Lecture No: 01

Name of topic/lesson – History of Pharmaceutical Legislation in India
Subtopic: Introduction and history of pharmaceutical Legislation in India
Objective: To Study Recommendations of Drug Enquiry Committee

Topic Outcomes: At the end of topic you will
1. Know the origin of pharmaceuticals

2. Learn objectives of pharmaceutical Legislation

I) Drug Enquiry Committee – 1931
II) Drug Bill – 1940
III) The Drug & Cosmetic Rules -1945
IV) Pharmacy Act – 1948
V) The Drug & Magic Remedies -1954
VI) The Medicinal & Toilet Preparations -1955
VII) Narcotic Drugs & Psychotropic Substances -1985

Lecture no.02

Name of topic/lesson – History of Pharmaceutical Legislation in India

Subtopic: Code of Pharmaceutical Ethics

Objective: To Study Pharmaceutical Code of Ethics

Topic Outcomes: At the end of topic you will

1. Know difference between law & ethics

2. Learn Pharmacist in Relation to his Job & to his Profession

Law- Rules of human conduct binding all persons in state or nation.

Lecture no.03

Type	Content
"J"	List Of Diseases And Ailments That Drug Should Not Claim To Cure
"K"	List Of Drugs That Are Exempted From Certain Provisions Regarding Manufacture
"M"	Requirements Of Manufacturing Premises, GMP Requirements Of Factory Premises, Plants And Equipments
"M_1"	Requirements Of Factory Premises For Manufacture Of Homeopathic Medicines
"M_2"	Requirements Of Factory Premises For Manufacture Of Cosmetics
"M_3"	Requirements Of Factory Premises For Manufacture Of Medical Devices
"N"	List Of Equipment To Run A Pharmacy
"O"	Standards For Disinfectant Fluids

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Type	Content
"P"	Life Period(expiry) Of Drugs
"Q"	Coal Tar Colors Permitted To Be Used In Cosmetics
"R"	Standards For Mechanical Contraceptives
"R_1"	Standards For Medical Devices
"S"	Standards For Cosmetics
"T"	Requirements (GMP) Of Factory Premises For Ayurvedic, Siddha, Unani Drugs
"U"	Manufacturing And Analytical Records Of Drugs
"U_1"	Manufacturing And Analytical Records Of Cosmetics
"V"	Standards For Patent Or Proprietary Medicines
"W"	List Of Drugs Marketed Under Generic Names- Omitted
"X"	List Of Narcotic Drugs And Psychotropic Substances
"Y"	Requirement And Guidelines On Clinical Trials For Import And Manufacture Of New Drugs

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Lecture no.04

Administration of the act and rules

A) Advisory :
1)Drugs Technical Advisory Board-DTAB
2)Drugs Consultative Committee-D.C.C.

B) Analytical :
1)Central Drugs Laboratory - CDL
2)Drug Control Laboratory in states
3)Government Analysts

C) Executives :
1)Licensing authorities
2)Controlling authorities
3)Drug Inspectors

D) Schedule N
E) Schedule M
F) Schedule Y

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Lecture no.05

Drugs Technical Advisory Board(DTAB)

Ex-Officio:

(i) Director General of Health Services (Chairman)
(ii) Drugs Controller, India

(iii)Director of the Central Drugs Laboratory, Calcutta
(iv) Director of the Central Research Institute, Kasauli

(v)Director of Indian Veterinary Research Institute, Izatnagar
(vi) President of Medical Council of India

(vii) President of the Pharmacy Council of India
(viii)Director of Central Drug Research Institute, Lucknow

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Lecture no.06

Central Drug Laboratory(CDL)

- Established in **Calcutta**, under the control of a director appointed by the Central Government.

Functions:

1. **Analysis or test** of samples of drugs/cosmetics sent by the custom collectors or courts.
2. Analytical **Q.C.** of the imported samples.
3. Collection, storage and distribution of **internal standards.**
4. Preparation of **reference standards** and their maintenance.
5. Maintenance of **microbial cultures.**
6. **Any other duties** entrusted by Central Government.
7. Acting as an **appellate authority** in matter of **DISPUTES.**
8. Training of drug analysis.
9. To advise the central drug control administration in respect of quality & toxicity.
10. To work out analytical specification of Monographs for IP & Homeopathic P.copoeia.
11. Analysis of cosmetics

Central drug testing Lab.(CDLT), CHENNAI, MUMBAI,GUWAHATI

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Lecture no.07

Government analyst

- State government appoint persons as government analysts for the purpose of analysis/testing of samples of drugs & cosmetics.
- The central government may also appoint such person as a government analysts.
- Government analyst should have **NO** direct or indirect interest in Import, Manufacture OR Sale of drugs & cosmetics.

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Lecture no.08

IMPORT OF DRUGS

A. Classes of drugs prohibited to import

B. Import of drug under license
   1)Specified in Schedule-C/C_1
   2)Specified in Schedule-X
   3)Imported for Test/Analysis
   4)Imported for personal use
   5)Import Of Homeopathic & Cosmetics Drugs

C. Drugs exempted from provisions of import
D. Custom Frontiers
E. Offences and Penalties

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Lecture no.09

Manufacture

A. Prohibition of manufacture

B. Manufacture of other than in Sch-C/C_1

C. Manufacture of those in Sch-C/C_1

D. Manufacture of Sch-X drugs

E. Loan license

F. Repackaging license

G. Offences & Penalties

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Lecture no.10

E. Loan license

Definition:

A person(applicant) who does not have his own arrangements(factory) for manufacture but who wish to avail the manufacturing facilities **owned by another licensee**. Such licenses are called Loan licenses.

Loan licenses are issued for:

1) Drugs other than specified in C/C_1 & X.
2) Drugs specified in Schedule-C/C_1

PRCEDURE:

- A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-24-A, 27-A) with prescribed fees (Rs. 6000, 1500)
- If the conditions fulfilled ,then license is issued in a prescribed Form (No.25-A, 28-A)

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F. Repackaging license

- Definition:

  Process of **breaking up** any drug from a bulk container into small packages and labeling with a view to their sale and distribution.

  Repackaging of drugs is granted of drugs other than Schedule-C/C $_1$ and X.

PRCEDURE:

- A License is obtained from licensing authority (Food & Drugs Control Administration) on application in prescribed form (No-24-B,) with prescribed fees (Rs. 500, 200)
- If the conditions fulfilled ,then license is issued in a prescribed Form (No.25-B,)

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Manufacture of cosmetics

Prohibited for the following classes of drug:

- Misbranded or spurious cosmetics and of substandard quality
- Cosmetics containing hexachlorophene or mercury compounds
- Cosmetics containing color which contain more than-
  - 2 ppm of arsenic, 20 ppm of lead, 100 ppm of heavy metals

- Eye preparations containing coal-tar color
- List of cosmetics

Skin Powders, Skin Powder For Infants, Tooth Powder, Tooth Paste, Skin Creams, Hair Oils, Shampoo-soap-based, Shampoo-synthetic Detergent Based, Hair Cream

OFFENCES	PENALTIES
Manufacture of spurious cosmetics	3 years imprisonment & fine.
Contravention of the provision	1 year imprisonment & Rs. 2000 fine

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Sale of Drugs

1. Classes of drugs prohibited to be sold
2. Wholesale of biological (C/C_1) drugs
3. Wholesale of other than those specified in C/C_1 and X
4. Wholesale of Sch-X drugs
5. Retail sale
    1. General licences
    2. Restricted licences
6. Offences & Penalties

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Lecture no.11

OFFENCES &PENALTIES

OFFENCES	PENALTIES FOR FIRST CONVICTION	PENALTIES FOR SUBSEQUENT CONVICTION
Anyone who sells any adulterated or spurious drugs or drugs which likely to cause death.	5 Years to life time Imprisonment & Rs.10,000 fine	Imprisonment up to10 years or Rs.20,000 fine or both
Seles of any adulterated or spurious drugs or drugs which is not likely to cause death.	1 -3 Years Imprisonment & Rs.5000 fine	2-6 Years Imprisonment & Rs.10,000 fine
Sales of any drugs in contravention of pro-vision of the Act	1 -2 Years Imprisonment & fine	2-6 Years Imprisonment & Rs.5000 fine
If records are not kept & information not disclosed	3 Years Imprisonment or Rs.1000 fine or both	3-6 Years Imprisonment or Rs.1000 fine or both

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Labelling special

Class of drugs	Nature of medicines	Specific particulars appeared on label
Schedule C/C1	In original form	1)Proper name in addition to patent name 2)Potency in units 3)Name & address of manufacturer 4)Licence No. under which manufacturer 5)Date of manufacture 6)Date of expiry 7)Precaution for preparation
Schedule G	Made up ready for internal use	It is dangerous to take the preparation except under medicinal supervision.
Schedule G	External use	No caution required

Class of drugs	Nature of medicines	Specific particulars appeared on label
Schedule H	Internal use Not narcotic & psychotropic substances	1) Rx symbol on left top corner of the label 2) Schedule H drugs. 3) WARNING: to be sold by retail on the prescription of a R.M.P. only
	Internal use narcotic & psychotropic substances	1) N.Rx symbol on left top corner of the label 2) Schedule H drugs. 3) WARNING: to be sold by retail on the prescription of a R.M.P. only
	External use	External use only
Schedule X	Internal use	1) N.Rx in red ink symbol on left top corner of the label 2) Schedule X drugs. 3) WARNING: to be sold by retail on the prescription of a R.M.P. only
	External use	External use only

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Class of drugs	Nature of medicines	Specific particulars appeared on label
Patent and proprietary containing vitamin	-----	" For Therapeutic Use " OR "For Prophylactic Use " OR : For Pediatric use"
Non sterile surgical ligature suture	-------	"non sterile" Operation unless sterilised
Mechanical contraceptives	-------	1) As per Schedule- R 2) Date of manufacture 3) storage condition

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Lecture no.12
Name of topic/lesson –Pharmacy Act 1948
Subtopic: Composition of PCI

Objective: To Study Pharmacy Act & composition of PCI

Topic Outcomes: At the end of topic you will
1. Learn objectives of Pharmacy Act 1948
2. Know the composition of Pharmacy Council of India

Lecture no.13

Subtopic: State council & Joint state council its functions

Objective: To Study functions of State council & Joint state council

Topic Outcomes: At the end of topic you will
1. Learn state council & Joint state council
2. Know different functions of state council & Joint state council

Lecture no.14

Subtopic: Approval of courses and Institutions, Corresponding offences & penalties

Objective: Approval of courses and Institutions, Corresponding offences & penalties

Topic Outcomes: At the end of topic you will
1. Approval of courses and Institutions under Pharmacy Act 1948
2. Corresponding offences & penalties under Pharmacy Act 1948

Lecture no.15
Name of Topic: Drug Price Control Order

OBJECTIVES

- ✓ TO ACHEIVE ADEQUATE PRODUCTION
- ✓ TO REGULATE EQUAL DISTRIBUTION
- ✓ TO MAINTAIN AND INCREASE SUPPLY OF BULK DRUGS
- ✓ TO MAKE AT FAIR PRICES.

