JAYPEE UNIVERSITY OF INFORMATION TECHNOLOGY, WAKNAGHAT
TEST -3 EXAMINATIONS- 2023
M.Tech-I/Ph.D. Semester (BT)

COURSE CODE (CREDITS):18MIIBT114 (3) MAX. MARKS: 35
COURSE NAME: Patenting in Biotech
COURSE INSTRUCTORS: Dr. Gopal Singh Bisht MAX. TIME: 2 Hours

Note: (a) all questions are compulsory. This paper contains two pages.
(b)Marks are indicated against each question in square brackets.
(c) The candidate is allowed to make Suitable numeric assumptions wherever required for solving problems

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Q1. Answer the following questions. [10]

a) What are the main differences between an agreement for license and assignment? [2]
b) What is not patentable in biotechnology? Is patenting of microorganism allowed in India? What is the status regarding patenting of genes, expressed sequence tags and single nucleotide polymorphisms? [3]
c) Under what circumstances it is mandatory to obtain prior permission from the patent office to file application for patent outside India or abroad? [2.5]
d) Which of the following statements is true? Comments on it [2.5]
Statement 1: The assignee acquires all the rights, which previously belonged to the assignor. The rights then do not revert back to the assignor.
Statement 2: if a patentee has a patent in country X, Y and Z, then he may assign his rights for invention for country Y only while retaining the rights in countries X and Z

Q2. Why do people invent? Explain the importance of prior art search before filling of patent application. Discuss technical advance/inventive steps in specifications in detail. [4]

Q3. What is the need for PCT? How are patent applications under PCT handled? What is the meaning of delayed processing of the application by the national phase or regional phase? What are the advantages of the Patent cooperation Treaty? [6]

Q4. After reading and analyzing following specification a) Provide an appropriate title b) Draft an abstract (max 150 words) c) Draft 2 claims [2+7+6]

Diclofenac (2-(2-[2,6-dichlorophenylamino]phenyl)aeetie acid) is one of the most widely used non-steroidal anti-inflammatory drugs due to its marked pharmacological activity. Thiocolchicoside, also known as 3-demethyl-thioeolehieine glucoside, is a glucoside extracted from the seeds of Colchicum autumnale, which possesses a muscle-relaxant. anti-inflammatory. analgesic and anaesthetic action. The prior art 1 demonstrates that dielofcnac is a substance which is relatively unstable in solution, and that the liquid formulations of said substance therefore require the presence of a stabilising agent. The patent prior art 2 discloses stable aqueous solutions of diclofcnac containing a mixture of propylene glycol and polyethylene glycol. The chemical stability of said solutions is obtained by adding a reducing agent which can be a sulphite, such as sodium bisulphite, cysteine and/or cysteine hydrochloride, acetylcysteine and/or acetylcysteine hydrochloride, or a thiosulphate. Their chemical stability is further improved by the presence of lidocaine in addition to the reducing agent. when preparing a liquid composition containing diclofenac and thiocolchicoside. the inventors of the present application have found that it is necessary to

overcome a number of technological difficulties, The most important requirement being to prevent the degradation of one or both of the active ingredients when formulated in a single unit dose solution. The antioxidant most widely used to stabilize diclofenac in liquid solutions is sodium bisulphite. There are numerous formulations on the market containing this antioxidant. Other antioxidants used are cysteine, acetylcysteine and reduced glutathione. Thiocolchieoside also presents stability problems in solution. The chemical and physical compatibility of thiocolchicoside with other injectable medicaments frequently combined with it, including anti-inflammatory, is described in prior art 3. The authors of the present invention have found that the addition of thiocolchicoside to a formulation containing diclofenac makes the use of the above-mentioned antioxidants problematic, if not impossible, as their presence in the solution causes significant degradation of thiocolchicoside and dielofenae under ambient and supra-ambient storage conditions (40°C). As the number of antioxidants suitable for parenteral/injectable use is limited, the impossibility of using said stabilizing agents makes it very complex to obtain formulations which arc potentially stable under the conditions required by the health authorities when the product is registered. Tert-butyl-4-hydroxyanisole, also known as butylated hydroxyanisole or BHA, is an antioxidant widely used in the food and pharmaceutical industry. It is used in fats and oils, foods containing fats, essential oils, and food packaging materials. BHA is a mixture of two isomers: 2-tertbutyl-4-hydroxyanisole (2-BHA) and 3-tert-butyl-4-hydroxyanisole (3-BHA). The present invention solves the technical problem of the instability of liquid formulations containing a combination of dielofenac and thiocolchicoside. Accordingly the composition of the invention contains tert-butyl 4-hydroxyanisole (BHA) as antioxidant. Diclofenac is preferably present in the composition as sodium salt. The composition of the invention can optionally also contain exeipients suitable for pharmaceutical use, such as mannitol and sorbitol, and can also contain a local anesthetic, such as lidocaine. The composition according to the invention can also contain solubilising agents, chelating agents, buffering agents or pH correctors, such as sodium or potassium hydroxide, sodium bicarbonate, tromethamine, mono ethanolamine or other organic bases. In one embodiment of the invention the composition takes the form of an aqueous solution consisting of a mixture of water and propylene glycol. In a preferred embodiment of the invention the composition takes the form of an aqueous solution containing propylene glycol and dielofenac sodium salt. Diclofenac sodium salt is preferably present in the composition in quantities ranging from 25 to 75 mg per unit dose administered. thiocolchicoside can be present in the composition in quantities ranging from I to) a mg per unit dose administered. BHA can be present in the composition in quantities ranging from 0.1 to 1.2 mg per unit dose administered. The exeipients mannitol or sorbitol can be present in the composition in quantities ranging from 6 to 32 mg per unit dose administered. Propylene glycol can be present in the composition in quantities ranging from 800 to 2000 mg per dosage unit. In a preferred embodiment of the invention the composition contains dielofenac sodium salt at the concentration of 18.75 mg/mL, corresponding to a dosage unit amount of 75 mg, and thiocolchicoside at the concentration of I mg/mL, Corresponding to a dosage unit amount of 4 mg. A further aspect of the invention relates to the use of the composition according to the invention for the treatment of rheumatic or traumatic pain and inllammation of the joints, muscles, tendons and ligaments. The composition according to the invention can be administered in dosage unit amounts of 75 mg of diclofenac sodium and 4 mg of thiocolchicoside once or twice a day.