

# **Biotech and Pharmaceutical Patents in Europe (7,5 p)**

## ***Module 2A***

### ***Master of European Intellectual Property Law***

#### ***Stockholm University***

## **Course Description**

### ***Introduction***

The course will engage into an in-depth comprehension of the special characteristics of biotech and pharmaceutical patents in the context of European patent law. The course consists of four days of lectures and seminars led by established patent specialists and one day of a negotiation exercise. Presence is compulsory. The students will receive a collection of articles and case law, but a further literature search is also required.

### ***Learning Objectives***

After completion of the course Biotech and Pharmaceutical Patents the students should be able to:

- define and explain legal issues which are specifically related to biotech and pharmaceutical patents
- identify, analyse and solve legal problems related to biotech and pharmaceutical patents
- produce a strategy for negotiating an agreement regarding biotech and pharmaceutical patents

### ***Teaching***

The teaching will take place in the form of seminars. The students are also required to conduct self-studies, group work and individual writing. At the seminars, you will have the opportunity to discuss practical issues with established patent specialists in the field.

## **Course Content**

The course will focus upon the following topics:

- Patentability of biotech and pharmaceutical inventions
- What is a Markush formula?
- Application of the patentability criteria on biotech and pharmaceutical inventions
- The second (and further) medical indication
- The special case of selection inventions
- Patentability of therapeutic, diagnostic and surgical methods in relation to Article 53 (c) EPC
- The application of the morality exception in Article 53(a) EPC in the field of pharmaceutical and biotechnological inventions, especially human embryonic stem cells
- The characteristics of gene patents
- Patent strategies in the biotech/pharmaindustry
- What is a Supplementary Protection Certificate and what is its scope?
- Patent Licensing
- Litigating in the Pharmaceutical Industry.

## **Examination**

The examination is divided into two parts:

- 1) Three written assignments
- 2) Negotiation exercise

On the first day the students will be divided into two groups, which represent two competing pharmaceutical/biotech companies: Genetech and LIVIA.

## **Assignments**

The assignments relate to the ongoing competition between Genetech and LIVIA. Each task covers some specific problems in patent law, where the companies have conflicting interests. Such conflicts relate e.g. to the use of a patented invention, the preparing and handing in of a patent application, or other patent-related problems encountered by the companies. The assignments will be published on the course website on specific dates during the course.

Each assignment is divided into individual questions, which you may distribute among the group members as you wish. You are encouraged to discuss the questions and possible solutions as a group, but each question must be written and handed in individually. In this process, finding the relevant legal basis and case-law is of major importance. In addition, you must also find an argumentation strategy for your company. Please identify arguments pro and con your company's position in the matter, and evaluate their strengths and weaknesses. You are always representing your company, which means that you have to have close contact within the group during your individual work and especially regarding your solution to the question, since all answers will have effect in the final examination; the negotiation exercise. Your company's strategies laid out in the individual assignments will have an impact on the final settlement, and cooperation within the group is therefore necessary.

In addition, a written preparation for the negotiation exercise is also required before the real negotiation between the companies take place. This Negotiation Preparation should be written collectively by each company, and will not be subject to grading. One part of the Negotiation Preparation consists of filling out a Table for Negotiation outlining the objective facts, your company's strength and weaknesses and your preferred outcome regarding each contentious issue. The answers will be kept secret to your opponent but the structure of the Table functions as a structure for the negotiation.

Schedule for the Assignments:

	Publication	Deadline
<i>Assignment No. 1</i>	9 April	16 April, 9 am
<i>Assignment No. 2</i>	16 April	26 April, 9 am
<i>Assignment No. 3, including Negotiation Preparation:</i>	26 April	3 May, 9 am

The Assignments shall be e-mailed to [asa.hellstadius@juridicum.su.se](mailto:asa.hellstadius@juridicum.su.se) and [Frantzeska@sinf.se](mailto:Frantzeska@sinf.se). The Negotiation Preparation should also be e-mailed to [bengt.domeij@indek.kth.se](mailto:bengt.domeij@indek.kth.se).

Please write the assignments in Times New Roman or Arial, 12 points, 1,5 line-separation. Each individual assignment answer may not exceed 10 pages. The Negotiation Preparation should not exceed three pages.

## **Negotiation Exercise**

The aim of the exercise is to reach a compromise/cooperation agreement between LIVIA and Genetech. The exercise will be in the form of a negotiation between the parties. The facts of the negotiation will be based on the facts given in the assignments, as stated in the Table for Negotiation.

Professor Bengt Domeij will act as a moderator at the negotiation. You will be asked to specify your view on the legal matters and your company's proposals for solutions of the legal conflicts. Your opponent will be asked to do the same thing. Then you will try to negotiate the contents of the agreement between the companies.

The negotiation exercise is an additional opportunity for each of you to be evaluated for your personal contribution. Please remember that you must prepare and represent your company as a group, but you should divide your tasks so that each of you will make an oral presentation and also be prepared to answer any questions from the moderator, or defend yourself in relation to your opponents. Your personal presentation at the exercise will be your single opportunity to present and distinguish yourself orally, although in a group context.

### ***Grading Criteria***

The seven-grade ECTS-scale is used for grading the fulfillment of the Learning Objectives according to the following description:

<b>A</b>	Excellent:	Outstanding performance with only minor errors
<b>B</b>	Very good:	Above the average standard but with some errors
<b>C</b>	Good:	Generally sound work with a number of notable errors
<b>D</b>	Satisfactory:	Fair but with significant shortcomings
<b>E</b>	Sufficient:	Performance meets the minimum criteria
<b>FX</b>	Fail:	Some more work required before the credit can be awarded
<b>F</b>	Fail:	Considerable further work is required

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### ***Preliminary Schedule***

#### **Friday 9 April**

9-10	Introduction	ÅH
10-13	Patenting in the pharmaceutical industry	PO
14-17	Sufficiency of Disclosure and Support by the Description	NM

#### **Saturday 10 April**

10-13	Principles and Recent Developments in Biotech, Nanotech and Pharmaceutical Patents	RU
13-15	Medical Methods, Selection Inventions, Genes and Stem Cells	FP, ÅH
15-17	Biotech patenting – a group exercise	FP, ÅH

#### **Friday 23 April**

9-12	Patent Licensing	RL
13-15	Enforcement, evidence and sanctions	JH
15-17	Research, patenting and publication – ethical and/or novelty dilemmas?	ÅH

#### **Saturday 24 April**

10-12	Group exercise	ÅH, FP
13-15	Litigation in the Pharmaceutical Industry – the Losec Case	AR
15-17	Conclusive Remarks and Negotiation preparation	ÅH, FP

#### **Thursday 5 May**

10-13	Examination	BD
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*AR Annika Ryberg, Court of Patent Appeals, Stockholm*  
*BD Bengt Domeij, Stockholm Royal Institute of Technology/Uppsala University*  
*FP Frantzeska Papadopoulou, Swedish Industry Association*  
*NM Niklas Mattsson, Awapatent*  
*PO Peder Oxhammar, Brann*  
*RL Richard Lewinson, Bird & Bird*  
*RU Ralf Uhrich, Hamburg Court of Appeal*  
*JH Jonas Hellberg, Stockholm University*

ÅH Åsa Hellstadius, Stockholm University