dated notes
   - Drawings, prototypes
   - Development timeline

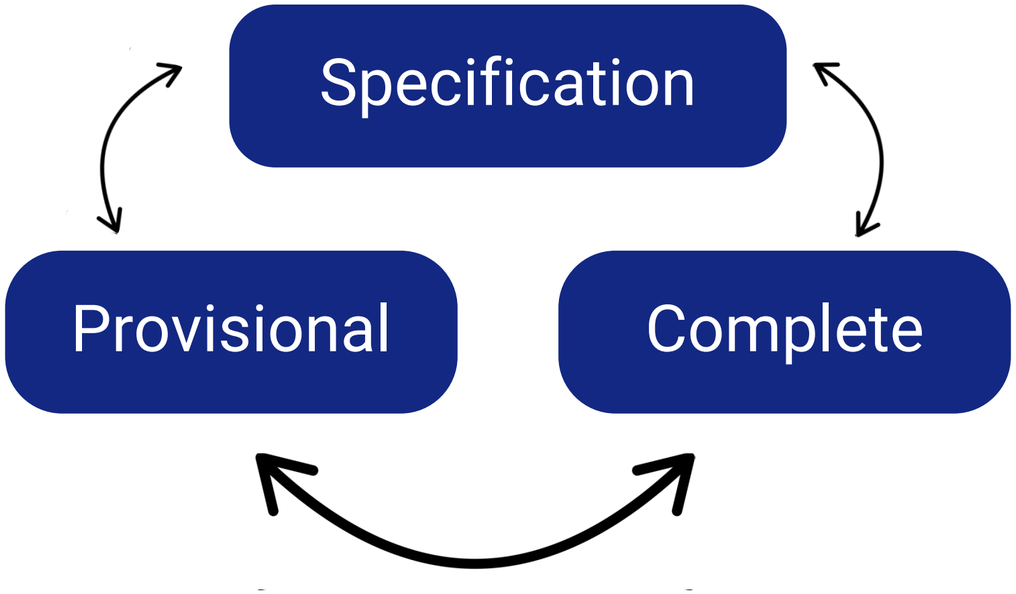
2. **Conduct a Patent Search**
   - Search databases (Google Patents)
   - Identify prior art

3. **Decide on Patent Type:**
   - Decide which type of IP you wish to file

4. **File a Provisional Application:**
   - Lower cost
   - Secures priority date
   - 12 months to file Complete specification



Idea → Research → Provisional → Complete specification → Examination → Grant → Maintenance



- To establish priority of the invention
- When the invention is only at a conceptual stage
- Very imp document to establish the earliest ownership of the invention
- Liberty to develop
- Disclose to interested person to obtain financial support

- Describes the invention and the manner in which it is to be performed
- Adequately exemplified
- Must contain at least one claim
- Must be submitted within 12 months of filing the provisional spec
- Can be filed right at the first instance

PATENT FILING STEPS cont...

