

INTELLECTUAL PROPERTY RIGHTS



CONTENTS

- Introduction
- Intellectual property rights
- Copyrights
- Design
- Trademark
- Trade Secrets
- Geographical Indications
- Patent
- Conclusion
- References

Introduction

The 21'st century was termed as the century of knowledge. However, merely having the knowledge is not enough, the protection of that knowledge and conversion of that knowledge in to profit are important for the survival of any high-tech business and economy. The intellectual property laws & the food and drug laws provide the pharmaceutical and biotechnology industry with unparalleled protection. These laws provide exclusivity, patent term restoration, a patent extension under various condition unmatched by any other industry.

INTELLECTUAL PROPERTY RIGHTS

“Protection of property created by the intellect of

- ← Intellectual ^{human mind} Property Rights (IPR) are the statutory rights once granted allows the creator(s) or owner(s) of the intellectual property to exclude others from exploiting the same commercially for a given period of time.
- ← It allows the creator(s)/owner(s) to have benefits from their work when these are exploited commercially.
- ← IPR are granted to an inventor or creator in lieu of the discloser of his/her knowledge.



For every individual proved mechanism

PATENT

DESIGN

For outer shape and contour/
configuration

**TRADE
MARK**

Brand name or logo for goods
denoted as ®

**TRADE
SECRET**

The client list, formula for a product

**COPY
RIGHT**

For music, art etc denoted as ©

COPYRIGHTS

- Copyright means exclusive right to do or authorize others to do certain acts in relation to
 - Literary, dramatic, music, and artistic works.
 - Books
 - Cinema/TV programmes
 - Sound recordings
- Permission is needed to reproduce the copyrighted material.

- **Term:** Author's life plus sixty years (Books)
60 years (Films, photographs)
25 years (Broadcasting)
- It protect the publications of the studies.
- Information provided by the drug companies may be protected by copyright law.
- Pharmaceutical companies routinely copyrighted their package insert yet the generic approval dictated that the package insert of the generic drug to be the same as the reference listed drug.

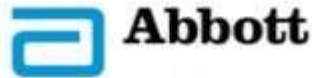
DESIGN

- The protection only for the appearance of the article and not how it work.
- Design registration protects designs having industrial or commercial use.
- Designs of stamp, labels, tokens, cards, or cartoons and part of an article sold separately can not be registered.
- Duration protection- 10 years and extendable for another term of 5 years.

TRADEMARK

- A trade mark is any design that can distinguish the goods of one trader from those of another.
- It includes words, logos, pictures, or combination of these.
- A trademark is used as a marketing tool for product positioning.
- The consumer will rely on the labels attached to the product with certain expectation of the quality of said product.
- Term: 10 years

- To register a trade mark the mark must be distinctive and not contrary to law or morality and not identical to the earlier mark for the same or similar goods
- The notion ® may be used for the trademark only if it is federally registered.
- In pharmaceutical arena, trade names for certain drug may be registered as a trademark



- Essential features of a trademark

- It must be a mark, brand, heading, name, label, signature or numerical shape of goods, packaging, or combination of these.
- It must be capable of being represented graphically.
- It must be capable of distinguishing the goods or services of one person from those of others.
- The use must be of a printed or other visual representation of the mark.

- Trademark which are not registerable

- Mark that contain or comprises of any matter likely to hurt the religious susceptibilities of any class or section of the citizens of India.
- Mark that comprises of scandalous or obscene matter.
- Mark which has nature as to deceive the public or cause confusion.
- Mark prohibited under the Emblems and Name Act, 1950

TRADE SECRETS

- A trade secret is something that offers an advantage in business if it keep as a secret.
- A trade secret can be a client list, the formula for a product, etc.
- A trade secret does not have to be patentable, but it must be capable of being maintained.
- For instance, a client list can be protected by computer password, and the formula can be safeguarded by disclosing it to a limited number of people.
- Trade secrets are not registered with any government or other agency

GEOGRAPHICAL INDICATIONS

- An indication used to identify agricultural, natural or manufactured goods originating from a definite territory in India.
- It should have a special quality or characteristics or reputation based up on the climatic or production characteristics unique to the geographical location.
- The registration of a geographical indication is from a period of 10 years.
- Renewal is possible for further period of 10 years each.
- Examples:Kancheepuram silk,Darjeeling Tea, Solapur Chaddar, Mysore Silk, Kullu Shawl etc

PATENT

DEFINITION:

Exclusive right for being the true and first inventor of a product or process, granted by the govt. for a limited period, to exclude others from making, using, selling or importing the patented product or process with out his consent, in exchange of full disclosure of his invention.

