

2025年2月25日

弊所弁理士駒谷剛志が、ポーランド・ワルシャワにあるポーランド科学アカデミー法学研究所にて現地時間2025年2月25日午後5時（日本時間26日深夜1時）から開催されたセミナー“KICK-OFF of the NCN-funded project RE-APPROACH: Regulatory Exclusivities: Protection and Access to Healthcare Technologies WEBINAR on current developments in IP protection for pharmaceuticals”において、「SPC (PTE) and Quasi-Regulatory Exclusivities in Japan」と称する講演を行いました。

<https://inp.pan.pl/en/news/zaproszenie-na-webinar-wylacznosci-i-nagrody-regulacyjne-w-prawie-farmaceutycznym-aktualne-wyzwania-i-reforma-prawa-ue-2/>

(ポーランド語)

**RE-APPROACH**  
Regulatory Exclusivities: Protection and Access to Healthcare Technologies

KICK-OFF of the NCN-funded project  
WEBINAR on current developments in IP protection for pharmaceuticals

**2025**  
THURSDAY, FEBRUARY 20TH  
ONLINE  
5:00 PM - 7:00 PM (WARSAW TIME ZONE)  
REGISTRATION OPENING SOON

**ON THE AGENDA**

The event will explore current challenges and developments in regulatory exclusivities, their impact and protection in the pharmaceutical policy, with a focus on European and international perspectives.

The speakers will address topics such as:

- the changing nature of regulatory exclusivities,
- recent case law on SPCs,
- the existing rules for clinical data protection and secondary data use.

We will begin with an outline of the research and a presentation of the team. The event will conclude with addresses and comments from the International Advisory Committee of the project.

**SPEAKERS**

**DR ZANETA ZEMLA-PACUD**  
Attorney at Law,  
Office of the Director  
of Legal Proceedings  
of the Patent Office,  
Warsaw

**DR GABRIELA LENARCZYK**  
Production Policy  
Director for Regulatory  
Affairs, European Union  
Commission, Brussels  
Belgium

**DR MARTA SZNAJDER**  
Production Policy  
Director for Regulatory  
Affairs, European Union  
Commission, Brussels  
Belgium

**TAKESHI S. KOMATANI, LL.M., PH.D.**  
LL.M., PH.D.  
Patent Attorney with  
international experience,  
Intellectual Property  
Department, National  
Institute of Advanced  
Industrial Science and  
Technology, Tsukuba  
Japan

**ACHINTE PANDITA, PH.D.**  
Senior Lecturer,  
Faculty of Law,  
University of  
Wolverhampton,  
Wolverhampton,  
England

**ILS PAS**

**AGENDA**

STARTS AT 5:00 PM (WARSAW TIME ZONE)

**DR ZANETA ZEMLA-PACUD**  
THE REFORM OF REGULATORY EXCLUSIVITIES IN EUROPE

**DR GABRIELA LENARCZYK**  
BALANCING SECONDARY DATA USE AND IP PROTECTION UNDER ERSAs

**DR MARTA SZNAJDER**  
LATEST DEVELOPMENT IN THE SPC IN EUROPE (CJEU JUDGEMENTS)

**TAKESHI S. KOMATANI, LL.M., PH.D.**  
SPC (PTE) AND QUASI REGULATORY EXCLUSIVITIES IN JAPAN

**KHUSHBU KUMARI, PH.D.**  
CLINICAL TRIAL DATA PROTECTION IN INDIA: POLICIES AND IMPLICATIONS FOR THE PHARMA INDUSTRY

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**ILS PAS**

**ORGANISING COMMITTEE**

**DR ZANETA ZEMLA-PACUD**  
**DR DOMINI ZIMNY**  
**DR MARTA SZNAJDER**  
**KRYSTINA PEZ**