GUJARAT NATIONAL LAW UNIVERSITY GANDHINAGAR

Course: Intellectual Property Rights Semester-VIII (Batch: 2016-21)

End Semester Online Examination: February 2021

Date: 05th February, 2021

Duration: 8 hours Max. Marks: 50

Instructions:

- The respective marks for each question are indicated in-line.
- Indicate correct question numbers in front of the answer.
- No questions or clarification can be sought during the exam period, answer as it is, giving reason, if any.
- The prescribed word limit is 300 words for a question of 05 marks.
- Do not exceed the prescribed word limit.

Marks

(3x5 = 15)

Jürg Zimmermann invented a number of derivatives of N-phenyl-2-pyrimidineamine, Q.1 one of which is CGP 57148 in free base form (later given the International Nonproprietary Name 'Imatinib' by the World Health Organisation). These derivatives, including Imatinib 2, are capable of inhibiting certain protein kinases, especially protein kinase C and PDGF (platelet-derived growth factor)-receptor tyrosine kinase and thus have valuable anti-tumor properties and can be used in the preparation of pharmaceutical compositions for the treatment of warm-blooded animals, for example, anti-tumoral drugs and drugs against atherosclerosis. as N-phenyl2-pyrimidine-amine derivatives, including Imatinib, were submitted for patent in the US. The application was made on April 28, 1994 and patent was granted on May 28, 1996 under US Patent No. 5,521,184 (hereinafter referred to as 'the Zimmermann Patent'). The Zimmermann compounds (i.e., derivatives N-phenyl-2-pyrimidineamine) were also granted a European patent under Patent No. EP-A-0 564 409.

In 1997, Novartis, a Swiss based pharmaceutical giant filed an application to grant patent to an anticancer drug *Glivec* which is used to treat Chronic Myeloid Leukemia (CML) and Gastrointestinal Stromal Tumors (GIST) on the basis that it invented the beta crystalline salt form (imatinib mesylate) of the free base, imatinib. It is a critical drug which is patented in about 35 countries of the world. In the application it claimed that the invented product, the beta crystal form of Imatinib Mesylate, has (i) more beneficial flow properties: (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate. It further claimed that the aforesaid properties make the invented product "new" (and superior!) as it "stores better and is easier to process"; has "better processability of the methanesulfonic acid addition salt of a compound of formula I", and has a "further advantage for processing and storing".

This application was made at the time when there was a different patent regime in India. After the application was made and before it was taken up for consideration, a number of amendments were introduced in the Indian Patents Act, 1970, which brought about fundamental changes in the patent law of the country. The Novartis was, however, fully

aware of these changes in the law and, in order to reinforce its claim for patent for the subject product and to bring its claim within the four corners of the changed law, it filed four affidavits of certain experts, two of which stated that the beta crystal form of Imatinib Mesylate has much higher bioavailability as compared to Imatinib in free base form.

In 1997, when this application for patent is filed, the law in India with regard to product patent was in a transitional stage and the application lay dormant under an arrangement called "the mailbox procedure". Before the application for patent was taken up for consideration, the Novartis made an application (Application No. EMR/01/2002) on March 27, 2002, for grant of exclusive marketing rights (EMR) for the subject product under Section 24A of the Act, which was at that time on the statute book and which now stands deleted. The Patent Office granted EMR to the Novartis by order dated November 10, 2003. The Novartis's application for patent was taken out of the "mailbox" for consideration only after amendments were made in the Patents Act, with effect from January 1, 2005. But before it was taken up for consideration, the patent application had attracted five pre-grant oppositions in terms of Section 25(1) of the Act. and it was in response to the pre-grant oppositions that the Novartis had filed the affidavits on the issue of bioavailability of Imatinib Mesylate in beta crystalline form. The Assistant Controller of Patents and Designs heard all the parties on December 15, 2005, as provided under Rule 55 of the Patent Rules, 2003, and rejected the Novartis's application for grant of patent to the subject product by five separate, though similar, orders passed on January 25, 2006 on the five opposition petitions. The Assistant Controller held that the invention claimed by the Novartis was anticipated by prior publication, i.e., the Zimmermann patent; that the invention claimed by the Novartis was obvious to a person skilled in the art in view of the disclosure provided in the Zimmermann patent specifications; and further that the patentability of the alleged invention was disallowed by Section 3(d) of the Act; and also that July 18, 1997, the Swiss priority date, was wrongly claimed as the priority date for the application in India and hence, the alleged invention was also anticipated by the specification made in the application submitted in Switzerland.