Term: 20 years from the Date of Filing

Patent jurisdictions

- A patent is only valid in the jurisdiction in which it is granted

- ✓ Mumbai

- ✓ Chennai

- ✓ New Delhi

- ✓ Kolkata

} Patent office branches

- ❖ WIPO - 1967

- ❖ PCT - 1970

- ❖ WTO - 1995

Lifecycle of a patent



What is patentable ?

- A product
- The apparatus for producing the product
- The process
- The composition of matter

Basic requirements for patentability

- Novelty
- Utility
- Nonobviousness
- Written Disclosure

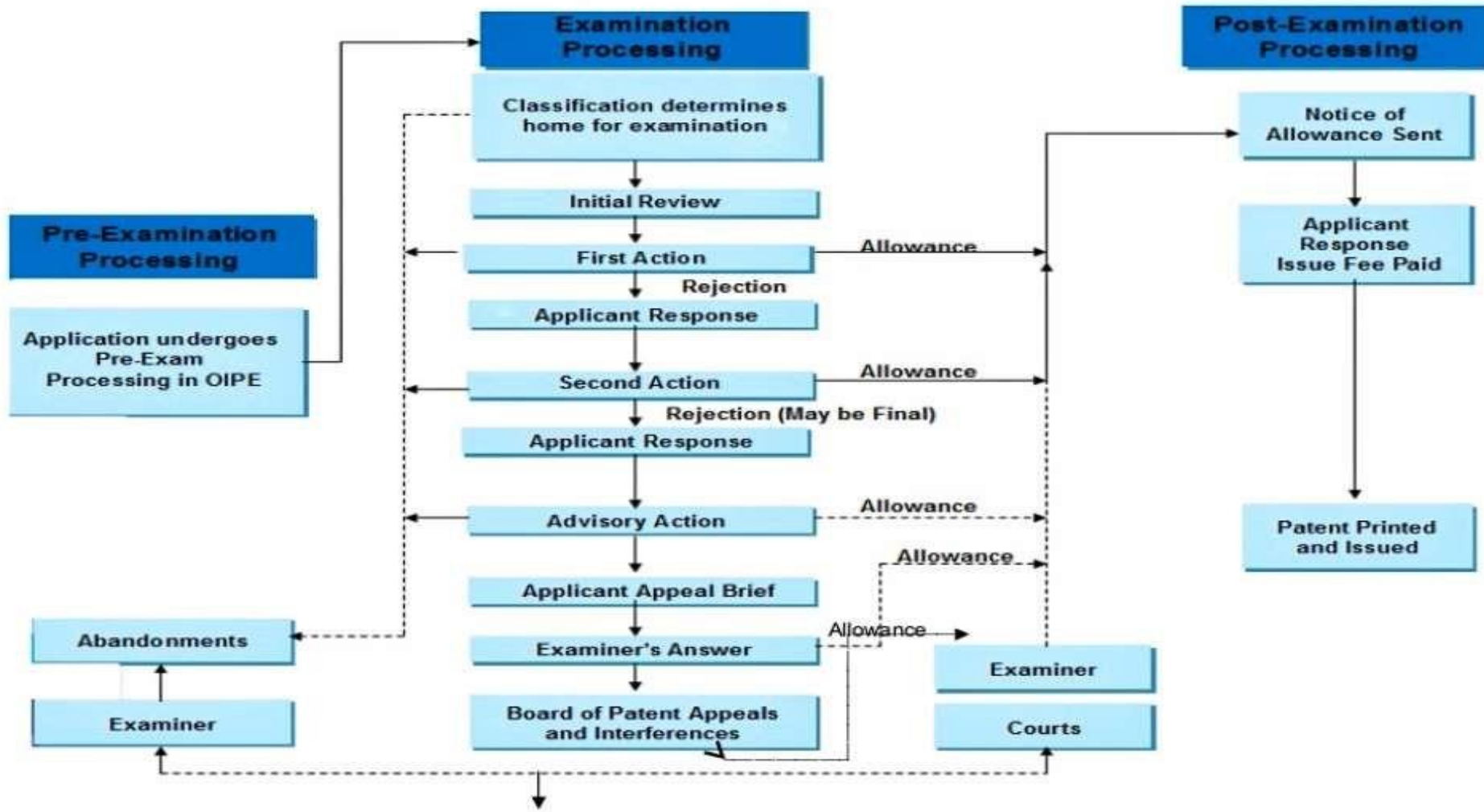
What is not patentable

- Computer programmes
- Medical and Surgical treatments
- Mathematical methods
- Business methods
- Discoveries
- Aesthetic creation
- New species of plant or animal
- The invention which are contrary to moral standards and public order
- Invention related to atomic energy

