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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 study and answer the following questions given at the end :

A patent (IN 161) was granted to AA, the plaintiff in October, 2015.

The invention patented was titled ‘‘3-[(2Z)-[1- (3, 4 -Dimethylphenyl) -1, 5 - Dihydro-3-Methyl-5-Oxo-4H-Pyrazol-4- Ylidene] Hydrazino]-2’-Hydroxy- [1,1’-Biphenyl]-3-Carboxylic Acid Bis-(Monoethanolamine)’’. Reckoned from 21 May, 2003, being the International Filing Date of the patent, the patent would remain alive till 21 May, 2023, by virtue of section 53(1) of the Patents Act, 1970 (Patents Act, for brief), read with the Explanation thereto. The invention was granted the non-proprietary name ‘‘Eltrombopag Olamine’’ (abbreviated, for the sake of convenience, as ‘‘EO’’). The Complete Specifications of the patent, as filed with the Indian Patent Office (IPO) for grant of the patent declares that Eltrombopag ‘‘is a compound which is disclosed and claimed, along with pharmaceutically acceptable salts, hydrates, solvates and esters thereof. EO is used for the treatment of thrombocytopenia, denoting insufficiency of platelets in the body and is marketed, by AA, the plaintiff, under the tradename ‘‘REVOLADE’’.

BB, the defendant in this case launched its branded EO in the market. This, alleges the plaintiff, infringes the patent (which is still alive) as the defendant had not obtained any licence from the plaintiff. Ergo, the plaintiff through a suit filed by it seeks an injunction against the defendant from infringing the patent. The plaintiff emphatically averred that, it was disentitled to seek to contend that IN 176 did not claim EO.

The defendant BB contests the suit by questioning the validity of the patent IN 161, invoking, for the purpose, section 107(1), read with clauses (a), (d), (e), (f), (j), (k) and (m) of section 64 of the Patents Act. The challenge is predicated on treating IN 213176 (in short, 'IN 176'), also held by the plaintiff, as prior art.

The title of IN 176 is ''a compound and a pharmaceutical composition for use in enhancing platelet production''. The International Filing date of IN 176 was 24th May, 2001; ergo, the patent expired on 24 May, 2021. EO was, according to the defendant, the subject matter covered by IN 176; hence, it was not entitled to any protection after 24 May, 202l, by virtue of section 53(4) of the Patents Act.

However, the plaintiff emphatically averred that IN 176 did not claim EO. The defendant submitted its contentions questioning the entitlement of AA, the plaintiff to an injunction, a summary of which runs as follows :

The Active Pharmaceutical Ingredient (API), which provides therapeutic activity against thrombocytopenia, is Eltrombopag, and not EO. EO functions only as a pro-drug, which enables delivery of Eltrombopag to the target site. EO does not have any inherent therapeutic activity. Reliance was placed, in this regard, on the leaflet prescribing information for REVOLADE, which indicated that EO was present, in the tablets, in a quantity which was sufficient to enable providing of equivalent specified, amounts/dosages of Eltrombopag to the patient.

The defendant further submitted that the patent was invalid on the ground of anticipation by prior claiming, under section 64(1)(a) of the Patents Act. BB's counsel exhorted the Court to read section 64(1)(a) in conjunction with section 13(1) (b). IN 176 being a patent granted in India, with priority dates (25 February, 2000 and 30 August, 2000) earlier than the priority date of the patent IN 161 (22 May, 2002), the coverage of the subject matter of the claims in the patent by the claims in IN 176, disentitles the claims of AA to any protection after 24 May, 2021.

Counsel of BB further submitted that the plaintiff AA cannot, seek to ‘‘evergreen" IN 176 beyond the life of the latter patent. As, according to him, IN 161 is invalid on the various grounds urged by him, Manufacture and marketing of EO, by his client, cannot be alleged to amount to infringement.

AA had, while applying for grant of patent CA 2486697 (‘CA 697’ in short) in respect of the compound claimed in the suit patent IN 161, before the Canadian Intellectual Property Office (IPO), admitted, in its response to objections raised by the Examiner in the Canadian IPO, that a salt form of some of the final compounds was inevitably formed during the reaction towards the final step. The following recital, as contained in the said response of AA to the objections of the Examiner in the Canadian IPO, was emphasised by BB’s counsel :

“{i] it is noted that the reaction conditions for the final step in certain Examples (e.g. 64 and 85) involve a solution that contains a strong acid, such as trifluoroaceticacid. Even though none of the final compounds in International Application No. PCT/US01/ 16863 specifically disclose a salt form, a salt form of some of the final compounds appears to have inevitably formed.”

