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Roll No. ..... **OPEN BOOK EXAMINATION**

Time allowed : 3 hours ***Maximum marks : 100***

Total number of questions : 6 ***Total number of printed pages : 16***

NOTE : *Answer **ALL** Questions.*

1. Read the following case study carefully and answer the questions given at the end :

Care and Cure Limited was established in Hyderabad in 1998. It was a manufacturer, exporter and importer of drugs and pharmaceutical formulations such as anti-hypertensives, anti-fungals, anti-depressants, anti-obesity treatments, bulk drug intermediates, active pharmaceutical ingredients, pellets and granules. Apart from India, the company marketed pharmaceuticals to many countries including the United States, Canada, Germany, Spain and Sweden. Despite its global marketing reach, the company was relatively lesser known in India.

Saxagliptin is a dipeptidy-1 peptidase-4 inhibitor used for lowering blood sugar levels in type-2 diabetes, a condition of high blood-sugar levels in the human body that occurred when the body did not produce or use enough insulin in the pancreas. Other comparable drugs are available in the Indian market and can be used for controlling blood sugar levels by inducing higher production of insulin in patients suffering from diabetes. Generic alternatives for comparable drugs are also available in the Indian market.

Bristol-Myers Squibb (BMS), a multinational company founded in the United States of America in 1858 developed the molecule that was used in Saxagliptin. BMS received the patent for Saxagliptin in India in 2007. AstraZeneca (AZ) another global company founded in Sweden, joined with BMS in 2007 to further develop the drug and commercialize its uses. During the codevelopment period AstraZeneca (AZ) bore the entire development cost. Subsequently in 2014, as a part of a broader diabetes market strategy, AZ acquired BMS's entire diabetes business, which gave AZ complete ownership of all the intellectural property rights of BMS's diabetes drugs, including Saxagliptin. This drug was marketed in stand-alone form under the brand name ONGLYZA and in combination with another active ingredient for enhanced diabetes management. Saxagliptin, in its stand-alone form, was available in the market at around ₹ 41 to ₹ 45 per tablet. Other comparable leptin drugs were also available in the market in the same price range, and generic alternatives for these leptin drugs were available in the market at a much lower rate.

In June, 2015, Care and Cure Limited filed an application for a compulsory licence with the Controller of Patents for manufacturing Saxagliptin. In its application, it presented several charges against AZ's business functioning and practices in India, including the following :

(*i*) AZ/BMS was not able to manufacture the drug in India, even eight years after receiving a grant of the patent. The patentee imported the drug into India from Ireland and the United States.

(*ii*) Even the imported quantity could satisfy only 0.23 per cent of the total market demand in India, which consisted of around 60 million type 2 diabetics. The actual quantity that could be sold in India was much lower because the drug was exported in large quantities from India to other countries.

(*iii*) The drug was imported at a cost of less than a rupee per tablet but sold as around ₹ 41 to ₹ 45 per tablet in the domestic market, where 30% of the population lived below the poverty line.

In added that Care and Cure Limited, on the other hand had the capacity to manufacture a million tablets a day and was capable of making Saxagliptin available to the general public at around ₹ 30 per tablet.

Pharmaceutical products, specifically, were protected by patents. The Trade Related Intellectual Property Rights (TRIPS) Agreement required the member countries to make patents available for any process or product inventions, irrespective of the place of invention and place of manufacturing. However, this basic rule of patentability was subject to three exceptions :

(*i*) Inventions that went against public morality, which included inventions dangerous to human, animal, or plant life or detrimental to the environment.

(*ii*) Medical methods used for the treatment of humans or animals; and

(*iii*) Plants and animals (other than micro-organisms and biological processes) used for reproduction.

INDIAN PHARMACEUTICAL INDUSTRY : PERFORMANCE, PRICING POLICY, AND PATENT REGIME.

The India Pharma Market (IPM) was among the world's top three pharmaceutical markets in terms of volume and 14th largest in terms of value. It was projected to grow to 55 billion US dollars by 2020 due to India's rising population, improved affordability, accessibility and acceptability of modern medicines and new therapies. Generic drugs dominated the IPM, possessing a 70% market share in terms of revenue. Over-the-Counter (OTC) medicines contributed 21% of the total revenue, and the remaining 9% came from the patented drugs. India was also among the top six global pharmaceutical products in the world. Due to the low cost of production, India was also a leading exporter of pharmaceuticals and the largest exporter of generic drugs globally, exporting medicines to more than 200 countries.

Indian medicines had a dominant presence in the US pharmaceutical market. In the past few years, the US Food and Drugs Administration (USFDA) and the UK's Medicines and Healthcare Products Regulatory Agency had raised some doubts about the quality of medicines manufactured in India. The IPM was a highly fragmented market with around 24,000 registered companies, of which 330 operated in the organised sector. The top 10 companies accounted for more than 40 per cent of the market share in India.