At that time, the appellate authority under the Act had yet to become functional. The Novartis, therefore, challenged the orders passed by the Assistant Controller in writ petitions filed directly before the Madras High Court. Apart from challenging the orders of the Assistant Controller, the Novartis also filed two writ petitions (one by the Novartis and the other by its Indian power of attorney holder) seeking a declaration that Section 3(d) of the Act is unconstitutional because it not only violates Article 14 of the Constitution of India but is also not in compliance with "TRIPS". After the formation of the Intellectual Property Appellate Board, the five writ petitions challenging the five orders of the Assistant Controller were transferred from the High Court to IPAB by order dated April 4, 2007. The other two writ petitions assailing Section 3(d) of the Act were finally heard by a Division Bench of the High Court and dismissed by the judgment and order dated August 6, 2007. The Novartis did not take that matter any further. The Novartis's appeals against the orders passed by the Assistant Controller were finally heard and dismissed by the IPAB by a long and detailed judgment dated June 26, 2009. The IPAB reversed the findings of the Assistant Controller on the issues of anticipation

and obviousness. It held that the Novartis's invention satisfied the tests of novelty and non-obviousness, and further that in view of the amended Section 133, the Novartis was fully entitled to get July 18, 1997, the date on which the patent application was made in Switzerland, as the priority date for its application in India. The IPAB, however, held that the patentability of the subject product was hit by Section 3(d) of the Act. Thus, the IPAB also observe that a grant of product patent on this application can create a havoc to the lives of poor people and their families affected with the cancer for which this drug is effective. This will have disastrous effect on the society as well. Though agreeing with the Assistant Controller that no product patent for the subject patent could be allowed in favour of the Novartis, the IPAB held that the Novartis could not be denied the process patent for preparation of Imatinib Mesylate in beta crystal form. Against the order of the IPAB the Novartis came directly to the Supreme Court in a petition under Article 136 of the Constitution.

The Supreme Court on consideration of Sections 2(1)(j), (ja) and 3(d) of the Patents Act 1970, ruled that the Novartis's application for patent on the **beta-crystalline salt** didn't meet any standard of novelty or inventiveness as the product "beta crystalline" was known prior to 1995 through an earlier patent Novartis held, and therefore the company can't be given any patent for this drug.'

(Excerpts from Novartis v. Union of India)

Answer the following questions in light of the above-mentioned facts.

- a) Discuss the interplay between Sections 2(1)(j), (ja) and 3(d) of the Patents Act, 1970.
- b) Examine the interpretation of section 3 (d), in light of the milestone decision of the Supreme court in the case of *Novartis v. Union of India*
- c) Critically analyze the ratio laid down by the Apex Court in Novartis v. Union of India.
- Q.2 Rameshwari Photocopy Services has a shop licensed to it within the precincts of the Delhi School of Economics (University of Delhi). The professors imparting teaching in the Delhi School of Economics had authorized preparation of course packs and Rameshwari Photocopy Services was entrusted with the task of photocopying the pages from the books published by the foremost publishers of scholarly, general and reference books in all disciplines of academia, namely, the Oxford University Press, the Cambridge University Press and the Taylor & Francis Group (Publishers hereinafter), and after binding the same, to supply them to the students charging 50 paisa per page. The Publishers alleged that the inclusion of specific pages of its publications by Rameshwari Photocopy Services, under the authority of the Delhi School of Economics, amounts to institutional sanction for infringement of its copyright. It is the further case of the plaintiffs that the professors of the Delhi School of Economics, through its Library, issued the books published by the plaintiffs to Rameshwari Photocopy Services for preparing course packs. The course packs, which contain no additional material apart from photocopies of its copyrighted publications, were being used like textbooks and therefore, the compilations prepared were competing with the publications of the publishers. According to the Publishers, Rameshwari Photocopy Services was operating

(2x5 = 10)

commercially as was evident from the rate charged by it for selling the course pack is 40/50 paisa per page, as distinct from the market rate of 20/25 paisa per page being charged by other photocopiers from the students while photocopying material given by the students to be photocopied. A suit was filed by the Publishers in Delhi High Court for permanent injunction against infringement of copyright in their publications by the University of Delhi and Rameshwari Photocopy Service operating in the University under a license from it. The Single Judge of the Delhi High Court held that the Defendants (Rameshwari Photocopy Services and Delhi University) were not infringing the Plaintiff's (Publishers) copyright and dismissed the Suit on the basis that the Defendant 's actions fell within the exception carved out by section 52(1)(i) of the Copyright Act 1957. The publishers preferred an appeal against the judgment of the Single Judge. The Division Bench also held that there is no infringement of copyright. (Excerpts from The Chancellor, Masters & Scholars of University of Oxford and Ors. v. Rameshwari

Photocopy Services and Ors)

Answer the following in view of the above mentioned facts.

