

Roll No.....

Time allowed : 3 hours

Maximum marks : 100

Total number of questions : 6

Total number of printed pages : 4

NOTE : Answer **ALL** Questions.

1. Read the Novartis case on patenting law of Gleevec and answer the questions that follow :

Novartis *vs.* Union of India & Others is a landmark decision by a two-judge bench of the Supreme Court of India on the issue of whether Novartis could patent Gleevec in India, and was the culmination of a seven-year-long litigation fought by Novartis. The Supreme Court upheld the Indian Patent Office's rejection of the patent application.

The patent application claimed the final form of Gleevec (the beta crystalline form of imatinib mesylate). In 1993, during the time India did not allow patents on products, Novartis had patented imatinib, with salts vaguely specified, in many countries but could not patent it in India. The key differences between the two patent applications, were that the 1998 patent application specified the counterion (Gleevec is a specific salt imatinib mesylate) while the 1993 patent application did not claim any specific salts nor did it mention mesylate, and the 1998 patent application specified the solid form of Gleevec the way the individual molecules are packed together into a solid when the drug itself is manufactured (this is separate from processes by which the drug itself is formulated into pills or capsules) while the 1993 patent application did not. The solid form of imatinib mesylate in Gleevec is beta crystalline.

In 2000, the United States Food and Drug Administration (FDA) approved imatinib mesylate in its beta crystalline form, sold by Novartis as Gleevec (U.S.) or Glivec (Europe/Australia/Latin America). TIME magazine hailed Gleevec in 2001 as the 'magic bullet' to cure cancer. Both Novartis patents on the freebase form of imatinib, and on the beta crystalline form of imatinib mesylate are listed by Novartis in the FDA's Orange Book entry for Gleevec.

As provided under the TRIPS agreement, Novartis applied for exclusive marketing rights (EMR) for Gleevec from the Indian Patent Office and the EMR was granted in November, 2003. Novartis made use of the EMR to obtain orders against some generic manufacturers who had already launched Gleevec in India. Novartis set the price of Gleevec at USD 2,666

per patient per month; while the generic companies were selling their versions at USD 177 to 266 per patient per month. Novartis also initiated a programme to assist patients who could not afford its version of the drug, concurrent with its product launch.

The Intellectual Property Appellate Board (IPAB) was formed and in 2007 the case was transferred before the IPAB in line with section 117G of the Patents Act, 1970. The IPAB on 26th June, 2009 modified the decision of the Assistant Controller of Patents and Designs stating that ingredients for grant of patent novelty and non obviousness to person skilled in the art were present in the application but rejected the application on the ground that the drug is not a new substance but an amended version of a known compound and that Novartis was unable to show any significant increase in the efficacy of the drug and it, therefore, failed the test laid down by section 3(d) of the Patents Act, 1970.

When examination of Novartis' patent application began in 2005, it came under immediate attack from oppositions initiated by generic companies that were already selling Gleevec in India and by advocacy groups. The application was rejected by the Patent Office and by an Appeal Board. The key basis for the rejection was the part of Indian patent law that was created by amendment in 2005, describing the patentability of new uses for known drugs and modifications of known drugs. That section, Paragraph 3d, specified that such inventions are patentable only if "they differ significantly in properties with regard to efficacy." At one point, Novartis went to court to try to invalidate Paragraph 3d; it argued that the provision was unconstitutionally vague and that it violated TRIPS. Novartis lost that case and did not appeal. However, Novartis did appeal the rejection by the Patent Office to India's Supreme Court, which took the case.

The Supreme Court case hinged on the interpretation of Paragraph 3d. The Supreme Court decided that the substance that Novartis sought to patent was indeed a modification of a known drug (the raw form of imatinib, which was publicly disclosed in the 1993 patent application and in scientific articles), that Novartis did not present evidence of a difference in therapeutic efficacy between the final form of Gleevec and the raw form of imatinib, and that therefore the patent application was properly rejected by the patent office and lower courts.

Although the court ruled narrowly, and took care to note that the subject application was filed during a time of transition in Indian patent law, the decision generated widespread global news coverage and reignited debates on balancing public good with monopolistic pricing and innovation with affordability. Had Novartis won and gotten its patent issued, it could not have prevented generics companies in India from continuing to sell generic Gleevec, but it could have obligated them to pay a reasonable royalty under a 'grandfather clause' included in India's patent law.

: 3 :

Questions —

- (a) Why did Novartis file the case in Supreme Court only after India signed TRIPS ?
(15 marks)
- (b) Gleevec patent is already granted in 45 other countries including China. What will Indian industry gain/loss in the rejection of the patent in India ?
(15 marks)
- (c) What is your opinion on Novartis' claim that the beta crystalline packing in solid form is a 'novelty' and is thus patentable ?
(10 marks)
- (d) What do you understand by 'grandfather clause' of the Novartis patent developed when India did not have product patents ?
(10 marks)

2. (a) 'Passing off' is a common tactics to use a similar trade mark.
- (i) Describe the typical actions and trade mark violation in 'passing off' an action of publicising a body called 'University of Universal Learning'.
 - (ii) Is it possible to resort to 'passing off' petition in unregistered trade mark ?
 - (iii) Does the Trade Marks Act, 1999 govern an act of 'passing off' ? If yes, why and if no, why not ?
(5 marks each)
- (b) Microsoft develops software applications. Thus, it is the 'author' with the copyrights. When you buy the Microsoft software, what is purchased, is it the software or is it licence to use the software ?
- (i) What are the rights of the user ? Can they be transferred ?
 - (ii) Does the user have right to free update versions of the software ?
 - (iii) If the price of a particular application is too high for the Indian consumers, what is the recourse with the Indian government to help the users in getting it at low price ?
(5 marks each)

3. What is the meaning of 'appeal to the eye' in the definition of a design ? A book designer prepares a jacket of a hard copy book. Will his work be covered under the Designs Act, 2000 or will it be a subject matter of the Copyright Act, 1957 ? Discuss.

(5 marks)

4. What are the essential requirements for the registration of a design ?

(5 marks)

5. What are the factors to be reckoned while defining technology in the licensing agreement ?

(5 marks)

6. Who are the beneficiaries of registration of geographical indications ?

(5 marks)