

Significance of IP Protection and Commercialization



Ministry of Education
Government of India



Innovation and IP Week celebrations

jointly organized by **AICTE** and the **Ministry of Education's Innovation Cell**

IP UTSAV

IP and Music: Feel the beat of IP (21st – 26th April, 2005)

25th April 2025

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वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्

Council of Scientific and Industrial Research

नवाचार परिसर/Innovation complex

**(विज्ञान तथा प्रौद्योगिकी मंत्रालय, भारत सरकार), (Ministry of Science and Technology, GoI),
4 बंगला/4 Bungalows, लोखंडवाला रोड / Lokhandwala Road, अंधेरी (पश्चिम)/Andheri (West),
मुंबई / Mumbai-400 053**



CSIR LEADERSHIP



Shri Narendra Modi, Hon'ble Prime Minister

President, CSIR



**Dr. Jitendra Singh,
Hon'ble Minister of State for
S & T and Earth Sciences**

Vice President, CSIR



Dr. (Mrs.) N. Kalaiselvi

Director General, CSIR and Secretary DSIR

CSIR: From Asia to Antarctica and Deep Sea to Space



- Network of 37 national laboratories
- 39 outreach centers & 3 Units
- 1 Innovation Complex

- Strength of 3521 active Scientists
- 4162 technical and support personnels



वैज्ञानिक तथा औद्योगिक अनुसंधान परिषद्
Council of Scientific and Industrial Research
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(विज्ञान तथा प्रौद्योगिकी मंत्रालय, भारत सरकार), (Ministry of Science and Technology, GoI),
4 बंगला/4 Bungalows, लोखंडवाला रोड / Lokhandwala Road, अंधेरी (पश्चिम)/Andheri (West),
मुंबई / Mumbai-400 053

**C-ICM, a new initiative to bridge the translational gaps
(lab to regulator and to the market)**

Catalyzing the Pharma/Biopharma innovation and translation ecosystem

Ready-to-move incubation labs and business development support

High-end scientific infrastructure, expertise and regulatory support

SOP driven GLP studies required for regulatory submissions and compliances



With artistically designed incubation labs, office space, CSIR-IC Mumbai stands on about 50,000 sq.ft of built-up space, ready to move 24 incubation labs and furnished office space spread over 4 floors with state-of-the-art infrastructure.

Work closely with innovative, technology driven...

Start-ups

MSMEs

CSIR Labs

University

**International Industry/
foundation/ institutions**

New Entrepreneurs

Industry

Potential stakeholders

**Government bodies/public-
funded organizations/ research
foundations involved in high-
end innovation and translation**

**Multinational
companies**

**Companies working with CSIR
labs Including the licensees of
CSIR patents and technologies**

**International funding
bodies and venture funds**

Significance of IP Protection

IPRs are **legal rights** which are granted to a person for **creations of the mind and intellect** which have **commercial value**.

Dictionary says “intellectual property: property (as an idea, invention, or process) that derives from the work of the mind or intellect : an application, right, or registration relating to this.”

Intellectual Property Rights (IPRs) protect different types of intellectual creations, fostering innovation and rewarding creators.

They encompass several categories, including

- **Patents,**
- **Trademarks,**
- **Copyrights,**
- **Trade secrets,**
- **Industrial designs, and**
- **Geographical indications.**

In addition, there are also:

- **Semiconductor Integrated Circuit Layout-Designs (Topographies)**
- **Plant Variety Rights**

CHOICE OF IP.....

- A cell phone's size, shape, color and overall look has as much to do with how desirable it is to consumers as to how well the phone actually functions.
- A cell phone owes its look to **industrial design**.
- The microchips and boards can be protected as an **integrated circuit topography**.
- The technology used in its antenna, microphone, speaker and internal chips are protected by way of **patents**.
- Additionally, the phone itself will usually carry the manufacturer's **trademark**.
- **© 2003 Nokia**. Nokia is a registered trademark of Nokia Corporation.



**This sketch qualifies as an artistic
work under copyright law.**

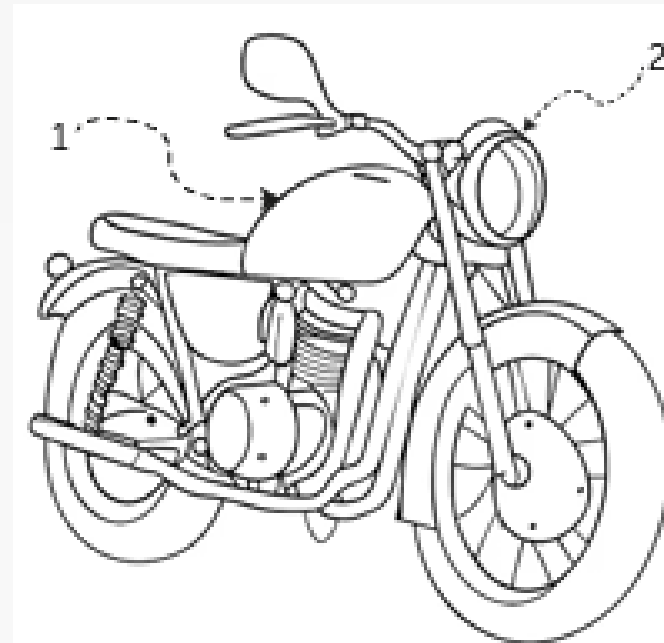


Copyright protects original artistic works.

- ✓ Valid from creation
- ✓ Lasts for life of author + 60 years

■■■■■■■■■■ Sakil Sheikh

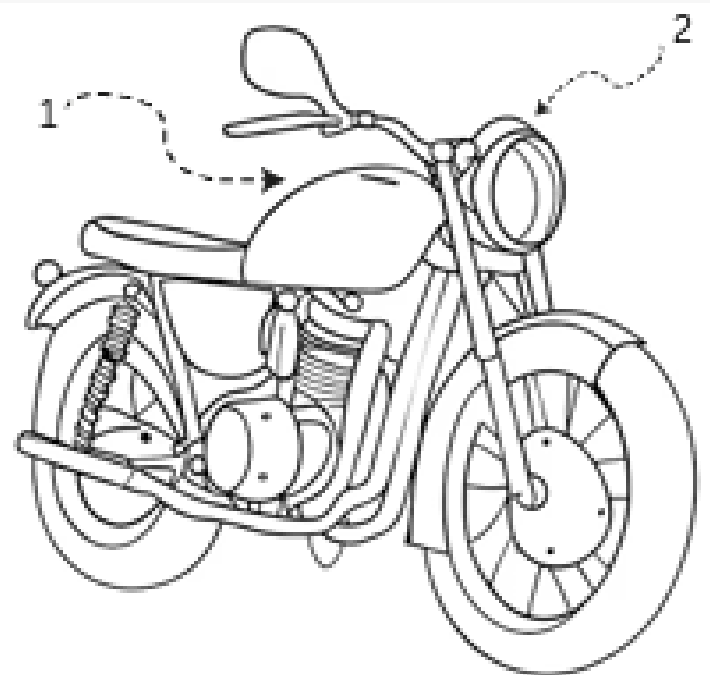
**But your sketch also has
design elements...**



✓ Design Element= (1,2) represent
visual features like shape or form that
are eye-catching or unique.

■■■■■■■■■■ Sakil Sheikh

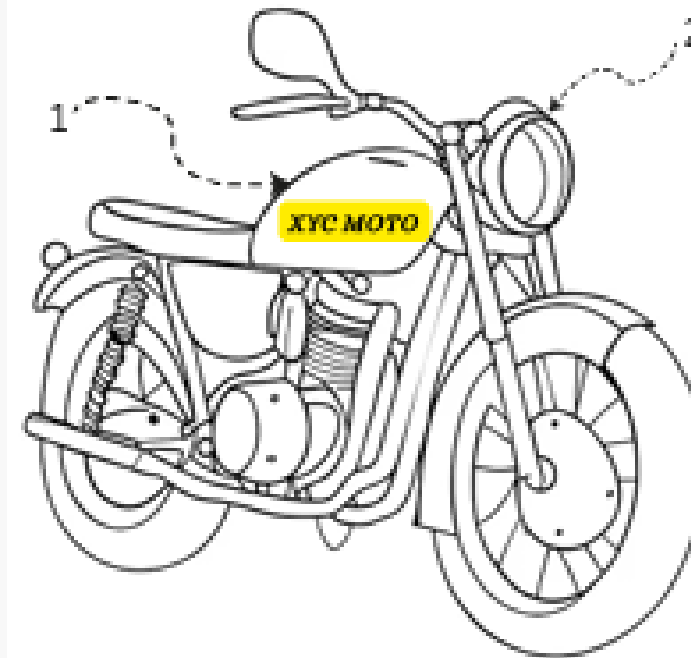
Functionality Test?
Check what is Dormant feature of
your design element
(Aesthetic / Functional)



Dormant Feature = Aesthetic = ☒ Design*
Dormant Feature = Functional = ☐ Not Design

*Provided all other conditions

**Ignoring Design Element, you
license the copyright to XYZ
Moto for industrial production**

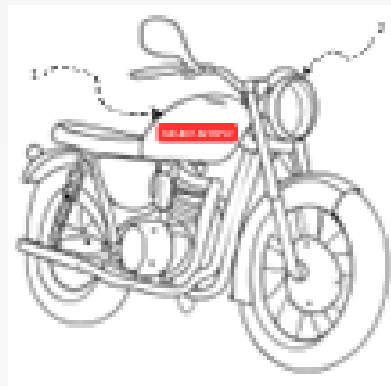


So far, XYZ has produced **1003** units of
this design for the market,
and you've earned ₹1 crore in royalty.

Sami Shneek

A line drawing of a motorcycle. A red rectangular label with the text "XERO MOTO" is positioned on the fuel tank. A dashed arrow labeled "1" points to the front wheel, and another dashed arrow labeled "2" points to the rear wheel.

Sahil Sheikh



- ☛ Not registered under the Designs Act, 2000, and ➡ and is reproduced >50 times by an industrial process ➡ Copyright ceases for the design.

1.✅ Copyright = Artistic Expression

2. 🎨 Design = Aesthetic Only

3. ⚙️ Function ≠ Design Protection

4. 50+ Copies = Copyright Ends

5. No Dual Long-Term Protection

- Must choose: copyright (for art) or design registration (for industrial use).

What constitutes a copyright infringement?

Copyright infringement can take place a number of ways.

- to import copyrighted items into the country without the copyright owner's permission.
- to reproduce or perform the copyrighted work, or to make derivative works.

