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Time allowed : 3 hours

Maximum marks : 100

Total number of questions : 6

Total number of printed pages : 7

NOTE : Answer **ALL** Questions.

1. Sorafenib Tosylate is a compound patented by Bayer Corporation (Bayer), a renowned USA based developer and manufacturer of innovative drugs. It is marketed as NEXAVAR (the Drug) and is used in the treatment of advanced stages of kidney and liver cancer. The Drug is a life-extending drug and not a life-saving drug. It can increase the life of a kidney cancer patient by 4-5 years and that of a liver cancer patient by 6-8 months.

Bayer was granted a patent as well as regulatory approval for importing and marketing the Drug in India in the year 2008. Bayer does not hold a manufacturing approval in India, but has only a marketing and import licence.

Natco Pharma (Natco) filed an application in July, 2011 under section 84(1) of the Patents Act, 1970 for grant of Compulsory Licence (CL) in respect of Sorafenib Tosylate covered under Bayer's patent. In its application, Natco proposed to sell the Drug at a price of INR 8,800 (about USD 175) for one month therapy as against Bayer's INR 2,80,428 (about USD 5,600).

The Controller of Patents (Controller), upon noting that 3 years had elapsed since the grant of patent and being satisfied that a *prima facie* case existed, issued an order for publishing the CL application in the official journal. Upon this, Bayer filed its opposition to the CL application. Each party filed its respective evidence. The parties were given a hearing by the Controller.

Natco urged that as per GLOBOCAN 2008, there were 20,000 patients of liver cancer and 8,900 cases of kidney cancer in India. Assuming 80% of patients needed the Drug treatment, approximately 23,000 patients required the Drug. According to the Form – 27 (statement of working of Patents) filed by Bayer, they imported no units in 2008 and approximately 200 bottles in 2009 and no further units in 2010. Hence, the reasonable demand or requirement of the public was not being met. Natco argued that Bayer did not manufacture the Drug in India but imported it and that it was exorbitantly priced and usually out of stock and available only in pharmacies attached to a few hospitals in metro cities. Bayer launched the product worldwide in 2006 and made thumping sales to the tune of USD 2,454 million. Thus, the insignificant number of bottles imported in India showed Bayer's neglectful conduct.

Bayer responded by demonstrating that the actual number of patients of kidney and liver cancer requiring treatment was 8,842 and not 23,000. The Drug was being made available by Bayer to all cancer treatment centres in India.

This objection was dismissed by the Controller on the basis that as per Form – 27 filed by Bayer at the Patent Office, Bayer had imported grossly inadequate quantities of NEXAVAR in the previous 3 years, which was ample material that a *prima facie* case had been made out. Furthermore, the Controller observed that the number of patients needing the Drug would be much higher than 8,842 and that as per Bayer's own numbers they had been able to supply the Drug to not more than 200 patients which is a mere 2% of the 8,842 patients who, according to Bayer's own estimate needed the Drug. He ruled that Bayer's conduct was not justifiable as it was already marketing the drug worldwide since 2006.

The next argument advanced by Natco was that the price of the patented product was too high and therefore, the patented invention was not available to the public at reasonably affordable prices. The exorbitant pricing was an abuse of its monopolistic rights and amounted to unfair and anti-competitive practice. Bayer countered this by contending that

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innovative drugs cost significantly more than generics since the innovator's costs included R&D expenses which generics did not incur as they merely copied the drugs. The higher price included the costs of failed projects also, which accounted for nearly 75% of total R&D cost. According to Bayer, it took an investment of more than €2 billion to bring a new medical entity (NME) to the market. Also, the price being charged by Bayer was comparable to other oncology drugs of innovation-based companies. Replacing innovative drugs with generics would in the long-run damage patients as originators also provided for the education of doctors and pharmaco vigilance which generics did not. Only the patentee, being the innovator and having invested in the R&D would be able to determine what would constitute a 'reasonably affordable price' for the Drug. The term 'reasonable' should be construed as to mean reasonable for both the patients and the patentee and a 'reasonable price' is needed to factor in R&D costs and reasonable commercial gain.

Bayer argued that 'public' denoted different sections of public – rich class, middle class and poor class. A blanket CL which gave the patented product at the same price to all sections of the public was not reasonable, amounted to treating 'unequal as equal' and was discriminatory. A CL would lower the price of a patented product even for people who could pay – which could not be the intention of the Legislature. One of the ways by which people afford medical treatment is medical insurance. 'Affordability' should be determined by asking whether the patient could afford insurance cover or not.