PRICING POLICY :

The National Pharmaceutical Pricing Authority (NPPA) in India regulated the prices of all essential medicines, with the objective of making essential medicines available at an affordable cost and with assured quality. The essential medicines were those took care of the health needs of the general public. There were 348 medicines in the National List of essential medicines in 2011. It covered just 17 percent of the total pharmaceutical market in India and did not contain several diabetes drugs including Saxagliptin, as well as certain drugs used in the treatment of tuberculosis, human immunodeficiency virus (HIV), and cancer. The ceiling prices of the medicines listed on the NPPA were fixed at a simple average price of all the branded or generic versions of all such medicines that had a market share of more than or equal to 1 per cent of the total market revenues for that medicine. Additionally, the manufacturers of medicines that were not under price control were allowed to increase the maximum retail price of those medicines only up to 10 per cent annually.

PATENT REGIME : PROCESS PATENT TO PRODUCT PATENT

The Patents Act, 1970 governs the patent system in the country. Prior to a 2005 amendment, the Act granted ‘‘process patents’’ that allowed the manufacturers to patent their manufacturing method for a given product. The other manufacturers could not produce the product using the patented process although they could produce it using a different process of their own

design. In the context of food and medicine, a process patent implied that the patent could be granted only for the process of manufacturing the substance rather than for the substance itself.

The pharmaceutical industry in India thrived under the process patent regime, as many drug manufacturers in India copied the drugs patented in other countries by inventing new processes of producing the same product. The competition among drug manufacturers drove down the medicines prices thus benefiting the consumers. It also helped Indian drug manufacturers to carve out a place for themselves in the international market, especially in poor countries.

The process patent regime discouraged the domestic manufacturers from investing enough in research and development and discovering altogether new products. The process patent regime also resulted in the ‘‘ever-greening’’ of pharmaceutical patents whereby patent owners tried to extend the life of their patented products by inventing a slightly different process and acquiring another patent for what was basically the same product. The system also went against multinational companies that had spent millions of dollars to develop new products, and it also deterred them from investing in Indian companies.

Although Indian pharmaceutical manufacturing industry was thriving under the process patent regime, in order to comply with the WTO’s TRIPS Agreement, India was forced to amend the Patents Act, 1970. The amendments for the Act in 2005 recognized patented original

drugs as products irrespective of the process used for manufacturing the same, and prevented domestic pharmaceutical companies from copying new drugs developed in other countries by designing new processes for manufacturing these products.

Indian technology and innovation companies welcomed the move to a new regime expecting that the new, stronger level of patent protection would encourage many multinational companies to tap into India's relatively inexpensive workforce for product design, medicine development and clinical testing and also to invest large amounts in R & D in the domestic market, which would help India become more competitive in the global market.

But stronger patent protection also sparked debate that the new patent regime would create tough competition among domestic pharmaceutical companies. Since inventing a new product was more expensive than inventing a new process for producing an existing patented product, the general public feared that the new patent regime would drive up the cost of medicines and make them unaffordable to the masses. Critics also feared that new patent regime would dry up the supply of generic drugs in the international market thereby affecting the interests of poor countries. The proponents of product patent regime set aside these fears by indicating that the generic drugs that were already patented under India's process patent regime could be sold on the payment of licence fees to the original patent holder.

To mitigate the public's apprehensions and fears, the proponents also referred to that provision of compulsory licencing in the WTO's TRIPS Agreement.

COMPULSORY LICENCING IN INDIA :

The WTO included a provision for compulsory licensing in its TRIPS Agreement to safeguard the interests of the general public in developing and least-developed countries. This provision enabled the governments of these countries to grant a licence to domestic manufacturers to produce a patented drug without seeking the patent holder's consent. Instead domestic manufacturers in these countries were required to make appropriate compensation to the patent holder, as decided by the government or through negotiations with the patent holder.

Under the following situations, a generic drug manufacturer in India could apply for a compulsory licence any time after the expiration of three years from the grant of patent (a condition was not required under the TRIPS Agreement) upon payment of a reasonable royalty.

(*i*) The patent-holding company was not able to make the patented invention available to the public.

(*ii*) The patented invention was not made available at a reasonable price.

(*iii*) There was a lack of working of the patented product within the territory of India.

The Patents Act, 1970 envisioned that the companies seeking a grant of a compulsory licence would consider doing so only as a last resort. Prior to seeking such a licence, the companies were expected to attempt to obtain a voluntary licence from the patentee. Once these attempts failed over a six-month period from the date of the initial request, the company could request patent-office intervention for the grant of a compulsory licence.

