



ORIGINAL RESEARCH PAPER

Pharmacology

OVERVIEW OF INTELLECTUAL PROPERTY RIGHTS & PATENTS FOR PHARMACEUTICAL INNOVATIONS

KEY WORDS: Intellectual property rights, Patent, Pharmaceutical inventions, Drug

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ABSTRACT Intellectual property has been defined as ideas, inventions, and creative expressions. Intellectual property rights (IPR) is necessary for protection of novelty. IPR provide certain exclusive rights to the inventors or creators of that property. Every Pharmaceutical industry should develop its IPR policies, management style, strategies, and so on depending on its area of specialty. Many industries currently have a developing IPR design, demanding a better focus and approach in the coming time. Patent, copyright, trademark, etc. these are some of the types of intellectual property protection. IPR is nothing but to understand what it is, why it is needed, and what we are going to do with it.

INTRODUCTION

Intellectual property (IP) refer to any innovative creation of the human brain such as imaginative, fictional, procedural, or scientific construction. Intellectual property rights (IPR) refers to the legal & exclusive rights given to the discoverer or creator to protect his discovery or creation for a certain period. [1] These are a right to the creator or his assignee to completely use his creation for a given period. IP play a vital role in the economy of today' research and development (R&D),

Economic implications of intellectual property rights (IPRs) has gained attention in the context of the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). [2] TRIPS intentions are to bring all countries under common international rules for IPR. Developing countries like India, are trying to strengthen their national intellectual property (IP) regimes. However, underscoring the absence of empirical evidence to justify the socio-economic benefits for developing countries from strengthening IPRs.

IPR is a strong tool, to protect investments, time, money, effort invested by the inventor. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth. Present review is regarding a brief-view of IPR in relation to pharmaceuticals.

Particularly developing countries should pay more attention to the way in which patents are examined and granted to avoid the negative effects resulting from the granting of patents on developments lacking inventiveness. This working document should be understood in the context of two major issues:

1. The accessibility of medicines to the world's population as a key element of public health policy; and
2. Innovation as an essential prerequisite for the existence of medicines.

it is necessary to explore, identify and implement mechanisms to improve the functioning and transparency of the patent system in the interest of public health. To develop a legal and normative framework for patent protection for pharmaceuticals that ensures a balance between the interests of the patent holders and the users of technology, several issues should be carefully examined and considered at the national level.

BRIEF HISTORY

IPR had its origin in Europe. The trend of giving patents was started in the 14th century. The very first known copyrights were taken in Italy. While in the Venice, for the first time in the world, laws and systems were made here and other countries followed it later. [3] Patent act in India is more than 150 years old. The inaugural one is the 1856 Act, which is based on the British patent system and it has provided the patent term of 14 years followed by numerous acts and amendments. [1]

DIFFERENT TYPES OF IPR

Intellectual property rights include patents, copyright, industrial design rights, trademarks, plant variety rights, trade dress, geographical indications [4] and in some jurisdictions trade secrets. There are also more specialized or derived varieties of sui generis exclusive rights, such as circuit design rights and supplementary protection certificates for pharmaceutical products (after expiry of a patent protecting them).

Patent

It is a right of inventor/ owner by the government and it help to exclude others from making, using, selling, offering to sell, and importing an invention. This is approved for a restricted period. [5] An invention generally must fulfil three main requirements:

- i. It must be new,
- ii. Not obvious and
- iii. There needs to be an industrial applicability.

Patents are granted for inventions, not for medicines. "invention" and patentability" are two distinctly separate concepts. Thus, even if there is an invention but it falls under non- patentable inventions then a patent cannot be granted to it. It may be granted for:

- 1) A chemical compound or molecule;
- 2) A medical indication or therapeutic effect of the molecule;
- 3) The combination of products (e.g., a fixed dose combination of two or more molecules); or
- 4) The manufacturing process (known as a process patent). There could be more than one patent for a single medicine, e.g. The chemical compound and its production process can both be patented. It needs to be kept in mind, however, that national laws may restrict the kind of patents that may be granted for medicines; some laws can explicitly bar the grant of patents for drug combinations (see the case study on India below).

Copyright

It provides the creator of an original work exclusive rights to it, usually for a definite time. Copyright cover the way they are expressed, and not the ideas and information themselves. [6]

Industrial design rights

Also known as "design right" or design patent protects the pictorial design of objects that are not purely practical. An industrial design consists of the outline or colour, or combination of pattern and colour in three-dimensional, attractive form.

Plant varieties

These are the rights to commercially practice a new variety of a plant which supposed to be novel and different.