Documents required for filing a patent application

1. Application Form (Form 1)
2. Specification (Provisional/ Complete) (Form 2)
3. Drawings
4. Undertaking under section 8 (Form 3)
5. Power of Authority

The patent process



Patent Laws

1856

- Patent rights were introduced in India.

1872

- The Patent and Design Protection Act.

1888

- Invention and Design Act

1911

- The Indian Patent And Designs Act.

1970

- The Patent Act

2005

- Product Patent regime in Pharmaceutical

What does patent system do ?

- It encourages research
- Induce an inventor to disclose his invention
- Encourage establishment of new industries
- Reasonable assurance for commercialization
- Facilitate technology transfer
- Stimulate R&D at Universities and Research centers
- Acts as catalysts for new technologies and new business

Compulsory Licence

- Any time after three years from the date of sealing of a patent, application for compulsory license to the government can be made by any other party interested in using that invention provided.
 1. Reasonable requirements of public have not been met.
 2. patented invention is not available to public at a reasonably affordable price.
 3. patented invention is not worked in India.

Infringement

- Infringement of a patent occurs when a competitor makes , uses,sells, offers to sell or imports an embodiment of the invention with out the permission of the patent owner.
- **Types:**
 - Direct infringement
 - Indirect infringement

Cosequences of infringement

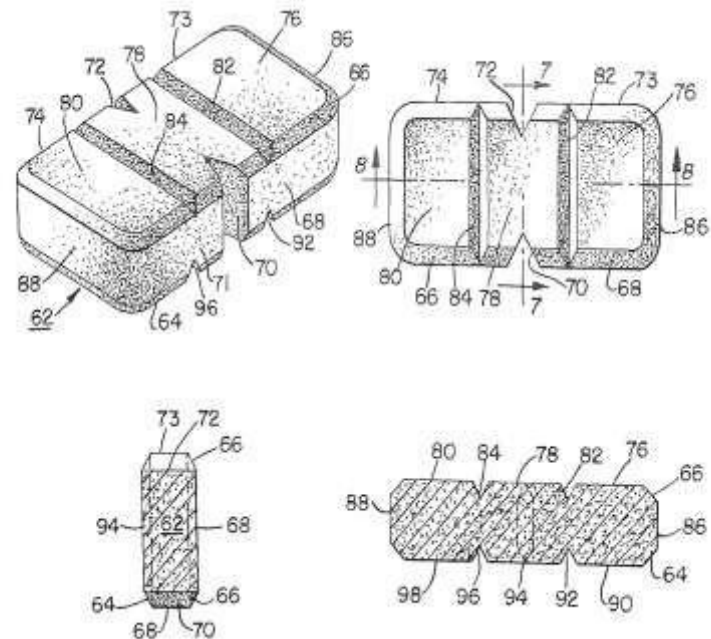
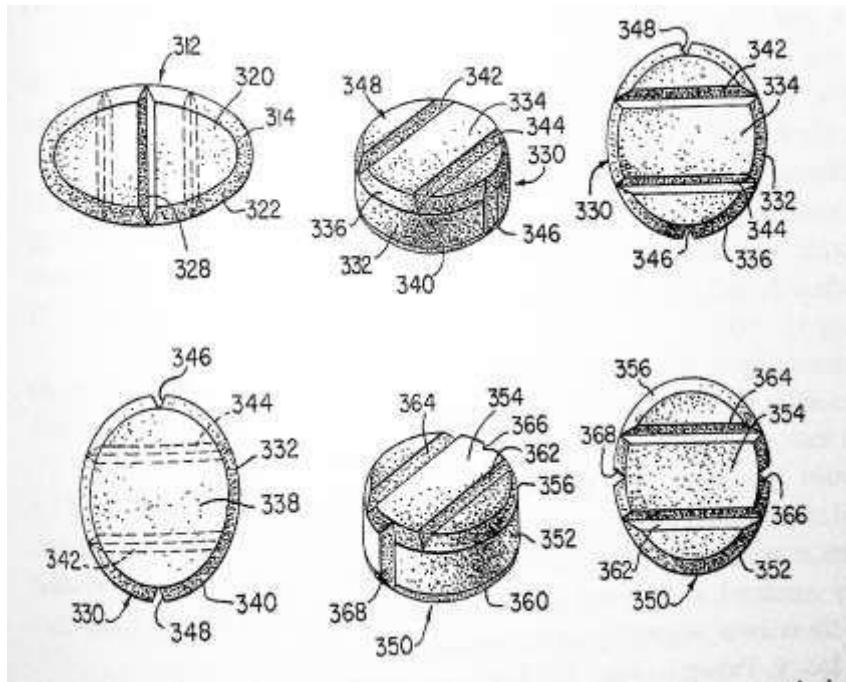
If you infringe someone else's patent you may risk:

- Injunction, which means that all your products may be removed from the market.
- Destruction of your products.
- Paying damages to the patent owner.
- Being sended to imprisonment.

Types of Pharmaceutical Patents in India

- A. Drug compound patent
- B. Formulation/composition patent
- C. synergistic combination patent
- D. Technology patent
- E. Polymorph patent
- F. Biotechnology patent
- G. Process patent

Desyrel® (Trazodone)



Example of the Desyrel® (Trazodone hydrochloride) 150-300 mg oral tablets that can be separated in to three equal parts (The so-called Dividose® design)

United States Patent [19]

Ullman et al.

[11] 4,215,104

[45] Jul. 29, 1980

[54] **MULTI-FRACTIONABLE TABLET
STRUCTURE**

[75] Inventors: **Michael K. Ullman; Stephen T. David;
Claude E. Gallian**, all of Evansville,
Ind.

[73] Assignee: **Mead Johnson & Company**,
Evansville, Ind.

[21] Appl. No.: **24,139**

[22] Filed: **Mar. 26, 1979**

[51] Int. Cl.² **A61K 9/44**

[52] U.S. Cl. **424/15; D1/12**

[58] Field of Search **424/15; D1/12**

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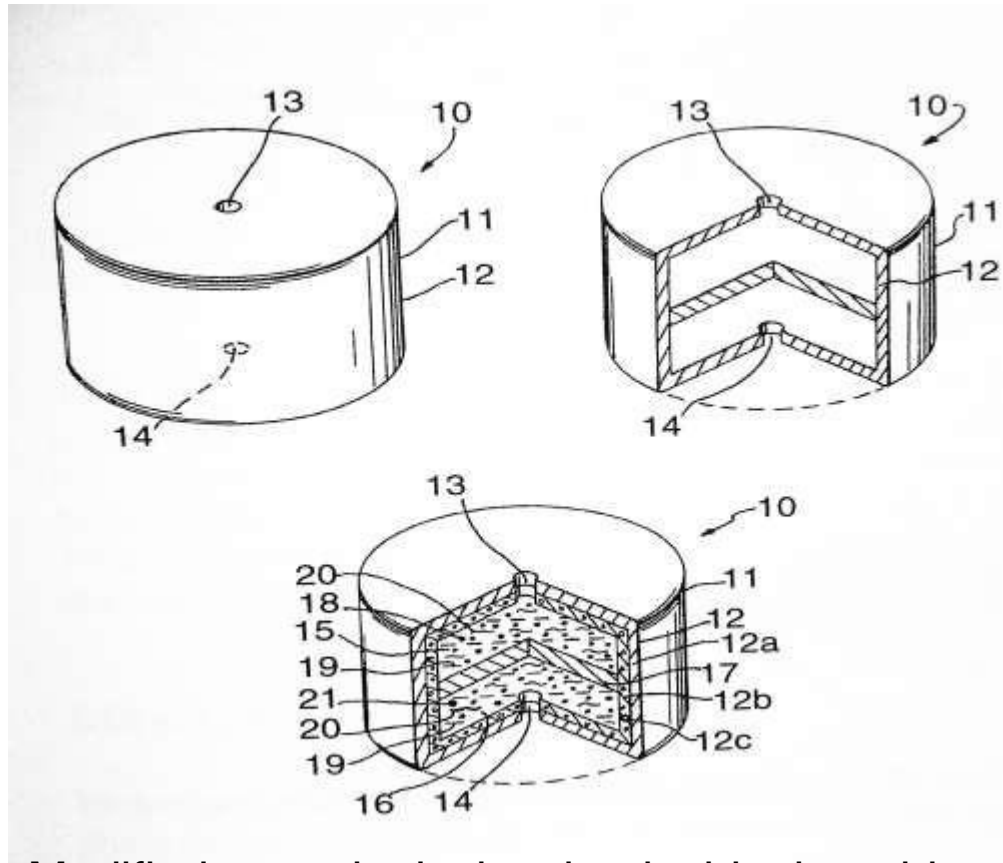
Primary Examiner—Shep K. Rose

