

Protection of intellectual property rights of medicines

Abstract

The aim of the thesis is to describe the development of the protection of intellectual property rights of medicines in the EU and in the Czech Republic, including the development of the European patent and the movement towards the European unitary patent. The thesis describes the specifics faced by the pharmaceutical sector within the EU with regard to the principle of free movement of goods in the EU internal market, the doctrine of exhaustion of intellectual property rights and EU competition protection and includes a selection of case law of the CJEU, which in its decisions addresses practical problems arising from the contradictory principles of the EU internal market and the territorial nature of intellectual property rights. The thesis also aims to explain the difference between patent protection and regulatory data protection considering the forthcoming reform of pharmaceutical law in the EU.

The first part of the thesis examines the development of patent protection in Europe, focusing on the TRIPS agreement and the essential standards it has brought to the legal systems of all WTO member states. This part also looks at the European Patent Convention and the resulting European patent, with reference to the new instrument of the European Unitary Patent and explains the new aspects of this instrument which may bring simpler and cheaper protection of pharmaceutical companies' patent rights.

The second part of the thesis describes the specifics of the EU internal market such as parallel trade in pharmaceuticals, the doctrine of exhaustion of intellectual property rights and competition protection in relation to intellectual property rights. The chapter on competition describes cases where pharmaceutical companies abuse patent or regulatory protection and try to artificially prolong the exclusivity of their product on the market. They use various patenting strategies or merely cosmetic changes to their products, for which they try to regain intellectual property rights protection that is disproportionate to these subtle changes. This part of the thesis also focuses on pay-for-delay agreements.

The third and final part of the thesis focuses primarily on regulatory protection of pharmaceutical product data. It describes the difference between data exclusivity and marketing exclusivity and explains the principle of this protection and its specific settings for specific medicines such as "orphan drugs" and "biosimilars". It also describes the difference between patent protection and regulatory data protection. In the final chapters of this part of the thesis, trademarks for pharmaceuticals are also discussed.

Key words: Intellectual property rights, data exclusivity, medicinal products