The Controller in his decision agreed with Bayer that public included different sections of the public, but also observed, that Bayer was free to have offered differential pricing to different classes, but chose not to. The Controller partially disagreed with Bayer that in determining reasonableness, both the patentee and the public needed to be factored in, but observed that "reasonably affordable price has to be construed predominantly with reference to public". The Controller added that the sales by Bayer during previous 4 years constituted only a fraction of the requirement of the public and came to the conclusion that lower sales

had been due to high price of the patented product. Therefore, the Controller held that the Drug was not available to the public at a 'reasonably affordable price'.

Natco advanced another argument that patented invention was not worked by Bayer in the territory of India. Natco pointed out to the Controller that since the Drug was being imported, it was not being commercially worked in India. Bayer responded by contending that the 'working' requirement of section 84(1)(c) of the Patents Act, 1970 did not mean that the patented product had to be locally manufactured. According to Bayer 'working' of a patent would mean that there should be a supply of the patented product in the territory of India. Bayer also argued that it had centralised its manufacturing in Germany for reasons of economies of scale and for maintaining high quality.

The Controller relied on the Paris Convention, TRIPS Agreement, the unamended Patents Act of 1970 and in particular sections 84(7), 83(b) and 90(2) thereof to come to the conclusion that importation would not amount to working of a patented product. He observed that the term 'work the invention' did not include imports, as a CL holder had to necessarily work the patent by manufacturing the patented invention in India.

The Controller granted a non-exclusive and non-assignable CL to Natco, solely for the purpose of making, using, offering to sell and selling the Drug for the purpose of treating kidney and liver cancer patients within the territory of India, adding that the Drug would have to be manufactured by Natco in its own manufacturing facility only and not outsourced.

Thereafter, Bayer filed an appeal challenging the order of the Controller before the Intellectual Property Appellate Board (IPAB). The IPAB, in March 2013, dismissed the appeal and upheld the decision of the Controller. However, in the order, IPAB raised the rate of royalty to be paid by Natco to Bayer from 6% to 7%.

Bayer challenged IPAB's order before the High Court of Bombay by way of a writ petition. The High Court examined the relevant provisions of the Act and upheld IPAB's Order and

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ruled that in respect of medicine the adequate extent for meeting the demand of the drug should be 100%. It further held that dual pricing could be applied to meet the requirement of the public and not for making available the drug under reasonably affordable price.

In the light of the aforesaid case and the relevant provisions of the Indian Patents Act (as amended), answer the following :

(i) Under what circumstances can CL be granted ?

(5 marks)

(ii) What factors are required to be taken into account by the Controller while considering the application for CL ?

(10 marks)

(iii) While settling the terms and conditions of a CL, what factors does the Controller secure ?

(15 marks)

(iv) Is manufacture in India the sole method of working a patent in the territory of India ? Do you agree with the Controller's decision on this question ?

(10 marks)

(v) Under what exceptional circumstances can CL be granted for export of patented pharmaceutical products ?

(10 marks)

2. (a) TV stations in Chennai and Mumbai published weekly TV guides covering their programmes exclusively and claimed the copyright protection. Arch TV Guide wanted to publish a comprehensive guide of TV programmes of both the stations but was

prevented by TV stations, Chennai and Mumbai on the ground of copyright infringement. By preventing this, the TV stations sought to ensure that third parties did not reproduce their programme listing. Arch TV Guide complained to the Competition Commission of India (CCI) citing the Competition Act, 2002 and arguing that the TV stations, Chennai and Mumbai were indulging in an anti-competitive practice of refusal to deal. The TV stations drew the attention of the CCI to section 3(5) of the Competition Act, 2002 and argued that the said section did not restrict the right of any person to restrain any infringement of or to impose reasonable conditions, as may be necessary for protecting any of the rights conferred upon them under IPR statutes. TV stations, Chennai and Mumbai contended that section 3(5) of the Competition Act, 2002 provided protection of their IPR, namely, copyright and prayed that the CCI should restrain Arch TV Guide from publishing the comprehensive guide. Arch TV Guide urged that the said anti-competitive practice should not be condoned while providing protection to IPRs, in this case, copyright. It prayed that it may be allowed to publish the comprehensive guide in customers' interest and public interest.

In the light of the facts provided, if you were the CCI, what would be your decision ?

(20 marks)

- (b) State the relationship between the 'TRIPS agreement' and the 'pre-existing international conventions' covered under it.

(10 marks)

3. How is computer software protected in India ?

(5 marks)

4. What rights are conferred by registration of a Trade Mark ?

(5 marks)

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5. Client XYZ has approached you for getting a patent on a drug for curing insomnia. What are the steps involved in registering the patent ? Describe with example.

(5 marks)

6. What do you understand by 'design' ? How is it different from 'copyright' ? What is the Act covering design ?

(5 marks)

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