Trademarks

It is an identity in the form of sign, design or expression which helps to distinguishes products or services of a trader from the similar or other traders. [7]

Trade dress

It refers to features of the visual and aesthetic appearance of a product or its packaging (or even the design of a building) that signify the source of the product to consumers. [8]

CLAIMS RELATING TO PHARMACEUTICAL INVENTIONS

It may relate to an active ingredient as such formulations, salts, prodrugs, isomers, etc. It may also extend over a manufacturing process. The following sections include some considerations for the evaluation of different types of claims that are typical in this area. [9]

- I. Formulations and compositions
- II. Combinations
- III. Dosage/dose
- IV. Salts, ethers and esters
- V. Polymorphs
- VI. Markush claims
- VII. Selection patents
- VIII. Analogy processes
- IX. Enantiomers
- X. Active metabolites and prodrugs
- XI. Method of treatment
- XII. Use claims, including second indications

Formulations and compositions

When a new single active ingredient is claimed in association with known or unspecified carriers or excipients, it should generally be deemed obvious in the light of the prior art. When a difficult problem or a long-standing need, such as a noticeable reduction in side effects, is solved in a non-obvious way, or when the solution found leads to a tremendous advantage compared to the state of the art, this type of claims could be patentable. [10]

Combinations

If, however, a new and nonobvious synergistic effect is considered a basis for patentability, it should be properly demonstrated by biological tests and appropriately disclosed in the patent specifications. For known active ingredients should be deemed non-inventive. [9]

Dosage/dose

New doses of known products for the same or a different indication do not constitute inventions. [11]

Salts, ethers and esters

When tests demonstrate unexpected advantages in properties as compared to what was in the prior art, claims could be patentable. Otherwise new salts, ethers, esters and other forms of existing pharmaceutical products are not inventive. [12]

Polymorphs

Processes to obtain polymorphs may be patentable in some cases if they are novel and meet the inventive step standard, apart from that Polymorphs are not created, but found. [12]

Markush claims

Sufficient information will be necessary, such as fusion point, Infrared Absorption Spectrum (IR) or Nuclear Magnetic Resonance (NMR), obtained through true testing and experimentation to enable the reproduction by the disclosed method of each embodiment of the invention for which protection is sought. Claims covering a large range of compounds should not be allowed. [13]

Selection patents

If the selected components have already been disclosed or claimed and, hence, lack novelty then only selection patents should not be granted. Patentability of a selection could be considered when an inventive step is present. [14][15][16]

Analogy processes

Non-novel or obvious pharmaceutical processes should be considered not patentable, regardless of whether the starting materials, intermediaries or the product are novel or inventive. [9]

Enantiomers

Single enantiomers should generally not be deemed patentable when the racemic mixture was known. However, processes for the abstention of enantiomers, if novel and inventive, may be patentable. [17]

Active metabolites and prodrugs

Active metabolites of drugs should generally not be patentable separately from the active ingredient from which they are derived. Patents over prodrugs, if granted, should disclaim the active ingredient as such, if previously disclosed or otherwise non-patentable. A prodrug should be sufficiently supported by the information. [17]

Method of treatment

Prevention, diagnosis or prophylaxis i.e. methods of treatment, should be considered non-patentable where industrial applicability is required as a condition for patentability. [18][19]

Use claims, including second indications

Claims relating to the use, including the second indication, of a known pharmaceutical product can be rejected, on grounds of deficiency of novelty and industrial applicability. [20]

DISCUSSION

Pharmaceutical industry is one of the most important catalysts in improving the quality of human life and raising the health care standards of any country, whether developed or underdeveloped. The industry makes wide range of therapeutic and prophylactic drugs available to mankind. Now a day, the patentability of health-related innovations has become topic of debate world-wide. Lots of money are invested each year in pharmaceutical research, but the percentage of people who can afford potentially life-saving drugs remains little. The development of drugs is costly for pharmaceutical companies, and without intellectual property law protection, the formula for the drugs can be easily reproduced and the drugs can be made at a cheaper cost. [21] Thus, intellectual properties laws often allow companies the exclusive right to manufacture and sell drugs which provides the necessary drive for drug discovery.

Patent regimes are critical to design them consistently with public health strategies. The scope of patentability be corresponding with public health policies, and that governments be aware that disproportionately expanding what can be patented may distort competition and reduce access to medicines. Patents over minor developments may depress competition. The analysis and criteria presented in this document intend to provide general guidance about patent and how to access to medicines. According to nationwide regulation they should be further polished and adjusted.

As discussed above, the following classes of product patent applications be admissible:

- A new salt, ester, ether or polymorph, including hydrates and solvates, of an existing chemical entity.
- A single enantiomer of an existing chemical entity.
- A new combination of two or more active ingredients that are already available as single entities.
- A new dosage form that allows a new route of administration (e.g. an injection when an oral tablet already exists).
- A controlled release dosage form when a non-controlled release dosage form already exists.
- A new route of administration of an existing dosage form (e.g. intravenous administration of an injection when subcutaneous administration is already approved).
- A change in formulation.

Conclusion

The Intellectual Property Rights (IPR) will have wide range of socio, economic, technological and political impacts. The stakes of the developers of technology have become very high, and hence, the need to protect the knowledge from dishonest use. The tools of IPR such as patents, trademarks, service marks, industrial design registration, copy rights and trade secrets. The legal framework for IPR is in a stage of dynamic adjustments and changes to accommodate the challenges.

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