The burden of enforcement is on copyright holder.

- **Direct Infringement:**

Direct infringement is a strict liability offence and guilty intention is not essential to fix criminal liability. The requirements to establish a case of copyright infringement under this theory are:

- (1) Ownership of a valid copyright; and
- (2) Copying or infringement of the copyrighted work by the defendant.

- **Contributory infringement:**

The contributory infringement pre-supposes the existence of knowledge and participation by the alleged contributory infringer. To claim damages for infringement of the copyright, the plaintiff has to prove:

- (1) That the defendant knew or should have known of the infringing activity; and
- (2) That the defendant induced, caused, or materially contributed to another person's infringing activity.



Courtesy: Erbil (Hawler) Governorate in Mobile Photos



Courtesy: Erbil (Hawler) Governorate in Mobile Photos



Courtesy: Erbil (Hawler) Governorate in Mobile Photos



Courtesy: Erbil (Hawler) Governorate in Mobile Photos



Courtesy: Erbil (Hawler) Governorate in Mobile Photos

Plagiarism Vs. Copyright violation

- **Plagiarism concerns with the protection of ideas, copyright doesn't protect ideas - it protects "fixed expression of ideas."**
- **Plagiarism** is using someone else's work and calling it your own, i.e. not giving them credit.
- **Plagiarism** is the act of misrepresenting the ownership of an idea, it usually means passing off someone else's ideas as your own in a research paper or other academic work. Plagiarism is wrong, dishonest, and can lead to serious negative consequences in any school or professional setting. One way to avoid plagiarism is to properly cite your sources – a key academic skill.

Citing an author in the 'Works Cited' page is not sufficient. If you use their exact words you must use quotation marks and footnotes or numbered endnotes.

Plagiarism Vs. Copyright violation

- **Copyright violation** is using someone else's work without their permission.
You may give them proper credit, but if it does not fall under a **fair use exclusion** then it is in violation of copyright law and you could be held liable for damages.

By contrast, copyright is a legal concept extensively embodied by laws and policies. Copyright law permits individuals to make copies under certain conditions, but violating certain copyright rules is copyright infringement. You can't avoid a copyright infringement claim just by citing your sources (though it may still be the right thing to do).

http://www.ric.edu/technologycompetency/tutorials_copyright_answers.php
<http://www.teachingcopyright.org/handout/copyright-faq>



Trademarks

ZEPTO

Formerly	KiranaKart
Company type	Private
Industry	Quick-commerce
Founded	July 2021; 3 years ago in Mumbai, India
Headquarters	Bengaluru, India
Number of locations	250 stores (2024)
Key people	Aadit Palicha (CEO) Kaivalya Vohra (CTO)
Services	Online grocer
Revenue	▲ ₹4,454 crore (US\$520 million) (FY24) ^[1]
Net income	▼ ₹-1,248 crore (US\$ -150 million) (FY24)
Website	zeptonow.com

In 2021, Kiranakart Technologies Private Ltd. registered the "ZEPTO" trademark under Class 29 (food items) and Class 39 (delivery services)

The Delhi HC ruled in favor of Kiranakart, ordering Arshad's "ZEPTO" trademark removal, emphasizing "use it or lose it" in trademark law.

Mohammad Arshad (Respondent)

In 2014, Mohammad Arshad registered the trademark "ZEPTO" under Class 35, covering services like advertising and retail of mobile phones and accessories

Arshad opposed Kiranakart's attempt to register "ZEPTO" in Class 35, claiming prior rights. Kiranakart challenged Arshad's trademark, arguing non-use for 8+ years under Section 47(1)(b) of the Trade Marks Act, 1999.

PATENTS

Mr. X

- works hard
- documents observations
- interprets results
- communicates to a journal
- contributes to knowledge

Mr. Y

- works hard
- documents observations
- interprets results
- **secures priority**
- communicates to a journal
- contributes to knowledge
- **gets rewarded**

Microsoft-Nokia Deal

- Total transaction price of USD **7.2** (EUR 5.44) billion in cash.
- USD **5.0** (EUR 3.79) billion to purchase substantially all of Nokia's Devices & Services business, and
- USD **2.17** (EUR 1.65) billion to license Nokia's patents.
- Approximately 32,000 people were expected to transfer to Microsoft.

IP Rewards

- 24,500 Motorola Mobility patents sold for \$12.5 Bn
- 6,000 Nortel patents sold for \$4.5 Bn
- 8,800 Interdigital patents sold for \$4.5 Bn
- 882 Novell patents sold for \$450 Mn

Source: Jeffrey L. Ranck, Microsoft Corp

PATENT

A patent is an exclusive right granted by a country for certain period to the owner of an invention to make, use, manufacture and market the invention, provided the invention satisfies certain conditions stipulated in the law.

Like any other physical property it can be bought, sold, assigned, licensed, gifted or inherited.

IPR is not Legal – IPR is Business



PROPERTY

- **LIVE**
- **SELL**
- **RENT**
- **MORTGAGE**
- **ABANDON**

- Controller General of Patents having offices at Kolkata New Delhi, Mumbai & Chennai.
- Term: 20 years from the date of filing of a non-provisional application.

By now, over the last 3-4 sessions you might have understood that Grant of patents is *quid pro quo* to disclosure.

It is for the disclosure of invention by the applicant that the patent rights are granted to him for a limited period of time, if all criteria of patentability is fulfilled.

The Patents Act, 1970 requires the applicant to specify “**what**” is the invention and “**how**” to perform it.

TYPES OF PATENTS

- **Product**
- **Process**
- **Utility**
 - **National Application**
 - **Convention Application**
 - **International Application (PCT)**
- **Design**
- **Plant varieties**

- **Patent of addition**
- **Divisional /Continuation in part**

PATENT DOCUMENT

- **Bibliographical Information**
- **Prior Art**
- **Description**
- **Claims**
- **Drawings**



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

(10) **Patent No.:** **US 6,340,484 B1**
(45) **Date of Patent:** **Jan. 22, 2002**

Title
(Area of invention)

Company
Name

IPC
Technology area
codes

(54) **COMPOSITIONS CONTAINING NEEM SEED EXTRACTS AND SACCHARIDE**

(75) **Inventors:** Sreenivasa Rao Damarla, Kalyananagar; Srinivasa Sridhar; Mambully Chandrasekaran Gopinathan, both of Bangalore, all of (IN)

(73) **Assignee:** E.I.D. Parry (India) Limited, Bangalore (IN)

(*) **Notice:** Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) **Appl. No.:** 09/545,295

(22) **Filed:** Apr. 7, 2000

(51) **Int. Cl.⁷** A61K 7/00; A61K 31/70; A01N 25/00; A01N 43/16; A01N 43/04

(52) **U.S. Cl.** 424/761; 424/776; 424/405; 514/453; 514/23; 514/53; 514/54; 514/57

(58) **Field of Search** 424/195.1, 405, 424/761, 776; 514/453, 23, 53, 54, 57

(56) **References Cited**

U.S. PATENT DOCUMENTS

3,920,442 A * 11/1975 Albert et al.
4,556,562 A 12/1985 Larson
4,946,681 A 8/1990 Walter
5,001,146 A 3/1991 Carter et al.
5,124,349 A 6/1992 Carter et al.
5,281,618 A 1/1994 Walter
5,352,697 A 10/1994 Butler et al.
5,372,817 A 12/1994 Locke et al.
5,405,612 A 4/1995 Locke et al.
5,409,708 A 4/1995 Locke et al.
5,503,837 A 4/1996 Roland et al.
5,635,193 A 6/1997 Walter
5,653,973 A * 8/1997 Lew et al.
5,695,763 A 12/1997 Kleeberg
5,730,986 A 3/1998 Bandyopadhyay et al.
5,736,145 A 4/1998 Murali
5,827,521 A 10/1998 Moorthy
5,856,526 A 1/1999 Sankaram et al.

FOREIGN PATENT DOCUMENTS

EP 0 579 624 B1 3/1992

IN 181845 8/1995
IN MAS/1855 8/1997
WO WO 92/16109 10/1992

OTHER PUBLICATIONS

Dimetry, et al., "Synergistic effect of some additives on the biological activity and toxicity of neem-based formulations against the cowpea aphid, *Aphis craccivora* Koch", Insect Sci. Applic., 17(3/4): 395-99 (1997).

Schauer, "Effects of variously formulated neem seed extracts on *Acyrthosiphon pisum* and *Aphis fabae*", Proc. 2nd Int. Neem Conf. (Rauischholzhausen), pp. 141-150 (1983).

Parmar et al., "Neem oil as a synergist for insecticides," Neem Newsletter, 3(1) (1986), pp 3-5.

Dureja et al., "Stability of Azadirachtin-A in different organic solvents and aqueous solution," Pesticide Research Journal, 11(1):90-92 (1999).

Rembold et al., Azadirachtins: Structure and Activity relations in case of *Epilachna varivestis*, "In" The Neem Tree *Azadirachta indica* A. Juss. And other meliaceous plants: Sources of unique natural products for integrated pest management, medicine, industry, and other purposes, Ed. Schmutterer, VCH Verlagsgesellschaft, Weinheim (FRG), pp. 222-30 (1995).

Kleenberg et al., "Analytical determination of Azadirachtin A and Azadirachtin B in neem extracts," In: Practice Oriented Results on Use and Production of Neem Ingredients and Pheromones, Proceedings of the 3rd Workshop, Ed. H. Kleeberg, Duck & Graphics, Giessen, pp. 139-148, (1994).

* cited by examiner

Primary Examiner—Leon B. Lankford, Jr.

Assistant Examiner—Susan D. Coe

(74) *Attorney, Agent, or Firm*—Kilyk & Bowersox, P.L.L.C.

(57) **ABSTRACT**

A solid pesticide composition is described wherein the composition contains a neem seed extract and at least one saccharide. The solid pesticide composition is preferably storage stable, has higher pesticidal activity, and can be easily dissolved and/or dispersed in a liquid medium, such as a water-based medium.

Abstract
Of the invention

18 Claims, No Drawings

BIBLIOGRAPHICAL INFORMATION

- **Title**
- **Inventor(s)**
- **Patent Assignee**
- **Priority Date**
- **Publication Date**
- **IPC**
- **Family or Equivalent patents**
- **Cited patents**
- **Abstract**

Title

- Must be relevant and meaningful, not more than 10 words.

Inventor(s)

- Inventor is the one who contributes to the conception and reduction to practice of one or more of the claims in a patent application or patent.

