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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 : 10***

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

1. Read the case law carefully and answer the questions at the end in detail :

Glivec is the beta-crystalline form of *imatinib mesylate* manufactured by a Swiss drug company XXX. The drug is administered to cancer patients suffering from chronic myeloid leukemia. It does not cure the disease but controls cellular action, thereby making cancer manageable to some extent for many patients. While this drug is a great advance in the treatment of cancer, patients are obliged to take it for the rest of their lives. XXX developed Glivec in the 1990s and received Food and Drug Administration (US) approval for marketing in the United States in May 2001. The drug is produced by XXX in *Beta* form, while it is generically produced in *Alpha* form in India.

XXX filed a mailbox application for a patent in India in July 1998, and was granted ‘‘Exclusive Marketing Rights’’ (EMR) in 2003. EMR meant that XXX could prevent Indian pharmaceutical companies from producing and selling generic versions of the drug for 5 years or until the decision on the application for a patent.

The *Beta* form has, according to XXX, many advantages over the *Alpha* form, including more beneficial flow properties, improved thermodynamic stability (better storage of drug), lower hygroscopicity (longer shelf life) and, most notably, a 30% increase in bioavailability (absorption into blood stream). It further claimed that the aforesaid properties make the invented product ‘‘new’’ (and superior !) as it ‘‘stores better and is easier to process’’.

Reckoning and availing of its rights under EMR dispensation, XXX filed an infringement suit against six generic competitors who were producing Glivec in the Indian market : A, B, C, D, E and F. The said producers, along with cancer patient advocacy groups and legal rights organizations, filed pre-grant opposition to the patent for Glivec. XXX, holding EMR rights priced Glivec at about 10 times the price that generic producers were selling at. Consumers suffered the high price at which XXX was selling and in many cases had to forego the drug on the account of affordability.

XXX's application for patent was taken out of the mailbox for consideration after amendments were made to the Patents Act. But before it was taken up for consideration, the patent application had attracted the said pre-grant oppositions in terms of section 25(1) of the Act.

The Assistant Controller of Patents and Designs at the Chennai patent office heard all the parties and rejected the application for grant of patent to the subject product by separate, though similar, orders passed on the opposition petitions. The Assistant Controller held that the invention claimed by XXX was anticipated by prior publication, the invention claimed was obvious to a person skilled in the art and further that the patentability of the alleged invention was disallowed by Section 3(d) of the Act. In particular, he was not convinced that the patent application presented a new substance because Glivec was simply the salt of a known substance. He observed that although the new *Beta* drug could be more effectively absorbed into the bloodstream, this bioavailability was not an improvement in efficacy as required by Section 3(d).

At that time, the Appellate authority under the Act had yet to become functional. The applicant XXX therefore, challenged the orders passed by the Assistant Controller in Writ petitions filed directly before the Madras High Court. After the formation of the Intellectual Property Appellate Board (IPAB), the writ petitions challenging the orders of the Assistant Controller were transferred from the High Court to IPAB.

The applicant's appeals against the orders passed by the Assistant Controller were finally heard and dismissed by the IPAB by a long and detailed judgment. The IPAB reversed the findings of the Assistant Controller on the issues of anticipation and obviousness. It held that the applicant's invention satisfied the tests of novelty and non-obviousness. The IPAB, however, held that the patentability of the subject product was hit by section 3(d) of the Act. Referring to section 3(d) the IPAB observed :

''*Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances*.''

The IPAB also noted the following observations of the Madras High Court :

''*We have borne in mind the object which the amending 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*.''

