IP Management in Pharmaceutical Sector

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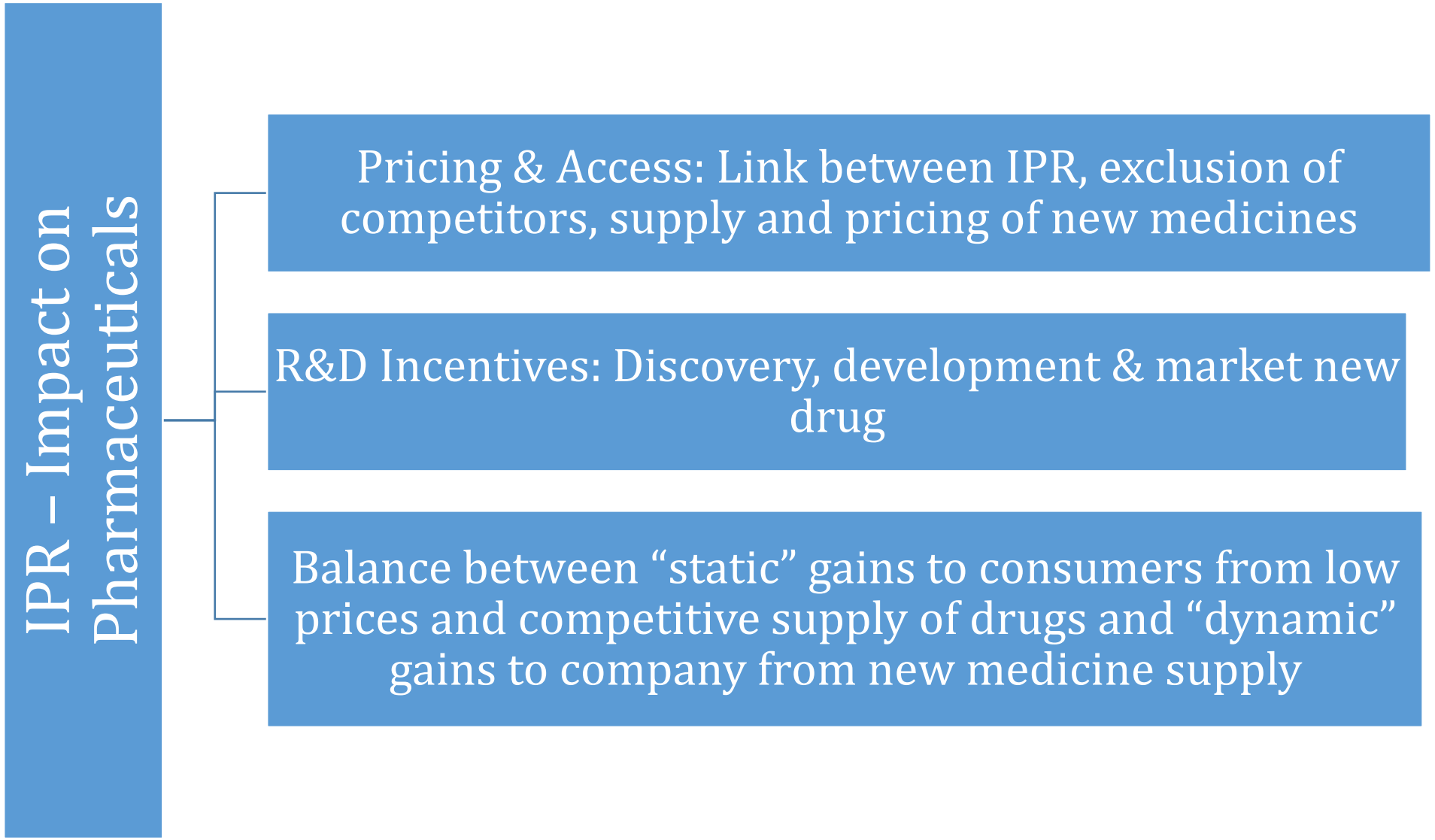
Introduction about Pharmaceutical IP