DEFINITIONS

BULK DRUGS :-

IT MEANS ANY PHARMACEUTICAL, CHEMICAL AND BIOLOGICAL OR PLANT PRODUCT CONFORM TO PHARMACOPOEIAL STANDARDS SPECIFIED IN D AND C ACT, 1940.

CEILING PRICE:-

PRICE FIXED BY GOVERNMENT FOR SCHEDULED FORMULATION.

DRUG :-

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SUBSTANCE INTENDED TO BE USED FOR OR IN THE DIAGNOSIS, TREATMENT, OR PREVENTION OF ANY DISEASE OR DISORDER IN HUMAN OR ANIMAL.

RETAIL PRICE :-

RETAIL PRICE OF DRUG FIXED IN ACCORDANCE WITH PROVISIONS OF DPCO 1995 AND INCLUDE CEILING PRICE.

SCHEDULED BULK DRUG :-

IT MEANS BULK DRUG SPECIFIED IN FIRST SCHEDULE.

PRICES OF BULK DRUGS

- **GOVERNMENT HAS POWER TO FIX THE MAXIMUM SALE PRICE.**

A. WHILE FIXING THE SALE PRICE GOVERNMENT SHALL TAKE INTO FOLLOWING CONSIDERATIONS:-

- POST-TAX RETURN OF 14% ON NET WORTH.
- RETURN OF 22% ON CAPITAL EMPLOYED.
- FOR NEW PLANT, RETURN OF 12% BASED ON LONG TERM MARGINAL COST.
- ON THE BASIC STAGE OF PRODUCTION, POST TAX RETURN OF 18% ON NET WORTH OR 26% ON CAPITAL EMPLOYED.
- AT THE TIME OF PRODUCTION OF DRUG, MANUFACTURER FILL DETAIL IN FORM-1 AND GIVE NECESSARY INFORMATION TO GOVERNMENT WITHIN 15 DAYS.

- MAKE NECESSARY INQUIRY AND THEN GOVERNMENT FIX MAXIMUM SALE PRICE IF BULK DRUG AND NOTED IN OFFICIAL GAZETTE.
- GOVR. ALSO FIX OR REVISE THE PRICE OF NON-SCHEDULED BULK DRUGS.

Lecture no.16

INFORMATION REQUIRED FROM MANUFACTURER TO THE GOVERNMENT

- FOR THE BOTH SCHEDULED AND NON-SCHEDULED BULK DRUGS
- LIST OF DRUG PRODUCED WITH COST IN FORM 1 AND 2 RESP.
- BUT FOR SCHEDULED BULK DRUGS IT SHOULD GIVEN BY 30 SEPTEMBER EVERY YEAR.

RETAIL PRICE OF FORMULATION CALCULATION- FORMULA

R.P. = (M.C.+C.C.+P.M.+P.C.) * (1+ MAPE / 100) + ED.

WHERE, R.P. = RETAIL PRICE

M.C.= MATERIAL COST

C.C.= CONVERSION COST

P.M.= PACKAGING MATERIAL COST

P.C.= PACKING CHARGES

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MAPE= MAXIMUM ALLOWABLE POST MANUFACTURING EXPENSES

ED = EXCISE DUTY

Lecture no.17

POWER TO FIX RETAIL PRICE OF SCHEDULED FORMULATION

- GOVERNMENT FIX THE RETAIL PRICE OF BULK DRUG.
- AND MANUFACTURER USE DRUGS IN SCHEDULED FORMULATION.
- FOR PRICE REVISION OF SUCH FORMULATION MANUFACTURER SHOULD APPLY WITHIN 30 DAYS.
- FROM DATE OF RECEIPT OF COMPLETE INFORMATION GOVR. FIX RETAIL PRICE WITHIN 2 MONTHS.

WITHOUT APPROVAL OF GOVERNMENT,

- MANUFACTURER SHOULD NOT INCREASE RETAIL PRICE OF DRUG.
- MANUFACTURER SHOULD NOT MARKETE NEW FORMULATION.
- NO PERSON SHALL SELL IMPORTED SCHEDULED FORMULATION.

POWER TO FIX CEILING PRICE OF SCHEDULED FORMULATION

- GOVERNMENT FIX THE CEILING PRICE OF SCHEDULED FORMULATION WITH FORMULA GIVEN IN THE PARAGRAPH 7 KEEP COST AND EFFICIENCY OR BOTH.
- CEILING PRICE FOR FORMULATION INCLUDING THOSE SOLD UNDER GENERIC NAME.
- FIXED REVISED CEILING PRICE FOR SCHEDULE FORMULATION EITHER ON IT'S OWN MOTION OR ON APPLICATION MADE IN PRESCRIBED FORM.

POWER TO REVISE PRICE OF BULK DRUG AND FORMULATION

- GOVERNMENT FIX OR REVISE RETAIL PRICE OF ONE OR MORE FORMULATION.
- AS THE PRE-TAX RETURN ON SALES TURNOVER OF FORMULATION THEN THE SCCHEDULED AND NON-SCHEDULED FORMULATION.

FIXATION OF PRICE UNDER CERTAIN CIRCUMSTANCES

- IF ANY MANUFACTURER OF BULK DRUG FAILS TO SUBMIT THE APPLICATION FOR FIXATION OR REVISION OF PRICE OR FAILS TO GIVE INFORMATION WITHIN SPECIFIED TIME PERIOD.
- THEN GOVERNMENT FIX PRICE OF THE BULK DRUG.

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POWER TO RECOVER OVERCHARGED AMOUNT

- IF ANY MANUFACTURER OR IMPORTER CHARGING HIGHER PRICE THAN THE PRICE FIXED BY GOVERNMENT

THEN GOVERNMENT MAY RECOVER THE OVERCHARGED AMOUNT

FIXATION OF PRICE UNDER CERTAIN CIRCUMSTANCES

- IF ANY MANUFACTURER OF BULK DRUG FAILS TO SUBMIT THE APPLICATION FOR FIXATION OR REVISION OF PRICE OR FAILS TO GIVE INFORMATION WITHIN SPECIFIED TIME PERIOD.
- THEN GOVERNMENT FIX PRICE OF THE BULK DRUG.

POWER TO RECOVER OVERCHARGED AMOUNT

- IF ANY MANUFACTURER OR IMPORTER CHARGING HIGHER PRICE THAN THE PRICE FIXED BY GOVERNMENT
- THEN GOVERNMENT MAY RECOVER THE OVERCHARGED AMOUNT.

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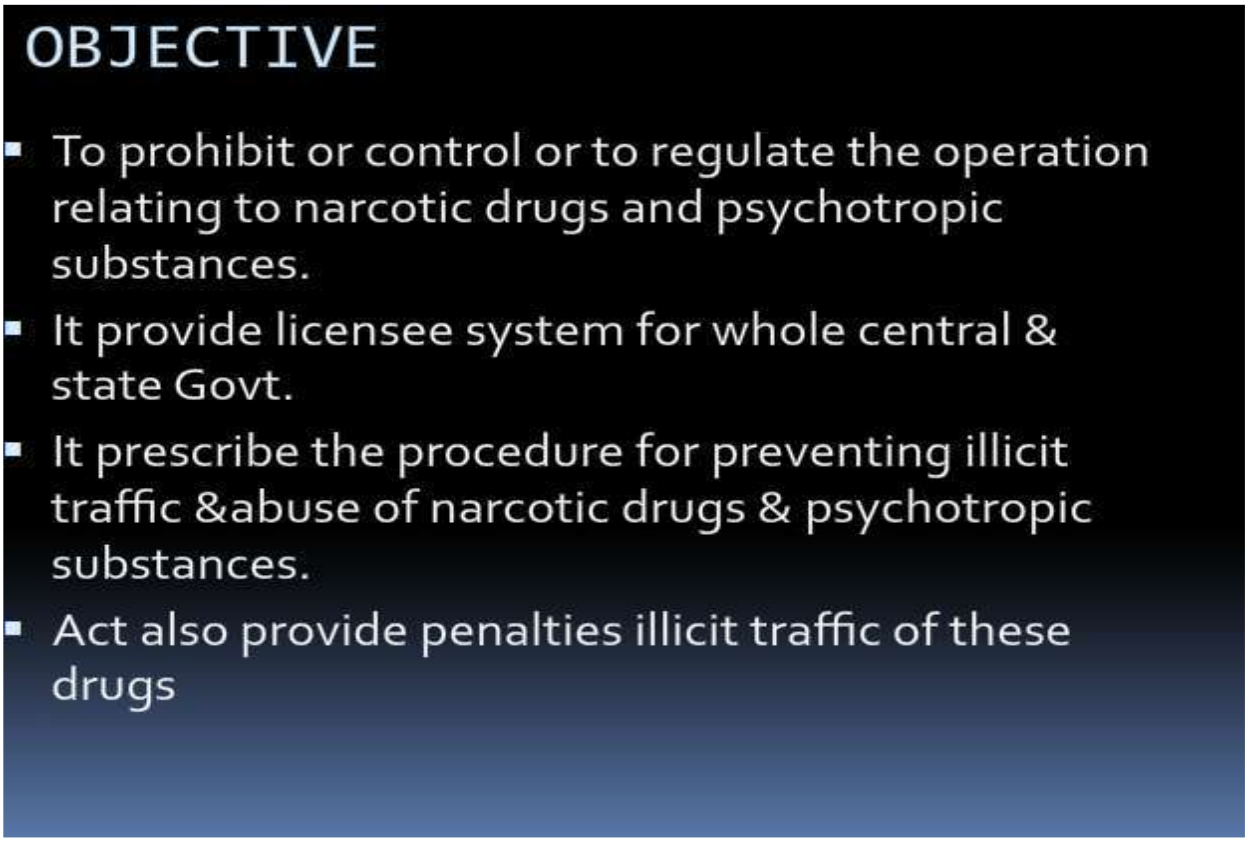
Lecture no.18
Name of Topic: Narcotics Drug & Psychotropic substances