Natco Pharma Ltd. (NATCO), a generic drug manufacturer in Hyderabad, received the first compulsory licence in India in 2012 to produce and market Nexavar, a patented drug of a major multinational pharmaceutical company, Bayer Corporation. The compulsory licence was granted to NATCO as Bayer had not made the drug available on a large scale or at an affordable price within the stipulated period. The compulsory licence stipulated that the company would pay a 6 per cent royalty to Bayer from the sale of the generic drug Nexavar. On Bayer's appeal, the royalty rate was modified to 7 per cent.

The decision to grant a compulsory licence to NATCO spurred some controversy and speculation in India as well as abroad. It was felt that in a country where almost 90% of all pharmaceutical patents were imported, the decision to grant a compulsory licence to NATCO would spur applications for grant of compulsory licences by local manufacturers for other essential patented drugs that were excessively priced by the patentee companies. Analysts also contemplated that the exercise of the compulsory licensing provision in developing countries would force multinational pharmaceutical companies to adopt a differential pricing scheme for essential drugs, charging significantly lower prices in developing countries for these drugs.

The compulsory licensing decision disappointed multinational pharmaceutical companies. Certain large multinational pharmaceutical corporations overtly articulated their disapproval with India's compulsory licencing process. It was said that inspite of being a member of the WTO, India

had failed to interpret and apply its intellectual property laws in a manner consistent with recognized global standards. Some other corporations stated that compulsory licensing should be used only in exceptional circumstances such as in the times of a national health crisis. If used arbitrarily, compulsory licences will serve to undermine the innovative pharmaceutical industry and will be to the long-term detriment of the patient.

The second application for compulsory licence for manufacturing BMS's cancer drug Dasatinib came from XYZ Ltd. The patent office rejected the application of XYZ Ltd. citing that it failed to establish a *prima facie* case for receiving compulsory licence. Care and Cure Limited was the third company to apply for a compulsory licence.

One Chief Executive of an American pharmaceutical manufacturing corporation stated that medicine is for the people. It is not for the profits. The Patent controller's grant of a compulsory licence to Care and Cure Limited for Saxagliptin would certainly address the public welfare concern in India and it would also break the monopoly of multinational giants and spur competition within the domestic market. Frequent use of compulsory licences, however, would surely result in retaliation by the developed world.

Alternatively, a rejection of Care and Cure Limited's compulsory licence application would show the world that India placed supreme importance in the intellectual property laws laid out by the WTO and that India was willing to provide sufficient protection to the rights of innovators.

How should the patent controllers proceed ? Should the compulsory licence application of Care and Cure Limited be rejected emphasizing international relations and compliance with multilateral agreements, inventions and innovations, or should the licence be granted to provide vital support for human life ? The patent office is faced with this dilemma.

Questions :

(*a*) What is the difference between a ‘‘product patent’’ and a ‘‘process patent’’ ? How will developing countries be affected if they adopt a product patent regime ?

(*b*) What is compulsory licence ? What is the economic rationale behind compulsory licensing ? On what grounds has Care and Cure Limited applied for compulsory licence for Saxagliptin ?

(*c*) Should the patent office grant a compulsory licence to Care and Cure Limited ? Justify your stand using an economic rationale.

(*d*) What strategic changes can multinational pharmaceutical companies make to their business processes in order to avoid the issue of compulsory licences for their patented drugs in developing countries ?

(10 *marks each*)

2. ABC Ltd. is a global automobile manufacturing company having headquarters in Japan.

In 1990, it launched a hybrid model car with the name PRIUS which got trademark registrations in various countries. It started selling in USA and Europe in 2001 and 2002.

M/s Pious Auto Industries Ltd. used to manufacture spare parts and accessories for cars in India since 2001 and got the trademark registered in 2002.

In 2009 ABC Ltd. started promoting its PRIUS vehicle in India and launched the PRIUS in the year 2010.

When ABC Ltd. discovered the fact that M/s Pious Auto Industries Ltd. has been using the mark ‘‘PRIUS’’ for autoparts and accessories, it approached the Trade Marks Registry for cancellation of the trademark and also brought a suit for infringement against the company, on the ground of claiming of passing off of its famous mark which led to an unfair advantage of their reputation and goodwill in the market.

ABC Ltd. contented that various advertisements and news reports about the trademark in India and across the globe have made PRIUS a well-known trademark. These promotional tools are sufficient to establish reputation and goodwill within a particular geographical area. Since 1997, ‘PRIUS’ was widely publicised and advertised in leading newspapers.