- The aim of every pharmaceutical is a drug discovery and generating profits on such investments. The rewards for success in innovation are generally high when it impacts several lives.
- Medication is developed by investing huge sums of money for the research and development of any drug.
- Any company that wishes to attain a good position in the market has to keep developing different strategies to gain a competitive edge and to protect their positions in the market.
- The Indian pharmaceutical industry has witnessed tremendous growth in the past decades, in terms of market capturing and contribution to the Gross Domestic Product of our country. India's domestic pharmaceutical market is estimated at USD 41 billion in 2021 and is likely to reach USD 65 billion by 2024 and further expand to USD 120-130 billion by 2030.

Introduction about Pharmaceutical IP

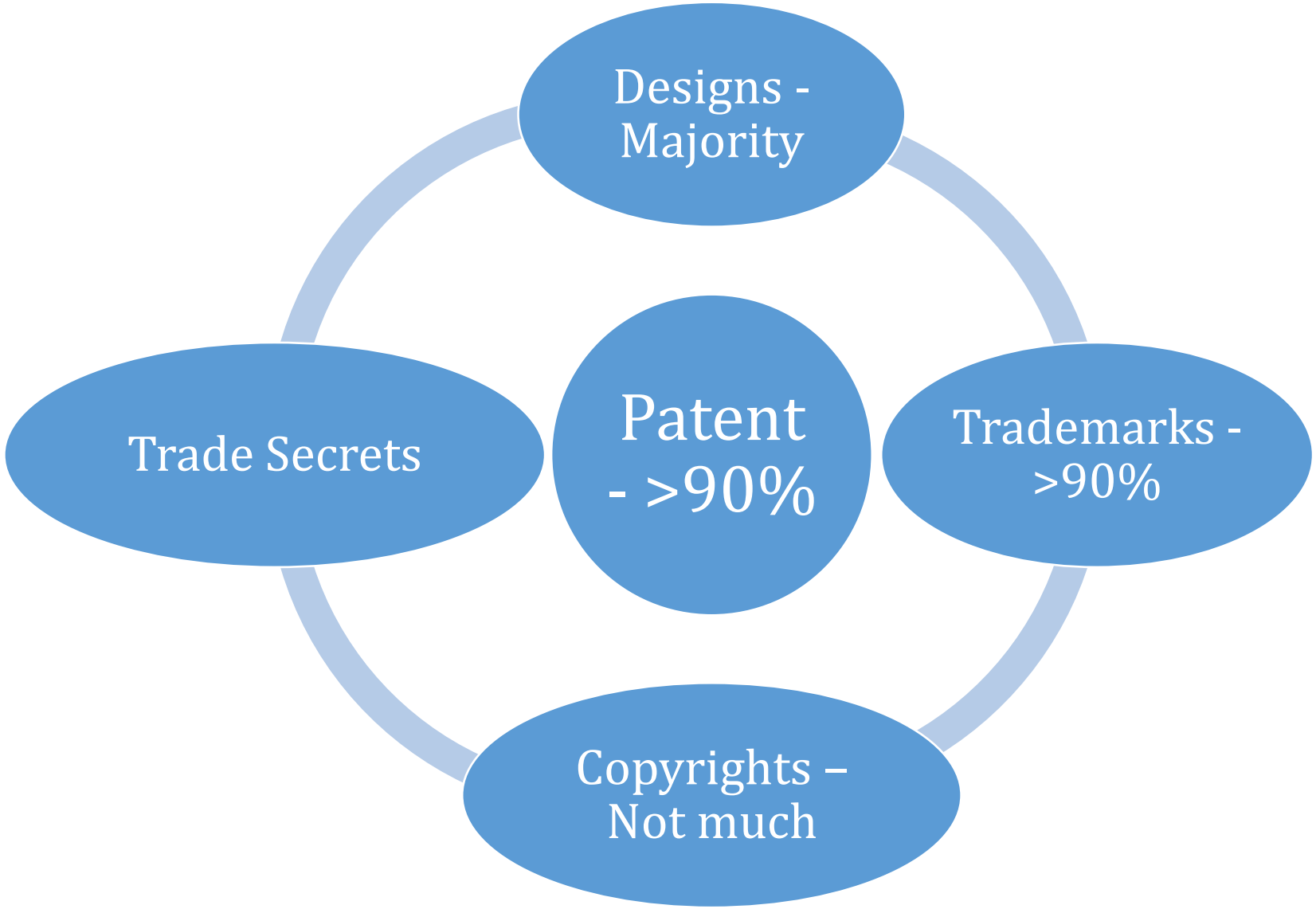


Introduction about Pharmaceutical IP

How does Intellectual Property protect the pharmaceutical industry?

- It provides fair and effective incentives for innovative processes.
- It helps to protect any company against potential infringement.
- It provides a strong enforcement mechanism for defending infringement in the case of patented drugs.

Different Types of IP in Pharmaceutical Sector



Importance of IP in Pharmaceutical Industry

- **Protection of invention:**

  You have designed or developed a drug and you need to protect it or else it is going to be stolen from you. So the way to protect is either by getting it patented or under trade secret. The problem with trade secret is that it the drug can be reverse engineered and hence your invention can be stolen. Whereas patent provides a much more water tight protection.

- **Economic growth and competitiveness:**

  IPR is very important for economic growth of a company. Awarding sole rights to the inventor gives him the privilege of reaping the profits without any division. The marketing rights over the product are solely the inventors and he can sell it or license it. The company can earn a lot and reinvest it. Investing in research and development is very important for a company as it has to stay in the forefront.

Importance of IP in Pharmaceutical Industry

❖ **Protects consumers and families:**

IPR's main interest lies in public safety. Protection and safety of public is always given importance. IPR helps the consumer in making the right choice when selecting a product. IPR helps in ensuring a standard and assures quality which helps the consumer make his choice and puts him at ease.

Example: Opt for brand product and not to select counterfeit product

❖ **Generate solutions to global challenges:**