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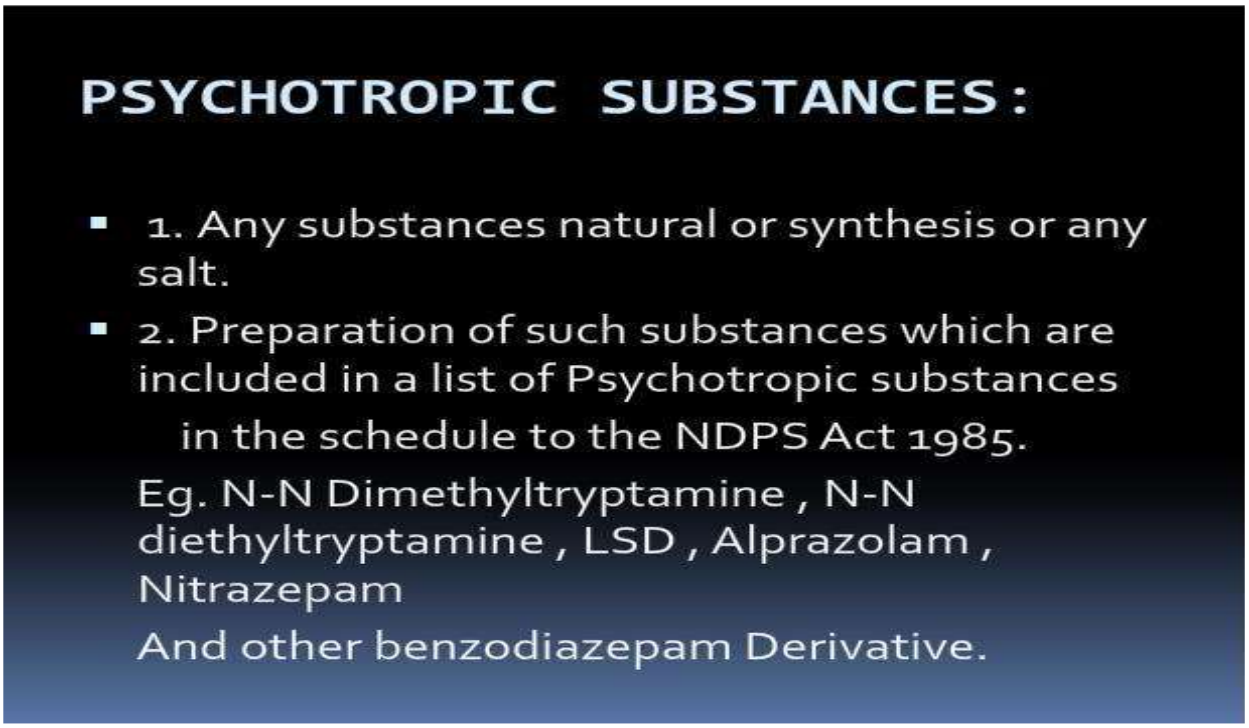
Lecture no.19



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COCA LEAF :

- Leaves of any plant of genus *Erythroxylon coca* ,Excluding leaves from which cocaine ecgonine And other egonine alkaloids is removed.
- Any mixture there of with or without any neutral material except any preparation containing Less than 0.1% of cocaine.

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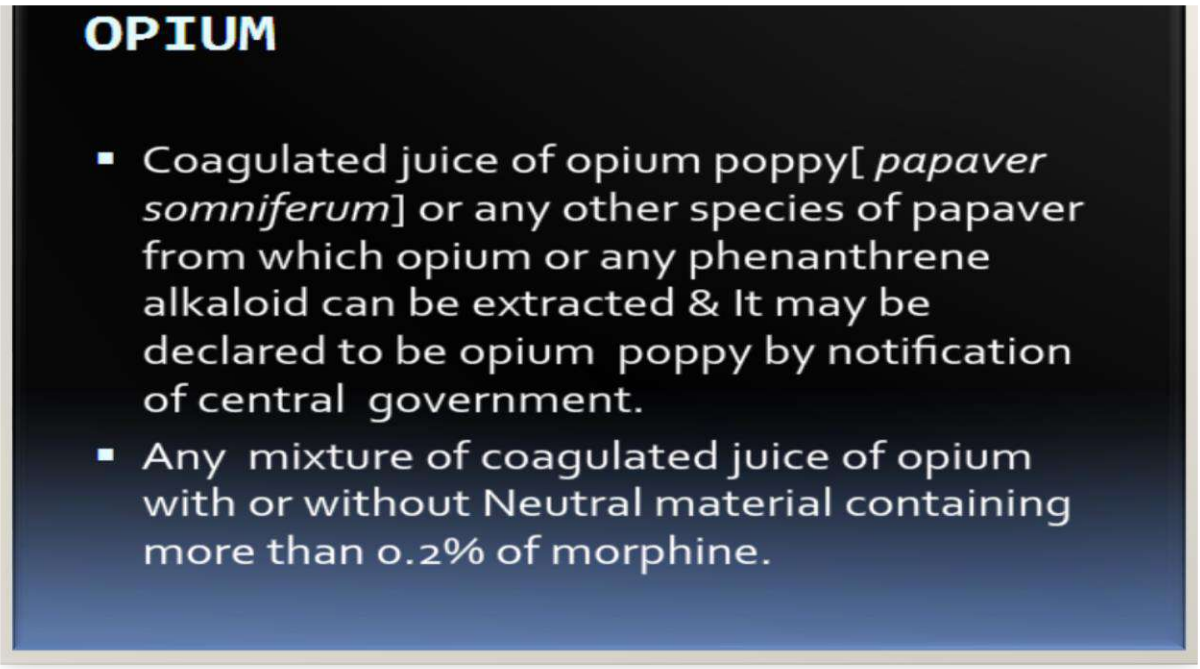
Lecture no.20



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Lecture no.21

Name of topic/lesson –The prevention of cruelty to Animals act 1960
Subtopic: – The prevention of cruelty to Animals act 1960

Objective: To Study Definition, Objectives of act

Topic Outcomes: At the end of topic you will
1. Learn objectives of prevention of cruelty to Animals act 1960

- To prevent the infliction of unnecessary pain or suffering on animals as well as to prevent to cruelty to animals.
- Animals: this term include any living creature except human being.
- Cruelty: it is not define under this act but it roughly means the infliction of unnecessary pain or suffering.

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Lecture no.22

Lecture no.23

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Lecture no.24

INTELLECTUAL PROPERTY

- Creation of human mind and intellect
- Idea or a concept or a thought at the beginning
- Research and Development to lead the idea or thought to practice
- The outcome of these ideas may be development of products, processes, works marks and design, etc.

COPYRIGHT

- Objective: To ensure protection from unlawfully exploitation of the work of owner(Author)
- Copyright act provides exclusive rights to authors and other owners of original works.
- Exclusive privilege to authors to reproduce, distribute, perform, or display their creative works.

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Lecture no.25

TRADEMARK

- Word or symbol used by manufacturers to identify goods.
- Customer able to distinguish product of one manufacturer from that of other.
- Initial registration for 10 yrs and further renewed by payment of fees for unlimited period.

GEOGRAPHIAL INDICATION

- Indication which identifies such goods (as agricultural goods, natural goods or manufactured goods) as originating or manufactured or processed in territory of the country or locality of the territory
- Quality and reputation of such goods are attributable to geographical origin

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Lecture no.26

DESIGN

- Includes shape; configuration; composition of colours, lines.
- Main criteria: a) Novelty
  b) Originality

Registration of design

- Currently governed by Design Act 2001
- Total time: 15 years

Initially right is granted for 10 yrs then can be extended by 5 yrs by making application along with necessary fee.

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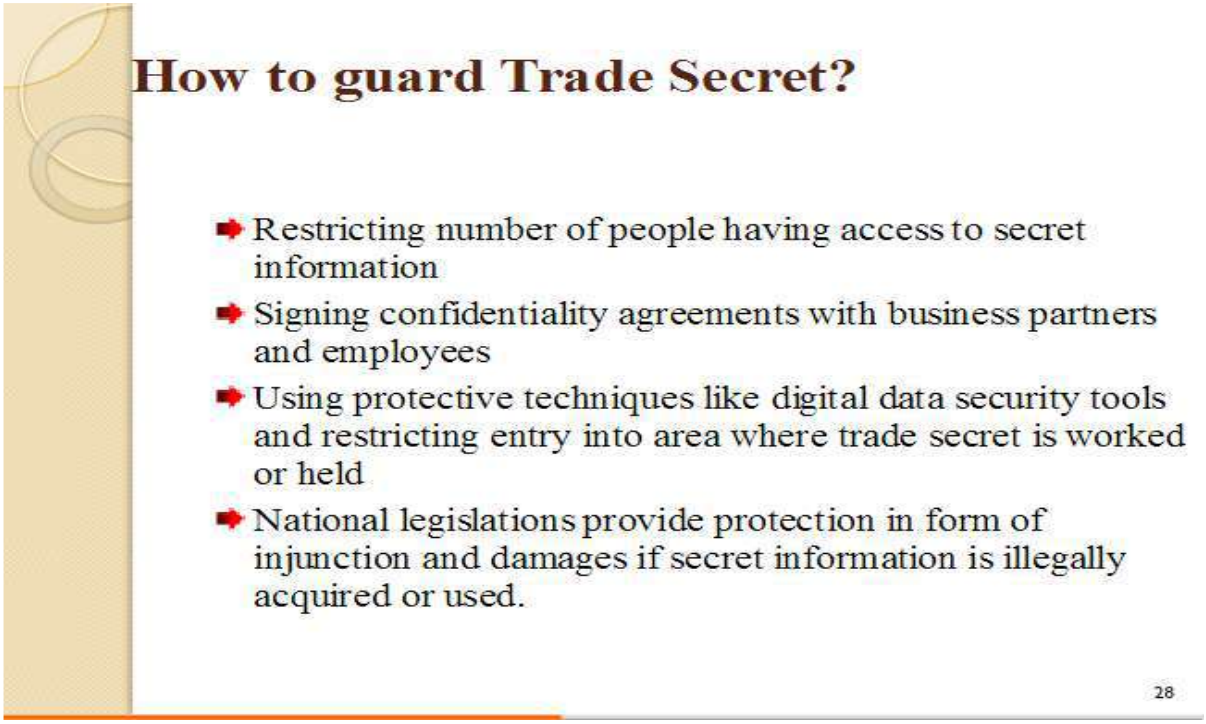
Lecture no.27

TRADE SECRET



Integrated Circuits

- Specific manner in which transistors & other circuitry elements of IC are laid out and includes connecting elements.
-

