

Editorial Issue 1 2023

The spring of 2023 has been an eventful one for the future of the IP system. The presentation of the pharmaceutical legislation package and of the patent package, as well as the entry into force of the unitary patent package triggers new developments in the field of patent law the effects of which are still difficult to overview.

EU pharmaceutical legislation (Directive 2001/83 and Regulation 726/2004) constituted a major breakthrough in creating a system providing for the authorisation of safe, effective and high-quality medicinal products. After four years of deliberation, the EU Commission submitted its proposals for new legislation on 26th April 2023. The proposed revision EU pharmaceutical legislation is the first momentous review of the pharmaceutical legislation since 2004. The reform has a double aim, to enhance innovation and ensure timely and equitable access to medicines. Another objective of the reform is to enhance security of supply and address shortages through specific measures. The overarching objective is of course to support the European pharmaceutical industry's innovative power and competitiveness. In order to achieve that, the right balance needs to be struck between giving incentives for innovation and taking measures towards more equitable access and affordability. The proposed revision of the pharmaceutical legislation will consist of two legislative proposals: a new Directive, repealing and replacing Directive 2001/83/EC and Directive 2009/35/EC of the European Parliament and of the Council and incorporating relevant parts of the Paediatric Regulation (Regulation (EC) No 1901/2006) and a new Regulation, repealing and replacing Regulation (EC) No 726/2004, repealing and replacing the EU Regulation No. 141/2000 on "orphan" medicinal products and repealing and incorporating relevant parts of the Paediatric Regulation (Regulation (EC) No 1901/2006).

The day after, the 27th of April 2023 the Commission presented yet one more legislative revision this time with the Patent Package. This reform package impacts on the pharmaceutical industry, as it contains proposals on **Supplementary Protection Certificates (SPCs)** and compulsory licensing (CL) in crisis situations. It also includes a new Regulation on **Standard Essential Patents (SEPs)**. The proposed reform, which is part of the EU Industrial Strategy, will now undergo the scrutiny of the European Parliament and Council. It aims to **improve European competitiveness, innovation and technological sovereignty**, with a special attention to the role played by SMEs. The proposal is based on comments received during the consultation on the Action Plan on Intellectual Property issued in November 2020. The IP legislative framework comes as a complement to the **Unitary Patent system**, that entered into force on 1 June 2023.

The Unitary Patent system provides a one-stop-shop for the registration and enforcement of patents in Europe. It allows companies and other innovators to receive a single

"unitary" patent for their inventions, valid across all the participating Member States. This replaces the need for patent holders to navigate a complex mosaic of national patent laws and procedures and sets aside the national validation requirements applicable to European patents.

In addition, a new Unified Patent Court (UPC), with jurisdiction over Unitary Patents and existing European Patents, will allow companies to enforce their patent rights more effectively. The UPC is expected to provide a more consistent legal framework for patent disputes and reduce the risk of inconsistent rulings.

Having these recent developments as a background one can only expect an IP rich 2023.

This issue of the Stockholm IP Law Review is characteristic of the geographic diversity not only of the issues analyzed and of our readers but also of our authors, from Canada to Australia, Italy and UK. We hope you enjoy reading this issue of the SIPLR that discusses timely IP issues. Darinka Tomic discusses the particularities of the Canadian system for the protection of geographical indications while in her article, Leila Magnini presents the new Regulation on Geographical Indication protection for craft and industrial products. In his contribution, Justin Lambert analyzes the use of plausibility as a concept under EPC and UK case-law respectively, while Matthew Rimmer introduces as to the very interesting interface of bioprinting and intellectual property rights.

Frantzeska Papadopoulou Skarp

Editor in chief
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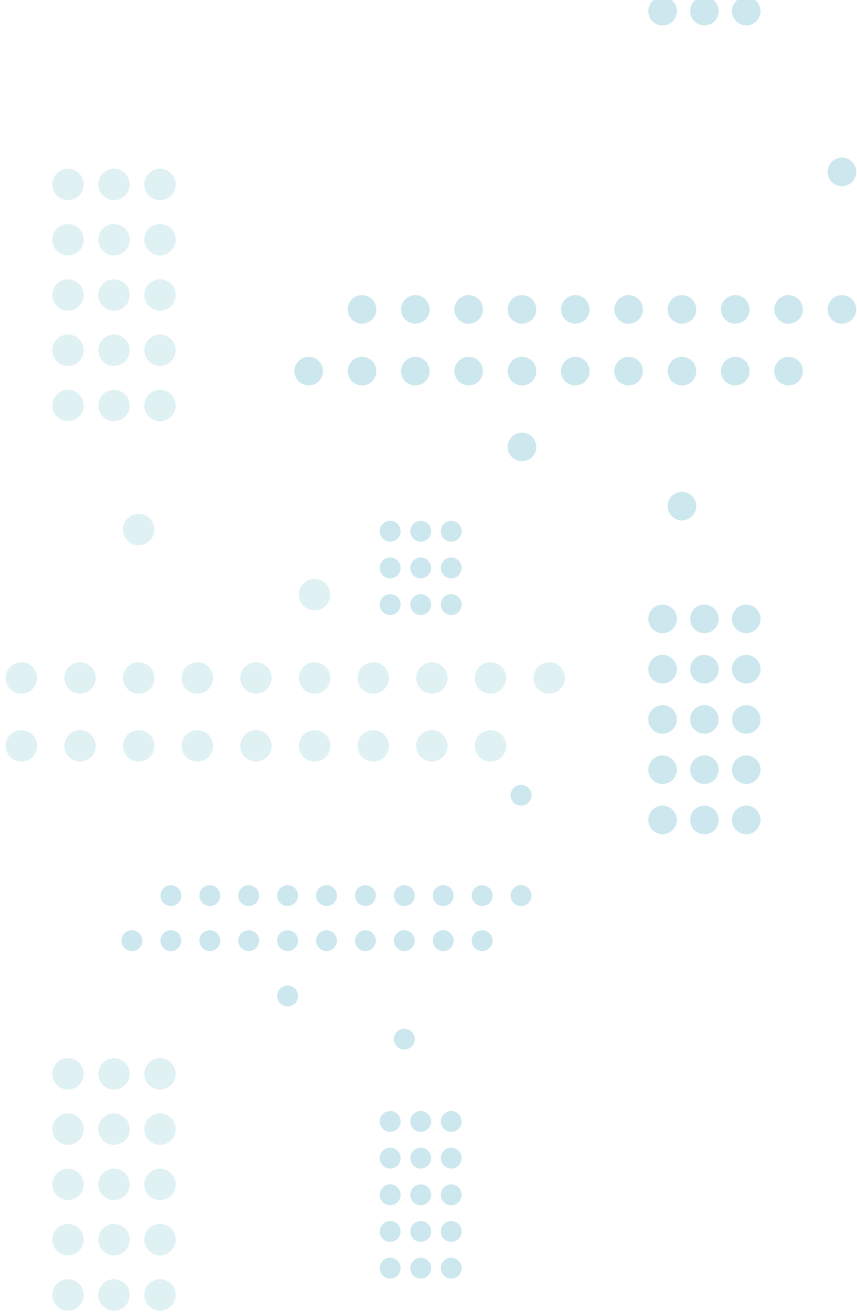
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