Promoting innovation is very important but at the same time you need funding to do it. IPR gives you the right encouragement to do it. There is a need for developing new drugs and vaccines as there are new diseases being discovered daily or there is resistance development by the pathogen.

Example: COVID-19 Vaccines, Influenza, and other disease

Importance of IP in Pharmaceutical Industry

❖ **Encourage innovation and reward entrepreneurs:**

It is very important that the right push is given for inventors to keep them motivated. It is also important that they are recognized for their work. IPR gives them this encouragement. It enables a free flow of information by enabling a safe environment. When you know it is safe to share your invention then there is going to be a safe channel for exchange.

Patents Protection for Pharmaceutical Products

- Patent encourages innovations to inventors as it protects the investments made for research and development as well as creates an incentive for innovation.
- Patents are granted for patentable inventions, which satisfy the requirements of novelty and utility under the stringent examination and opposition procedures prescribed in the Indian Patents Act, 1970, but there is not even a prima-facie presumption as to the validity of the patent granted.
- Most countries have established national regimes to provide protection to the IPR within its jurisdiction.

India – Pharmaceutical Patents Practice

Patents granted for Product & Process:

Novelty, Inventive Step, Industrial Utility

- Section 3(d)
- Section 3(e)
- Section 3(i)

India – Pharmaceutical Patents Practice

Section 3(d) of the Patents Act, 1970:

This section deserves special attention in the context of the pharmaceutical inventions and which states -

> *"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*.
>
> This section stipulates that an invention, already claiming the new form of a known substance, or second and subsequent use of a known substance, having established medicinal activity, shall be deemed to be treated as the same substance and shall not be considered as patentable, unless the invention in question significantly demonstrates the **improved therapeutic efficacy** with respect to that known compound.
>
> Explanation - For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy".

India – Pharmaceutical Patents Practice

Section 3(e) of the Patents Act, 1970:

"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" is not patentable"

It is a well-accepted principle of the Indian Patent Laws, that mere collocation of more than one component, not involving the exercise of any inventive faculty and performs its function independently, is not patentable. In case the working interrelations brought about by the collocation of these components is linked to produce new or improved results, then the subject matter is considered to be patentable.