Lecture no.28

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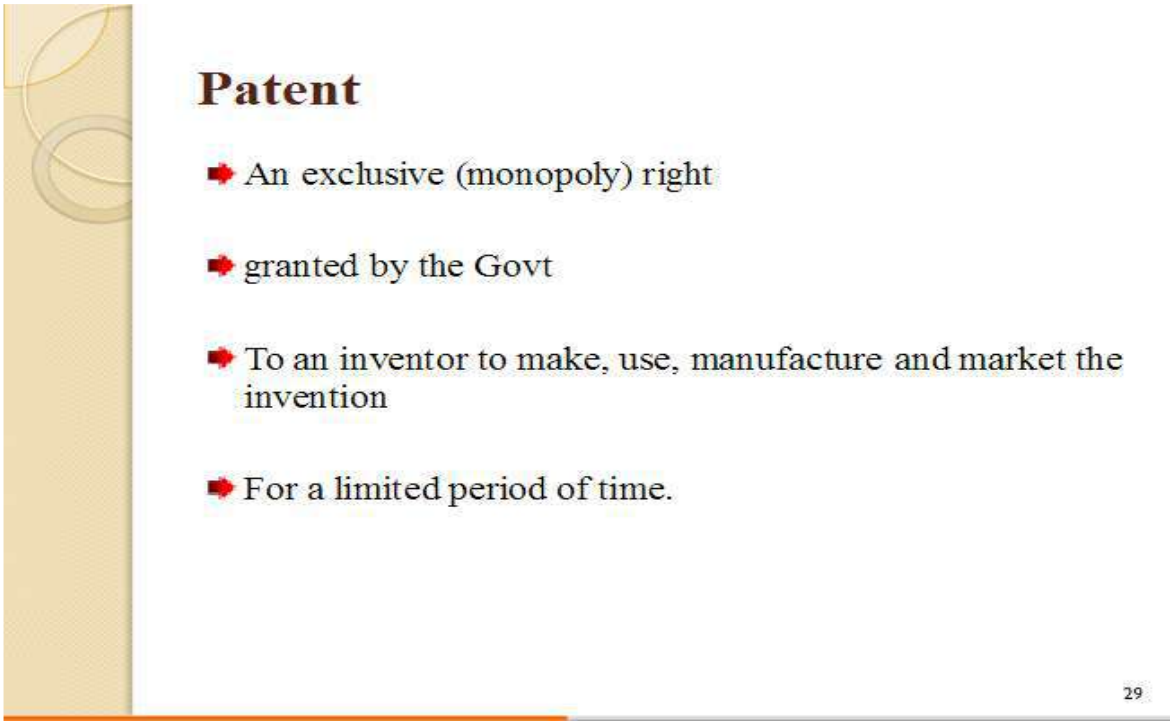

Lecture no.29

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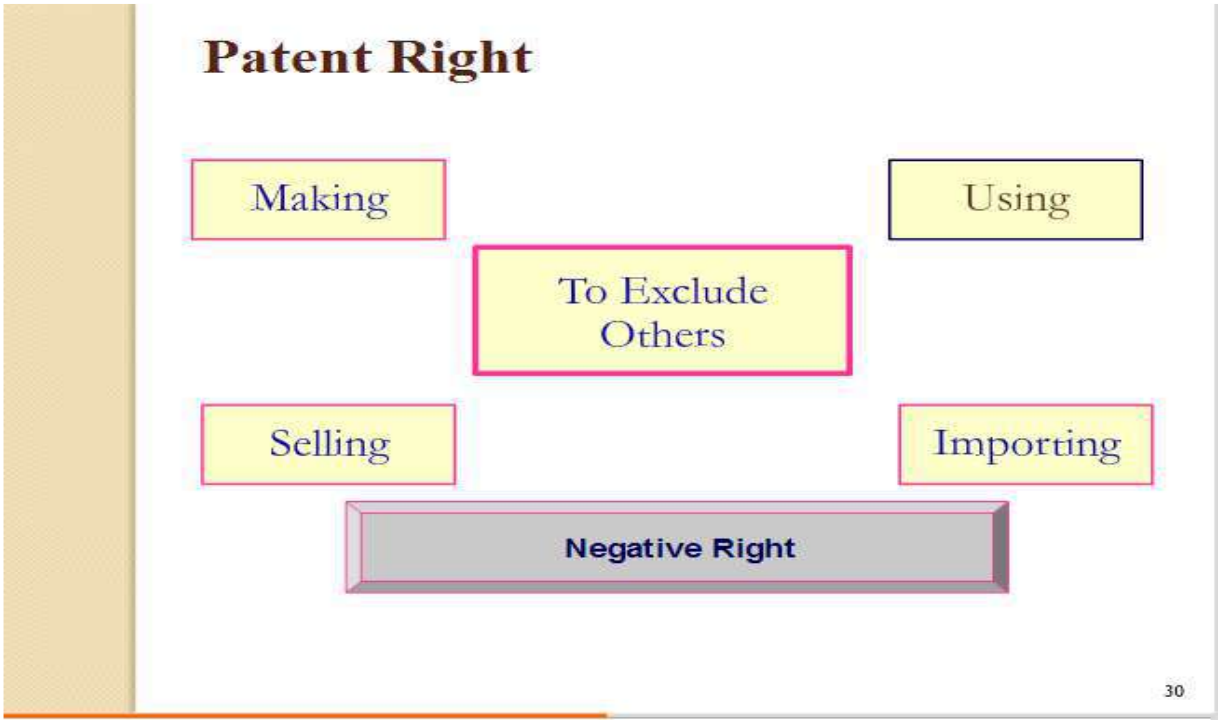

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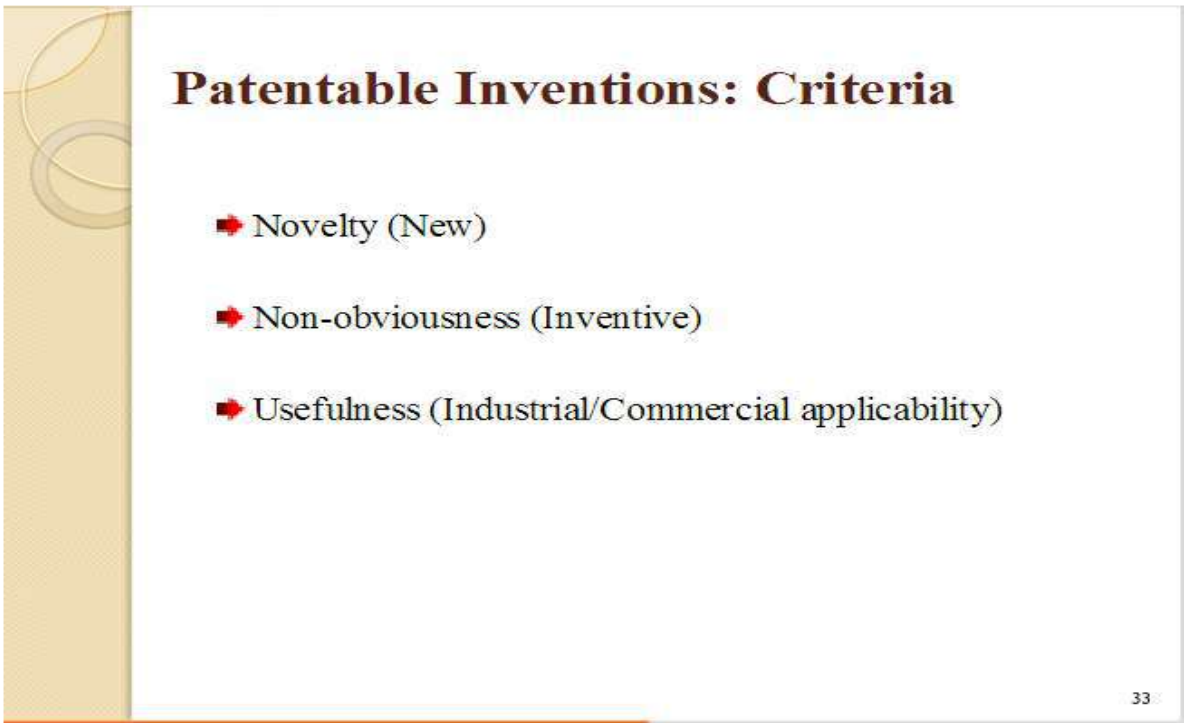
Lecture no.30



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Non-patentable Inventions

- Contrary to public order or morality or which causes **serious harm to human, animal or plant life** or health or to the environment.
- The **mere discovery of a scientific principle or the formulation** of an abstract theory (or discovery of any living thing or non-living substances occurring in nature).
- The mere discovery of a **new form of a known substance** which does not result in the enhancement.

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Continued....

- 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.
- **Plants and animals** in whole or any part thereof other than micro-organisms
- A **literary, dramatic, musical or artistic** work or any other aesthetic creation.
- Duplication of **traditional knowledge**.
- Any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other **treatment** of human beings or any process for a similar treatment.