The sum and substance of BB’s counsel was that AA having made the aforesaid admissions, before foreign jurisdictions, in respect of patents corresponding to IN 176, it was disentitled to seek to contend that IN 176 did not claim EO.

Referring to section 3 (d) of the Patents Act, BB’s counsel submitted that the subject matter of IN 161 was not patentable, in view of the said express provision. Eltrombopag being a ‘‘known substance’’ by virtue of IN 176, he contended that in order for any new form of Eltrombopag to be eligible for a patent, the complete specifications had to disclose the existence of additional efficacy. The only assertions of the plaintiff, regarding the advantages of EO over Eltrombopag *per se*, were that EO had better solubility and bioavailability and, therefore, better pharmacodynamic factors. Therapeutic effect, even to EO, was owing to

Eltrombopag. He added that the Supreme Court in the Novartis case, had clearly held that enhanced bioavailability was insufficient to indicate enhanced therapeutic efficacy, for the purposes of the Explanation to section 3(d). IN 161 was, therefore invalid on this ground as well.

It has also been sought to be contended by BB that its price was lower than that of the plaintiff's product and that public interest justified the refusal of the plaintiff's prayer for interlocutory injunction. BB's counsel repeatedly emphasised the fact that, at the interlocutory stage, the defendant was only required to make out a case of a credible challenge regarding the vulnerability of the suit patent to revocation. This standard, he submitted, had amply been met by the grounds raised by him.

Responding to the submissions of BB, the counsel for the plaintiff submitted that EO was a novel and inventive compound. EO, he submitted, was a salt which did not form part of any approved drug prior to the suit patent IN 161. It was a technical advancement over Eltrombopag *per se*, which was claimed and disclosed in prior art. EO, was, therefore, a new and inventive product.

Comparing IN 176 with the suit patent IN 161, counsel for AA submitted that the subject matter of IN 176 was Eltrombopag *per se.*

EO, the subject matter of the suit patent IN 161, was the outcome of protracted research and development undertaken on Eltrombopag. EO was a breakthrough drug used for treatment of chronic idiopathic thrombocytopenia, and had been marketed, in India, since 2011 under the brand name ''REVOLADE''. EO itself had been granted patent protection in over 60 jurisdictions. The therapeutic efficacy of EO stood recognised in over 90 countries, in which patent protection had been granted to it. EO was, therefore, a novel, inventive and technical advancement over IN 176.

The subject matter of the invention claimed in the suit patent IN 16l was, therefore, distinct and different from the entity IN claimed in Claim of IN 176. AA's counsel contended that there could be no question of any claim, or disclosure, of EO in IN 176, as EO was not a pharmaceutically acceptable salt of Eltrombopag prior to the priority date of IN l61.

Acceptance of the submissions canvassed by BB, submitted the counsel for AA, would render incremental inventions, resulting in technical advancements over the known prior art, non-patentable, as all derivatives would be covered by the prior art. Section 3(d) would, thereby, be rendered otiose.

Thereafter, the counsel for AA addressed section 3(d) of the Patents Act. This provision, he submitted, was *ex facie* inapplicable, as no drug came out of IN 176 and no drug, containing Eltrombopag, was ever approved prior to IN 161. The subject matter of IN l6l, i.e. Eltrombopag Olamine, he submitted, was not a ''known substance" within the meaning of section 3(d), but was a ''new compound" altogether.

Even if, it were to be assumed that EO was a new form of a known substance, within the meaning of section 3(d), he submitted that it would, nonetheless, be patentable, as it had enhanced therapeutic efficacy over the claims in IN 176. IN 176, he submitted, claimed the free acid Eltrombopag, which had no known efficacy. He relied on the decision in *Bristol-Myers Squibb Holding Ireland Unlimited Co. v. B.D.R. Pharmaceuticals International Pvt. Ltd.* to contend that the very fact that the marketable drug had first emerged from the suit patent IN 161 was itself an indicator of its enhanced efficacy over the claims in IN 176.

As EO had higher yield of Eltrombopag, as well as enhanced solubility and bioavailability as compared to the free acid form, counsel for AA submitted that the therapeutic efficacy of EO was greater than Eltrombopag in the free acid form. He also submitted that the maximum plasma concentration of EO was thrice the plasma concentration of Eltrombopag in free acid form. This indicated that the bioavailability of EO was thrice the bioavailability of Eltrombopag in free acid form. This enhanced solubility and bioavailability, he submitted, had led to drug development and consequently, enhanced therapeutic efficacy of the compound

claimed in the suit patent IN 161. It needs to be mentioned that BB acknowledged before the Court that the fact that it is manufacturing and dealing in Eltrombopag Olamine. Furthermore, BB contended that the plaintiff may have itself applied for grant of patent in respect of the allegedly infringing product but it did not.