Patent Assignee

- The patent 'assignee (s)' is/are the owner(s) of the patent; they have all the rights to manufacture, license or sell to someone, who will then become the new owner of the patent.

Priority Date

- The date on which the first patent application is filed in that Technology platform.

Publication Date

- The date on which the application appears in the official gazette of the Patent Office.

IPC

WIPO Reformed IPC: Internet Publication - Microsoft Internet Explorer

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WIPO

Version: 2007.01
Current symbol:
Jump Print
A | B | C | D | E | F | G | H
Level: core ☐ adv. ☒
Lang.: En. ☒ Fr. ☐
View mode: path ☐ full ☒ hierarchic ☐
Standard seq.: yes ☐ no ☒
Display: deleted ☒

IPC Definitions Illustrations RCL Catchwords Help Options **2007.01**

A	SECTION A — HUMAN NECESSITIES	
B	SECTION B — PERFORMING OPERATIONS; TRANSPORTING	
C	SECTION C — CHEMISTRY; METALLURGY	
D	SECTION D — TEXTILES; PAPER	
E	SECTION E — FIXED CONSTRUCTIONS	
F	SECTION F — MECHANICAL ENGINEERING; LIGHTING; HEATING; WEAPONS; BLASTING	
G	SECTION G — PHYSICS	
H	SECTION H — ELECTRICITY	

WIPO Reformed IPC: Internet Publication - Microsoft Internet Explorer

Internet

WIPO Reformed IPC: Internet Publication - Microsoft Internet Explorer

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WIPO Reformed IPC: Internet P... Add Tab

WIPO



Version:
2007.01
Current symbol:
A

Jump Print

A | B | C | D | E | F | G | H

Level: core ☐ adv. ☒

Lang.: En. ☒ Fr. ☐

View mode: path ☐ full ☒ hierarchic ☐

Standard seq.: yes ☐ no ☒

Display: deleted ☒

IPC

Definitions

Illustrations

RCL

Catchwords

Help

Options

2007.01

A

SECTION A — HUMAN NECESSITIES

FR

AGRICULTURE

A01

AGRICULTURE; FORESTRY; ANIMAL HUSBANDRY; HUNTING; TRAPPING; FISHING

FR

FOODSTUFFS; TOBACCO

A21

BAKING; EQUIPMENT FOR MAKING OR PROCESSING DOUGHS; DOUGHS FOR BAKING [1,8]

FR

Note(s)

Processes using enzymes or micro-organisms in order to:

i. liberate, separate or purify a pre-existing compound or composition, or to

ii. treat textiles or clean solid surfaces of **materials**

are further classified in subclass **C12S**. [5]

A22

BUTCHERING; MEAT **TREATMENT**; PROCESSING POULTRY OR FISH

FR

A23

FOODS OR FOODSTUFFS; THEIR **TREATMENT**, NOT COVERED BY OTHER CLASSES

FR

Note(s)

1. Attention is drawn to the following places:

C08B

Polysaccharides, derivatives thereof

C11

Animal or vegetable oils, fats, fatty substances or waxes

C12

Biochemistry, beer, spirits, wine, vinegar

C13

Sugar industry. [4]

2. Processes using enzymes or micro-organisms in order to:

i. liberate, separate or purify a pre-existing compound or composition, or to

ii. treat textiles or clean solid surfaces of **materials**

are further classified in subclass **C12S**. [5]

A24

TOBACCO; CIGARS; CIGARETTES; SMOKERS' REQUISITES

FR

PERSONAL OR DOMESTIC ARTICLES

A41

WEARING APPAREL

FR

A42

HEADWEAR

FR

A43

FOOTWEAR

FR

HEALTH; AMUSEMENT

A61

MEDICAL OR VETERINARY SCIENCE; HYGIENE

FR

A62

LIFE-SAVING; FIRE-FIGHTING (ladders **E06C**)

FR

A63

SPORTS; GAMES; AMUSEMENTS

FR

A99

SUBJECT MATTER NOT OTHERWISE PROVIDED FOR IN THIS SECTION [8]

FR



2007.01 ▼

A61

Jump Print

A	B	C	D	E	F	G	H
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Level | core ☐ adv. ☒

Lang. | En. ☒ | Fr. ☐

View mode

- path ☐
- full ☒
- hierarchic ☐

Standard seq.	yes <input type="radio"/>	no <input checked="" type="radio"/>
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IPC

Definitions

Illustrations

RCL

Catchwords

Help

Options

2007.01

A61J

CONTAINERS SPECIALLY ADAPTED FOR MEDICAL OR PHARMACEUTICAL PURPOSES; DEVICES OR METHODS SPECIALLY ADAPTED FOR BRINGING PHARMACEUTICAL PRODUCTS INTO PARTICULAR PHYSICAL OR ADMINISTERING FORMS; DEVICES FOR ADMINISTERING FOOD OR MEDICINES ORALLY; BABY COMFORTERS; DEVICES FOR RECEIVING SPITTLE

 A61K

PREPARATIONS FOR MEDICAL, DENTAL, OR TOILET PURPOSES (bringing into special physical form **A61J**; chemical **aspects** of, or use of **materials** for deodorisation of air, for disinfection or sterilisation, or for bandages, dressings, absorbent pads or surgical articles **A61L**; compounds per se **C01**, **C07**, **C08**, **C12N**; soap compositions **C11D**; micro-organisms per se **C12N**)



Note(s)

1. This subclass **covers** the following subject matter, whether set forth as a composition (mixture), process of preparing the composition or process of treating using the composition:
 - a. Drug or other biological compositions which are capable of:
 - preventing, alleviating, treating or curing abnormal or pathological conditions of the living body by such means as destroying a parasitic organism, or limiting the effect of the disease or abnormality by chemically altering the physiology of the host or parasite (biocides **A01N 25/00-A01N 65/00**);
 - maintaining, increasing, decreasing, limiting, or destroying a physiological body function, e.g. vitamin compositions, sex sterilants, fertility inhibitors, growth promoters, or the like (sex sterilants for invertebrates, e.g. insects, **A01N**; plant growth regulators **A01N 25/00-A01N 65/00**); [1,7]
 - diagnosing a physiological condition or state by an **in vivo** test, e.g. X-ray contrast or skin patch test compositions (measuring or testing processes involving enzymes or micro-organisms **C12Q**; **in vitro** testing of biological material, e.g. blood, urine, **G01N**, e.g. **G01N 33/48**);
 - b. Body treating compositions generally intended for deodorising, protecting, adorning or grooming a body, e.g. cosmetics, dentifrices, tooth filling materials.
2. Attention is drawn to the definitions of groups of chemical elements following the title of section **C**.
3. Attention is drawn to the notes in class **C07**, for example the notes following the title of the subclass **C07D**, setting forth the rules for classifying organic compounds in that class, which rules are also applicable, if not otherwise indicated, to the classification of organic compounds in **A61K**. [8]
4. In this subclass, with the exception of group **A61K 8/00**, in the absence of an indication to the contrary, classification is made in the last appropriate place.
5. Therapeutic activity of medicinal preparations is further classified in subclass **A61P**. [7]

PRIOR ART

- Constitutes **all information** that has been made available to the public in any form before a given date that might be relevant to a patent's claims of originality.
- If an invention has been described in prior art, a patent on that invention is not valid.

DESCRIPTION INFORMATION

Examples

(actual laboratory experiments conducted along with the results)

Interpretation of data

Comparative tables

- Field of Invention
- Background of the invention
- Summary of invention
- Brief Description of Drawings (if any)
- Detailed Description of Invention
- Examples

CLAIM INFORMATION

- Main Claim
- Dependent Claims
- Independent Claims
 - **Compound(s)**
 - **Composition/Formulation**
 - **Method**
 - **Process of preparation**
 - **Design**
 - **Use**
 - **Method of treatment**

What is claimed is:

- 1.** A solid pesticide composition comprising at least one saccharide and a neem seed extract, wherein said neem seed extract comprises azadirachtin, wherein said composition is a free flowing powder, and wherein said saccharide and said neem seed extract are not chemically bonded.
- 2.** The solid pesticide composition of claim **1**, wherein said composition is storage stable.
- 3.** The solid pesticide composition of claim **2**, wherein said composition retains at least 90% of said azadirachtins..... in a sealed container.
- 4.** The solid pesticide composition of claim 1, wherein
- 5**
-
-
-
- 15.** A liquid pesticide composition comprising the solid pesticide composition of claim 1 present in a liquid medium.
- 16.** The liquid pesticide formulation of claim **15**, wherein said liquid medium is a water-based medium.
- 17.** A solid pesticide composition comprising at least one saccharide and azadirachtin, wherein said composition is a free flowing powder and wherein said saccharide and said azadirachtin are not chemically bonded.
- 18.** The solid pesticide composition of claim 1, wherein said pesticide composition is formed by mixing at least one saccharide and a neem seed extract together.

rachtin by proton donating or proton accepting interactions.

The storage stable azadirachtin formulations of this invention can be prepared by either of two general procedures:

A first embodiment of this invention is to extract azadirachtin and neem oil together from dried neem seeds that have been coarsely ground to about 5 mesh. The ground neem seeds are extracted by using an aprotic solvent having azadirachtin solubility. This aprotic solvent extraction may be repeated to optimize the concentration azadirachtin in the solution.

Because dried neem seeds retain between 6 and 15% water, this polar solvent extraction, in addition to extracting azadirachtin, also extracts a significant amount of water. The neem seed extracts typically contain about 20% by volume water. Since water is an azadirachtin-degrading, protic solvent, its presence in neem seed extracts about the previously defined allowable limits will reduce the storage stability of the azadirachtin formulations. The allowable limit to the amount of water in a neem seed extract is dependent upon the aprotic/protic character of the particular solvent system of the extract. Specifically, if the solvent system is comprised of greater than 50% by volume aprotic solvents such as ketones or esters, the concentration of water must be less than 15% by volume of the total solution. Alternatively, if the solvent system comprises greater than 50% alcohol solvents, (which are more protic) the concentration of water must be less than 5%, preferably less than 2%, and most preferably less than 1% by volume of the total solution.

There are various techniques to reduce the concentration of water in the final solutions to within the above defined acceptable limits including, but not limited to, further extracting the neem seed extracts with a water-immiscible solvent, diluting the extracts with an appropriate aprotic solvent, or drying the extracts over a suitable adsorbent.