5. File Complete Specification:

- Claims (most important part)
- Drawings
- Detailed description

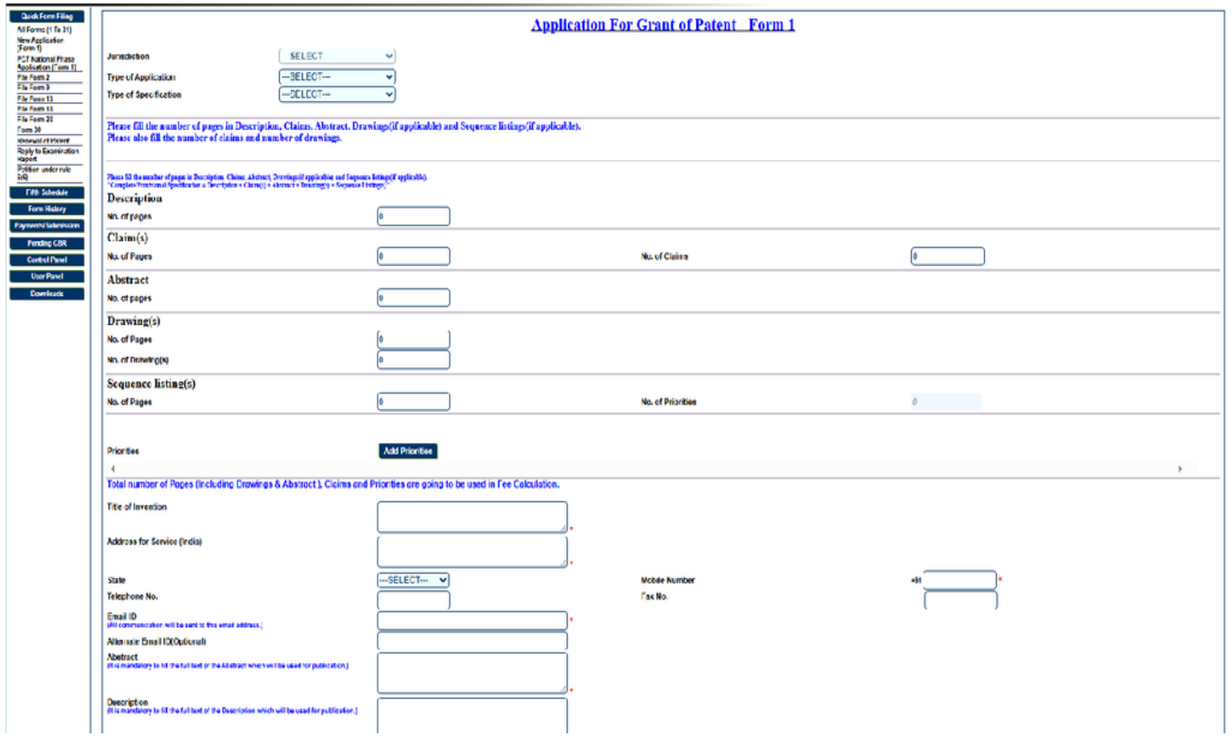
6. Patent Examination:

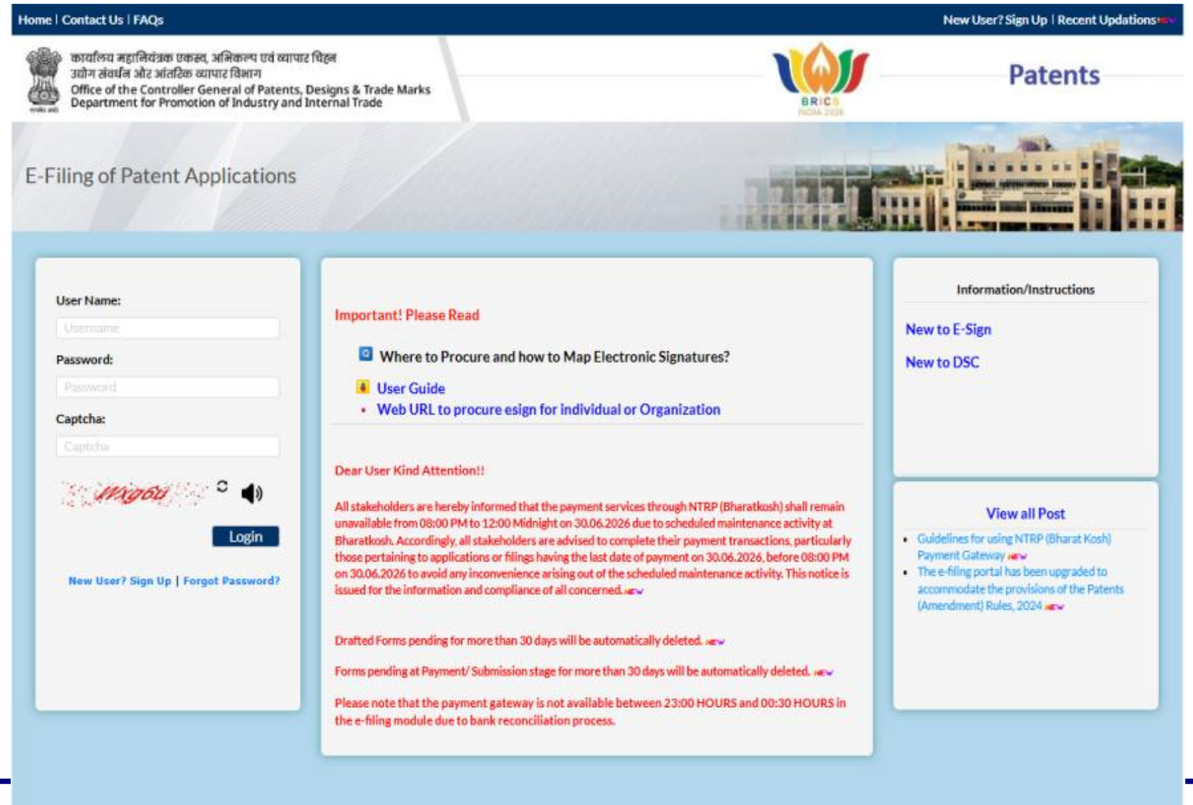
- Assigned to examiner
- Office Actions (rejections or objections)
- Amendments & responses
- Hearing