The claims relating to pharmaceutical compositions are mostly objected by the Indian Patent Office under Section 3(e) of the Patents Act, 1970, as it relates to a known composition or mere admixture of known components which does not involve any synergistic effects. One of the most significant reasons behind objections against such patent applications is the ambiguity in understanding terms such as "mere admixture" and "aggregation of the properties" of Section 3(e) of the Patents Act, 1970.

India – Pharmaceutical Patents Practice

Section 3(i) of the Patents Act, 1970:

"any process for the medicinal, surgical, curative, prophylactic, diagnostic, therapeutic or other treatment of human beings or any process for a similar treatment of animals to render them free of disease or to increase their economic value or that of their products" is not a patentable invention.

US – Pharmaceutical Patents Scenario

Different Types of Pharmaceutical Patents in US

- Product/Compound
- Process/Mfg
- Polymorph
- Method of Treatment
- Pharmaceutical Formulation/Pharmaceutical Composition
- Product administration
- Pharmaceutical Product Packaging
- API Impurity
- Pharmaceutical clinical study

US – Pharmaceutical Patents Litigation Scenario

All Pharmaceutical patent litigation fall under Hatch-Waxman (HW) practice.

- Governs the procedure for approval and marketing of generic drugs.
- Under Hatch-Waxman, the marketing approval process for generic drug products is streamlined.
- Generic manufacturers may file an abbreviated New Drug Application (ANDA) that incorporates the safety/effectiveness data submitted by original pioneer drug manufacturer and adds only bioequivalence studies.
- Generic manufacturers may develop and test the product without fear of an infringement action by the patent holder.
- Paragraph IV provides a mechanism for the litigation of patent infringement disputes.

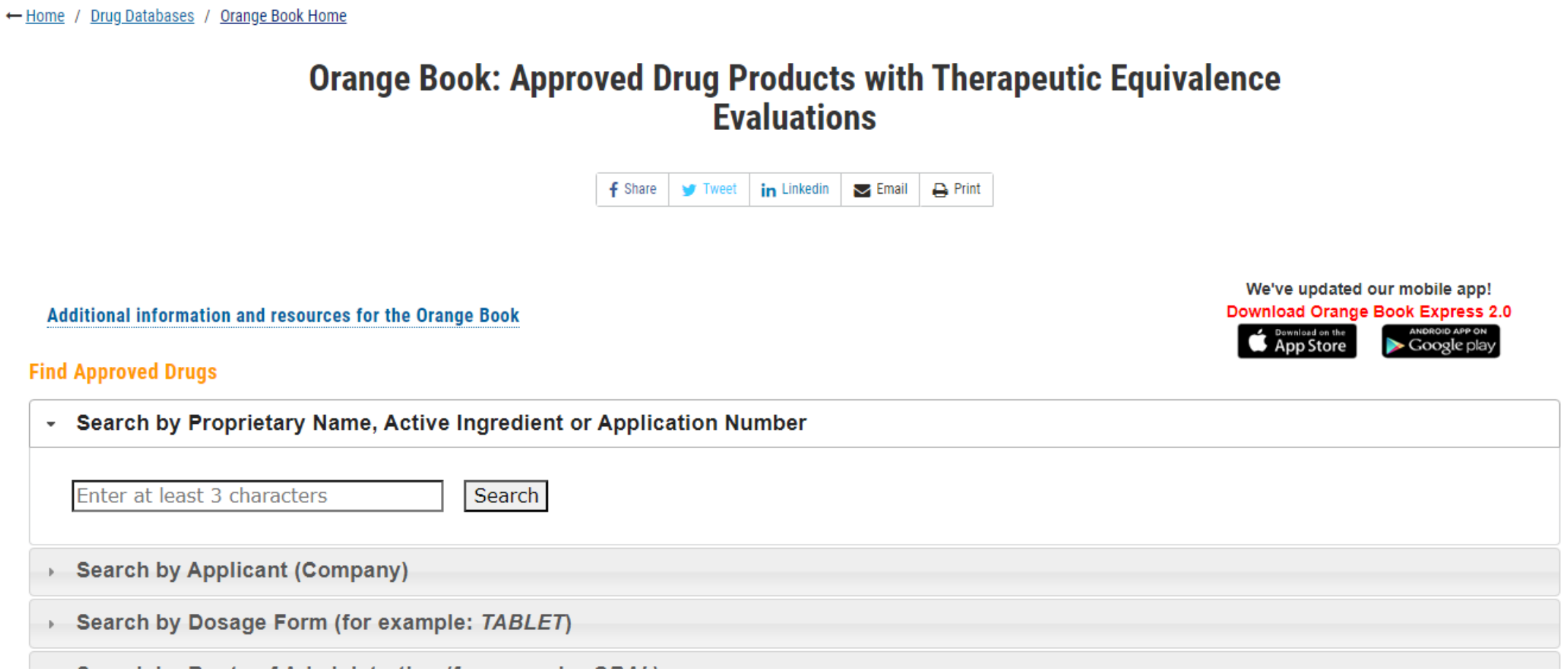
US – Pharmaceutical Patents Litigation Scenario

