



Analysis of the Proposal for a European Health Data Space (EHDS): An IP and Competition Perspective

Carolina Banda (Ecuador), Class of 2016/17

Carolina Banda works as a research fellow at the MPI for Innovation and Competition, specialising in data regulations, competition law, and innovation in the life sciences sector. Additionally, she conducts research on sustainable development and data governance in emerging economies. In parallel, Carolina is completing her PhD at the University of Munich, where she proposes data governance mechanisms to facilitate adequate access and exchange of health data collected by wearable medical devices (mHealth). Leveraging her expertise in digital

healthcare, she will teach in 2024 at the MIPLC.

Abstract

This presentation examines the 2022 European Health Data Space (EHDS) proposal and its interplay with IP rights and trade secrets. The EHDS will be an ecosystem encompassing rules, common standards, practices, infrastructures, and a governance framework. Specifically, the EHDS is designed with three key objectives: 1) empowering individuals through increased digital access to and control of their electronic personal health data, both nationally and EU-wide; 2) fostering a framework for secondary use of health data in research, innovation, policy-making, and regulatory activities; and 3) ensuring the effective functioning of the digital health single market. Regarding secondary use, researchers—both private and public entities—may request access to health data for specific purposes, such as training AI algorithms. This access is facilitated by data access bodies in each member state. However, access to and sharing of such data for secondary purposes may be constrained if the datasets are protected by IP rights and Trade Secrets. Against this background, the research first explores the legal and institutional governance model of EHDS to facilitate data access and sharing for research and innovation. Second, it assesses the potential implications of IP rights and Trade Secrets on the secondary use of health data.