

Roll No.

OPEN BOOK EXAMINATION

Time allowed : 3 hours

Maximum marks : 100

Total number of questions : 4

Total number of printed pages : 8

NOTE : Answer **ALL** Questions.

1. Rice Pharmaceutical is a renowned MNC, holding many patents worldwide. One of the famous drug of this company is its anticancer drug which is marketed in the name of Glivec. The company holds patent on alpha crystalline form of this drug in 35 country around the world which was about to expire. The company came up with the new form of this drug as beta crystalline salt form of the free base Imatinib. This drug is administered to cancer patients who are suffering from chronic myeloid leukemia. Though the said drug does not cure the disease but still it controls cellular action. As such the cancer becomes manageable to some extent for many patients.

It filed a patent application in India claiming that Beta form has many advantages over the Alpha form including more beneficial flow properties, improved thermodynamic stability (better storage of drug) lower hygroscopicity (longer shelf life) and 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. At the time of filing of patent application by Rice Pharmaceuticals Alpha crystalline was manufactured by six pharma company in India as generic version as affordable prices.

The Assistant Controller of Patents rejected the application for the grant of patent to Rice pharmaceuticals on the grounds that the said drug is pre existing version of Alpha form with no superior efficacy therefore it is not novel. As per Sec. 3(d) of the Patent's Act 2005 no significant improvement has been made.

Against this order Rice pharma filed Writ Petitions before Madras High Court contesting that sec.3(d) of the Indian Patents Act is not in accordance with TRIPS agreement, is vague, arbitrary and against the Article 14 of the Constitution. The Court held that sec.3(d) is not unconstitutional as its goals is to give residents convenient access to life saving drug. As such it cannot be regarded as ambiguous and arbitrary.

There are certain issues which arise here. They are whether the Appellant's product satisfies the tests and thus qualifies as "invention" within the meaning of Clauses (j) and (ja) of section 2(1) can its patentability still be questioned and denied on the ground that sec 3(d) puts it out of the category of "Invention". Rice Pharmaceutical filed appeal in Supreme Court of India against this order.

The court came up with the concept of superior efficacy in the case of pharma patent. The court held that in case of chemicals and especially pharmaceuticals, if the product for which patent protection is claimed is a new form of a known substance with known efficacy, then the subject product must pass. In *Bishwanath Prasad Radhey Shyam v. Hindustan Metal Industries* (PTC (suppl) (1) 731 (SC)), Supreme Court held that the object of patent law

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is to encourage scientific research, new technology and industrial progress. The price of the grant of monopoly is the disclosure of the invention at the Patent Office, which after the expiry of the fixed period of monopoly, passes into the public domain. The fundamental principle of patent law is that a patent is granted only for an invention which must have novelty and utility.

Section 3(d) was amended to make it even more constructive than before. The test of enhanced efficacy in case of chemical substances, especially medicine, should receive a narrow and strict interpretation. A subject matter in order to get a patent under the Patents Act, 1970 has to pass the test of invention and patentability, both being distinct concepts. Section 3(d) provides a bar that incremental inventions of chemical and pharmaceutical substances need to pass extra threshold of enhanced efficacy in order to be patentable.

Normally, the patent-eligibility examination should precede and the patentability examination should follow. But in the case of Section 3(d), the patentability examination is conducted right at the beginning and under the garb of a patent-eligibility examination. Section 3(d) of the Patents Act, 1970 is construed as a refinement of patentability criteria to cater for “evergreening” – a specific problem inherent in pharmaceutical innovations. More specifically, the “enhanced efficacy” criterion can be seen as refinement of “non-obviousness” principles, i.e. most forms of existing pharmaceutical substances are deemed obvious, unless they demonstrate increased "efficacy." At some level, section 3(d) could also be said to embody a utility test,

i.e. unless the new form has significantly enhanced utility over and above what existed before
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in the art, it is not patentable. Efficacy need not be quantified in terms of numerical value to determine whether the product is efficacious because it is not possible to have a standard numerical value for efficacy for all products including pharmaceutical products.

Questions :

- (a) A new test of enhanced efficacy for claims that covers incremental changes to existing is a threshold to get patent. Explain.
- (b) Explain the meaning and scope of the term “Invention”.
- (c) There are certain requirements to be fulfilled for an invention to get patent. Discuss.
- (d) Explain the significance of PCT.
- (e) Discuss the importance of patent search before filing a patent application.

(5 marks each)

2. Manshing is running a photocopy shop which was established in the year 1997 in the name and style of Maheswari Photocopy Services (defendant in this case). The said shop is located at the premises of Indian Institute of Technology, Delhi. There are many students visiting this shop more frequently as the shop serves main source of course materials by way of xerox copies from various books both national and international published by different publishers. As such some Professors and Associate Professors of the said IIT creates course packs which contained excerpts from books written by other various authors of different publishing houses. The pages were xeroxed, bound and given to students at a nominal rate of Re. 0.50 paise per page.

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Oxford University Press Cambridge University Press (UK), Taylor & Francis Group (UK), Cambridge University Press India Ltd. and Taylor & Francis Books India P. Ltd. came to know about this course pack, they sued the defendant for the infringement of Copyright for distributing copies of their published books without proper authorization. The plaintiffs instituted this suit for the relief of permanent injunction restraining the two defendants from infringing the copyright of the plaintiffs in their publication by photocopying reproduction and distribution of copies of plaintiffs' publication on a large scale and circulating the same and by sale of unauthorised compilations of substantial extracts from the plaintiffs publications by compiling them into course packs/anthologies for sale.