The defendant, in the present case, neither launched any pre-grant nor any post-grant, opposition to IN 161. It has not initiated any proceeding before IPAB or any other authority, for revocation, cancellation or removal of the suit patent from the register of patents.

Counsel for AA further observed that, in the present case, EO was an unknown substance prior to IN 161. As such, the suit patent IN 161 could not be regarded as vulnerable to invalidity on the ground of section 3(d) of the Patents Act. He pointed out that the grounds of challenge, raised by BB to the validity of the suit patent IN 161 were, thus, without substance. Infringement of the suit patent having been admitted by the defendant, AA would be entitled to injunction and that the defendant should not be entitled to manufacture and market EO, during the subsistence of the suit patent IN 161.

Both the parties relied on the judgements of the Indian Courts and Foreign Courts.

After going through the narrative above, answer the following questions with supporting legal principles and case law if any.

Questions :

(*a*) What are the principles of patentability under the Indian Patents Act, 1970 ? (10 marks)

(*b*) What should be the guiding principles in relying on the judgements of Indian Courts and Foreign Courts ? (10 marks)

(*c*) Explain the concept of ever-greening in section 3 (d) of the Patents Act bringing out the scope and meaning of ‘efficacy’ and ‘efficiency’. (10 marks)

(*d*) What do you understand by ‘credible challenge’ and ‘vulnerability’ in the context of the case narrative ? (10 marks)

2. XX is a renowned company manufacturing different kinds of soft drinks. The company got registered a Trademark SOFTA for its soft drinks. The soft drinks became very popular with customers and the company registered a good turnover and enviable profit. Its balance sheet and Profit and Loss accounts were very appreciative with its shareholders satisfied.

XX came across a general advertisement of a Trademark SIFTA which was deceptively and confusingly similar to its own Trademark SOFTA. The said advertisement was by a competitor YY in soft drinks. XX filed a notice of opposition and a plaint before the Registrar of Trademarks. It is the case of XX that the adoption of the Trademark SOFTA by YY was a deliberate attempt by it to ride piggy back on the reputation and goodwill of XX. XX sought a decree of permanent and mandatory injunction against YY from continuing with the aforesaid advertisement. The company also claimed damages against YY.

Initially YY appeared before the Registrar on receiving a notice from him and put in its appearance through its representative. But subsequently, it chose to absent itself from the proceedings before the Registrar. But, YY in its only appearance orally defended its Trademark SIFTA contending that SOFTA and SIFTA were clearly distinguishable and would not result in confusion or deception in the soft drink consumers. It did not submit to the Registrar any written reply to the plaint of XX or evidence. In order to establish its case, XX through its senior official who was formally authorised by its Board of directors to appear in courts and legal proceedings on behalf of the company adduced its evidence. The official was produced as a witness who deposed in favour of the company XX.

Study the narrative above and answer the following questions, quoting the relevant legal provisions and case laws, if any.

Questions :

(*a*) In the case above, is there any infringement of the registered Trademark 'SOFTA' by the company YY ? Give reasons.

(*b*) What would be your decision regarding the claim for damages made by XX against YY ? Justify your decision citing some relevant case laws.

(6 marks each)

3. (*a*) Is IPR recognised in Competition Law ? Discuss the need for relationship between Competition Law and IP Law.

(*b*) What are the benefits of Registration under Geographical Indications of Goods (Registration and Protection) Act, 1999 ? Certain Geographical Indications are prohibited. What are they ?

(6 marks each)

4. (*a*) List the criteria for Registration of Plant Variety. Who can apply for Registration of Plant Variety ?

(*b*) The registration of layout design which has been commercially exploited anywhere in India or a Convention country has been Prohibited. Explain this with the SICLD Act, 2000.

(6 marks each)

5. (*a*) Section 13 of the Copyright Act provides that copyright shall subsist throughout India in certain classes of works. Enumerate this section with examples.

(*b*) What kind of Trade Secrets Protection is promised in Brazil and Japan and how it is different from India ?

(6 marks each)

6. (*a*) If any person working for the benefit of person with disability on a profit basis or for business can apply Copyright Board for a compulsory licence to publish any work in which copyright subsists for the benefit of such person. Comment.

(*b*) What are the grounds and procedure to register a 'Patent' under the law relating to Patents in India ? Once a patent is granted can it be challenged further ? State your answer with reasons and relevant provisions.

(6 marks each)

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