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Lecture no.31

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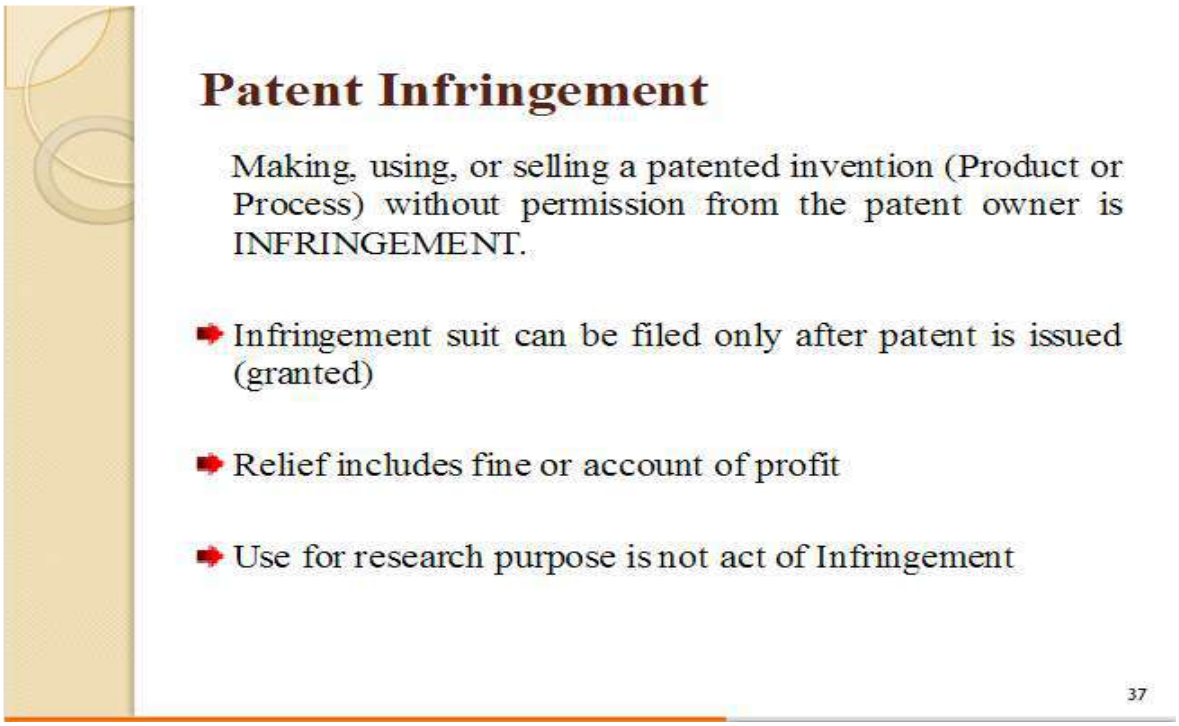
Lecture no.32



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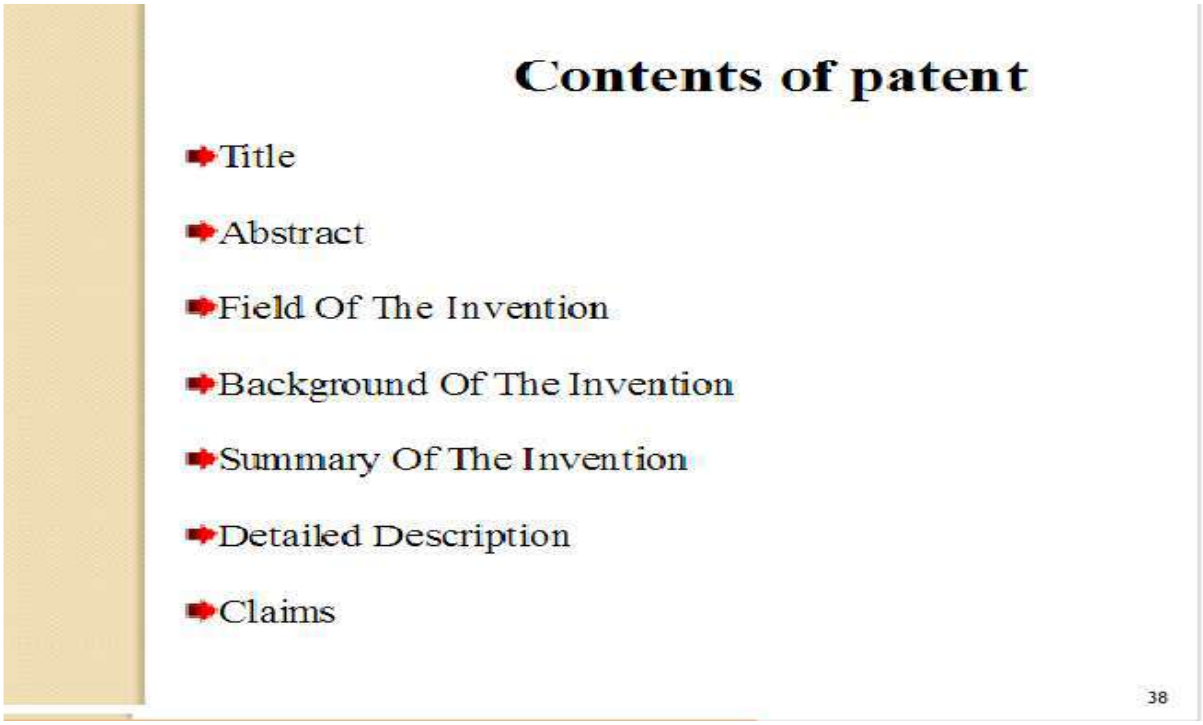

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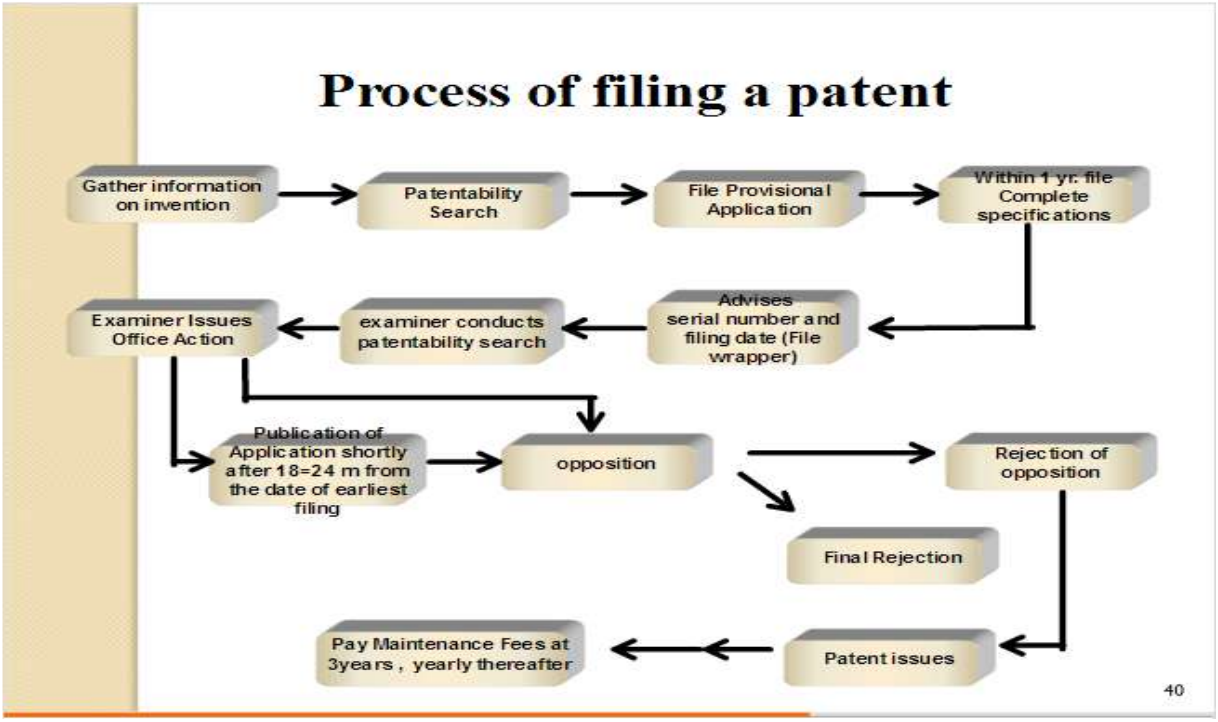

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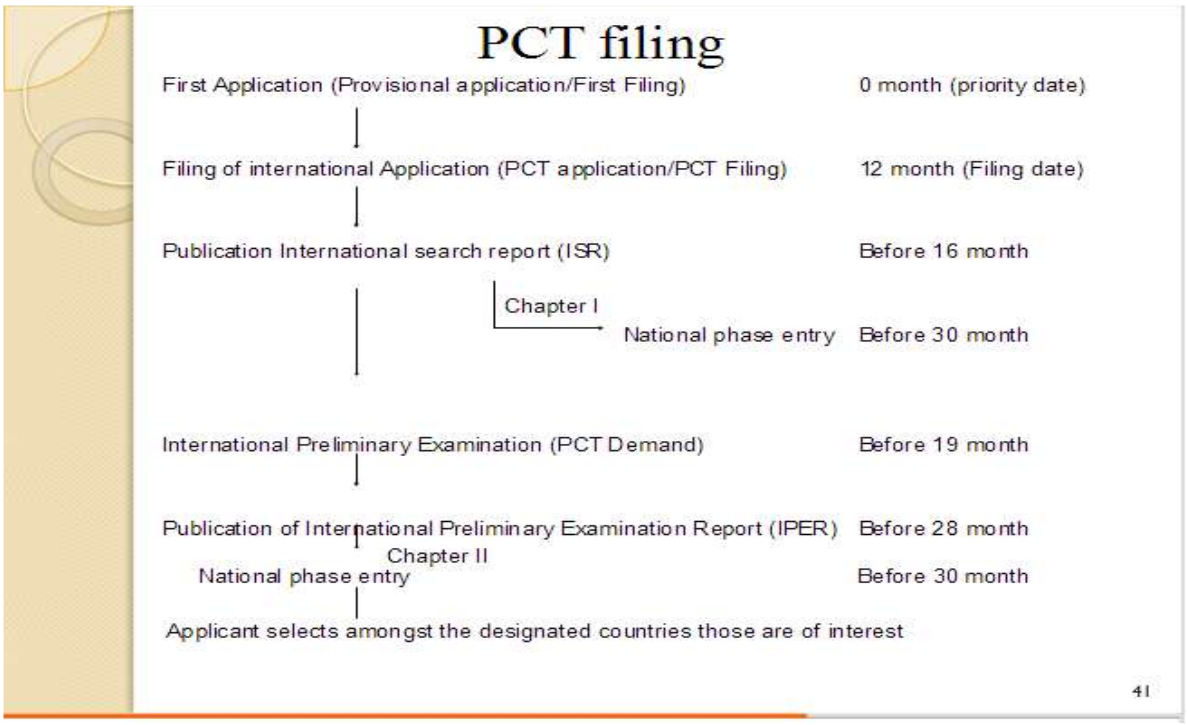
Lecture no.33



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- **Patent Agent -** Means a person for the time being registered under this act as a patent agent . Sec 2 (1)(n).
- **Patent Article & Patent process** – Means respectively an article or process in respect of which a patent is in force . Sec 2 (1)(o).
- **Patentee**- Means the person for the time being entered on register as the grantee or proprietor of the patent Sec 2(1)(p).
- **Invention** – Means a new product or process involving an inventing step and capable of industrial application

Sec 2 (1)(j.)

(OR)

Invention is a creative process . An open and curious mind allows an inventor to see beyond what is known. Seeing a new possibility, connection, or relationship can spark an invention. Inventive thinking frequently involves combining concepts or elements from different realms that would not normally be put together. Sometimes inventors disregard the boundaries between distinctly separate territories or fields.