Maheswari Photocopy Services received support from academics, activists, and students alike in response to the law suit and several petitions were submitted to be impleaded as defendants including the Society for Promoting Educational Access and Knowledge (SPEAK) and the Association of Students for Equal Access to Knowledge (ASEAK).

A temporary injunction prohibiting defendant from selling the cloned course packages was issued by the Court. The defendant contended that no violations of copyright is committed by them as the reproduction is for educational reasons. They mentioned that Copyright specially in literary work is thus not an inevitable, divine, or natural right that confers on authors the absolute ownership of their creation. It is designed rather to stimulate activity and progress in the arts for the intellectual enrichment of the public. Copyright is intended to increase and not to impede the harvest of knowledge. It is intended to motivate the creative activity of authors and inventors in order to benefit the public.

Questions :

- (a) Comment on the case with the help of decided cases.
- (b) What are the powers of Government of India to extent copyright to foreign works.
- (c) Software piracy has assumed enormous proportions in various jurisdictions, it has thrown up serious challenges. Discuss.
- (d) Besides traditional remedies the non-traditional form of remedies have assumed more popularity nowadays. Explain.
- (e) Copyright do not protect ideas but the particular expression of ideas. Explain.

(5 marks each)

3. A registrable trademark must be able to differentiate between the products or services of one person and those of another. In the age of technology the proprietor of a registered trade mark has to take some safeguards to protect his rights.

A domain name is a unique name that identifies a website. It was intended to provide specific address on the internet. The internet has however developed from a mere means of communication to a mode of carrying on commercial activity. Domain names are more than just addresses, since they can be selected by the "addressee" and are usually closely associated with a particular service or product. The value of domain names cannot be under estimated. Recent statistics indicate that most expensive domain names [Cars.com) and (Voice.com) were sold at a price of \$872 million and as well as \$30 million in 2019. It is common-place for traders to have their electronic mail address and use the same in respect of their goods/

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services as trade name. In other words, the domain name is being used as a trade name or trademark. The Registrar subject to the usual criteria of the Act, permits domain names to be registered as trademarks if otherwise registerable. Elements of the domain name such as “.com” or “.co.in” are considered to be totally non-distinctive, much in the same way as “Ltd” and “Plc” :

Questions :

- (a) “The trademark law has been stretched to the extent that it may cover the arena of internet. Explain with the help of decided cases.
- (b) The Supreme Court pointed out that “where common marks are included in the common trademarks, more regard is to be paid to the parts not common and the proper course is to look at the marks as a whole”. Discuss.
- (c) A trademark shall not be refused registration, if the mark has in fact acquired a distinctive character. Explain.
- (d) How unregistered trademarks are protected under Trademark Act ?
- (e) Registrar may permit the registration of trademarks which are identical or similar in respect of the same or similar goods or services, irrespective of the fact that any such trademark is already registered or not. Explain.

(5 marks each)

4. Tea industry is India’s oldest industry in the organised manufacturing sector. The history of Darjeeling tea dates back to the 1840's, when India was a British colony. Before the arrival of the British, the forests of the region were known as Darjeeling today was inhabited by the Lepcha tribes. In 1828, while visiting this region located in the backdrop of the snow-clad Himalayan range, a young British called Captain Lyoyd discovered the possibility of converting the region into a hill station or a sanitarium. In 1839, Darjeeling was handed

over to Dr. A. Campbell, a civil surgeon, who got transferred from Kathmandu to Darjeeling to become the first Superintendent of the Darjeeling district, a position which he held for the next twenty two years. In 1841, Dr. Campbell brought the seeds of China variety of tea from Kumaon hills of North India and planted them near his residence in his Beech wood garden in Darjeeling, 2134 meters above the mean sea level. Seeing the success of Dr. Campbell's experimental tea nursery, the British Government decided to put out tea nurseries in the region in the year 1847. Even after the Indian independence from British rule in 1947, the British ownership continued in many tea gardens of Darjeeling. By the end of the 1970's, most of the tea gardens of Darjeeling were in the hands of Indian owners.

It supplies around 30% of world's Favourite hot drink. India is not only the world's largest consumer of Tea but also exports sizeable portion of its production. Tea leaves are grown in different hill areas and among them Darjeeling Tea offers distinctive characteristics with regard to its quality and flavour. As such Darjeeling Tea has global reputation for more than a century. There are two main reasons for the same and they are exceptional and distinctive taste due to geographical origin and processing. Darjeeling tea is cultivated, grown and produced in tea gardens in a well known geographical area — Darjeeling district of West Bengal State for over one and half centuries. An adequate legal protection is necessary for the protection of legitimate right holders of Darjeeling tea from the dishonest business practices of various commercial entities.

Questions :

- (a) Discuss how the rights of legitimate right holders of Darjeeling tea can be protected.
- (b) Discuss prohibition of Registration of certain layout designs under Layout – Designs of Integrated Circuits of IPR.
- (c) What are the Farmers' Rights under the Act for Protection of Plant Varieties ?
- (d) What are the advantages and disadvantages of 'Trade Secret' ?
- (e) Discuss the interrelations between biodiversity and Traditional knowledge.

(5 marks each)

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