

Special issues in patent law: Patent protection for biotechnological and pharmaceutical inventions from a European and international perspective.

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In this course, we will analyse in detail specific issues arising around the patentability and scope of protection of biotechnological and pharmaceutical inventions, which to this day are the subject of many debates in society, and the importance of which has increased substantially since the start of the COVID-19 crisis. Due to the specific nature of the above technological inventions, the standard rules of patent law have been somewhat “adapted” to accommodate those areas of technology.

In a first chapter, we will cover the patentability of biotechnological inventions in the context of medicinal products: To accommodate the specificity of the subject matter of biotechnological inventions, certain rules have been created which differ from the standard patent law rules. This is not only the case for issues relating to patentability as such, but also relating to scope of protection. This chapter is related to issues of patentable subject matter, patentability requirements and infringement.

In a second chapter of this course, we will also discuss the special topic of the patentability of plant related inventions, also in the context of technological developments in the area of genome editing. Agricultural products are still important in Italy in general, and in Sicily in particular. Patent law has struggled for many years with whether and how to provide patent protection for inventions in this area. We will discuss the specific provisions created for plant related inventions, their interpretation, and whether it is beneficial to society or not to allow patent protection for such inventions. This chapter is related to issues of patentable subject matter, patentability requirements and infringement.

In a third chapter, we will discuss pharmaceutical inventions. This course will in particular discuss the following issues:

- The patentability of second and further medical uses (also sometimes called repurposing of drugs), and the so-called evergreening strategies that are put in place by using this system. This part of the course can be seen in the context of the patentability requirements of novelty, inventive step and enabling disclosure.
- Second medical use patents also present specific problems in the context of patent infringement, in particular in situations where generic drugs are on the market, whilst there is still patent protection for a medical use of the active substance which is otherwise no longer patent protection.

In a fourth and final chapter, we will apply the knowledge acquired in the previous chapters to the specific case of the COVID-19 crisis, which provides a good illustration of what the potential reach of IP protection can be in an era of pandemics. In that regard, we will not only discuss what type of inventions relating to COVID-19 can and are patented, but also what the consequences could be of the existence of a plethora of IP rights relating to COVID-19. In this context, we will also discuss the proposed so-called “IP-waiver”, at the time of writing this course description still under discussion at the WTO. This chapter is related to issues of patentable subject matter, patentability requirements, infringement and (compulsory) licensing.