TRIPS- **TRADE RELATED ASPECTS OF INTELLECTUAL PROPERTY RIGHTS**

- TRIPS requires that member countries of the WTO not having provision in their laws for granting product patents in respect of drugs and agrochemical, must introduce Exclusive Marketing Rights (EMR) for such products, if the following criteria are satisfied:
- A patent application covering the new drug or agrochemical should have been filed in any of the WTO member countries after 1 January, 1995;
- A patent on the product should have been obtained in any of the member countries (which provides for product patents in drugs and agrochemical) after 1 January 1995;

- Marketing approvals for the product should have been obtained in any of the member countries;
- A patent application covering the product should have been filed after 1 January 1995 in the country where the EMR is sought;
- The applicant should apply seeking an EMR by making use of the prescribed form and paying requisite fee.
- EMR is only a right for exclusive marketing of the product and is quite different from a patent right. It is valid up to a maximum period of 5 years or until the time the product patent laws come into effect.
- Patent is a technical as well as legal document that must be drafted by an expert who is registered as patent agent or patent attorney
- Main parts of patent are :
    - Title
    - Field of invention
    - Summary of invention
    - detailed description of invention
    - Claims
    - Abstract
    - Drawings if any

In order to be patentable , an invention must pass four test :

1. The invention must fall into one of five "**statutory classes**":

- Processes
- Machine
- Manufactures
- composition of matter and,
- New uses of any of the above

2. The invention must be "**useful**".

3. The invention must be "**Novel**".

4. The invention must be "**Non obvious**".

Form 1 - Application for Grant of Patent

In this form, you will have to furnish information, such as, name and address of the inventor(s), name and address of the applicant(s), information corresponding to prior patent applications

Relating to the current invention, which you or any authorized entity has filed, and some declarations, among other information.

Form 2 - Provisional/Complete Specification

Form 2 is used to furnish your patent specification. The patent specification can be provisional or a complete patent specification depending of the type of patent application (provisional or complete) you are filing.

If you are filing a provisional patent application, then use the following preamble in the first page of Form 2:

Form 3 - Statement and Undertaking Under Section 8

Form 3 is used to furnish information/actions relating to patent applications filed in other countries for the current invention.

Form 5 - Declaration as to Inventorship

This application is used to declare the inventors of the subject matter sought to be protected using the current patent application.

Form 9 - Request for Publication

If this form is not filed, then the patent specification will be published by the patent office after 18 months from the priority date (filing of the first patent application for the current subject matter). On the other hand, by filing this form, you can generally have your patent specification published within 1 week from filing this form. Note that the patent rights start from the date of publication of the patent application (enforceable after grant of patent).

Form 18 - Request for Examination of Application for Patent

This form can be filed within 48 months from the priority date. The patent office will not consider your patent application for examination unless this form is filed. Hence, if you wish to expedite the patenting process, filing of form 9 and 18 at an early stage is advised.

Please note that, the most important factor in filing a patent application is preparing a patent specification. Drafting a patent specification is a highly skilled job, which can be only preformed by persons who have both technical as well as patent law expertise.

Lecture no. 34

OPPOSITION TO GRANT OF PATENT

An opposition of grant of patent is an administrative process available under the patent and trademark law of most jurisdictions which allows 3rd parties to dispute the validity of a granted patent or trademark.

There are two procedure of opposition :

1). **Pre Grant Opposition –**

Any person can file an opposition for grant of patent after the application has been published .

Opposition may be filed on any of the following grounds:

a) Non compliance of patentability requirements.

b) Non disclosure or wrongful disclosure of genetic resource s or traditional knowledge .

). **Post-Grant opposition** : Any person can file an opposition within a period twelve month after the grant of a patent .It can be filed based on the following grounds:

a) Wrongful obtainment of the invention by the inventor

b) Publication of the claimed invention before the priority date.

c) Sale or import of the invention before the priority date.

d) Public use or display of the invention .

e) The invention doesn't satisfy the patentability requirement.

f) Disclose of false information to patent office .

g) Nondisclosure or wrong disclosure of the biological source .

h) Invention is anticipated by traditional knowledge

Lecture no.35

Process of Opposition :

On receiving a notice of opposition , the controller notifies the patentee . He then constitute an opposition board to deal with the opposition .The opposition board decide the issues after giving reasonable opportunity to hearing both the parties .

The opposition board might invalidate the patent ,require amendments or maintain the status quality .If amendments are required ,they have to made within the prescribed period in order to maintain the patent

Surrender of patents:

(1) A patentee may, at any time by giving notice in the prescribed manner to the Controller, offer to surrender his patent.

(2) Where such an offer is made, the Controller shall advertise the offer in the prescribed manner, and also notify every person other than the patentee whose name appears in the register as having an interest in the patent.

(3) Any person interested may, within the prescribed period after such advertisement, give notice to the Controller of opposition to the surrender, and where any such notice is given the Controller shall notify the patentee.

(4) If the Controller is satisfied after hearing the patentee and any opponent, if desirous of being heard, that the patent may properly be surrendered, he may accept the offer and, by order, revoke the patent

Patent infringement :

- Patent infringement is the commission of a prohibited act with respect to a patented invention without permission from the patent holder.

- The definition of patent infringement may vary by jurisdiction, but it typically includes using or selling the patented invention.
- **Direct patent infringement:-**
- Direct patent infringement is the most obvious and the most common form of patent infringement. ,i.e. anyone who makes, uses or sells the patented invention.
- 2**) Indirect patent infringement :-**
- It is an action or an activity by a third party encouraging another to make, use or sell the invention.

- The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations.
- The WTO agreements, are negotiated and signed by the bulk of the world's trading nations and ratified in their parliaments.
- The goal is to help producers of goods and services, exporters, and importers conduct their business.
- The grant and enforcement of patents are governed by national laws and international treaties.
- There is a trend towards global harmonization of patent laws and the WTO is actively participating in this area.
- The TRIPS [Trade Related Intellectual Property Rights] agreement has been successful in providing a forum for nations to agree on an aligned set of patent laws.

Lecture no.36

ABBREVIATED NEW DRUG APPLICATION

INTRODUCTION

- "ANDA" is the abbreviation for "Abbreviated New Drug Application". It contains data which when submitted to FDA's Center for Drug Evaluation & Research, Office of Generic Drug, provides for the review & ultimate approval of a generic drug product.
- Once approved an applicant may manufacture & market the generic drug product provided all issues related to patent protection, safe, effectiveness, low cost alternative to the public.
- Generic drug applications are termed "abbreviated" because they are generally not required to include preclinical (animal) & clinical (human) data to establish safety & effectiveness.
- A generic drug product is one that is comparable to an innovator drug product in dosage form, strength, route of administration, quality, performance characteristics & intended use.

- All approved products, both innovator & generic, are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations.
- Generic applicants must scientifically demonstrate that their product is bioequivalent (i.e. performs in the same manner as the innovator drug).
- The rate of absorption or bioavailability of the generic drug, is compared to that of the innovator drug.
- The generic version must deliver the same amount of active ingredients into a patient's bloodstream in the same amount as that in the innovator drug.
- Using bioequivalence as the basis for approving generic copies of the drug products was established by the "Drug Price Competition & Patent Term Restoration Act of 1984", also known as the Waxman-Hatch Act.
- At the same time, the branded name companies can apply for up to five additional years longer patent protection for the new

medicines they developed to make up for time lost while their products were going through FDA's approval process.

- Generic drug application reviewers focus on bioequivalence data, chemistry & microbiology data, request for plant inspection, & drug labeling information.

Lecture no.37

ANDA REQUIREMENT

1) Signed FDA form. Provides information regarding the applicants name & address, name of the drug product, the product strength & route of administration, indication of drug master files cited, proposed indications, a statement regarding whether the product is for prescription or over the counter.
2) An index should specify volume & page number for each complete & detailed item.
3) Information on the basis for which the ANDA is being submitted.
    a) Name of the reference drug, its dosage form & strength.

b) Information on exclusively for the listed drug.

c) If a suitability petition is approved a reference to the FDA number that was assigned to that suitability petition.

Condition for use, including,

a) A statement regarding the condition for which the drug will be used.

b) A reference to the noted labeling for the product & the currently approved labeling for the listed drug product.

5) A statement that active ingredient is the same as for that of the reference drug. For the combination product this must be shown for both active ingredient.

6) Route of administration, dosage form & strength. This should include a statement that the route of administration, dosage form & strength are same as the reference drug.

Bioequivalence. This should include information to demonstrate that the proposed drug is bioequivalent to the listed drug product.

Labeling. Include a copy of currently approved labeling for the listed drug as well as the proposed labeling for the drug being provided for in the ANDA. A side by side comparison of two sets of labeling is also necessary.

8) Chemistry, Manufacturing & Controls. Describe the composition, manufacture, specifications & analytical procedures for the drug substance & drug product.

9) Human Pharmacokinetics & Bioavailability.

This include information concerning

- The Design
- The Dosing procedure
- The number & frequency of blood & urine collection & Methodology for the assay.

- Samples.
- 10) The sample of the Drug substance & finished product should be provided in four individual units with sufficient quantities in each unit to permit the FDA to perform all the tests included in the specifications at least three times
- 11) Analytical method for drug substance & drug product. This section should consists of the specifications, analytical method, certificates of analysis,

method of analysis, method validation & stability indicating data as contained in the chemistry, manufacturing & control part of the application.

- 12) Labeling. 12 specimen of the final printed label & all labeling for the drug product are to be included.
- 13) Case report forms & tabulations. The need for these should be discussed with appropriate personnel of the division of bioequivalence prior to submission of the ANDA.

