OPEN BOOK EXAMINATION

NEW SYLLABUS

344

Roll No.……

Time allowed : 3 hours *Maximum marks : 100*

Total number of questions : 6 *Total number of printed pages : 7*

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

1. Read the case given below and answer the questions given at the end :

This case is between US-based multinational Bristol-Myers Squibb and a mid-sized Mumbai based company BDR Pharma over 'Dasatinib', an anti-cancer drug.

Bristol-Myers is the exclusive owner of Dasatinib and its derivatives by the claims of Patent No. IN203937 in India. The patent is valid and subsisting and has a term of 20 years from 12th April, 2000 in India. It enjoys patent protection in several other countries such as United States, Australia, New Zealand, Japan, *etc*.

Chronic Myeloid Leukemia (CML), one of the most common forms of leukemia, arises from the excessive production of abnormal stem cells in the bone marrow which eventually suppress the production of normal white blood cells. The development of imatinib mesylate, a small-molecule tyrosine kinase inhibitor (TKI), was the first rationally designed drug for CML.

Bristol-Myers product Dasatinib was approved by the US Food and Drug Administration on 28th June, 2006. It is presently sold in approximately 50 countries throughout the world. A marketing approval for Dasatinib was also granted by the Drug Controller General of India (DCGI) on 30th August, 2006.

Apart from the above patent, Bristol-Myers also made a patent application in India for crystalline monohydrate form of Dasatinib. The said application is numbered 4309/DELNP/2006 dated 4th February, 2005 and is currently pending before the Indian Patent Office. The monohydrate

form of Dasatinib has been granted patents in 45 countries and is an improvement patent of the Indian Patent No. IN203937.

Cause of Action and Grounds

In December, 2008, Bristol-Myers received information that Mumbai based company, BDR Pharma had applied to the DCGI for the marketing approval for Dasatinib. It sent a 'cease and desist' letter to BDR Pharma on 12th January, 2009 asking them to restrain from infringing its Patent No. IN203937. In view of the apprehension that the defendant may infringe the plaintiff's exclusive right of the patent, the plaintiff filed a suit in the nature of a *quia timet* action against the defendant on 3rd December, 2009 for the infringement of IN203937.

The defendant has not launched the product in the market, hence, no loss or irreparable harm will be caused to BDR Pharma if it is restrained from doing activities that they have not yet commenced.

BDR Pharma admitted that the defendant is intending to launch the generic version of Dasatinib only if the DCGI grants licence to the defendant to manufacture under the provisions of Drugs and the Cosmetics Act, 1940.

Patent Licensing

On 5th May, 2013 the Controller of Patents considered the compulsory licence application filed by BDR Pharma and opined that the BDR Pharma had not made out a *prima facie* case for grant of a licence as the applicant (BDR Pharma) did not make efforts to obtain a licence from the patentee on reasonable terms and conditions and relegated the applicant to approach the plaintiff for voluntary licence.

By letter dated 13th March, 2012, Bristol-Myers, the patentee raised certain queries on BDR Pharma's application for voluntary licence such as 'facts which demonstrate an ability to consistently supply high volume of the API, Dasatinib, to the market', 'facts showing your litigation history or any other factors which may jeopardise Bristol-Myers Squibb's market

position', 'quality related facts and in particular compliance with local regulatory standards and basic GMP requirement', 'quality assurance system due diligence', 'commercial supply terms', 'safety and environmental profile' and 'risk of local corruption'.

BDR Pharma argued that the drug in question is important in the treatment of Leukemia and is exorbitantly priced at ₹1,67,000 for a month's course, putting it beyond the reach of majority of Indian population. Therefore, public interest lies in compulsory licences with royalty being given to Bristol-Myers. Blood cancer patients have a right to get the drug at low price.

Ever since the launch of Dasatinib in India, Bristol-Myers has addressed the access and affordability needs of the patients by an aggressive commercial Patient Access Program (PAP) through which prices of the drug are reduced to a fraction of the MRP. This has evolved over time thereby consistently reducing the cost of drug to patients. The program is available through a third party service provider, for the self paying patients prescribed 'Dasatinib', by an Oncologist. The service provider through a centralised call center delivers the drug to the prescribed patients at their doorstep anywhere in India with no additional delivery cost.

BDR Pharma Defense

BDR Pharma claimed that Dasatinib patent is invalid as it doesn't pass the non-obviousness test and that in any event, the public interest lies in granting an alternative remedy such as ongoing royalties instead of an injunction. The arguments for invalidity of the patent were stated under section 3(d). Under section 3(d) of the Patents Act, 1970, BDR Pharma said that Dasatinib is a mere derivative of a previously-known compound and that Bristol-Myers is 'evergreening' the patents by patenting minor modifications to previously patented inventions. The other aspect is that of efficacy. The compound should display enhanced efficacy over the previously known compound.

BDR Pharma further contended that it is a *quia timet* injunction, *i.e.*, based on an expectation of harm rather than actual harm. A *quia timet* action is a bill in equity. It is an action preventive in nature and a specie of precautionary justice intended to prevent apprehended wrong or anticipated mischief.

