UNIVERSITY COLLEGE LONDON

University of London

EXAMINATION FOR INTERNAL STUDENTS

For The Following Qualification:-

M.Sc.

Biochem Eng G24: Integrated Biochemical Engineering Design

COURSE CODE	:	**BENGEG24**
DATE	:	**18-MAY-06**
TIME	:	**10.00**
TIME ALLOWED	:	**3 Hours**

TURN OVER

*Answer **BOTH parts, A and B.***
Both questions carry a total of 50 marks each distributed as shown []

Part A

1.

You are the lead researcher of a team working on a novel method for producing a known therapeutic macromolecule. Your employer is a large pharmaceutical company. Owing to a new process you have used, the recovery of the desired product is several times greater than has been achieved before. To date, the low yield of this product has made it very expensive to produce and as a result it has not been very competitive on the market. You have also discovered that the new process modifies a constituent of the product and you believe this will enhance its activity. You believe this new method has commercial importance.

a) Is there an intellectual property worth protecting? Describe? [5]

b) Who would own these rights in thee vent that they are worth protecting? [5]

c) You are invited to represent your findings at an international conference in Mexico next month. What considerations arise and what safeguards need to be put in place if any? [5]

d) What advice would you give the company on the regulatory implications of the above new method of processing [10]

e) What are the implications if the company decides to outsource its manufacture based on the above changes? [10]

f) Assuming that this was a completely new product what steps need to be taken to get this therapeutic drug on the market. [15]

Part B

2.

a) The choice of flowsheet for a given biological product must reflect a compromise between yield, purity, cost and robust operation. Taking the case of a periplasmically expressed protein discuss how you would set about establishing a suitable process route. Your answer will need to include a series of questions which would need to be answered before you could make any firm decisions eg. size of molecule. [25]

b) How would you anticipate using scale-down approaches to help in part a)? Describe how scale-down differs from ultra scale-down for the example of high speed centrifugation . [25]

END OF PAPER