Attorney, Agent, or Firm—R. E. Carnahan; R. H. Uloth

[57] **ABSTRACT**

The invention disclosed provides a multi-fractionable tablet structure initially configured in a unitary dosage while having readily severable sub-dosage units as components thereof. Score markings are positioned variously about the tablet both along the top and bottom surfaces of an approximately rectangular configuration whereas in preferred embodiments thereof, score markings additionally appear along opposite vertical side surfaces of the tablet. Special placement of the score markings readily permit at least either an accurate bisectonal fracture or accurate trisectional fracture of the tablet as may be desired for patient consumption.

15 Claims, 18 Drawing Figures



Modified osmotic device that inside the tablet comprises of two separate drug compartments separated by a swellable Hydrogel partition. When hydrogel swells it pushes both drug compartments to deliver two drug simultaneously in a controlled manner

United States Patent [19]

[11] **4,449,983**

Cortese et al.

[45] **May 22, 1984**

[54] **SIMULTANEOUS DELIVERY OF TWO DRUGS FROM UNIT DELIVERY DEVICE**

[75] Inventors: **Richard Cortese**, San Jose; **Brian Barclay**, Menlo Park; **Felix Theeuwes**, Los Altos, all of Calif.

[73] Assignee: **ALZA Corporation**, Palo Alto, Calif.

[21] Appl. No.: **360,589**

[22] Filed: **Mar. 22, 1982**

[51] Int. Cl.³ **A61M 31/00**

[52] U.S. Cl. **604/892**

[58] Field of Search **604/890-900;**
424/18-25

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Primary Examiner—Benjamin R. Padgett

Assistant Examiner—T. J. Wallen

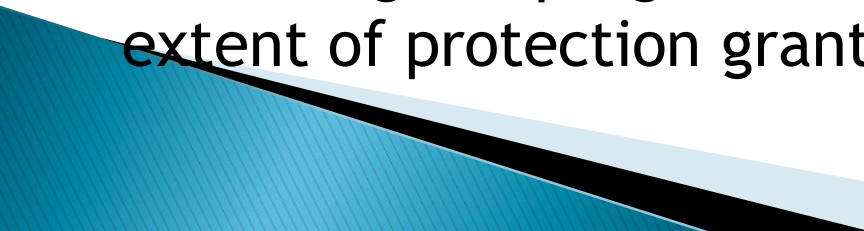
Attorney, Agent, or Firm—Paul L. Sabatine; Edward L. Mandell; Steven F. Stone

[57] **ABSTRACT**

An osmotic device is disclosed for delivering two beneficial drugs to an environment of use. The device comprises a wall surrounding a lumen divided into a first compartment containing a drug that is separated by a hydrogel partition from a second compartment containing a different drug. An orifice through the wall communicates with the first compartment for delivering drug formulation from the first compartment, and another orifice through the wall communicates with the second compartment for delivering drug formulation from the second compartment. In operation, drug formulation is dispensed separately from each compartment by fluid being imbibed through the wall into each compartment at a rate controlled by the permeability of the wall and the osmotic pressure gradient across the wall against the drug formulation in each compartment thereby producing in each compartment a solution containing drugs, and by the expansion and swelling of the hydrogel, whereby drug formulation is dispensed through their orifices at a controlled and continuous rate over a prolonged period of time.

18 Claims, 8 Drawing Figures

CONCLUSION

- Intellectual property (IP) is a category of property that includes intangible creations of the human intellect, and primarily encompasses copyrights, patents, and trademarks
 - It also includes other types of rights, such as trade secrets, publicity rights, moral rights, and rights against unfair competition.
 - The main purpose of intellectual property law is to encourage the creation of a large variety of intellectual goods. This gives economic incentive for their creation, because it allows people to profit from the information and intellectual goods they create. These economic incentives are expected to stimulate innovation and contribute to the technological progress of countries, which depends on the extent of protection granted to innovators.
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THANK YOU