A preferred embodiment of this invention is to extract dried neem seeds that have been milled to a coarse powder of about 5 mesh with a non-polar, azadirachtin-insoluble aprotic solvent such as hexane to remove the neem oil from the seeds. This "cleanup" extraction is then followed by a second extraction of the defatted neem seeds using a more polar, azadirachtin-soluble solvent. As in the first embodiment, this extraction may be repeated to optimize the concentration of azadirachtin in the aprotic solvent extraction.

The hydrophillic, aprotic solvent extraction obtained from either embodiment is then cooled to a temperature of no greater than 10° C., preferably at a temperature of about 0° C. to 10° C., to precipitate residual waxes from the neem extract. The dewaxed extract is then treated to remove the solvent at a temperature and a pressure sufficient to obtain a concentration of azadirachtin of greater than 10 g/l azadirachtin to as high as the solubility of azadirachtin.

cally acceptable suspensions and dispersions, oily dispersions, pastes, dusting powders, wettable powders, emulsifiable concentrates, flowables, granules, baits, invert emulsions, aerosol compositions and fumigating candles.

In general, azadirachtin pesticide formulations of this invention preferably contain 5 to 50% emulsifying surfactant, 0 to 40% neem oil, 0 to 1% para-aminobenzoic acid or its esters, and less than 1% acetic acid or sodium hydroxide to adjust the PH to between about 3.8 and 4.2.

Azadirachtin pesticide compositions in accordance with the invention contain greater than 10 g/l azadirachtin in solution. Preferably, storage-stable compositions of the invention contain from about 11 g/l to about 200 g/l of azadirachtin or up to solubility of azadirachtin in solution.

Without further elaboration, it is believed that one skilled in the art, using the preceding detailed description can utilize the present invention to its fullest extent.

The following examples are provided to illustrate the invention in accordance with the principles of this invention, but are not to be construed as limiting the invention in any way except as indicated in the appended claims. All parts and percentages are by weight unless otherwise indicated.

EXAMPLE 1

Three hundred (300) lbs. of neem seeds were ground to ~10 mesh and the shells were separated from the kernels by elutriation.

The kernels were then placed in an agitated tank and extracted with 2000 lbs. of hexane for three hours. The seeds were separated by centrifugation and the hexane evaporated to separate the extracted oil. The de-oiled kernels were then dried to remove the excess hexane and then extracted with ethylacetate to remove azadirachtin. The ethyl acetate neem extract contained 30 grams of azadirachtin per liter of ethylacetate. The ethylacetate was then evaporated at 55° C., 20 inches of Hg vacuum to concentrate the solution to 8% azadirachtin. The concentrate was then blended with 1% PABA, 20% Tween, and 32% propylacetate or 36% methylethylketone. The products were analyzed and found to contain less than 1% H₂O.

The stability of the solution was determined at 55° C. The results showed only a 10% decrease in azadirachtin titer on 21 days storage at 55° C.

We claim:

1. A storage-stable pesticide composition comprising a neem seed extract solution containing azadirachtin wherein the solution has at least 50% by volume aprotic solvent and less than 15% by volume water and wherein said solution is non-degrading to azadirachtin, has greater than 10 g/l of azadirachtin and is prepared from a dewaxed, azadirachtin-containing neem seed extract.

Examples

Claims
of the invention

Inventorship

- Inventorship is decided by claims and the title of “inventor” is earned, not bestowed.

Eg: Claim 1. (as filed)

An adhesive composition

comprising part A, part B, part C, **part D** and a catalyst.

- Inventor 1: Parts A, B, C
- **Inventor 2:** **Part D**
- Inventor 3: Catalyst

all 3 are inventors – *as filed*,

*during prosecution if the claims part is withdrawn, then the **inventorship** of that inventor is **lost**.*

- Incorrect inventorship is difficult to fix once the application is filed.

CRITERIA FOR PATENTING

All the inventions are not patentable.

Certain criteria have to be fulfilled for the grant of patents:

- **Novelty**

The novelty of an invention is judged taking into consideration the knowledge available anywhere in the world at the time of filing the application for patent. In other words the invention should not be publicly known anywhere in the world prior to the date of filing of the patent application.



Prior Art Reference Claim

Claim of Present Invention

- **Non obviousness**

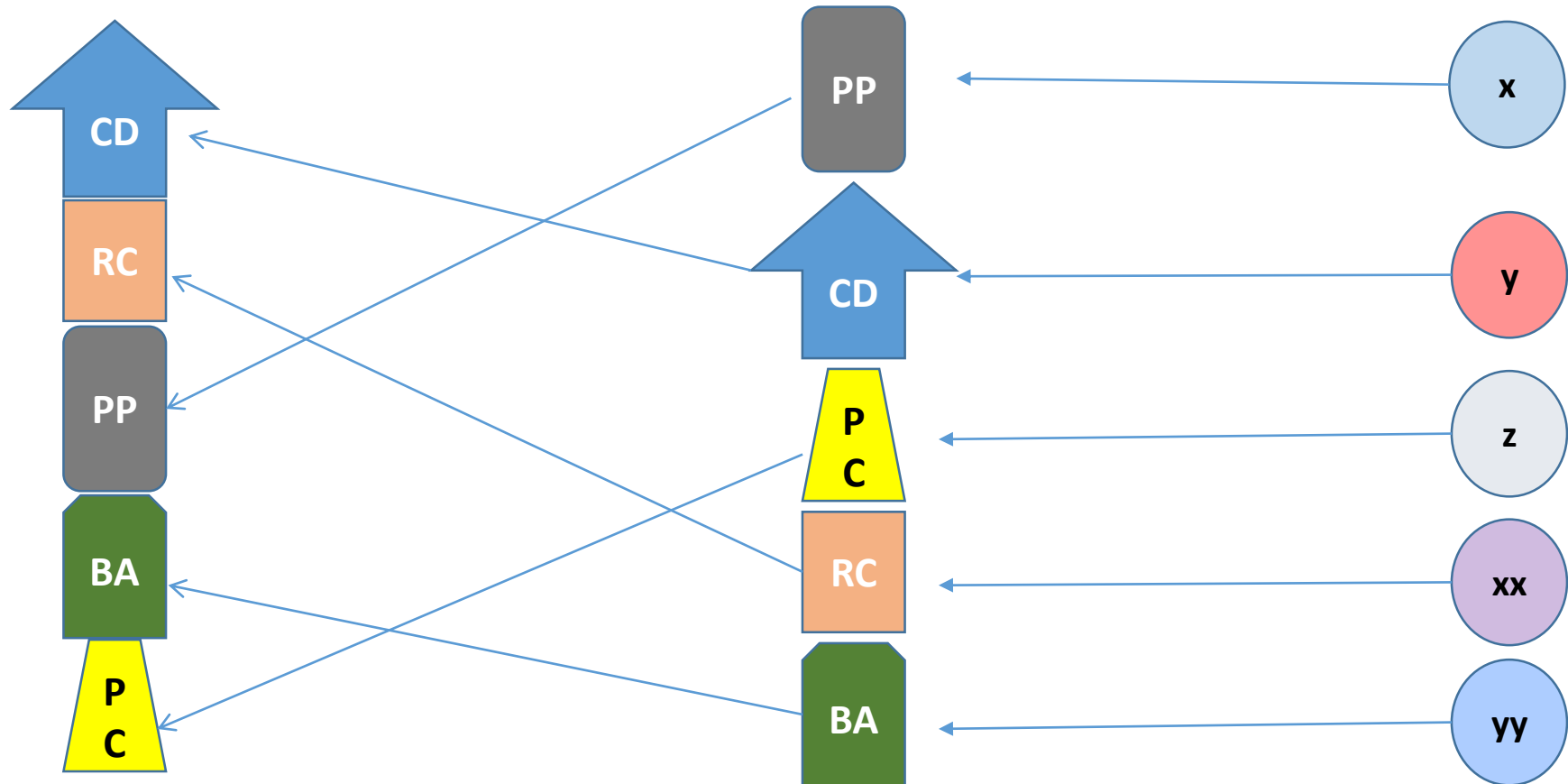
[PHOSITA]

An invention is considered to be non obvious when compared to what is already known.

ELEMENTS OF THE PRESENT INVENTION

ELEMENTS FROM PRIOR ART REFERENCES

PRIOR ART REFERENCES



- **Utility (Industrial Application)**

The invention must have utility and must take practical form such as apparatus, device a product such as new material, compound, substance or an industrial process producing the same product. Improvement in the existing process is also included in this.

Non-patentable inventions - INDIA

- a. an invention which is frivolous or which claims anything obviously contrary to well established natural laws;

Eg: A method of showing time on the basis of metric system wherein the dial having three hands(hour, minute and seconds) was divided into 10 parts for hour, each hour into 100 minutes and each minute into 100 seconds.

The invention was held frivolous. (Indian Patent Application 101/Bom/72s)

- b. an invention the primary or intended use or commercial exploitation of which could be contrary to public order or morality or which causes serious prejudice to human, animal or plant life or health;

Eg: a process for making cocaine
 a machine to print counterfeit currency notes
 any device to help in robbery

- c. the mere discovery of a scientific principle or formulation of an abstract theory;

Eg: Newton's laws of motion
 Theory of Relativity
 Microbe occurring freely in nature

Abhishek Sharma and Pushpa Sharma filed a patent application bearing no. 202111053480, titled “INNOVATIVE CHANGE TO SOLVE ANY DISPUTE, UNEXPECTED BUSINESS LOSS, CLOSURES, FINANCIAL LOSS, UNEXPECTED ACCIDENTS.” with the Indian Patent Office in 2021. The application contained three claims, each quite more interesting than the other, and are provided below.

“We claim:

1. A wearing’s comprising:

- a. a cloth or any cloth;***
- b. a band;***
- c. a foot wear;***
- d. an accessory;***
- e. an asset; or***
- f. any coating.***

wherein the color of the article is black.

2. The black coloured wearing’s as claimed in claim 1, wherein the wearing’s have affects on the human brain.

3. The black coloured wearing’s as claimed in claim 1, wherein the wearing’s transfer the negative energy from the self to others or else to an outside environment.”

The controller finally refused the application on 10th November 2022 after a hearing maintaining that the invention was not patentable.

The court further noted that the controller’s finding that the application was merely an abstract theory without scientific or technical basis and did not qualify as an invention under the Patents Act was indeed correct and irrefutable.

contd....

d. The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant;

Explanation: For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and others derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy;

The **Novartis v. Natco Pharma** case involves a dispute over the patent of the drug Eltrombopag Olamine (ELT-O), a cancer treatment drug. Novartis argued that their patent on ELT-O was valid, while Natco argued that the patent was invalid because ELT-O was not a novel invention, and it was covered by an earlier expired patent (IN'176).

