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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 : 8***

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

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

DDD is a compound patented by a company called CCC, a renowned USA based developer and manufacturer of innovative drugs. It is marketed as DDD Drug ("the Drug") and is used in the treatment of advanced stages of kidney cancer and liver cancer. The drug is 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.

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

NNN filed an application in 2011 under section 84(1) of the Indian Patents Act for grant of Compulsory Licence (CL) in respect of DDD covered under CCC's patent. In its application, NNN proposed to sell the drug at a price of ₹ 8,800/-, (about USD 175) for one month therapy as against CCC's ₹ 2,80,428/- (about USD 5,600) for one month therapy.

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, CCC filed its opposition to the CL application. Each party filed its respective evidence. The parties were given a hearing by the Controller.

NNN argued 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 CCC, the number of imported units in 2008, 2009, 2010 were zero, 200 and zero, respectively. Hence, the reasonable demand or requirement of the public was not being met. NNN argued that CCC 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. CCC launched the product worldwide in 2006 and made thumping sales to the tune of 2,454 million dollars. Thus, the insignificant number of bottles imported in India showed CCC's neglectful conduct.

CCC 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 CCC to all cancer treatment centres in India. This objection was dismissed by the Controller on the basis that as per Form 27 filed by CCC at the Patent Office, importing inadequate quantity of the patented drug in the previous 3 years was an ample material for a prima facie case to be 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 CCC's own numbers they had been able to supply the Drug to only 200 patients which is a mere 20% of the 8,842 patients in need of drug. The Controller further stated that CCC's conduct was not justifiable as it was marketing the drug worldwide since 2006.

The next argument advanced by NNN was that the price of the patented product was too high and that 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. CCC countered this by contending that 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 which accounted for nearly 75% of total R & D cost. According to CCC, 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 CCC was comparable to other oncology drugs of innovation-based companies. Replacing innovative drugs with generics would damage patients in the long run as originators provides for the education of doctors and pharmaco vigilance which generics did not provide. Only the patentee, being the innovator and having invested in the R&D would be able to deterntine 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.

CCC argued that "public" denoted different sections of public - rich class, middle class and poor class. A blanket CL which provide 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 afforded medical treatment was medical insurance. "Affordability" should be determined by asking whether the patient could afford insurance cover or not.

The Controller in his decision agreed with CCC that public included different sections of the public, but also observed, that CCC was free to have offered differential pricing to different

classes, but chose not to. The Controller partially disagreed with CCC that in determining reasonableness, both the Patentee and the public is to be taken into consideration but observed that "reasonably affordable price has to be construed predominantly with reference to the "Public". The Controller added that the sales by CCC 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.

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

The Controller relied on Paris Convention, TRIPS, 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 NNN, 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 NNN in its own manufacturing facility only and not outsourced.

Thereafter, CCC 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. In the order IPAB raised the rate of royalty to be paid by NNN to CCC from 6% to 7%.

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

The creative work of the human mind is protected through several measures and the main motivation for the same is that such protection is a definitive measure of encouragement for the creative activity.

The exciting developments in the domain of biotechnology have resulted in intensive R&D activities all over the world including India. After information technology, biotechnology is increasingly recognized as the next wave in the knowledge base economy. Biotechnology has been at the core of a number of important developmental sectors. In particular, progress in the field of molecular biology, biotechnology and molecular medicine has highlighted the potential of biotechnology for the pharmaceutical industry. This has led to the inventions of New Chemical Entity in the pharma sector for the new generation diseases. On the other hand, the darker side of this development is the Intellectual Property Rights Issue. The pharma

companies are protecting their inventions through patents. Generally, patent is a monopoly grant and it enables the inventor to control the output and within the limits set by demand, the price of the patented products. But the greed of the Multinational company is escalating, they want to have the maximum profit for their patented product, without taking into consideration the socio-economic factor. We have borne in mind the object which the Patents Act wanted to achieve namely, to prevent ever greening, to provide easy access to the citizens of the country to life saving drugs and to discharge their constitutional obligation of providing good health care to its citizens.

The provisions for compulsory licenses are made to prevent the abuse of patent as a monopoly and to make the way for commercial exploitation of the invention by an interested person. The patent grant do not impede protection of public health and nutrition and should act as instrument to promote public interest specially in sectors of vital importance for socio-economic and technological development of India.

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

Questions :

(*a*) Under what circumstances can CL be granted ?

(*5 marks*)

(*b*) In considering the application for CL, what factors are required to be taken into account by the Controller ?

(*10 marks*)

(*c*) While settling the terms and conditions of a CL, what factors are to be taken into account by the Controller ?

(*15 marks*)

(*d*) 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*)

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

(*10 marks*)

2. Weekly Television guides are helpful to viewers of TV Channels. TV stations in Bengaluru and Hyderabad published weekly TV guides covering their programmes exclusively and claimed copyright protection. Popular TV Guide wanted to publish a comprehensive guide of TV programmes of both the stations but was prevented by TV stations, Bengaluru and Hyderabad on the ground of copyright infringement. By this prevention, the TV stations sought to ensure that third parties did not reproduce their programme listing. Popular TV Guide complained to the Competition Cornmission of India (CCI) citing the Indian Competition Act, 2002 and arguing that the TV stations Bengaluru and Hyderabad 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 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 Bengaluru and Hyderabad contended that section 3(5) of the Competition Act provided protection of

their IPR, namely, Copyright and prayed that the CCI should restrain Popular TV Guide from publishing the comprehensive guide. Popular TV Guide argued 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.

Questions :

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

(*10 marks*)

(*b*) Intellectual Property Law and Competition Law both are necessary for efficient operation of marketplace. Comment.

(*20 marks*)

3. What are the types of IP Audit ?

(*5 marks*)

4. What is the purpose behind section 134(2) of the Trade Marks Act, 1999 ?

(*5 marks*)

5. What is not a design under the Designs Act, 2000 ? Provide illustrations.

(*5 marks*)

6. What do you understand by 'Geographical Indications' ? What is meant by 'Goods' ?

(*5 marks*)

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