Invitation to an open seminar

# PROTECTION OF REGULATORY DATA IN LIFE SCIENCES

## at the intersection of IP, regulatory regimes and new technologies

**10 NOVEMBER 2022**

Institute of Law Studies at the
Polish Academy of Sciences
Nowy Świat 72
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# CALL FOR PAPERS

The extraordinary development of highly advanced technologies in life sciences has gradually transformed how cutting-edge knowledge is protected by available legal instruments. The higher the degree of technological complexity of innovations in this field, the less likely they can be reverse engineered and imitated. Consequently, **patents and SPC are no longer the most attractive instruments providing the competitive advantage in the life science sector, and the emphasis has been increasingly placed on trade secrecy and protection of regulatory data**. The latter is provided in Europe via confidentiality and exclusivity of data submitted to regulatory agencies. Anchored in the regulatory requirements, these two protective regimes are concurrently an important part of the overall IP framework and, as such, need the highest possible coherence with other instruments protecting life science innovation. This, however, is easier said than done, and currently, the complex system of regulatory data protection poses numerous challenges for a well-thought, balanced IP system.

Part of regulatory data is protected against disclosure as commercially confidential information on the grounds of various EU and domestic laws. **The rules of data confidentiality are not entirely harmonized and are subject to only a few judgements of the CJEU.** They differ from country to country, and among the relevant industries, from pharmaceuticals to novel food, to GMOs. The increasing significance of access to life science data, necessary for public health and nutrition interests and vital for the independent scientific verification of it, has been manifested in the introduction of the **Clinical Trial Information System**. Since it has become operational only very recently, its practical consequences are yet to be evaluated.

Data and market exclusivity, in turn, may be crucial when the patent or SPC protection is no longer available. Such occasions trigger questions about the scope of rights resulting from market exclusivity in particular EU jurisdictions – an issue which has not been adjudicated by the CJEU so far. **Serious controversies are raised by strategic usage of orphan and paediatric exclusivities and rewards**: changing the status of an orphan drug for non-orphan, using the 6-month SPC paediatric reward for non-paediatric MA extensions, or prolonging protection for orphan indication on the grounds of the orphan exclusivity of a similar product. Recently, the system of regulatory exclusivities for orphan and paediatric medicines has been **revisited by the European Commission, which intends its far-reaching amendments**, focusing on incentives to unmet medical needs and equal access to innovative medicines across the EU.

The complex framework of protection for Life Science innovation may result in a **linkage between authorisation or reimbursement procedures to existing protection from patents, SPC or exclusivity periods**. Whereas the EU traditionally presents a negative approach to any form of patent linkage, it does exist in other legislation, triggering the attention of scholarly debate.

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Finally, in the light of the COVID-19 pandemic, and in the perspective of other potential health or environmental crises to come, the need to ensure a **sustainable, well-balanced system of IP for life science innovations is more pressing than ever**. Whereas there is a broad discussion on how to improve the patent and SPC system, the significance of regulatory data protection seems underestimated.

Our seminar aims at contributing to the discussion on the current challenges to the protection of regulatory data. It is co-organised by the **Department of Polish and European Industrial Property Law, the Centre of New Technologies and the Life Science Legal Lab**, with the view of enhancing an open debate among scholars, students, practitioners, representatives of the Life Science industries and policymakers.

Therefore, we invite **all interested parties to contribute to the seminar**. The keynote speeches will be delivered by scholars with great expertise in the field of life science innovation: **Daria Kim**, PhD, Senior Research Fellow at the Max Plank Institute for Innovation and Competition in Munich and **Duncan Matthews**, Professor of Intellectual Property Law at the Queen Mary Intellectual Property Research Institute, Queen Mary University of London.

All submissions shall be sent via e-mail to **LifeScienceLegalLab@inp.pan.pl** by **9 October 2022**. **They need to include** a title and an abstract (up to 400 words) of the planned presentation (ca 15 minutes) as well as short information about the author's professional affiliation. The submissions will be peer-reviewed and the selection of seminar presentations will be announced by 20 October.

Registration for the seminar will be open from 20 October. It will be held in a hybrid format. All detailed information will be available at www.inp.pan.pl.

We look forward to welcoming you to our seminar!

**The Seminar Committee**
*Dr Żaneta Zemła-Pacud*
*Prof. INP PAN Helena Żakowska-Henzler*
*Prof. INP PAN Paweł Podrecki*
*Dr Tomasz Zimny*
*Dr Anna Miszczak*
*Gabriela Lenarczyk*

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