Paragraph IV of the Hatch-Waxman (HW) Act:

- Generic applicant asserts non-infringement or invalidity of patents
- Brand manufacturer can file suit for infringement upon receiving notice
- If filed, suit will delay marketing approval for 30 months
- If more than one generic files Paragraph IV, first to file can be eligible for 180-day market exclusivity

US – Pharmaceutical Patents Scenario

Orange Book – Pharmaceutical Products Information Database



US – Pharmaceutical Patents Scenario

Orange Book – Patent Information for Pharmaceutical Products

Product 003
SACUBITRIL; VALSARTAN (ENTRESTO) TABLET 97MG;103MG

Patent Data

Product No	Patent No	Patent Expiration	Drug Substance	Drug Product	Patent Use Code	Delist Requested	Submission Date
003	7468390	11/27/2023		DP			08/06/2015
003	7468390*PED	05/27/2024					
003	8101659	01/15/2025		DP			08/06/2015
003	8101659*PED	07/15/2025					
003	8404744	01/14/2023		DP			08/06/2015
003	8404744*PED	07/14/2023					
003	8796331	01/14/2023			U-1723		08/06/2015
003	8796331*PED	07/14/2023					
003	8877938	05/27/2027	DS	DP			08/06/2015
003	8877938*PED	11/27/2027					
003	9388134	11/08/2026			U-1723		09/07/2016
003	9388134*PED	05/08/2027					
003	9517226	08/22/2033			U-3084		03/16/2021
003	9937143	08/22/2033			U-3084		03/16/2021

US – Pharmaceutical Patents Scenario

Patent Term Extension for Pharmaceutical product

- Patent Term Extension (PTE) is a mechanism for extending patent term for patents covering approved drug products.
- Compensation for patent term "lost" to delays attributable to the pre-market FDA approval process.

Infringement Types of Pharmaceutical Patent in US

- Direct Infringement
- Indirect Infringement
- Induced Infringement

Landmark Pharmaceutical Patent Case Study

Dapagliflozin Patent Case 2021

Disclosed Single Compound Vs Better Disclosed Single Compound

ASTRAZENECA AB & ANR Vs. INTAS PHARMACEUTICALS LIMITED & ORS

Can a disclosed single compound enjoys one more round of 20 years protection for a better disclosed single compound ?

Date of decision: 20th July, 2021

In the High Court Of Delhi At New Delhi

Landmark Pharmaceutical Patent Case Study

Facts of the case

The matter primarily issues two patents of Dapagliflozin drug used in diabetes.

- a) Indian Patent No. 205147 (Exp: October 02, 2020) – disclosing broad chemical structure with dapagliflozin
- b) Indian Patent No. 235625 (Exp: May 15, 2023) – disclosing only dapagliflozin compound structure

Issues

- Whether or not the compound-in-issue i.e. Dapagliflozin ["DAPA"] which, according to the plaintiffs, is included in IN 147 stands disclosed both, in law moreover as on facts?
- Whether subject matter of species patent held by AstraZeneca was disclosed in the genus patent held by the same person, thereby invalidating the species patent for lack of inventive step and being obvious to a person skilled in art?