In the light of the High Court's observation, the IPAB also referred to the pricing of the drug Glivec by the applicant, while it enjoyed EMR over it, and held that the patentability of the subject product would also be barred by section 3(b) of the Act. In this regard, the IPAB observed that when the applicant was holding the right as EMR, it used to charge ₹ 1,20,000/- per month for a required dose of the drug from a cancer patient, which was too unaffordable to the poor cancer patients in India. Furthermore, the grant of product patent on the application may create a havoc on the lives of poor people and their families affected with cancer for which this drug is effective. This will have disastrous effect on the society as well. Considering all the circumstances placed before the IPAB, it observed that the applicant's alleged invention was not worthy of a reward of any product patent on the basis of its impugned application for not only for not satisfying the requirement of section 3(d) of the Act, but also for its possible disastrous consequences on such grant as stated above, and also for attracting the provisions of section 3(b) of the Act which prohibits grant of patent on inventions, exploitation of which could create public disorder among other things. IPAB upheld the decision of the Assistant Controller on section 3(d) of the Act to the extent that product patent cannot be made available to the Applicant.

Against the order of the IPAB, XXX directly moved the Supreme Court through a petition under Article 136 of the Constitution. XXX engaged senior counsels to argue their case in the Supreme Court.

Counsels appearing for XXX strenuously argued that section 3(d) was not meant to be an exception to Clauses (j) and (ja) of section 2(1) of the Act. They insisted that section 3(d) had no application to the case of the subject product. The subject product, having satisfied the tests of invention as provided in Clauses (j) and (ja) of section 2(1), could not be denied patent for allegedly failing to satisfy the tests under section 3(d). XXX's counsels submitted that section 3(d) was a provision put in *ex abundanti cautela non nocer* (abundant caution does no harm) to remove all doubts and also that it was a provision *ex majore cautela* (out of abundant caution). The counsels submitted that the primary purpose of section 3(d), as was evidenced from the legislative history, was to prevent ''evergreening'' and yet to encourage incremental inventions. ''Evergreening'' is a term used to label practices that have developed in certain jurisdictions wherein a trifling change is made to an existing product, and claimed as a new invention. The coverage/protection afforded by the alleged new invention is then used to extend the patentee's exclusive rights over the product, preventing competition. It was further argued that, by definition, a trifling change, or in the words of the section ''a mere discovery of a new form of a known substance'', could never ordinarily meet the threshold of novelty and inventive step under clauses (j) and (ja) of section 2(1). An invention cannot be characterized by the word ''mere''. The word ''invention'' is distinct from the word ''discovery''. The counsels therefore, submitted that section 3(d) operated only as *ex majore cautela*, ensuring that mere discoveries could never, by an effort at interpretation of clauses (j) and (ja) of section 2(1), be considered inventions.

Questions :

(*a*) If you have to judge this case, what would be your Judgment ?

(*10 marks*)

(*b*) What ''efficacy'' means under the Patent Act ?

(*10 marks*)

(*c*) Section 2(1)(j) defines invention. What is its scope ?

(*10 marks*)

(*d*) What are the requirements of 'invention' and 'patentability' ?

(*10 marks*)

(*e*) What is 'enhanced efficacy' ?

(*10 marks*)

2. Read the case below carefully and answer the questions at the end in detail :

PPP, a small scale industry company, is engaged in manufacturing of low cost backhoe loaders, called 'Bull Smart', light construction equipment. It informed the Competition Commission of India (CCF) alleging that QQQ, a competitor company, *inter alia,* was contravening the provisions of section 4 of the Indian Competition Act, 2002.

QQQ is stated to be India's largest manufacturer of construction equipments and has been engaged in manufacturing of 21 different construction and earthmoving machines under 7 product types such as Backhoe Loaders, Loading Shovels, Tracked Excavators, Compactors, Telehandlers, Skid Steer Loaders and Pick and Carry Cranes in India. QQQ's market share was 75%. The large sized QQQ has been operating independently of competitive forces in the relevant market.

As per the information furnished by PPP, the product 'Bull Smart' was exhibited at an 'Exhibition' in Bangalore, one of India's premier earthmoving machinery exhibitions and the product was due to be launched in November, 2011 in the said Exhibition. It was stated by PPP that 'Bull Smart' became a sensation and received overwhelming appreciation from existing and potential customers and peers from across the industry and attracted heavy crowds on the very first day of the Exhibition because it was an indigenously developed 60 HP hydrodynamic transmission based backhoe loader.