- Novartis' Argument:**

- Novartis claimed that their patent on ELT-O was valid because ELT-O had enhanced solubility and bioavailability over the free acid base, ELT. They argued that this made **ELT-O a novel invention with greater therapeutic efficacy.**

- Natco's Argument:**

- Natco argued that ELT-O was not a novel invention and that it was covered by the earlier expired patent (IN'176). They claimed that ELT-O was merely a new form of ELT, a known substance, and did not enhance ELT's efficacy.

- Court Decision:**

- The Delhi High Court initially granted Novartis an injunction against Natco, but the Division Bench later overturned the decision. The court found that the patent on ELT-O lacked novelty because it was covered in the earlier patent (IN'176). The court also found that the patent was **not valid because it was a mere salt form of a known substance and did not have greater therapeutic efficacy.**

contd....

- e. A substance obtained by a mere admixture resulting only in the aggregation of the properties of the components thereof or a process for producing such substance;**
- f. The mere arrangement or rearrangement or duplication of features of known devices each functioning independently of one another in a known way;**

Electric bulb is known to emit light

Umbrella is known to protect from rain

If an umbrella is fitted with bulb to give light to the person walking at night and in rain, the purpose is served but it is a mere rearrangement.

contd....

g. A method or a process of testing (omitted sec 4. of 2002 amendment);

h. a method of agriculture or horticulture;

Terrace farming cannot be patented(eg: 64/Cal/79).

i. any process for the medicinal, surgical, curative [diagnostic, therapeutic] or other treatment of human beings or animals to render them free of disease or to increase their economic value or that of their products;

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

contd....

BTS Research International Pty Ltd. Filed an application “*Method of Generating Hybrid/Chimeric Cells and Uses Thereof.*” The 0041/KOLMP/2012, involved an artificial process for fusing tri-hybrid cells through the fusion of three somatic cells of which at least two are of different types and can be cells of humans and a mouse.

The Assistant Controller rejected on the grounds that it involved the use of cells with attributes of naturally occurring parent cells (human or non-human), thereby deeming the process biological rather than artificial and the invention fell under Section 3(j). Additionally, the invention fell under Section 3(c), as it constituted a discovery of a living thing occurring in nature and was therefore not patentable.

BTS challenged the refusal order.

The Court held that the rejection of the patent application under Sections 3(j) and 3(c) of the Patents Act was unsubstantiated and based on a fundamental misinterpretation of the statutory provisions. Accordingly, was set aside, and the matter was remanded for fresh adjudication by a different Hearing Officer, with a direction to dispose of the application within 12 weeks from the date of communication of the order.

k. a mathematical or business method or a computer program *per se* or algorithms;

The Draft Guidelines for Examination of Computer Related Inventions (CRIs), issued by the Indian Patent Office in March 2025, aim to bring greater clarity to the examination of patent applications concerning emerging digital technologies.

These include

Artificial Intelligence (AI), Blockchain, Quantum Computing, Cloud Computing, and the Internet of Things (IoT).

The guidelines cite multiple judicial decisions that have contributed to the evolution of CRI patent law in India.

These include:

Ferid Allani v. Union of India (2019)

Microsoft Technology Licensing LLC v. Assistant Controller of Patents and Designs (2023 and 2024)

OpenTV Inc v. Controller of Patents and Designs (2023)

Raytheon Company v. Controller General of Patents and Designs (2023)

Ab Initio Technology LLC v. Assistant Controller of Patents and Designs (2024)

Blackberry Limited v. Assistant Controller of Patents and Designs (2024)

Caleb Suresh Motupalli v. Controller of Patents (2025)

Telefonaktiebolaget LM Ericsson (Publ) v. Lava International Ltd (2024)

The guidelines reiterate that **technical effect** is a critical determinant in assessing patentability. As per the Guidelines, a technical effect, as defined, must represent a concrete technological improvement beyond abstract ideas or mental processes.

- Higher speed
- Reduced hard disk access time
- More economical use of memory
- More efficient database search
- Improved user interface
- Better control of robotic arm
- Improved reception/transmission of a radio signal
- Simultaneous recording/playback of audio/video
- Improved data compression techniques
- Enhanced data security and authentication

Examination procedure related to CRI applications

1. Novelty

- Understand the claims
- Identify relevant prior art
- Analyse prior art
- Determine explicit and implicit disclosures
- Assess material differences in view of claim scope
- Verify novelty through combinations and specific elements
- Document the novelty analysis and findings

2. Inventive Step

- Identify the person skilled in the art
- Establish general knowledge in the domain
- Define the inventive concept
- Compare with prior art
- Determine if the differences are obvious

If the innovation lies entirely in excluded subject matter such as an algorithm, the invention will not qualify as inventive.

3. Sufficiency of Disclosure

CRI specifications must fully describe:

- The invention
- The best method of performance
- All technical components and operations

Disclosures must be clear, replicable, and complete.

For AI Inventions:

- Clearly explain input-output transformations in AI systems
- Detail training data, learning model, and outcomes for trained AI models
- Describe pre-processing steps and their effects
- For reinforcement learning, explain environment interactions
- Show algorithm interaction with hardware or architecture
- Disclose dataset traits when technical effect depends on them

For blockchain related inventions:

- Describe cryptography, consensus, and network interaction

For novel ML techniques:

- Provide complete architectural and functional descriptions

Claim Drafting and Interpretation

The guidelines reiterate that claims must be:

- Clear and succinct and must comply with unity of invention requirements under Section 10(5) of the Patents Act, 1970.
- Fairly based on the disclosure
- Substantively examined for exclusions under Section 3(k)
- For means-plus-function claims, corresponding structural features must be disclosed in the specification. Claims without such disclosure are not allowable.

Assessment of Excluded Subject Matter under Section 3(k)

The guidelines provide clarification on the following:

Mathematical Methods: Not patentable unless applied in a technical process solving real-world problems

Business Methods: Excluded if they automate known practices without technical improvement

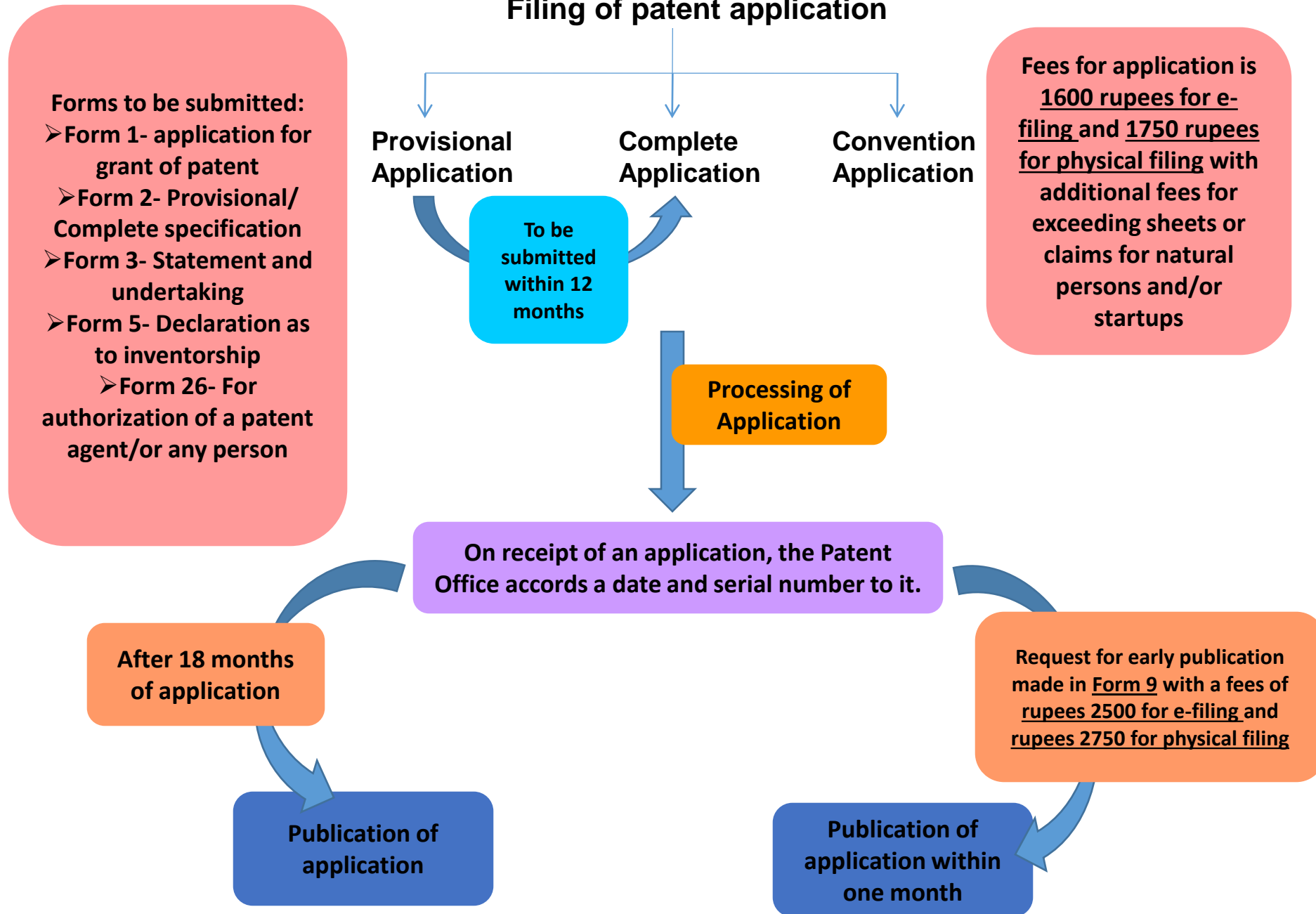
Algorithms: Non-patentable in isolation; may be considered if producing tangible technical effects

