**DESCRIPTION FOR THE GENERAL PUBLIC**

The subject of research in this project is the protection of regulatory data as an instrument of legal protection for pharmaceuticals, plant protection products, and novel food.

The development of a new drug is a time-consuming and extraordinarily expensive process; a commercialized medicinal product may be however copied easily. Therefore, the availability of legal protection for medicinal products is perceived as crucial to the pharmaceutical industry. Public health institutions are on the one hand interested in highly innovative products and on the other one – in the access to medicines for patients. Legal regulations concerning the protection of innovative medicines shall thus balance the various interests at stake, catching up with rapid technological changes in this sector. Similar considerations are visible in the agrochemical and novel food industries.

Traditionally these were patents that were used to protect pharmaceutical innovations by granting a temporary market monopoly for patentees. Within the last decades however other legal instruments have been introduced in the European Union for the same purpose: supplementary protection certificates (SPC) and system of data exclusivity. The latter is subject of interest in this research project.

The subject of the discussed exclusivity in the EU is a specific type of data – these are the results of clinical and preclinical tests that must be presented by the producers of an innovative medicinal product in a market authorization procedure. Producers of generic drugs do not have to present their own results of the mentioned tests, but they can refer to the data of the respective innovative drug, which have been submitted earlier. However, the reference to these data may take place only after the time of data exclusivity has expired. The introduction of a generic drug on the market may take place only after the additionally defined market exclusivity period has expired. In this way, data exclusivity makes it factually impossible to introduce generic medicinal products on the market, even if they are not covered by patent protection. Data exclusivity is therefore of great importance for the protection of innovative medicines and for shaping legal conditions on the pharmaceutical market and especially for ensuring a balance between the protection of particular stakeholders' interests, which are mainly innovative and generic industry as well as patients and public institutions providing health services.

The rules of data and market exclusivity vary depending on the type of medicinal products they are assigned to. The basic category of drugs covered by data exclusivity are medicinal products authorized for the market on the ground of full research results (reference medicinal products); special types of drugs for which data and market exclusivity is provided are orphan drugs and pediatric medicines.

The aim of the project is to analyse and discuss the regulation of data exclusivity in the EU to the widest possible extent, including, i.a., the following questions and research issues: If and how does the EU data exclusivity regulation meet the requirements for protection of undisclosed information, as provided in the TRIPS Agreement? What are the rules for the legal protection of innovative medicines on the ground on data exclusivity? What is the role of data exclusivity in the legal protection of medicinal products, when taking into account its links with patents and SPCs? What is the significance of data exclusivity in patent strategies and market practices of pharmaceutical companies? What is the shape of data exclusivity in the US and how does it differ from the EU regime? Is the shape of data exclusivity homogenous in EU member states? What changes of current data exclusivity rules could be postulated? How is data exclusivity regulated in free trade agreements? Analogous questions are posed as regards plant protection products and novel food.

The research will cover acts of the Polish, the EU, and the international law as well as judgments of national courts and the Court of Justice of the European Union, decisions of patent offices and of institutions authorizing medicinal products. Comparative legal studies will include respective regulations in the US law. The institution of data exclusivity is regulated in pharmaceutical law and thus remains outside the domain of intellectual property law and outside the mainstream of considerations regarding the legal protection of pharmaceuticals. Therefore, this is a subject that is undervalued and analyzed much less frequently than patents or SPC.

The domestic literature on the subject is very fragmentary. The monograph, which will be one of the results of the project, will be a comprehensive and innovative elaboration of the subject of data exclusivity as an instrument of the legal protection of innovative medicines. Results of research will also be presented at several international conferences and published in the form of several articles in English-language magazines, and thus made available to a wide range of interested persons - to scientists and practitioners, national and supranational authorities authorizing medicines, as well as to policymakers in the field of pharmaceutical law and intellectual property rights.