It added that the mark PRIUS was a well-known mark under section 2(1) (zg) read with sections 11(6) and 11(a) of the Trade Marks Act, 1999 as the mark PRIUS had acquired a great deal of goodwill in several other jurisdictions in the world much prior to Prius Auto's use and registration in India.

M/s Pious Auto Industries highlighted the principle of territorial jurisdiction over universality principle. It also referred to the judgement of Starbucks vs. British Sky Broadcasting, wherein the court had held.

''No trader can complain of passing off as against him in any territory ..... in which he has no customers, nobody who is in trade relation with him.''

M/s Pious Auto further contended that to establish goodwill and reputation in a particular jurisdiction, one has to show adequate evidence that he has acquired a substantial goodwill in India for its mark. Further, prior use of trade mark in one jurisdiction would not *ipso facto* entitle its owner or user to claim exclusive rights to the said trade mark in other jurisdiction.

Questions :

(*a*) Whether, using the mark PRIUS by M/s Pious Auto Industries Ltd. to market automobile parts manufactured by it amounts to infringement of reputation of ABC Ltd. in the market ?

(*b*) Whether M/s Pious Auto Industries Ltd. is guilty of passing off its products as those of ABC Ltd. ?

Give reasons and case law, if any in support of your answer.

(6+6=12 marks)

3. (*a*) ''Over the past fifteen years, intellectual property rights have grown to a stature from where it plays a major role in the development of global economy.''

In the light of this statement, prepare a brief note on recent developments that have taken place in the regulatory regime of intellectual property in India.

(*b*) ''Patent information is more than just technological or legal information.''

In the light of this statement, enumerate the practical applications of patent information.

(6 *marks each*)

4. (*a*) Ushodaya Enterprises Ltd. is engaged in the business of publishing a newspaper in Telugu called Eenadu. The company is in the business of publishing a newspaper, broadcasting, financing and developing a film city. Its products and services are co-related, identified and associated with the word Eenadu in the entire State of Andhra Pradesh. Its trade mark Eenadu has acquired reputation and goodwill in the entire state.

S.V. Venugopal is the sole proprietor of a firm carrying on business *inter alia* as manufacturers of and dealers in incense sticks in the name and style of ASHIKA Incense Incorporated at Bangalore and adopted the mark ASHIKA's Eenadu.

S.V. Venugopal states that the word Eenadu in Kannada language means 'this land'. In Malayalam and Tamil language, it conveys the same meaning. In Telugu, it means 'today'. In consonance with the above meaning, he has devised an artistic label comprising

a rectangular carton in bottle green background with sky blue border and in the centre in an oval tricolour, the word 'Eenadu' is written. He started using the name 'Eenadu' for his incense sticks and used the same artistic script, font and method of writing as that of Ushodaya Enterprises Ltd.

Ushodaya Enterprises Ltd. has instituted a suit for infringement of copyrights and passing off trade mark against S.V. Venugopal. Will the company succeed ? Give cogent reasons in support of your answer.

(6 *marks*)

(*b*) In Sept. 1990, XYZ Pvt. Ltd. started manufacture of Cetadine Microbicidal solution consisting of a Providone Iodine combination which is being marketed in pack sizes of 100 ml and 500 ml bottles under the trademark CETADINE. It has been extensively advertised by the company.

The bottles bear distinctive labels having distinct colour combination, layout and get up which qualify as original artistic work within section 2(c) of Copyright Act, 1957 and is registered with the Registrar.

R. Pharma Works manufactures microbicidal solutions in bottles with a label having an identical and/or substantially similar get up, layout and colour scheme as that of XYZ Pvt. Ltd. Its bottles contain the name Povidone Iodine Solution.

XYZ Pvt. Ltd. instituted a suit against R. Pharma Works for infringement and consequent damages. What are the defences that R. Phama Works can plead in his favour ? Will XYZ Pvt. Ltd. succeed ?

(6 *marks*)

5. (*a*) Discuss the nature and scope of infringement of a copyright in the judicial pronouncements of the Apex Court in the matters of Copyright Act, 1957.

(6 *marks*)

(*b*) For a design to be called new or original under the Designs Act, 2000.

(*i*) There should be some original mental application involved; and

(*ii*) The design must be significantly distinguishable from known designs or combination of designs.

Discuss and refer to decided case law, if any.

(3+3=6 *marks*)

6. (*a*) India is among first countries in the world to have passed legislation granting farmers' rights. Write an exhaustive note on the provisions contained in The Protection of Plant Varieties and Farmers' Rights Act, 2001 regarding farmers' rights.

(6 *marks*)

(*b*) These is no substantive authoritative separate statute to deal with trade secrets.

How are, then, trade secrets (a form of intellectual property) sought to be protected in India ?

(6 *marks*)

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