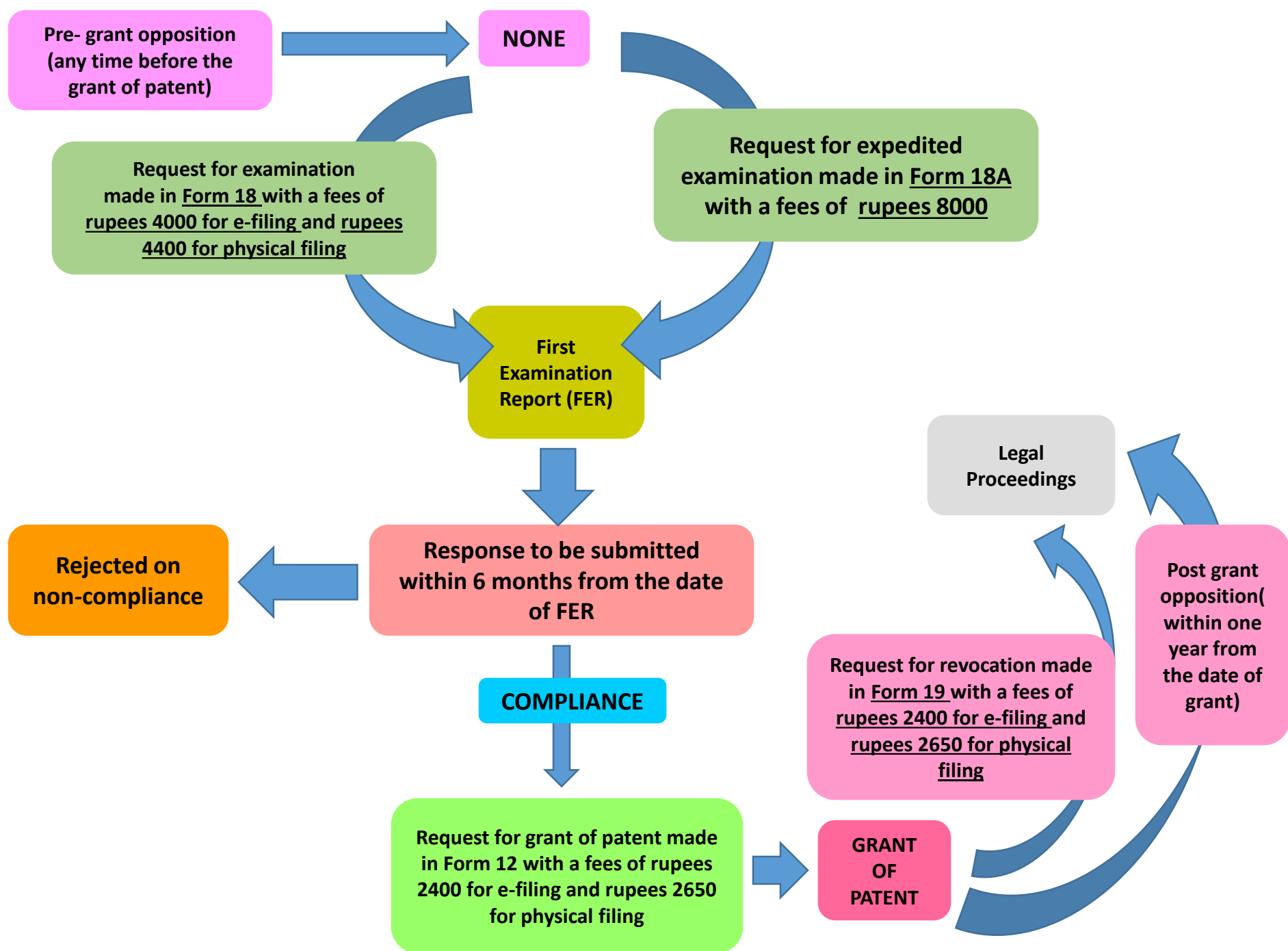
Computer Programmes *per se*: Excluded unless the programme results in technical contribution or solves a specific technical problem via hardware interaction

contd....

- l. a literary, dramatic, musical or artistic work or any other aesthetic creation whatsoever including cinematographic works and television productions;**
- m. a mere scheme or rule or method of performing mental act or method of playing games;**
- n. a presentation of information;**
- o. topography of integrated circuits;**
- p. an invention which, in effect, is traditional knowledge or which is aggregation or duplication of traditionally known component or components.**

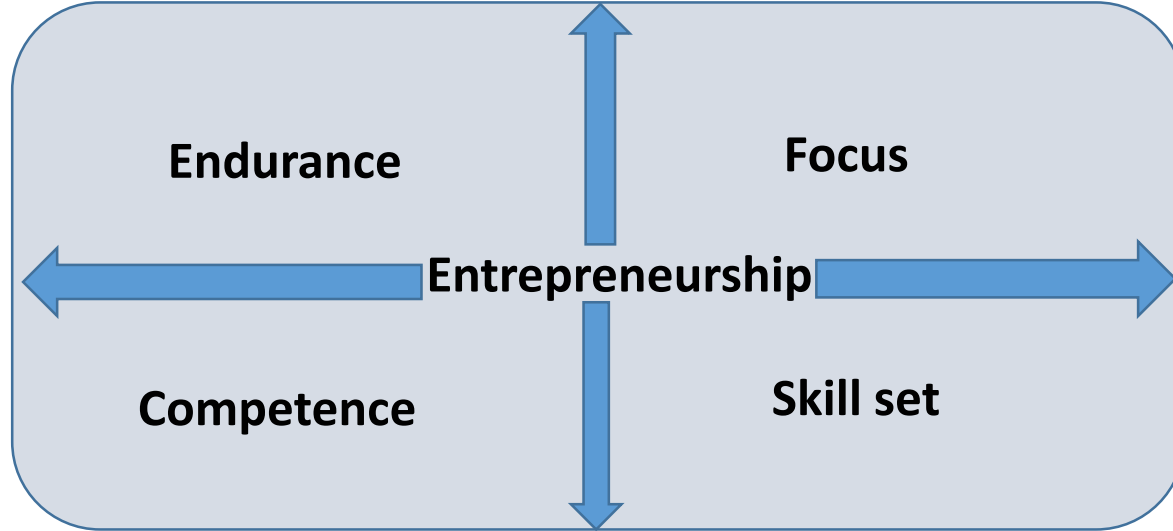
Filing of patent application





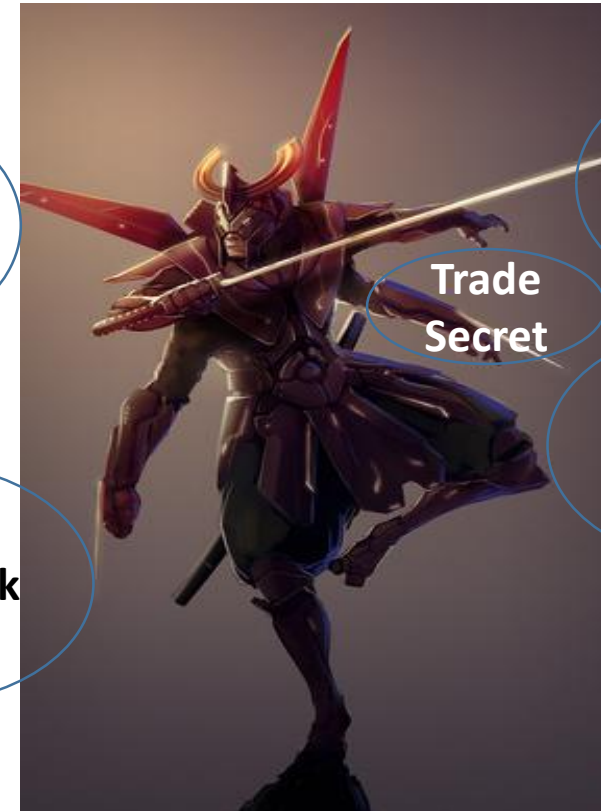
- Bearing an 'idea' in mind is different from 'putting it into practice'.
- This is where it is significant to understand 'conversion into an intangible asset'.
- For success in it, one needs to build the scope of the invention with strong 'Claims' and sufficient 'Disclosure'.
 - *If you have described what is claimed – No ambiguity, you get a patent grant*
 - *If you have NOT described what is claimed – You don't want others to know but there is a chance of rejection on insufficient disclosure*
 - *If you have NOT described what is NOT claimed - Could be a know-how and royalty term*
 - *If you have described but NOT claimed – Great loss to the invention and applicant.*
- Have to convince the authorities.

For path-breaking entrepreneurship it is significant to have



Copyright

Trademark



Trade
Secret

Patent

Industrial
Design

Entrepreneur has to face Examiners, IP Administrators, Regulatory authorities, Commercial Partners and Competitors

Entrepreneur has to wage wars with the help of M & Ms i.e. Mind & Money as the IP protection process is an expensive affair;

- IP Protection related Fees,
- Court Fees in case of infringement,
- Damages based on the verdict of courts.

Questions before the applicant

WHAT TO FILE?

- Compound
- Process
- Composition

WHEN TO FILE ?

- Filed early, one might have less time for commercialization
- Filed at a later stage, one might lose on competition

WHERE TO FILE ?

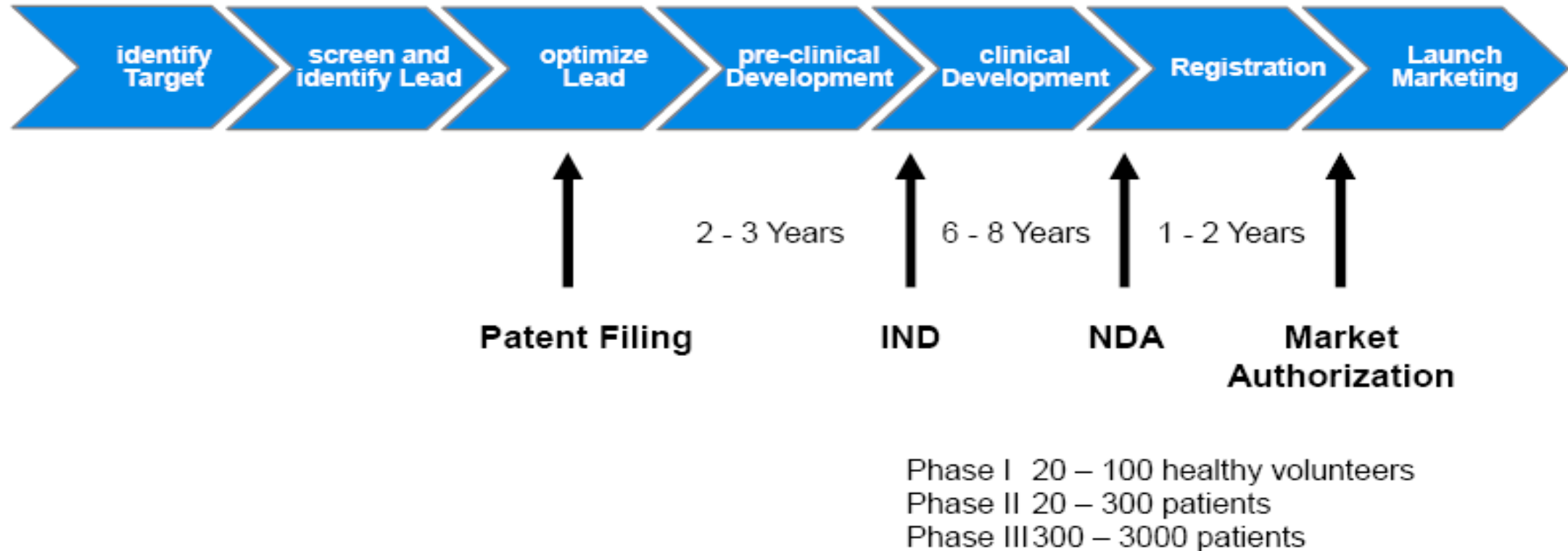
Decision on territories is key, need to have local representative and know local laws

