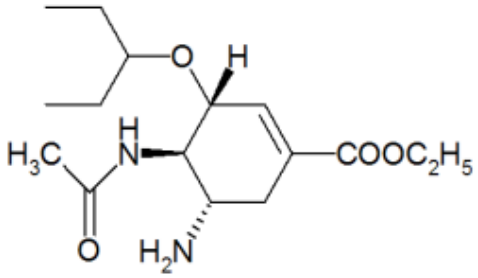
Biotech and Pharmaceutical Patents

Module 2A
Master of European Intellectual Property Law
Stockholm University
2010



Background and Assignment 1

LIVIA

LIVIA is a multinational pharmaceutical company with tradition in the field of vaccines and antivirals. *LIVIA* owns a considerable patent portfolio that allows a strong position in the market. Their most income-generating patent of ”old generation” pharmaceuticals is for the influenza drug with the active substance *oseltamivir*.

During the past few years, the company has extended beyond traditional pharmaceuticals, to gene-based therapies. The biotech section of the company is growing steadily and along with that the number of biotech patents. In the specific market segment where *LIVIA* is operating, a patent granted to a competitor or a potential infringement lawsuit could have detrimental effects on the future of research and operations of the company. Thus, *LIVIA* has been very active in following patent applications/patents of competitors, filing for invalidation proceedings and suing for infringement.

The head office of *LIVIA* is situated in Germany.

LIVIA is:

Seble Gebre Giorgis Baraki

Lina Hedin

Pavel Savitsky

Buket Cagla Yesil

genetech

genetech is a start-up biotech company. During the first years of its operation, the company focused on research tools, such as bacteria and vectors. The success of this part of its activities allowed for the company to enter another market, that of gene-based pharmaceuticals and vaccines.

genetech owns a considerable part of its success to its patent portfolio. The patented research tools, major part of its business activities, have been licensed and sometimes even sold to competitors and other biotech companies. Safeguarding the validity and enforcement of these patents is obviously of crucial importance. In the new field of interest, that of gene-based pharmaceuticals, patents are also very important in order to stabilise *genetech's* growing position in the market.

The head office of *genetech* is situated in United Kingdom.

genetech is:

Vincensia Fuko

Tihitina Ayalew Getaneh

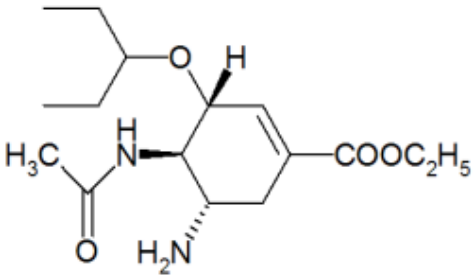
Prokopios Tsologlou

Yajie Zhao

Assignment No. 1

Deadline: 16 April, 9 am

The patent for the antiviral drug *oseltamivir* is the most valuable in *LIVIA's* IP portfolio. The pharmaceutical functions as an anti-viral drug used in the treatment and prophylaxis of both Influenzavirus A (e.g. swine flu and avian flu) and Influenzavirus B. The active substance is *oseltamivir*, a neuraminidase inhibitor, acting as a transition-state analogue inhibitor of influenza neuraminidase and thereby preventing new viruses from emerging from infected cells. The substance's mode of action relies on blocking the function of viral neuraminidase protein, thus preventing the virus from budding from the host cell. *LIVIA's* patent cover the active substance *oseltamivir*, the method of treatment along with the process for its preparation.



Oseltamivir

(3R,4R,5S)-4-acetylamino-5-amino-3- (1-ethylpropoxy)-1-cyclohexene-1-carboxylic acid ethyl ester

In the light of the recent influenza pandemic, *LIVIA's* patent is proven very valuable. *LIVIA's* patent is valid in several jurisdictions worldwide, however, *LIVIA* never acquired a patent for oseltamivir in, for example, Thailand, Philippines, Indonesia or many other countries.

Many competitors and states wish to produce generic equivalents to the valuable pharmaceutical. *LIVIA* has so far only sublicensed the manufacture and sale of the drug in the Indian and Chinese markets to the Chinese company Broche, by an exclusive licence. However, the protection term for the patent will expire in 2012, and many companies have already made preparation for and in some cases started the manufacturing of generic equivalents, among those *genetech*.

genetech has a production facility in Thailand and takes the chance of using the method of preparation for *oseltamivir* there. Before starting up the production, *genetech* experiments with the method and makes some minor modifications with the aim of lowering the costs of the production process. To *genetech's* surprise, the modified process does not only lead to the production of *oseltamivir*, but they also discover a new bi-product of the process, an unknown protein (*X20*) in Influenzavirus A, which may be used as a very valuable research tool in influenza research. *genetech's* researchers have soon discovered the gene that codes for the protein. They want to protect the gene, the protein and all future functions of the gene in the major European and international jurisdictions.

LIVIA wishes to protect its rights and markets as far as possible.

genetech wishes to acquire as much protection for its discoveries and gain as much market share from LIVIA as possible.

Questions

1. When can the production of generic equivalents to *oseltamivir* start? What can the generic companies do with the produced stock? Will the generic companies have to produce data to acquire the authorisation to sell the generics or could they depend on the clinical data submitted by *LIVIA*? Under which circumstances?

2. *genetech* wishes to patent the *X20* protein as well as the gene. Please describe the application of the patentability criteria and the associated problems with patenting of genes and proteins. Is there a difference between human and non-human material? What are the differences between the major European states with regards to the protection of such subject-matter?

3. Is *genetech* committing patent infringement by the use of the patented method? Does it matter where *LIVIA's* method is used? Would it be possible for *genetech* to claim experimental use as a possible defence? Can *LIVIA* have any claims on *X20*? Apart from the gene patent issues in question 2 above, would it be possible for *genetech* to patent *X20* considering its origins?

4. When drafting patent applications, one major aspect to consider is sufficiency of disclosure and support by the description. Analyse the major UK cases with regard to sufficiency of disclosure (especially *Biogen* and *Lundbeck*), explain the principles contained therein and incorporate the reasoning of the Court in the general argumentation of your respective company.

The main perspective you need to apply to your answers is European law (even though there may be some international implications). In your argumentation please find relevant legal basis and refer to relevant case-law as well as legal doctrine. Please identify arguments pros and cons your company's position in the matter, and evaluate their strengths and weaknesses.

Each of you should be responsible for the answer to one of the questions. But even though you will answer them individually, cooperation within the group is strongly recommended. The questions relate to each other and you need to check so that you don't hand in contradictory or conflicting answers. Please remember that everything you write down will have effect in the negotiation exercise at the end of the course, which makes it important to consider and make joint decisions on the strategic effects of your answers already from the beginning.

The questions should be put together and e-mailed as one complete document (with each of your names after the relevant individual question) named after your company and the assignment number (e.g. LIVIA_1 or genetech_1) to asa.hellstadius@juridicum.su.se , frantzeska@sinf.se at 9 am on 16 April (the latest).

Do not hesitate to contact us should you have any questions!

Good Luck!
Åsa & Frantzeska