7. Approval & grant:

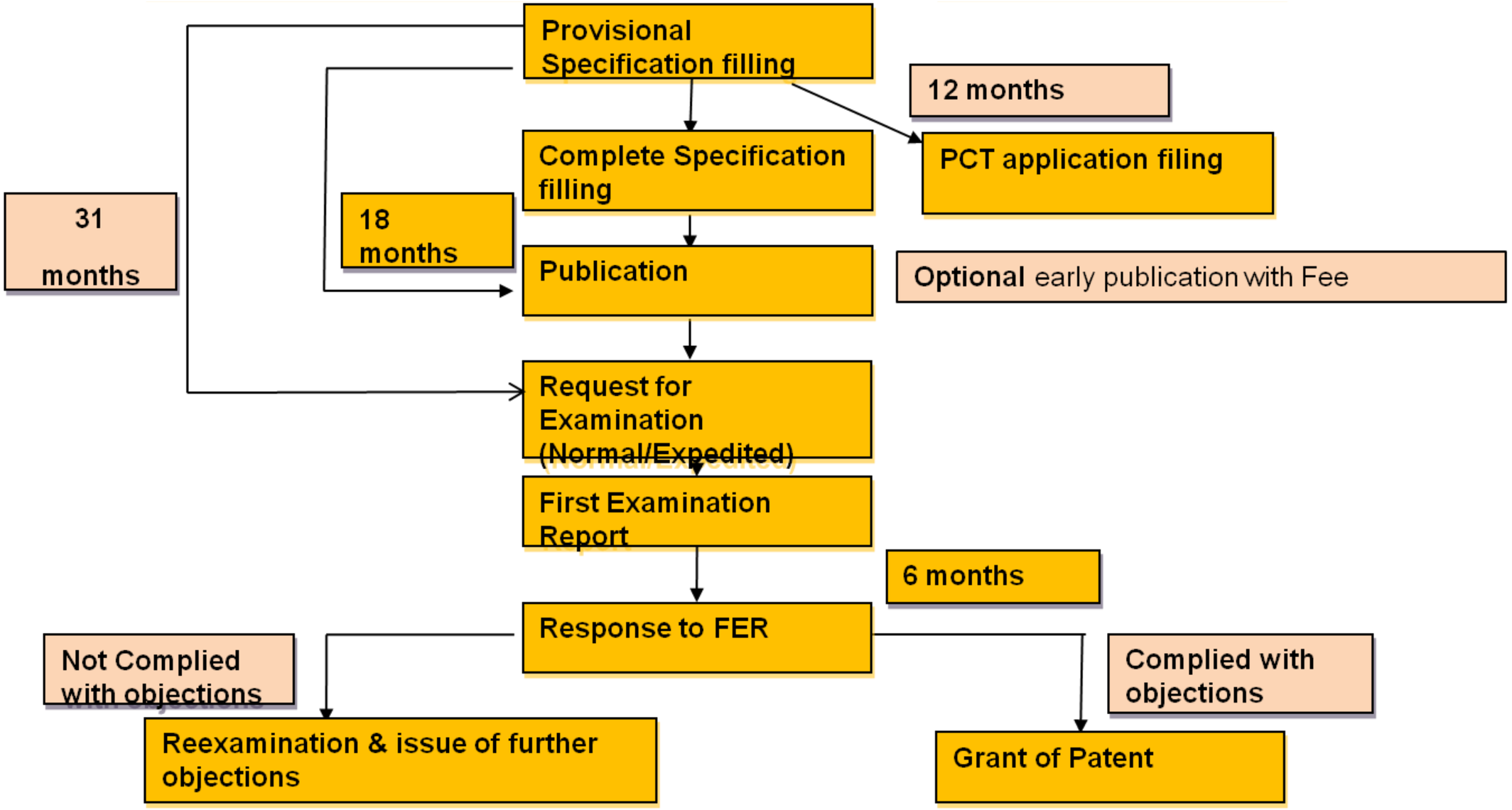
- Certificate of grant is issued

E-FILING of PATENT APPLICATION

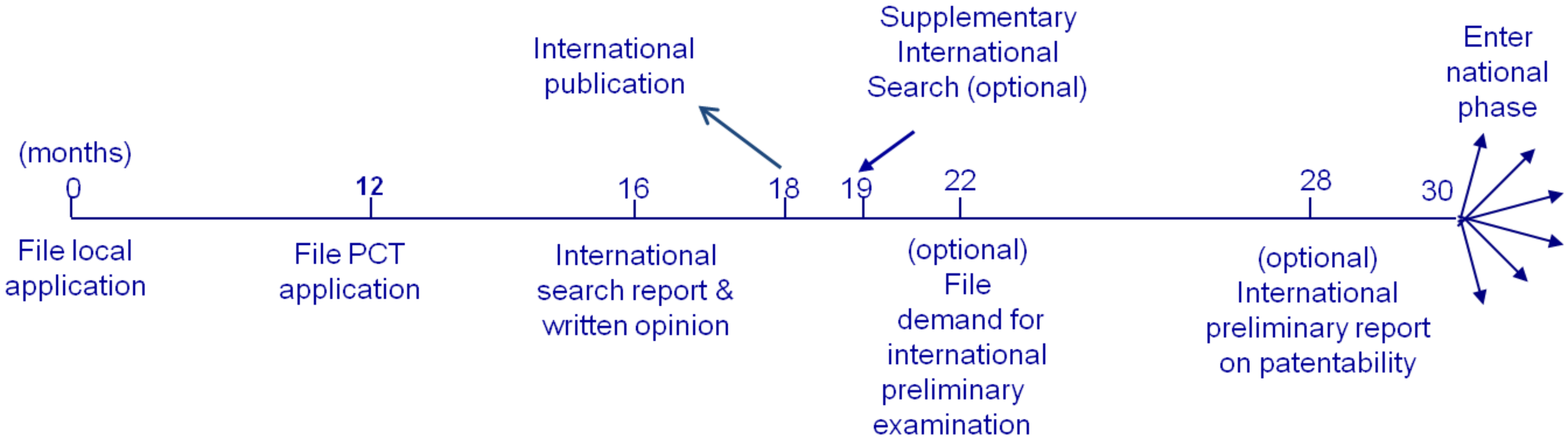




PATENT PROSECUTION TIMELINES



PCT TIMELINE



APPLICABLE STATUTORY FEE

On what payable	For E- filing Fees (INR)		For physical filing Fees (INR)	
	Natural person/Start-up/SME/ Educational Institutions	Others	Natural person/Start-up/SME/ Educational Institution	Others
On application for a patent ***(Form 1)***	1600	8000	1760	8800
For each sheet in addition to 30	160	800	176	880
For each claim in addition to 10	320	1600	352	1760
Request for publication ***(Optional)***	2500	12500	2750	13750
Request for examination of application for patent	4000	20000	4400	22000

PATENT DRAFTING EXAMPLE

(For illustrative purpose only)

Example: Smart Water Bottle Reminder

- **Title:** Smart Water Bottle with Hydration Reminder System

(Describes the invention, clearly identifies the product & does not use promotional words like "Best" or "Amazing")

- **Field of the Invention:** The present invention relates to portable drinking containers and, more particularly, to a smart water bottle incorporating a hydration reminder system for reminding users to consume water at predetermined intervals.

