

Assignment No. 2

Deadline: 28 April, 9 am

One of LIVIA's research teams has long been focused on finding a cure for certain types of *atopic dermatitis* ("eczema"). The research team focuses on compounds within the large HYDROGENA group of chemicals, characterised by a specified hydrogen structure including a substituent factor ("R"). "R" covers a particular group of radicals.

The research team is able to prove surprisingly good results for treatment of *atopic dermatitis* with one specific compound within the HYDROGENA group, the so-called MADROGENA compound, which contains an additional chloride atom to the hydrogen structure. LIVIA starts preparing a European patent application for the MADROGENA compound for the use of MADROGENA in eczema treatment.

Words of the situation reach genetech in the UK. By the work of their excellent undercover industrial spies, genetech becomes aware (in detail) of LIVIA's research and immediately wants to stop the patent application.

genetech performs a prior art search and discover that several compounds within the HYDROGENA group have been disclosed in the prior art over a period of 20 years. The MADROGENA compound is already known as having acid-reducing effects, as well as the closely related compounds of CADROGENA (containing an additional fluoride atom) and EDROGENA (containing an extra carbon atom). It is briefly mentioned in a research paper that due to their specific structure, the HYDROGENA group of compounds may be generally useful as pharmaceuticals in the treatment of different skin conditions. Additional prior art documents show different results as to the activity of individual compounds within the group. CADROGENA works as a mild acne-inhibitor and can therefore be used in anti-acne face cleaners. The EDROGENA compound is to a certain extent useful in the treatment of severe

sunburns. But the compounds also have unwanted side-effects. Some patients participating in clinical trials involving EDROGENA developed skin cancer, and the trials were cancelled. CADROGENA is not well tolerated by persons with sensitive skin types. The scientific papers in the field also contradict each other as to possible uses and which compounds that had the most potential in different areas. However, the main use of compounds within the HYDROGENA group are so far only related to metal and how to reduce corrosion. Also, there seem to be difficulties to predict the effects of structurally related substances within the HYDROGENA group. On the other hand, they all possess certain effects that relates to the human skin, as well as acting as anti-corrosives.

genetech's employees are busy these days. Despite the fruitful undercover work of genetech, they also manage to keep up their research activities.

One of their research teams has for several years worked with the identification of a certain gene, the so-called BT1-gene. A person carrying this particular gene type has an increased risk (50-70%) of developing brain tumours later in life compared to a person without the specific gene. Once the gene and resulting protein is identified, a diagnostic tool kit for the screening of blood is developed. The diagnostic tool kit is developed primarily for use by health care professionals and contains everything needed to ascertain whether a person is a carrier of BT1 (e.g. syringes, vials, test tubes with fluids for the screening etc.).

Brain tumours can be treated by chemotherapy. Some of the side-effects of chemotherapy is hair-loss and fatigue. genetech develops two new type of drugs. The first drug (DA) is delivered orally, in combination with scalp massage, which in combination increases the acetylcholine level in the brain and tissue and thereby reduces the perception of fatigue both before and after chemotherapy. The other drug (DB) consists of a extremely small chip covered with the active substance, which is implanted in the neck via a minor incision. The active substance is then

diffused for period of at least three months, thus counteracting the hair loss caused by the chemotherapy.

genetech wishes to protect its innovations as far as possible, and to stop LIVIA's MADROGENA patent application.

LIVIA wishes to file a successful patent application on MADROGENA and to stop genetech's upcoming patent applications. In addition, faced with the problems of genetech's discovery of prior art and their new diagnostic tool and drugs, LIVIA has to strengthen its position in the market by strategically using the *oseltamivir* patent for a period as long as possible.

Questions

Group question (to be discussed and answered in short by the whole group)

What kind of patent protection can and should LIVIA claim for the MADROGENA compound (product/process/use, or combination of them) considering the prior art?

1. Is there a way for LIVIA to prolong the exclusive right on *oseltamivir*? What is the regulatory system available in the EU? How is the term of the prolongation to be calculated? How is the subject-matter of protection during the new protection term to be defined? What happens if the basic patent is owned by two different patent holders?
2. Please describe the situation in Europe with regard to the patenting of so-called selection inventions and the application of the criteria of novelty and inventive step for such inventions. Please assess the patentability (novelty and

- inventive step) of the MADROGENA compound in view of the relevant facts and prior art.
3. genetech wishes to patent its new revolutionary screening method (diagnostic kit). Are there any hinders to overcome in the patent application procedure? What will genetech have to prove? How has EPO case-law evolved in the field and what are the criteria to be fulfilled in order for genetech to acquire a patent for the new screening method? You should refer to and analyse major relevant case-law.
 4. Besides patenting DA as a substance, genetech wants to patent the method by which the drug is administered (massage etc.). It is equally important to protect the chip (DB). How could genetech acquire the maximum level of protection for DA and DB? Which are the different available subject-matter? Analyse relevant statutory exceptions and EPO case-law that could influence the patentability of DA and DB in a negative or in a positive way respectively.