Lecture no.38

BIOEQUIVALENCE

Two products are bioequivalent if

- they are pharmaceutically equivalent
- bioavailabilities (both rate and extent) after administration in the same molar dose are similar to such a degree that their effects can be expected to be essentially the same

Therapeutic equivalence

Two products are therapeutically equivalent if

- pharmaceutically equivalent
- their effects, with respect to both efficacy and safety, will be essentially the same as derived from appropriate studies
    - bioequivalence studies
    - pharmacodynamic studies
    - clinical studies
    - *in vitro* studies

NEED OF BIOEQUIVALENCE STUDIES

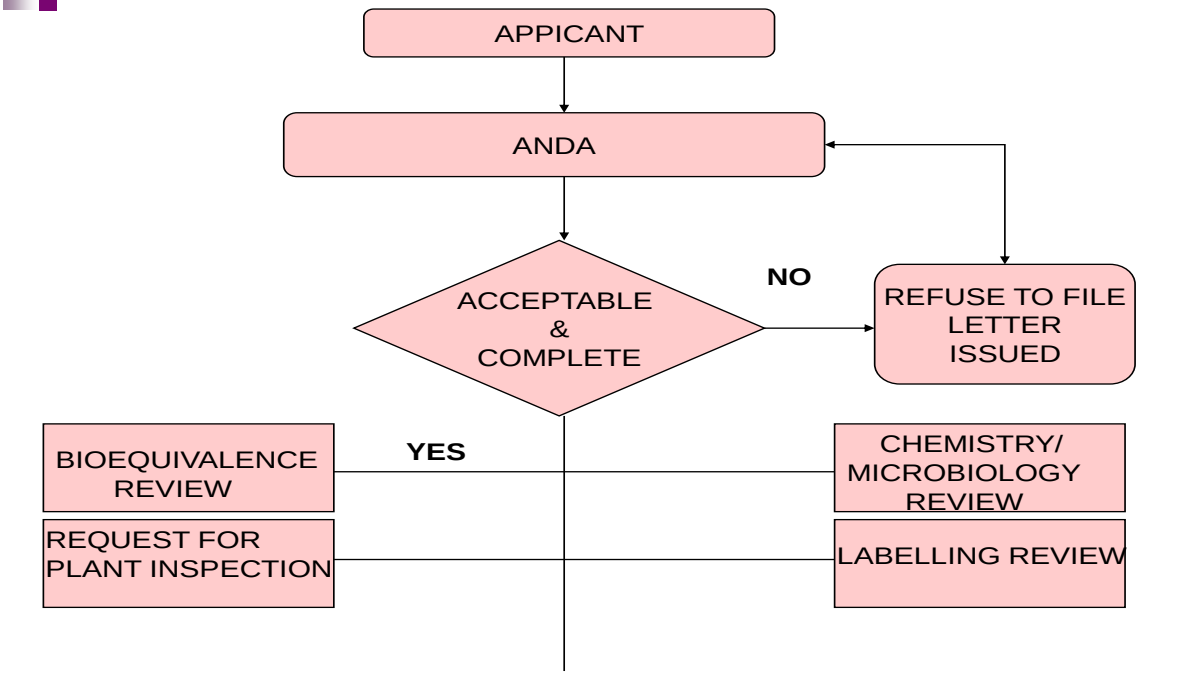
- No clinical studies have been performed in patients with the Generic Product to support its Efficacy and Safety.
- With data to support similar in vivo performance (= Bioequivalence)
  Efficacy and Safety
  data can be extrapolated from the Innovator Product to the Generic Product.

Bioequivalence (BE):

Ultimate: Bioequivalence studies impact of changes to the dosage form process after pivotal studies commence to ensure product on the market is comparable to that upon which the efficacy is based

- Establish that a new formulation has therapeutic equivalence in the rate and extent of absorption to the reference drug product.
- Important for linking the commercial drug product to clinical trial material at time of NDA.

Important for post-approval changes in the marketed drug formulation.



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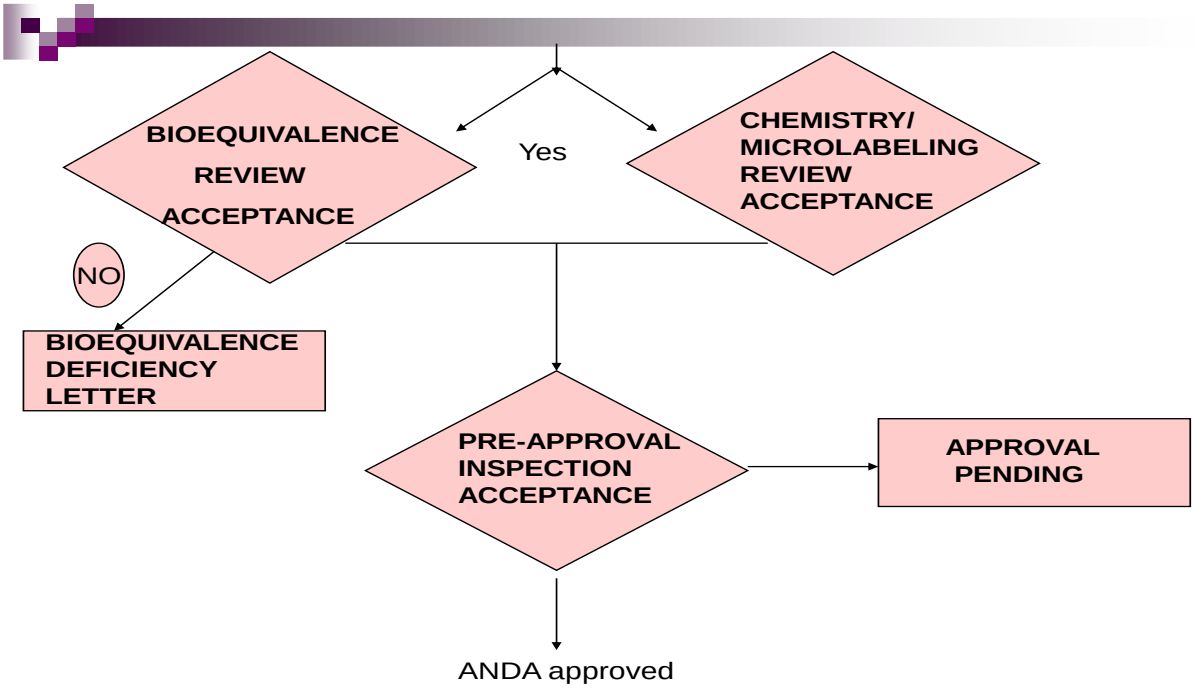

GENERIC DRUG APPROVAL

- In 1970 FDA established the ANDA as a mechanism for the review and approval of generic versions.
- Before 1978, generic product applicants were required to submit complete safety and efficacy through clinical trials.
- Post 1978, applicants were required to submit published reports of such trials documenting safety and efficacy.

Neither of these approaches was considered satisfactory and so originated **Hatch Waxman Act on 1984**.

Indispensability Grounds

For Generics

- Contain the same active ingredients as the innovator drug (inactive ingredients may vary).
- Must be identical in strength, dosage form, and route of administration.
- Must have same use/indications.
- Must be bioequivalent.
- Must have same batch requirements for Identity, Safety & Purity.

Must follow strict standards of FDA's GMPs.

Lecture no.39

HATCH-WAXMAN ACT

- **Commonly known as "Drug Price Competition & Patent Term Restoration Act" of 1984.**
- "The Hatch-Waxman Act is an act dealing with the approval of generic drugs and associated conditions for getting their approval from FDA, market exclusivity, rights of exclusivity, patent term extension and Orange Book Listing."

Necessitated By :

1. Absence of Generic drug manufacturing.
2. Cumbersome regulatory procedures.
3. Patients were denied the option of cheaper drugs.

General Provisions of the Act

1. **Maintaining list of patents which would be infringed.**
2. **Only Bioavailability studies and not clinical trials needed for approval.**
3. **Para I, II, III and IV certifications.**
4. **Data exclusivity period for New Molecular Entities.**
5. **Extension of the original patent term.**
6. **The "Bolar" Provision.**

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RECENT ADDITIONS TO THE HATCH-WAXMAN ACT

Under the "Medicare Prescription Drug and Modernization Act", 2003:

1. Non-extension of the 30-month period.
2. Time limit for informing patent owner.
3. Provision for allowing declaratory judgment.
4. Benefit of exclusivity for several ANDAs filed on same day allowed.

Lecture no.40

THE ORANGE BOOK

- The FDA publishes a list of all drugs approved for marketing in the US under the title "***Approved Drug Products with Therapeutic Equivalence Evaluations***" - **"Orange Book"**
- Lists the NDA's and ANDA's along with the expiry dates of patents and generic exclusivities
- Ready reference of brand drug products for the generic companies who usually use this information to identify the reference for developing their generic version
- Also contains therapeutic equivalence codes (two letter coding system e.g. AB)
  - A- prefixing product is considered to be substitutable
  - B- prefixing is a safe and effective product for use but is regarded in-equivalent and non-substitutable with the brand name drug product

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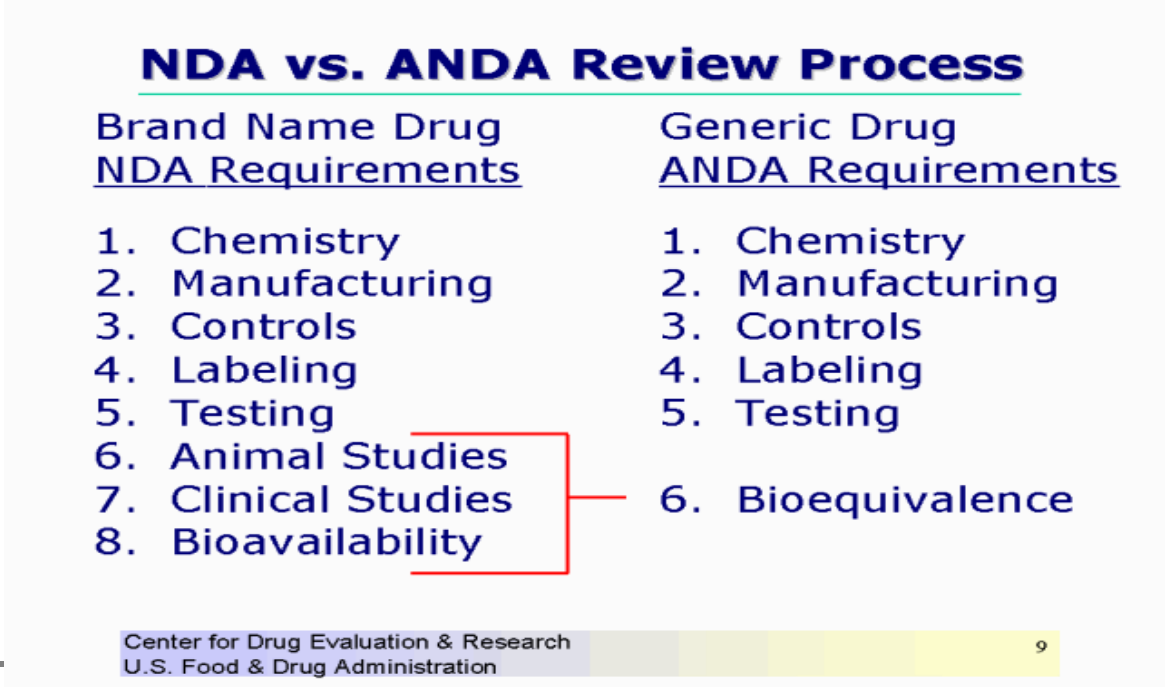
ANDA CERTIFICATIONS

- **Para I** – there is no patent for the drug listed in the Orange Book
- **Para II** – patent is listed but has expired
- **Para III** – patent is listed, is valid but the generic wants approval to market the drug once the pertinent patent expires
- **Para IV** – the generic manufacturer either challenges the validity of the patent asserting it to be invalid or fake, or it affirms the non-infringement of the brand name patent claims.