(Short, d*efines the technical area, use to classify patent application by patent office*)

- **Background of the Invention**: There exists a need for a water bottle that automatically reminds users to drink water.

(State problems in prior art)

PATENT DRAFTING EXAMPLE

(For illustrative purpose only)

- **Summary of the Invention**: The invention provides:
  - A reusable water bottle
  - Timer circuit
  - LED light
  - Small buzzer
  - Push button to reset the timer
  - Rechargeable battery

When one hour passes without the reset button being pressed, the LED flashes and the buzzer sounds.

- **Drawings**: Overall Bottle, Cap, battery circuit, LED buzzer etc. Block diagram etc. (illustrative purpose & specifies components of Invention)
- Components and specific numeral assign to them:

  e.g. *100- Bottle, 110-Cap, 120- LED etc…*

PATENT DRAFTING EXAMPLE

(For illustrative purpose only)

- **Detailed Description:** The smart water bottle (100) includes a bottle body for storing water. A timer circuit (140) is positioned in the base of the bottle and powered by a rechargeable battery (150). The timer activates an LED indicator (120) and a buzzer (130) after a predetermined time interval. The user may press the reset button (160) after drinking water, thereby restarting the timer.

(detailed description of invention with specific embodiments, working, arrangement of components & interconnection etc.)

- **Working of the Invention**: User drinks water | Press Reset Button | Timer Starts | One Hour Passes | LED Flashes | Buzzer Sounds | User Drinks Water | Reset Timer
- **Abstract**: A smart water bottle is disclosed that includes a bottle body, a timer circuit, a rechargeable battery, an LED indicator, a buzzer, and a reset button. The timer monitors elapsed time after a user drinks water and activates the LED indicator and buzzer after a predetermined interval to remind the user to drink water. The timer is reset when the reset button is pressed. The invention provides a simple and portable hydration reminder system.

PATENT DRAFTING EXAMPLE

(For illustrative purpose only)

- **Example Claim**:

  Claim 1: A smart water bottle comprising:

  - a bottle body;
  - a timer circuit;
  - a rechargeable battery;
  - an LED indicator;
  - a buzzer; and
  - a reset button,
  - wherein the timer circuit activates the LED indicator and the buzzer after a predetermined time interval to remind a user to drink water.

MISTAKES TO AVOID

- **Public Disclosure Before Filing**
  - ❌ Posting online
  - ❌ Pitching without NDA
  - ❌ Selling product before filing
- **Skipping Prior Art Search**
  - ❌ Leads to rejection
  - ❌ Wastes money
- **Writing Weak Claims**
  - ❌ Too narrow → easy to design around
  - ❌ Too broad → rejected
- **Waiting Too Long**
  - ❌ First-to-file system
  - ❌ Someone else may file first
- **Filing Provisional and Doing Nothing After**
  - ❌ Must file Complete specification within 12 months
- **Filing only in India**
  - ❌ Patent is a territorial right
  - ❌ Filing separately in each country Vs PCT application
  - ❌ Filing without market assessment

AFTER FILING A PATENT

- If you filed a provisional application first, you must submit a full specification of your invention within 12 months or your patent application will be lapsed or abandoned
- Track prosecution of patent application such as Publication, examination, response etc. Missing a deadline can result in loss of right
- Consider filing follow-on patent applications for improvements.
- Maintain records of experimental results, design changes, laboratory notebooks etc. These records can support future patent applications, publications, and commercialization.
- If commercialization outside India is planned, identify target countries & consider filing in those countries
- A filed patent can increase credibility during discussions with investors and industry partners. Explore licensing or collaboration opportunities with Industry partners.

THANK YOU

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