According to section 83 read with section 90(d) of the Patents Act, 1970, the patent has to be worked in India by manufacture and not by import. BDR Pharma submitted that same principles would apply in respect of the Indian law and thus, in the absence of definition of commercial scale, natural and ordinary meaning should be given to the expression.

It said that in terms of the said treaties the general principles set out are that, a patentee must manufacture the product in that country and it should not also be mere improvement.

In light of the above, answer the following questions —

(a) In this case, BDR Pharma has not actually infringed the Bristol-Myers patent by way of manufacture or trade. The court has, nevertheless, given an injunction against BDR Pharma not to work the patent. Explain the provisions under which the injunction was given.

(15 marks)

(b) The question of public interest in compulsory licensing on grounds of high price of the drug is relevant. How can BDR Pharma work the Bristol-Myers patent to undercut the high prices of Dasatinib ? Give suggestions.

(15 marks)

(c) What do you understand by 'evergreening' ? Discuss this in the above case in the context of 'efficacy'.

(10 marks)

(d) Who grants patent ? What is the role of Drug Controller General of India (DCGI) in the patent process, does it grant patents ? While giving approval for marketing a drug, does it consider patent status ?

(10 marks)

2. Ericsson is a Swedish multinational company and is the registered owner of eight patents pertaining to AMR technology, 3G technology and Edge technology in India. It is amongst the largest patent holders in the mobile phone industry along with Qualcomm, Nokia and Samsung. The patents owned by Ericsson are considered to be standard essential patents. Standard essential patents are those patents which form a part of a technical standard that must exist in a product as a part of the common design of such products. In the past two years, Ericsson has been suing various mobile handset companies on the ground of patent infringement in India, such as Xiaomi Technology (Xiaomi), Micromax Informatics Ltd. (Micromax) and Intex Technologies (India) Ltd. (Intex), which are major handset and smartphone provider companies in India.

Contentions of Ericsson

Ericsson moved to the Delhi High Court against companies named above contending that licences on the standard essential patents were offered to be granted to these companies on fair, reasonable and non-discriminatory (FRAND) terms. However, these companies had refused to undertake such licences and were using these patents without licence and accordingly were infringing Ericsson's patents.

Decision of the High Court

The High Court held that *prima facie* Micromax and Xiaomi were dealing with a patent infringing product and therefore, granted *ex-parte* injunction orders against them. Furthermore, the court also directed the Customs Authorities to take note of any consignment of the products undertaken by these companies. In the case of Xiaomi, Flipkart was also impleaded in the order and was directed to get rid of all the products of Xiaomi that may be patent infringing. Although, Xiaomi managed to acquire an order allowing the company to import and sell the devices that use the chipsets imported from Qualcomm Inc., a licensee of Ericsson, it was asked to deposit an amount of ₹100 for the sale of every device. Furthermore, the court also directed Micromax to pay certain royalty rates per set to Ericsson pending the final outcome of the patent infringement suit, if Micromax wanted to continue selling the devices.

The aforesaid *ex-parte* injunction orders by the High Court were with respect to selling, advertising, importing and/or manufacturing devices that infringed the patents owned by Ericsson.

CCI Investigation Orders

Some of the aggrieved parties like Micromax decided to file a complaint under section 19(1)(a) of the Competition Act, 2002 before the Competition Commission of India (CCI) against Ericsson. These parties claimed that Ericsson did not negotiate the terms of the licence for the standard essential patents as per FRAND terms.

The main contention raised by the parties was that the royalty rates prescribed by Ericsson were excessive and discriminatory and that Ericsson, being a dominant player in the relevant market with respect to the essential patents, had taken advantage of its position and charged exorbitant rates for royalty from the companies for use of its patents. The CCI considered this contention and after examining the evidence presented, agreed with the companies and passed an investigation order. However, this order suffered a blow as the Delhi High Court passed an order restraining the CCI from passing final orders with respect to the contention of the companies. The Delhi High Court held that the CCI's order resulted in raising a question of conflict of jurisdiction with the orders of the Delhi High Court. The High Court held that the order of CCI was adjudicatory and determinative due to the nature of the order being detailed and as a result of which the remedy available to Ericsson had been discarded.

After perusing the narrative above, answer the following questions :

(i) Under what provisions of the Patents Act, 1970, can the court grant injunction orders ? Is the injunction order justified in this case ?

(10 marks)

(ii) What are the likely implications of such *ex-parte* orders for the public ?

(10 marks)

(iii) How does the Competition Act, 2002 deal with matters relating to IPRs ?

(10 marks)

3. Explain the restrictive trade practice of 'grant-back provisions' in IPR licensing.

(5 marks)

4. What is not a design under the Designs Act, 2000 ? Explain with illustrations.

(5 marks)

5. How is valuation of intellectual property done ?

(5 marks)

6. The TRIPS agreement provides protection to trade secrets. Elucidate.

(5 marks)

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