NDA vs ANDA Review Process



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Case Study – Buspar Case : BMS v Mylan Pharmaceuticals

- BMS had US Patent 4,182,763 (Expiry – July 21, 2000)
- Claims cover buspirone as an anxiolytic agent
- Mylan filed para III against this patent and obtained tentative approval to market the drug not before July 22, 2000
- BMS obtained another patent just *12 hours before the expiry* of first patent covering the active metabolite of the buspirone having anxiolytic activity and listed it in the OB
- Mylan filed para IV against this newly listed patent
- BMS responded by filing infringement lawsuit immediately halting the final market approval
- This gives the brand name manufacturer at least an additional two and a half years of product monopoly

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Important for post-approval changes in the marketed drug formulation.

KEY FUNCTIONS OF DRUG REGULATORY AGENCY:

- Product registration (drug evaluation and authorization and monitoring of drug efficacy and safety);
- Regulation of drug manufacturing, importation, and distribution;
- Regulation & Control of drug promotion and information.
- Adverse drug reaction (ADR) monitoring.
- Licensing of premises, persons and practices.
- Main goal of drug regulation is to guarantee the **safety, efficacy and quality of drugs available to public.**

The drug regulation consists of:

1. Drug Laws
2. Drug Regulatory Agencies
3. Drug Regulatory Boards
4. Quality Control
5. Drug Information Centers etc.

Responsibilities of regulatory affairs professionals

1. Submission of applications to government-
   a) For the purpose of examination , test, analysis.
   b) For grant of permission to import or manufacture of a new drug or to undertake clinical trail,
   c) For conducting bioavailability and bioequivalence study,
   d) For registration of products,
   e) For certificate of incorporation tracking of licenses etc.,
2. Supporting clinical research trails with review if regulatory document prior to study start up.
3. Providing regulatory strategic direction to the clinical team.

Responsibilities of regulatory affairs professionals

3. Preparing and reviewing the scientific technical reports for regulatory adequacy and compliance with appropriate regulatory bodies to ensure timely initiation of clinical studies and market release.

4. Submitting the clinical trail reports to regulatory bodies.

5. Reporting serious adverse events happening during the clinical trails.

6. Obtaining the permission , approval , license from the regulatory authorities.

Responsibilities of regulatory affairs professionals

8. Responsible for providing regulatory support to marketed drugs to ensure compliance, which includes reviewing, proposed product labels specifications and method.

9. Supervising the preparation of marketing authorization applications for new pharmaceutical products.

10. Keeping the company management up to date on status of specific products registration actions, problems and solutions.

11. Gaining a rapid and successful approval and maintaining drugs on the market.

Need for regulatory affairs

- Drugs meant for improving public health and in that sense they are different from any other consumer goods.
- Their development, manufacture, importation, subsequent handling within the distribution chain and use requires specialized knowledge and skills.
- They should conform to prescribed standards and their quality should be controlled rigorously.
- Experience has shown that poor regulation of drugs can lead to the release of substandard, counterfeit, harmful and ineffective drugs to national and international markets resulting in serious harm to the health of consumers.

AGENCIES

- The Food and Drug Administration (FDA)
- National Institutes of Health (NIH)
- Centers for Disease Control and Prevention
- Department of Health and Human Services (DHHS)
- Fed World - US Government Information
- National Center for Complementary and Alternative Medicine (NCCAM)
- National Center for Infectious Diseases (NCID)
- National Library of Medicine
- National Science Foundation
- Office of Disease Prevention

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Agencies of united states of America

The Pan American Health Organization (PAHO)

1. PAHO is an international public health agency with hundred years of experience.
2. Serves as the specialized organization for health of the inter American system
3. Serves as the regional office for the American world health Organization
4. International recognition as part of the United Nations System.

Food and Drug Administration (FDA)

5. Agency of the united states department of health human services.
6. Led by a commissioner of food and drugs, appointed by the president with the advice and consent of senate.
7. Responsible for protecting and promoting public health through the regulation and supervision of food safety, tobacco products, dietary supplements, prescription and over-the counter pharmaceutical drugs (medications), vaccines, biopharmaceuticals, blood transfusions, medical devices, ERED, cosmetics etc.,

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It is divided into 7 main divisions or centers:-

1) Office of regulatory affairs
2) Canter for biologics evaluation and research
3) Center for drug evaluation and research
4) Center for devices and radiological health
5) Office of combination products
6) Team biologics
7) Pharmaceutical inspectorate

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FDA is responsible for

- Protecting the public health by assuring that foods are safe, wholesome, sanitary and properly labeled;
- Assuring human and veterinary drugs, and vaccines and other biological products and medical devices intended for human use are safe and effective
- Protecting the public from electronic product radiation
- Assuring cosmetics and dietary supplements are safe and properly labeled
- Regulating tobacco products
- Advancing the public health by helping to speed product innovations
- Helping the public get the accurate science-based information they need to use medicines, devices, and foods to improve their health
- Initiation of a Recall. Includes voluntary, FDA requested, and FDA mandated.

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Agencies

- Ministry of Health and Welfare
- National Institute of Infectious Diseases
- National Institute of Health Sciences

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FUNCTION OF MHLW

- **Social Welfare :**
  - Services for elderly people
  - Services for persons with disabilities
- **Social Security :**
  - Pension systems that will ensure income in elderly age
  - Long term insurance to provide nursing care services
  - Public assistance systems that guarantee minimum standards.

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➢ **Public Hygiene :**

- ➢ Appropriate medical services for diseases & injuries
- ➢ Ensuring the safety of food, Water and medical supplies
- ➢ Research into health science in order to make technological advances
- ➢ Maternal and child health

➢ **Job Security :**

- ➢ Promotion of employment
- ➢ Employment of elderly people
- ➢ Employment of persons with disabilities
- ➢ Management of the employment insurance system

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AGENCIES

- EU Legislation - Eudralex
- European Directorate for the Quality of Medicines and Healthcare (EDQM)
- European Medicines Agency (EMEA)
- Heads of Medicines Agencies (HMA)

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- Drugs and Health is in concurrent list of Indian Constitution It is governed by both Centre and State Governments under the **Drugs & Cosmetics Act, 1940**.

MAIN BODIES:

- Central Drug Standard Control Organization (CDSCO)
- Ministry Of Health & Family Welfare (MHFW)
- Indian Council Of Medical Research (ICMR)
- Indian Pharmaceutical Association (IPA)
- Drug Technical Advisory Board (DTAB)
- Central Drug Testing Laboratory (CDTL)

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- Indian Pharmacopoeia Commission (IPC)
- National Pharmaceutical Pricing Authority (NPPA)

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Agency of India

Central drugs standard control organization (CDSO):

- Largely works on developing standards and regulatory measures for drugs, diagnostics and medical devices.
- Headed by Drug Control General of India.
- Located at New Delhi , functions under the Directorate General of Health Services.

ZONAL OFFICES OF CDSO

EAST ZONE:

Andaman and Nicobar Island, Arunachal Pradesh, Assam, Bihar, Jharkhand, Manipur, Meghalaya, Mizoram, Nagaland, Orissa, Sikkim, Tripura & West Bengal.

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Agency of India

ZONAL OFFICES OF CDSO

WEST ZONE:

Chhattisgarh , Goa , Daman & Diu , Gujarat, Madhya Pradesh and Maharashtra

Sub zonal office: Ahmedabad

NORTH ZONE :

Haryana, Himachal Pradesh, Jammu and Kashmir, Punjab, Rajasthan, Uttaranchal, Uttar Pradesh, N.C.T of Delhi & union territory of Chandigarh.

SOUTH ZONE:

Andhra Pradesh, Karnataka, Kerala, Pondicherry and Tamil Nadu.

Sub zonal office: Hyderabad

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Functions of CDSDC

1. Laying down standards of drugs, cosmetics, diagnostics and devices.
2. Laying down regulatory measures amendments to acts and rules.
3. To regulate market authorization of new drugs.
4. To regulate clinical research in India.
5. To approve licenses to manufacture certain categories of drugs as central license approving authority i.e., for blood banks large volume parenterals and vaccines and sera.
6. To regulate the standards of imported drugs.
7. Testing of drugs by central drug labs.
8. Publication of Indian pharmacopoeia.

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Functions of CDSDC

9. Coordinating the activities of the state drugs control organizations to achieve uniform administration of act and policy guidance.
10. Participation in the WHO GMP certification scheme.
11. Conducting the activities of the regulatory officials & Govt. analysts.
12. Distribution of quotas of narcotic drugs for use in medicinal formulations.
13. Screening of drug formulations available in Indian market.
14. Evaluation / screening of applications for granting No Objection Certificates for export of unapproved / banned drugs.

Indian patent offices are located at Delhi, Kolkata, Mumbai and Chennai.

Form	Title	Fee (INR)		Comment
		Natural person	Other than natural	

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			person	
1	Application for Grant of Patent	1000	4000	Mandatory
2	Provisional/Complete Specification	No fee*	No fee*	Mandatory
3	Statement and Undertaking Under Section 8	No fee	No fee	Mandatory
5	Declaration as to Inventorship	No fee	No fee	Mandatory
9	Request for Publication	2500	10000	Optional
18	Request for Examination of Application for Patent	2500	10000	Mandatory

THE WORLD HEALTH ORGANIZATION

A specialized agency of the UN that act as a coordinating authority on international public health.

Objective: Attainment of the highest possible level of health by all people.

- Approves the WHO program and the budget.
- Provides government and pharmaceutical manufacturers with the means to establish and maintain mechanisms, which measures quality, safety and efficacy of pharmaceutical products and their rational use.
- Quality assurance of pharmaceuticals , prevention of counterfeit drugs , drug safety, support to drug regulatory authorities and monitoring of narcotic and psychotic substances.

Role of WHO in Drug Regulation

Regulates in fourfold..

First : Issuing necessary norms and standards through its expert Committees.

Second : implementation of drug regulation on national level and its harmonization on regional and global level.

Third : selecting areas of essential products , ensuring the quality , safety and efficacy of limited high public health value essential medicines and vaccines.

Fourth : facilitates exchange of regulatory information for which it has developed a number of tools.

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