Significance of Commercialization

IP as a tool for studding/culling

<p>New Technology (Stars)</p> <p>IP with the potential to protect newly developed technology expected to be commercialized in the near future.</p>	<p>Strategic Technology (Question Marks)</p> <p>IP with the potential to provide strategic value, such as excluding competitors from using alternative technology.</p>
<p>Commercial Technology (Cash Cows)</p> <p>IP with the potential to protect a current technology generating a cash flow.</p>	<p>Misaligned Technology (Dogs)</p> <p>IP that has no strategic fit within the company.</p>

Drug Discovery and Development

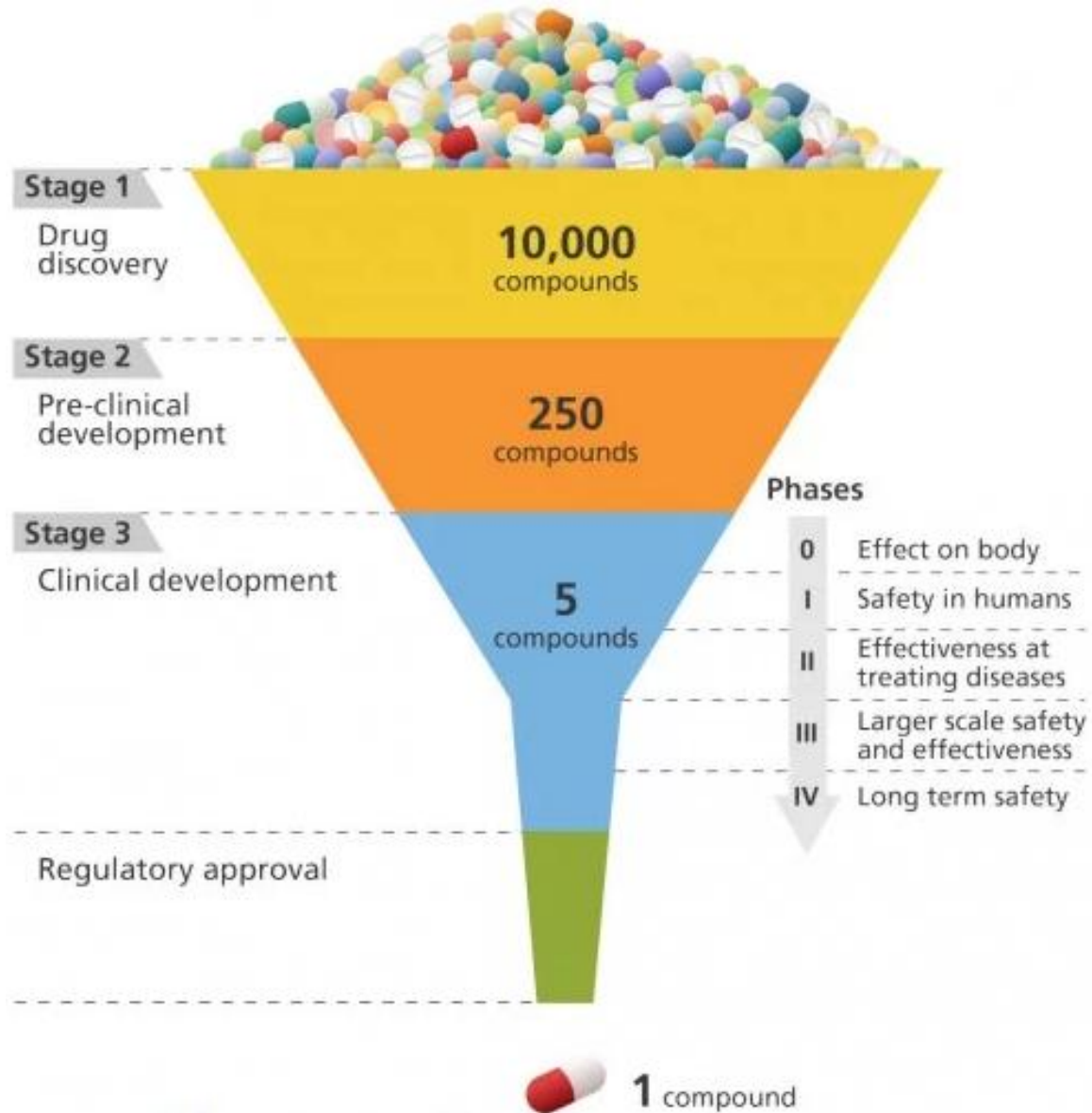


IND = Investigational New Drug

NDA = New Drug Application

- Patent as an incentive to innovate

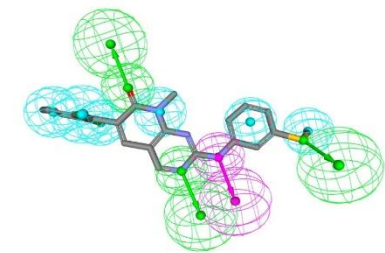
Rate of Success



Drug Design based on Bioinformatics Tools

- **Chemical Modification of Known Drugs**
 - Drug improvement by chemical modification
 - Pencillin G -> Methicillin; morphine->nalorphine
- **Receptor Based drug design**
 - Receptor is the target (usually a protein)
 - Drug molecule binds to cause biological effects
 - It is also called lock and key system
 - Structure determination of receptor is important
- **Ligand-based drug design**
 - Search a lead compound or active ligand
 - Structure of ligand guide the drug design process
- **Identify Target Disease**
 - Identify and study the lead compounds
 - Marginally useful and may have severe side effects
- **Refinement of the chemical structures**
 - Detect the molecular basis for disease
 - Detection of drug binding site
 - Tailor drug to bind at that site
 - Protein modeling techniques
 - Traditional Method (brute force testing)

Identifying the 'Pharmacophore'



The structural features directly responsible for activity - Pharmacophore
Optimizing structure to improve interactions with target

- Find hits and leads

“Lead compound” = structure that has some activity against the chosen target, but not yet good enough to be the drug itself.

- If not known, determine the structure of the “lead compound”.
- Synthesize analogs of the lead.
- Identify Structure-Activity-Relationships (SAR).

ADME

- *In vitro* permeability studies
- Pharmacokinetics in Mice (Single dose)
- Pharmacokinetics in Rats (Single dose & Multiple oral dose)
- Pharmacokinetics in Dogs (Single dose & Multiple oral dose)
- Distribution
 - *In vitro* protein binding study
 - Tissue distribution study
- Metabolism studies
 - *In vitro* metabolism in Mouse, Rat, Rabbit, Dog, Monkey & Human Liver Microsomes / Hepatocytes.

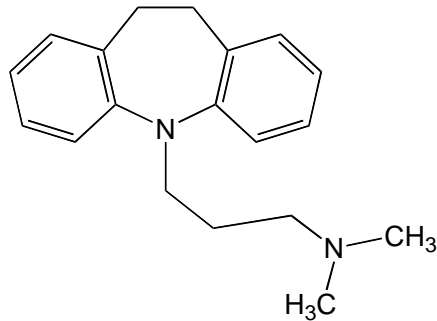
Choosing a Drug Target is a Challenge; Selectivity is important

- Drug Target = a macromolecule, or a biological system, which the drug specifically interacts with.
- Sometimes this can happen through incidental observation.

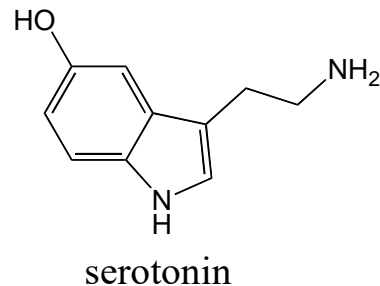
Tricyclic antidepressants were observed to “incidentally” inhibit serotonin uptake, instead of inhibiting uptake of noradrenaline

Idea of preparing molecules which could specifically inhibit serotonin uptake.

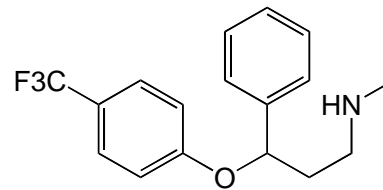
It eventually resulted in the production of Fluoxetine



Imipramine
(a classical tricyclic antidepressant)



serotonin



prozac

Problems can arise at anytime

- The chosen target, may over time, lose its sensitivity to the drug

Example

The penicillin-binding-protein (PBP) known to be the primary target of penicillin in the bacterial species *Staphylococcus aureus* has evolved a mutant form that no longer recognizes penicillin.



***In vitro* testing**

- Speed, requires relatively small amounts of compound
- High throughput screening
- Results may not translate to living animals.



***In vivo* testing**

- Expensive, requires relatively higher amounts of compound
- May cause suffering to animals
- Results may be clouded by interference with other biological systems.

Toxicity

- Toxicity standards are continually becoming tougher
- Must use *in vivo* (i.e. animal) testing to screen for toxicity
 - Each animal is slightly different, with different metabolic systems, etc.
 - Thus a drug may be toxic to one species and not to another.
- Single Dose Toxicity
- Multiple Dose Toxicity
 - Oral dose range finder study in rats
 - 28 day oral toxicity study in rats
 - Oral dose range finder study in dogs
 - 28 day oral toxicity study in dogs
- Genotoxicity (AMES, CA)
- Safety Pharmacology
 - Effects in CN, CV, Renal, Respiratory, Gastric systems.

