

INTELLECTUAL PROPERTY RIGHTS IN PHARMACEUTICAL, BIOTECHNOLOGY AND BIOMEDICAL INDUSTRY.

Pharmaceutical

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ABSTRACT

Intellectual Property has acquired the term Property because the owner of the right has legal power to lease, sell, donate, license etc with similar status to a property. Intellectual property rights (IPR) deals with Patents, Designs, Trade Marks, Copyright, and Geographical Indications. The Patents Act, 1970 was amended in 1999, 2002 and in 2005(1). Finally amended law effective from Jan 01, 2005 allowed patents on products of chemical change, new drug molecules, agrochemicals, drug or pharmaceutical compositions, foods etc. which were earlier unavailable for patent. In case of invention for a patent related to biological material that will be deposited to the international depository authority under the Budapest treaty with disclosure of source and geographical origin of the biological material.

KEYWORDS

IPR, Pharmaceutical, Biomedical Engineering, Drug Development.

INTRODUCTION:

A patent is a monopoly right granted to an inventor, giving the inventor the right for a limited period of time to prevent others from making, using and selling his invention without due permission from the inventor. The invention for granting a patent must be satisfied in novelty of the invention, inventive step and industrial application. Objectives of Patents are to encourage inventions, inventions become known instead of remaining secret, industrial development and wealth of technical information.

DISCUSSION:

Discovery is not patentable subject matter. Only invention is patentable but sometimes discovery can be basis for invention and invention means creative application of scientific knowledge on the technical field, requires additional steps towards a technical solution of a problem with enables technical domination of nature for the use of public. Such as finding a new substance in nature and elucidation of the chemical structure of a natural product is may be considered as a patentable subject matter provided it satisfies others norms (2).

As example, a fungus, named amanita phalloides(Fig1) is used for isolation a compound called antamanide (Fig2) which is using cyclic decapeptide antidote against poisoning. In this case isolated compound from fungus is a patentable matter because it is satisfied in the terms of novelty, inventive step and industrial application.



Fig1Fungus Amanita phalloides

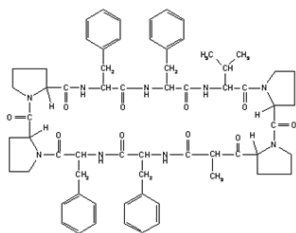


Fig2 Antamanide:

Drugs discovery based on nucleus modification if we study compounds related to proton pump inhibitors like omeprazole, lansoprazole, rabeprazole. Parent structure is same and only difference in end group. These three compounds individually novel and difference in its efficacy and have different patents.

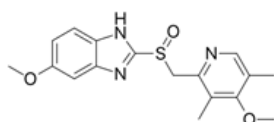


Fig3 Omeprazole

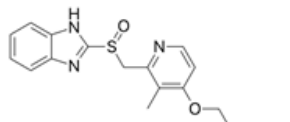


Fig4 Rabeprazole

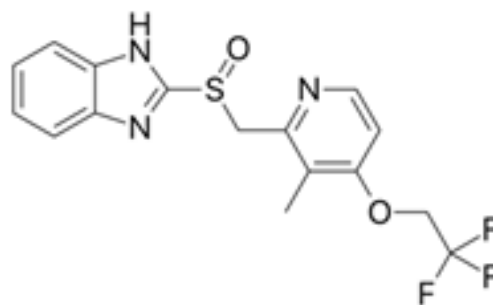


Fig5 Lansoprazole

Use patents are not patentable substance in India. As example, Sildenafil is used for heart diseases and it is also used for erectile dysfunction. Acetylsalicylic acid is used against headache but acetylsalicylic acid is also used for heart diseases.

The second medical use creates novelty for a known substance but not patentable in India. So it is called as per Indian Patent Act that mere discovery of a new form of a known substance or a new property or use. Method of treatment is not patentable in India but method of treatment is patentable in USA. Example surgery for the prevention and reversal of baldness method for the prevention of bald head formation whereby the intermediary tendon of the frontal muscle is cut 2 cm above the glabella.

Scope of non-patentable inventions as per Indian Patent Act: (i) Invention which is frivolous or anything obviously contrary to well established natural laws.(ii) Invention against public order or morality or harmful to human, animal or plant life or health or to the environment. (iii) 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.(iv) Mere discovery of a new form of a known substance or a new property or use.(v) Admixture resulting in aggregation of properties and process of preparing them.(vi) Mere arrangement or rearrangement or duplication of known devices each functioning independently.(vii) A method of agriculture or horticulture. (viii) Medicinal, surgical, curative, diagnostic etc. or treatment of human beings or animals to render them free of disease or to increase their economic value. (ix) Plants and animals in whole or parts thereof other than microorganisms but including seeds, varieties and species and essentially biological processes for production or propagation of plants and animals. (x) Mathematical or business method or a computer program or algorithms.(xi) A literary, dramatic, musical or artistic work.(xii) Method of performing mental act or method of playing game.(xiii) Presentation of information.(xiv) Topography of integrated circuits.(xv) Traditional knowledge.(xvi) Inventions relating to atomic energy(2).

Invention related to only new gene sequence is not patentable but a set of claims in patent specification are together in one patent sharing the same inventive concept. As example, a invention related to i. new sequence A ii. A method of expressing sequence A iii. An antibody made to the protein of sequence A iv. A kit made from the antibody to sequence A v. All of these claims are linked by the same inventive concept that sequence A is new and inventive (3). So all these claims will be incorporated in same patent specification. Transgenic animals are not patentable but the living entity of artificial origin such as micro-organism, vaccines are considered patentable in India. Transgenic animals are patentable in USA (4).

Drug discovery is a long process it includes discovery the molecules, preclinical trials, clinical trials Phase I, Phase II, Phase III and approved by regulatory bodies. It will take normally more than 10 years to complete the steps. Patent applications are normally to be filled at the discovery stage.

Conclusion: Patentee has the right to use, exercise, sell or distribute of article/substance from date of notification after grant of Patent. Pharmaceutical companies can earn profit using patented drug through protected global market judiciously. Researcher can use patent literature for further development of the pharmaceutical molecules or formulation development of the product (5).

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