PPP alleged that during the formal launch of 'Bull Smart' at the Exhibition, it was served with an ex parte interim injunction order granted by the Hon'ble High Court of Delhi on an application by QQQ alleging that PPP had infringed the design registrations/ copyright of QQQ in developing the backhoe loader 'Bull Smart'. The said order restrained PPP and its dealers 'from making, selling, offering for sale, dispatch, advertising, directly or indirectly dealing in/launching backhoe loaders in any manner'.

It was the case of PPP that QQQ obtained the *ex-parte ad interim* injunction order based on misrepresentation of images/design registration number/documents and bogus numbers, suppression of its pre-existing UK patent, misrepresentation by comparing the wrong angle of the images in the application and reliance upon fraudulent design registrations which were pre-existing in the public domain.

It was further averred that QQQ, armed with the *ex parte* order of the Hon'ble Delhi High Court, forced PPP to remove the backhoe loader 'Bull Smart' from the Exhibition in front of a huge crowd of dealers, existing and potential customers, end-customers, financing company officials, bankers, suppliers, foreign delegates and peers in the industry and media.

Furthermore, PPP stated that pursuant to the said order, teams consisting of local commissioners appointed by the Hon'ble Delhi High Court along with the officials of QQQ and their advocates visited PPP's manufacturing plant and stopped the operations and production of the backhoe loader 'Bull Smart'. In the process, all the documents, moulds and components were seized and sealed. The said *ex parte* order of the Hon'ble Delhi High Court prohibited even the dealers from displaying any sales, promotional material or the product itself at the dealer(s) showroom and, as a result, the dealerships were closed across India on the day of the formal launch and even before the formal sale of 'Bull Smart' could commence.

On 29 Nov, 2011, PPP moved the High Court for vacation of the *ex-parte* interim stay order and submitted all the evidence required to show that there was no similarity in the design of backhoe loader 'Bull Smart' developed by it and the designs registered by QQQ. Further, stated PPP, that in its application for vacating the *ex-parte* ad interim order, it had submitted evidence to show that QQQ misrepresented the images and the design registration numbers/documents and misled the Hon'ble Delhi High Court to secure an *ad interim ex-parte* injunction order in its favour. PPP adduced evidence before the Controller of Designs to show that the design registrations obtained by QQQ were fraudulently obtained.

After hearing the parties, a consent order was passed by the Hon'ble High Court on 12 Dec, 2011.

''*.....that parties have arrived at a workable interim arrangement by which it is agreed that : (i) the interim order shall stand suspended, till further orders; and (ii) the defendants will permit the engineers of the plaintiff to inspect the product in question at a time, date and place to be mutually agreed upon between the parties within ten days*.'

PPP informed the CCI that after nearly 10 months, QQQ, much to its surprise, voluntarily withdrew its application for *ex-parte interim* injunction and the Hon'ble Delhi High Court dismissed the case as withdrawn and vacated its *ex-parte interim* order and that all this had caused huge irreparable damages to PPP. It was prayed by PPP before the CCI that QQQ should be directed to cease and desist from misusing or abusing judicial process to exclude competitors, including PPP, and all other anti-competitive activity and that CCI should penalize QQQ for its anti-competitive practices in contravention of the provisions of the Act.

Questions :

(*a*) What are the requirements for the registration of a design ?

(*10 marks*)

(*b*) What nature of work cannot be protected as design under Design Act ?

(*10 marks*)

(*c*) As per your judicious understanding, what orders should be passed in the instant case ?

(*10 marks*)

3. Discuss the need for registration of work under the Copyright Act, 1957.

(*5 marks*)

4. What are the exclusive rights under Copyright Act, 1957 in case of computer programme as subject matter of copyright protection ?

(*5 marks*)

5. Differentiate between substantive and non-substantive examination of designs under Design Act.

(*5 marks*)

6. Differentiate between the concept of ‘‘authorship’’ and ‘‘ownership’’ in a copyright work under the Copyright Act.

(*5 marks*)

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