Clinical Trials



***The journey of the world's first non-steroidal contraceptive from Academic venture to National Family programme**

- India launched its first national programme for family planning in 1952.**
- To achieve population stabilization, Government of India in association with WHO, posed a challenge to CSIR-CDRI to initiate a programme on safe contraception for Indian women.**
- The available oral contraceptives in those times caused many side effects such as nausea, cramps, headaches, breast tenderness, breakthrough bleeding and weight gain.**

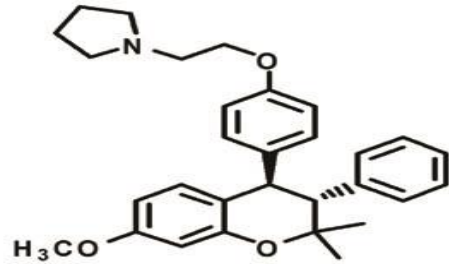
- In India, due to socio-cultural nurturing, anti-fertility drugs did not gain popularity. Therefore, the challenge was to develop a prototype which has anti-implantation rather than interfering in the development and maturation of the ovum itself, to increase its social acceptability.
- Scientists at CDRI rationalized the design of a series of compounds, based on the existing knowledge about the receptor for the female sex hormone 17-beta-estradiol.
- Although it is known that two different forms of this receptor are expressed in different tissues, a hypothesis was formulated to make a molecule that selectively binds to the receptor in the reproductive tissue, but not in other tissues.
- Scientists chemically synthesized several prototypes and evaluated their contraceptive activities.

- **Indoles and Coumarins were tried and found to be inactive, while benzofurans and naphthofurans showed good anti-fertility activity, but were associated with liver toxicity.**
- **Interestingly, chromenes and chromans turned out to be promising molecules with good contraceptive potential and minimal toxicity.**
- **Lead optimization resulted in synthesis of trans-2,2- dimethyl-3-phenyl-4-(p-[β -pyrrolidinoethoxy] phenyl)-7-methoxychroman which was christened as Centchroman (INN: Ormeloxifene), a **chroman** molecule from **Central** Drug Research Institute.**
- **Preclinical studies demonstrated that Centchroman disrupts the coordination between the rates of maturation of the developing embryo and the ripening of the uterus wall to accept it.**
- **Pharmacokinetics studies revealed that Centchroman is very well absorbed from the gut and is widely distributed in all body tissues including lungs, breasts, ovaries, uterus, etc.**

- **Centchroman is non-steroidal and is devoid of side effects reported for available steroidal contraceptives like vomiting, nausea, dizziness, weight gain, blood clots in small blood vessels, fluid retention, hypertension, breakthrough bleeding or excessive menstrual flow.**
- **Centchroman imparts anti-implantation contraceptive activity at the uterine level without disturbing the normal menstrual cycle or key elements of the brain, pituitary gland and ovaries.**
- **In clinical trials, a thorough follow-up for both nursing and non-lactating women was conducted to monitor changes in their physiology.**
- **An effective reversal to fertility upon discontinuation of Centchroman was observed making Centchroman suitable for spacing in child birth.**

- **Phase I (safety in humans) trial included single and multiple dose studies in women of reproductive age as per the drug regulatory guidelines.**
- **Centchroman has long elimination half-life and hence low dosing schedule (once a week).**
- **In phase II clinical trial, different groups of women received different doses ranging from 10 to 120 mg once a week.**
- **Phase III trials were carried out in about 2000 volunteers with an average use period of 12–18 months. The trials were conducted at 10 family welfare centres and 7 medical colleges.**
- **The dose-schedule which emerged most effective was to begin with 30 mg twice-a-week for 3 months, followed by 30 mg once-a-week till contraception is desired.**
- **CSIR-CDRI licensed Centchroman to HLL (Trivandrum) in 1991 which was launched as ‘Saheli’ in 1992.**
- **Further, Centchroman also turned out to be a drug of choice for dysfunctional uterine bleeding (DUB).**
- **HLL re-launched Centchroman as Novex and Novex DS for DUB.**

- Centchroman followed a long journey from discovery phase to reaching the market and national family programme



Journey of Centchroman (Ormeloxifen)

1967
CDRI
identifies
Centchroman

1978
Pre-clinical
studies
1988
Clinical trials

1991
Centchroman
licensed to
HLL

1992
Centchroman
launched
as "Saheli"

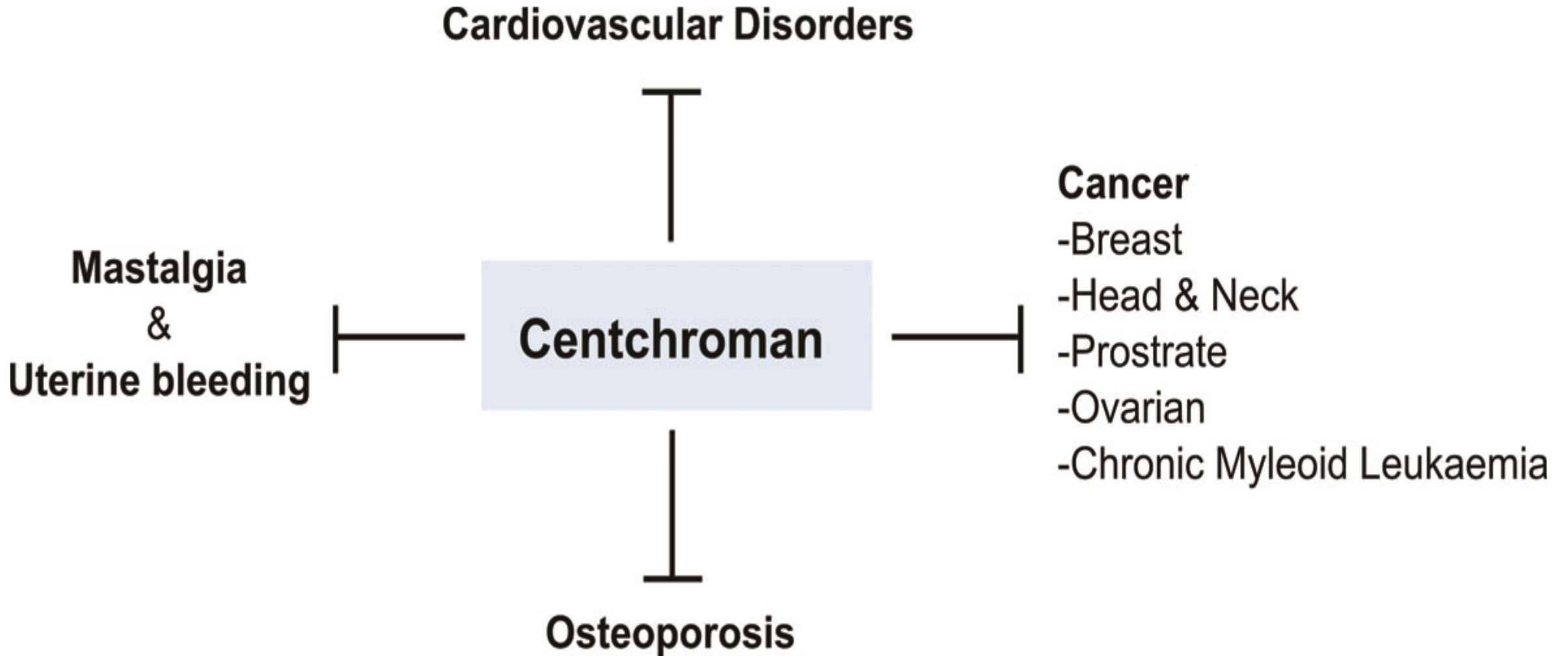
2006
HLL launches
Novex DS
for Menstrual
bleeding and
Mastalgia

2016
Available as
"Chhaya"
in National
Family
Programme

2016-
Clinical
evaluation for
Drug
repurposing



Repurposing of Centchroman

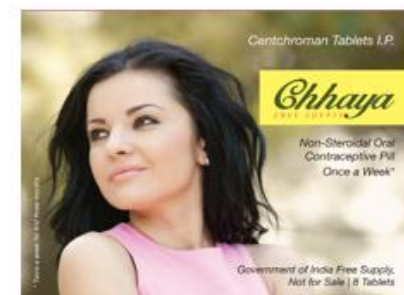


Saheli (Centchromon) – World's first non-steroidal once-a-week oral contraceptive pill

Developed by CSIR-CDRI; WHO proposed its INN as Ormeloxifene in 1983

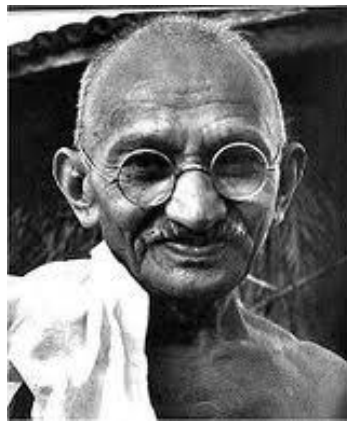
Marketed as Saheli, Centron, Sevista, Novex, Novex DS for various indications

- **Licensees/Beneficiaries**
 - HLL Lifecare Ltd., Thiruvananthapuram (1990)
 - Torrent Pharma. Ltd., Ahmedabad (1991)
- **Production/Turnover/Sale**
 - Total of 438.14 Mn pills sold (1991-2019)
 - Current annual user base of 6 lakhs
- **Market Value Generated (1991-2019): > Rs 120 Crore**
- **Sale of Novex & Novex DX (2010-2018): > Rs 25.65 Crore**
- Part of “National Family Planning Programme – 1995 (as Saheli) & 2016 (as Chhaya)”
- Chhaya- Government of India supply for home delivery by ‘ASHA’.
- Socio-economic class B populace are the main beneficiaries
- It is also indicated for Uterine dysfunction, Mastalgia, Fibroadenoma and as Emergency contraceptive.



FY	Brand Name	Order dispatched Qty	dispatched Qty
2017-18	Chhaya (FS)	2.99476 L. Srs.	2.99476 L. Srs.
	Chhaya Asha	6.98776 L. Srs.	6.98776 L. Srs.
2018-19	Chhaya (FS)	60.41833 L. Srs.	40.00 L. Srs.
	Chhaya Asha	60.41833 L. Srs.	40.00 L. Srs.
2019-20	Chhaya (FS)	31.3766 L. Srs.	Orders are under process
	Chhaya Asha	31.3766 L. Srs.	





“You be the CHANGE that you want to see in the world”

There has not been a single invention from India in the last 60 years that became a household name globally, nor any idea that led to “earth shaking” invention to “delight global citizens”.

- N R Narayana Murthy

1. "Alone I can 'Say' but together we can 'Talk'.

2. "Alone I can 'Enjoy' but together we can Celebrate.

3. 'Alone I can 'Smile' but together we can 'Laugh'.

That's the BEAUTY of Human Relations. We are nothing without each other

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