New healthcare products and technologies require official authorization following clinical trials that prove their safety and efficacy, before they can enter the market. The trials and the subsequent authorization process are connected with considerable costs and are time consuming. During the authorization period the patent protection (which is limited in time) of a given pharmaceutical product is already running, but the developer of such a product is unable to place their invention on the market. In order to compensate developers for the time lost in the process of obtaining the market authorization, various legal instruments were introduced, which allow for the extension of the developer's monopoly beyond what is offered by pure patent protection. These instruments include supplementary protection certificates (SPCs), which allow for the extension of the patent protection of a given healthcare product, and regulatory exclusivities – special rights, which prevent the competitors of the original developer from using data that were obtained in the process of registration of the original product or market products based on such data (data and merket exclusivities).

During the exclusivity period, competitors (developers of generic drugs) either need to obtain their own data at their own expense, or wait for the data exclusivity period to expire. This delays the entry of competitive (and cheaper) drugs on the market, which may have negative consequences for the healthcare systems and ultimately – the patients. On the other hand, the additional protections are considered to be important incentives for the companies to invest in (often highly uncertain) research on new healthcare technologies, which makes the complex system of the protection of intellectual property rights a delicate structure, requiring delicate balancing of the interests of the developers of innovative technologies on the one hand, and the interests of the generic producers and patients on the other.

Seeing certain phenomena on the European Union (EU) market, in particular the fact that the regulatory data exclusivity often remains the longest protections left for a given healthcare product, oftentimes delaying the entry of its cheaper counterparts on the market, the European Commission (EC) has decided to revisit the current legislative framework and announced in April 2023 its proposal for pharmaceutical directive and pharmaceutical regulation.

In order to identify the actual performance of the system, the investigators plan to analyze the current and proposed regulatory solutions, as well, as perform research on actual data on the expiry times of and complex interactions between various intellectual property rights used to protect healtcare products in different regulatory scenarios.

The performance of the research project will help answer several important questions, such as: How have individual, EU member states implemented market exclusivity provisions in their national orders? What is the extent of market exclusivity in the selected countries with regard to the possibility of manufacturing, distribution, and import/export of healthcare products for the benefit of the holder of the Market Authorization? Which strategies for exploiting regulatory exclusivity and rewards – tactically combined with the patent and SPC systems - are most commonly used by right holders? What is the scale of the investigated phenomenon? By how long does the strategic use of regulatory instruments increase the duration of protection for innovative medicines? Is the use of regulatory strategies relevant for immediate generic entry to the market? What opportunities for strategic use does the planned revision offer?

Answering those and some other research questions will allow to achieve the following research objectives:

1. Determining the scope of market exclusivity in EU law and in the law of individual EU Member States, to identify potential differences between these regimes and to recommend a systemically consistent interpretation of the relevant provisions. The effects of these works will be of use to national courts and the CJEU in the event of a dispute concerning this issue, which - given the recent increase in disputes related to regulatory exclusivity - is highly likely to arise.

2. Analysing and evaluating amendments proposed by the EC from the perspective of the innovative and the generic industry, the reimbursement payer and, ultimately, from the point of view of the public health interests, thus contributing to a broad public debate on this issue in Poland and Europe. The research findings will be important for developing a position on the proposed changes for policymakers and other stakeholders.

3. Identifying how regulatory exclusivity can be strategically exploited, establishing the scale of the investigated phenomenon and evaluating it from the perspective of a sustainable system for supporting competitiveness, innovation and access to healthcare technologies. This research will be performed on real-life data from a database, which contains data on SPCs, regulatory data and market protection for the EU and individual EU countries. The findings will serve to validate the proposed legislative changes given the potential use of the new regulations to achieve the strategic objectives of the healthcare industry

The results of the study will be disseminated through conference contributions, articles, and a monograph prepared by the research team.