Landmark Pharmaceutical Patent Case Study

Observations:

- On a comparison of relevant extracts from both patents '147 and '625 there emerges no substantial technical advancement or economic significance that would make the synthesis of DAPA an "inventive step" under Section 2(1)(ja).
- Court observed that, there is no enhancement of the known efficacy, within the meaning of Section 3(d) of the Act, between the product subject matter of IN 147 and the product subject matter of IN 625.
- With respect to one invention, there can be only one patent, as DAPA was already disclosed in IN 147, the same compound cannot enjoy double patent term protection.

Landmark Pharmaceutical Patent Case Study

Ticagrelor Patent Case 2019

It is "Covered", Yes, but is It "Disclosed"?

ASTRAZENECA AB & ANR Vs. EMCURE & MSN PHARMACEUTICALS LIMITED

- The Delhi High Court in this case vacated interim injunctions against defendants with respect to species, polymorph and formulation patents relating to TICAGRELOR, which is used as a platelet aggregation inhibitor.
- The Court arrived at the conclusion based on the reasoning that the defendants raised a credible challenge to patent validity of plaintiff's patents on grounds of novelty, inventive step, and Section 3d. The Court in the case relied heavily on an expired genus patent of the plaintiff, which covered several species including TICAGRELOR.

Landmark Pharmaceutical Patent Case Study

- The Court stated that the genus patent covered TICAGRELOR, and that the said patent's specification and statements of working corroborated the same.
- The same is also substantiated by the infringement suits filed by the plaintiff against Milan and others in the US, where claims for infringement of TICAGRELOR have been made.
- As TICAGRELOR was disclosed in the genus patent, the Court reasoned that novelty and inventive step of the suit patents may be seriously questioned.
- As the plaintiff did not submit any data with respect to efficacy, the Court stated that the patent validity is also in question based on Section 3d.
- Based on the aforesaid, the Court vacated the injunctions against defendants and directed the defendants to submit accounts to the Court at regular intervals until the case is finally decided.

Compulsory License for Pharmaceutical Product India

Under the Indian Patent Act, compulsory license can be granted after the expiration of a period of three years from the date on which the patent has been granted. The grounds include:

- The reasonable requirements of the public with respect to the patented invention have not been satisfied; or
- The patented invention is not available to the public at a reasonably affordable price; or
- Patented invention is not worked in the territory of India.

Section 146 (2) of the Indian Patent Act requires every patentee and licensee to provide information on the extent to which the patented invention has been worked on a commercial scale in India.

Compulsory License for Pharmaceutical Product India

Relevant information is submitted by patentees and licensees with Form 27. It is required to be filed every calendar year, within three months of the end of each year.

- The information includes the following:
- Whether the invention has been worked;
- If not worked, the reasons for non-working, and steps being taken to work the invention;
- If worked, quantum and value of the patented product;
- If manufactured in India;
- Whether imported from other countries, giving details of the countries concerned;
- Licenses and sub-licenses granted during the year.

Whether the public requirement has been met, at a reasonable price either partly, adequately or to the fullest extent.

Compulsory License for Pharmaceutical Product India

Bayer Corp. v. Natco Pharma

- This case illustrates license sought for Nexaver® used in the treatment of advanced liver and kidney cancer
- In 2012, India's first ever compulsory license was granted by the Indian Patent Office to Natco Pharma for generic production of Bayer Corp's Nexaver® (Sorafenib Tosylate), a life-saving medicine used for treating liver and kidney cancer.
- Bayer sold this drug at a very high rate with one month's worth of treatment costing around Rs. 2.8 Lakh (3,737.89 USD, at Rs. 74.84 to a USD). Natco Pharma offered to sell the drug for Rs. 9000 (120.15 USD, at Rs. 74.84 to a USD) making it affordable for general public.
- Thus, all the three conditions of Section 84 of the Indian Patent Act were fulfilled.