- a) Whether the defendant's action constitute an act of infringement under the Copyright Act, 1957? Critically evaluate by referring to relevant statutory provisions.
- b) Critically analyze the decision of the Division Bench in *The Chancellor, Masters &* Scholars of University of Oxford and Ors. v. Rameshwari Photocopy Services and Ors
- Q.3 Dr. Meera is a feminist who wrote a contemporary analysis of many of the mythological characters like Draupadi, Kunti and Sita from a feminist point of view. Dr. Meera's work was appreciated being distinct. She analysed these characters to be foolish, false role models who made the Indian women follow the beaten path of subjugation by men happily. She also obtained copyright registration for her work. However, some of the treatment and analysis of the character were similar from an earlier work 'Yugantar" by Dr. Rukamani Krishanan. Hence, the publisher of 'Yugantar' issued a legal notice to Dr. Meera for infringement of the copyright. Advise Dr. Meera. Answer by referring to relevant provisions and case laws.
- Q.4 ABC Industries Pvt. Ltd. (hereinafter Plaintiff) is a manufacturer of a variety of stationery products including writing instruments and Prarthana Stationers as well as Pooja Instruments Ltd. (hereinafter Defendants) are manufacturers, traders and sellers of stationery products. Plaintiff has filed a suit for permanent injunction restraining the Defendants from manufacturing, selling, advertising, trading, dealing either directly or indirectly an identical duplication or obvious and/or fraudulent imitation of the Plaintiffs' copyright in the registered design of their in a writing instrument(boll point pen) called Write well. According to the Plaintiff, the novelty of its design lies in the shape and configuration of the pen and was registered in the year 2019.

The Plaintiff pleaded that under Section 22 of the Designs Act, 2000 (hereinafter Act) during the existence of the copyright in any design, no other person shall use the registered design for commercial purposes, sale of the article, etc., being a design, which is identical or an imitation of the registered design of the Plaintiff.

10)

(2x5 =

(5)

The Plaintiff claimed that its pen design had two unique features: 1) The main body of the ball point pen is placed in a transparent plastic box, which gives an excellent grip; 2) The ball point used is sharp enough to give clarity in writings. Accordingly, the Plaintiff's product appeals to the customer's eye, as per Section 2(d) of the Industrial Designs Act 2000.

The Defendants contended that the features which are alleged by the Plaintiffs to be their exclusive creation and being different parts of their registered design have been used by the Defendants from their own earlier designs commencing from the year 2011. Thus, as per Section 4 of the Act, the Plaintiff's product falls under the category of designs that cannot be registered.

Answer the following in view of the above mentioned facts by considering the relevant provisions and case laws:

- a) Identify and evaluate the interplay between section 4 and 19 of the Industrial Designs Act 2000.
- b) Enlist and analyze the factors that were considered by the court in determining whether there was an act of design piracy in this case?
- Q.5 The Tirumala Venkateshwara temple in Tirupati, is believed to be the world's richest Hindu shrine and also the most frequently visited one. It has acquired a unique sanctity in Indian tradition. Tirumala-Tirupati Devasthanams (TTD), is the Trust that manages the temple and its affairs. Tirupati laddu is offered as prasadam (sacred food) to devotees of Lord Venkateshwara (the presiding deity of the temple) for more than three centuries. The increasing demand for these delicious Laddus had given birth to a thriving black market in and around Tirupati during the last two decades. Attempts made by the temple authorities, including raids by its security and vigilance wings, had failed to remedy the situation. According to the temple officials, they were left with no option but to seek GI protection in order to tackle the menace of hawkers and black marketers who were producing fake and spurious Laddus and selling them to unsuspecting pilgrims. It applied for a GI certification before the GI Registry in Chennai for the famous Tirupati Laddu in March 2008, The TTD received GI tag in 2009.

Answer the following in view of the above mentioned facts by considering the relevant provisions in light of the above facts.

- a) Objectively analyze the process of grant of GI taking into consideration requirement of registration.
- b) Do you agree with the grant of GI tag in this case? Justify your answer with objective and critical analysis of the object and purpose of the GI Act, 1999.

10)

(2x5 =