Compulsory License for Pharmaceutical Product India

BDR Pharmaceuticals v. Bristol-Myers Squibb

- This case illustrates licence sought for Sprycel® which is used in cancer treatment
- On March 4, 2013 the Controller rejected BDR Pharmaceuticals' (BDR) application for a compulsory license for the cancer drug Sprycel®.
- The controller stated that BDR failed to make a prima facie case for the grant of compulsory license. Specifically, the Controller found that BDR had made no credible attempt to procure a license from the patent holder and the applicant had not acquired the ability to work the invention to public advantage.
- Thus, the compulsory license was denied.

Compulsory License for Pharmaceutical Product India

Lee Pharma v. AstraZeneca

- This case illustrates license sought for Saxagliptin® which is used in the treatment of Type-II Diabetes Mellitus
- On June 29, 2015, Lee Pharma filed an application for compulsory license for patent covering Astra Zeneca's diabetes management drug Saxagliptin®. The application was rejected stating that no prima facie case had been made out on any of the three grounds under section 84 (1) of the Indian Patent Act.
- Reasonable requirements of the public had not been satisfied: Lee Pharma failed to demonstrate reasonable requirements of the public with respect to Saxagliptin® and further failed to demonstrate the comparative requirements of the drug Saxagliptin® vis-à-vis other drugs.
- The patented invention was not available to the public at a reasonably affordable price: It was held that all related drugs were in the same price range and that Saxagliptin® being sold at unaffordable price was not justified.
- The patented invention had not been worked in the territory of India: Lee Pharma also failed to show the exact quantitative requirements of Saxagliptin® in India. Therefore, it could not be concluded whether manufacturing of the drug in India was necessary or not.

Trademark Cases for Pharmaceutical Product India

Sun Pharmaceutical Laboratories Ltd v Hetero Healthcare Ltd. 2022

- Sun Pharma contended that it was one of the largest generic medicine manufacturing pharmaceutical companies in the world and that it had been manufacturing a generic drug for second line treatment of advanced breast cancer containing the active ingredient **'LETROZOLE'** under the trademark **'LETROZ',** registered in Class 5 since 1 September 2001.
- In 2017, it gathered that the mark **'LETERO'** was being used by the respondent HETERO. It relied on its registration to claim that it has the statutory right to exclusively use its trademark 'LETROZ' and that it was entitled to an order restraining HETERO from using the trademark 'LETERO', because it was deceptively similar to its registered trademark 'LETROZ'.

Trademark Cases for Pharmaceutical Product India

- HETERO, in its defence, argued that its mark **'LETROZ'** was derived from the word **'LETROZOLE',** which is an international non-proprietary name (INN) of a salt; therefore, Sun Pharma was not entitled to claim monopoly over the said word. HETERO further contended that it is common practice in the pharmaceutical industry to use trademarks derived from the active pharmaceutical ingredient (API). It further argued that the mark 'LETERO' is a registered trademark of HETERO and is coined by combining the first two letters of the salt 'LETROZOLE' with the last four letters of HETERO, that is, 'TERO'.

- After going through these contentions, the learned Commercial Court held that there was no deceptive similarity between the competing marks that could confuse a doctor or a chemist and that it was beyond understanding as to how the plaintiff could stop the defendant from using first two alphabets when they themselves were using all the six letters LETEROZ of the generic name, namely, LETEROZOLE.

Conclusion

- Management of IP in pharmaceutical industry is a multidimensional task and calls for many different actions and strategies which need to be aligned with national laws and international treaties and practices.
- Pharmaceutical IP and its associated rights are seriously influenced by the market needs, market response, cost involved in translating IP into commercial venture and so on.
- In other words, pharmaceutical trade and commerce considerations are important in the management of IPR.
- Different forms of pharmaceutical IP demand different treatment, handling, planning, and strategies and engagement of persons with different domain knowledge such as science, engineering, medicines, law, finance, marketing, and economics.

Thank You