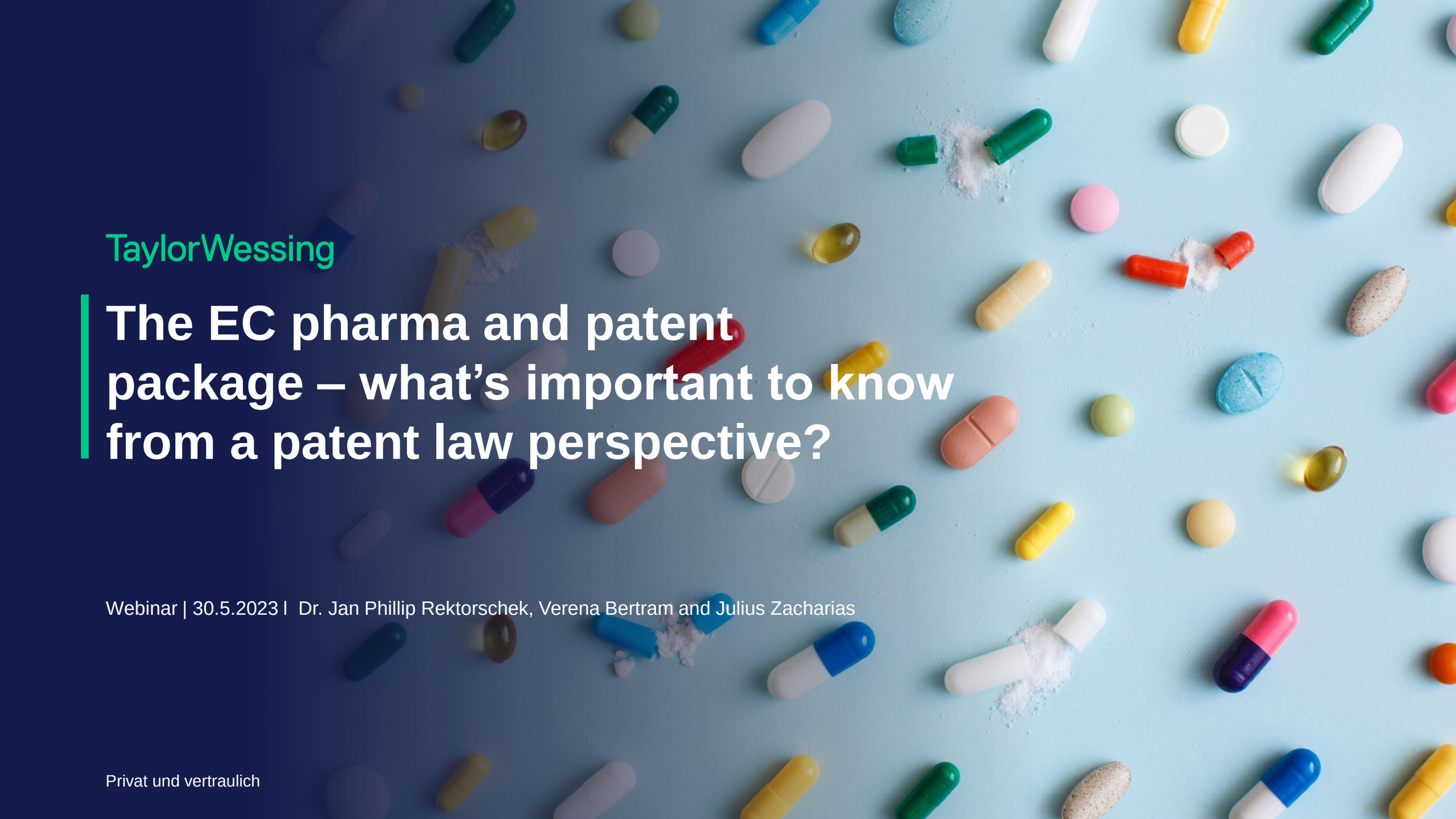

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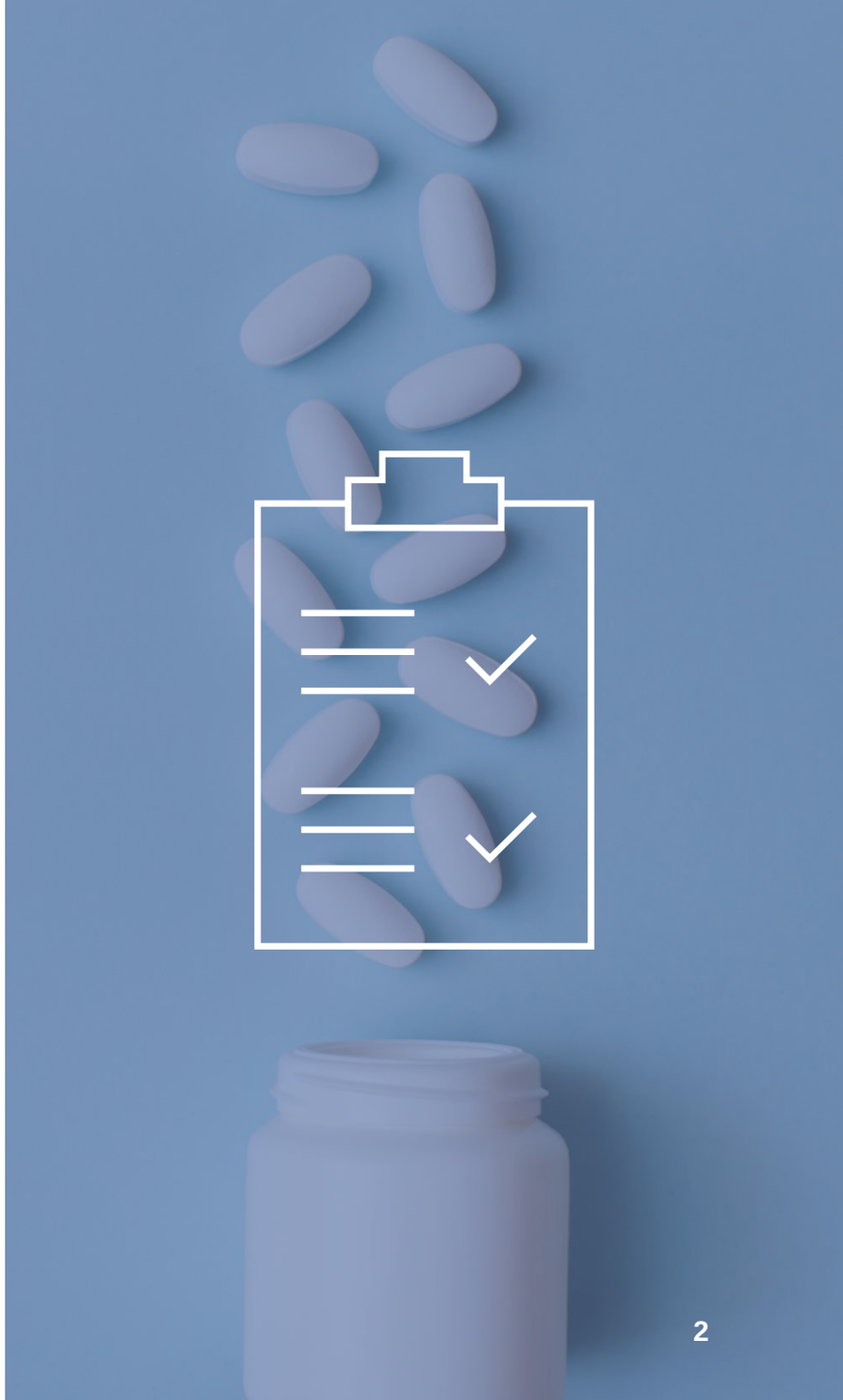
The EC pharma and patent package – what's important to know from a patent law perspective?

Webinar | 30.5.2023 l Dr. Jan Phillip Rektorschek, Verena Bertram and Julius Zacharias

Topics

Draft Regulations on



1 | Unitary SPC and SPC applications in centralised procedure

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Background draft Regulations

- Draft Regulation COM(2023)222 on a unitary SPC (“uSPC Regulation”):
  - Despite entry into force of the Unified Patent Court System on 1 June 2023 no unitary SPC (uSPC) yet;
  - uSPC already part of Commission work programme 2022;

- Draft Regulation COM(2023)231 on the SPC, providing a centralised procedure for SPCs (“SPC Regulation”):
  - Several updates on existing SPC Regulation (EC) No 469/2009 over the years justify recast;

- Both drafts published on 27 April 2023.

Main aspects of the draft Regulations

- Aim: simplification of SPC system
  - uSPC: one SPC application and right (based on a unitary patent („UP“)) for all UPC Member States;
  - „classical SPC“: a centralised SPC application based on a UP or EP to streamline the SPC examination proceedings for several Member States and to avoid diverging decisions in national grant proceedings;
    - „classical“ SPC also possible based on UP;

- Fundamental changes to current system:
  - One SPC application and unitary right for UPC area (uSPC);
  - One centralised SPC application for several EU Member States (SPC);
  - Legal remedies before SPC/uSPC is granted (opposition);
  - Establishment of a European authority for SPCs/uSPCs.

Scope

- uSPC:
  - Art. 5 Sec. 2 draft uSPC Regulation:

    „A unitary certificate shall have a unitary character. It shall provide uniform protection and shall have equal effect in all Member States in which the basic patent has unitary effect. The unitary certificate may ***only be limited, transferred or revoked, or lapse, in respect of all those Member States****.“*
  - Establishment of a unitary right.

Scope

- „classical“ SPCs applied for in centralised procedure:
  - Art. 32 Sec. 2 SPC Regulation:

    „In respect of a centralised application, where a positive examination opinion has been issued for one or more designated Member States, ***the competent national authority of each of those Member States shall grant a certificate in accordance with applicable national rules and procedures****.“*
  - Establishment of a „bundle“ of national SPCs, granted by national authorities after the centralised application was successful.

Competent authority

- European Union Intellectual Property Office (EUIPO) in Alicante, Spain is competent for uSPC application and grant and for centralised SPC application, Art. 18, 20 Sec. 3 SPC Regulation; Art. 10, Art. 2 Sec. 8 uSPC Regulation;
- Set up of „Supplementary Protection Certificate Divisions“ („SPC Divisions“), Art. 39 uSPC Regulation, Art. 40 SPC Regulation;
- Appointment of competent national authorities as participating offices in the examination procedure possible.

Procedure

- Lodging an application for a uSPC/SPC with the EUIPO, Art. 10 uSPC Regulation; Art. 20 Sec. 3 SPC Regulation;
- Publication of the application in the newly formed Register (≠ EPO register), Art. 12 uSPC Regulation, Art. 23 SPC Regulation;
- Third party observations have to be submitted within 3 months after publication of the application in the Register, Art. 14 Sec. 3 uSPC Regulation, Art. 25 Sec. 3 SPC Regulation;
- Examination panel: 1 examiner from the EUIPO, 2 examiners from different competent national authorities;
- Positive/negative examination opinion, Art. 13 uSPC Regulation, Art. 24 SPC Regulation;
- No substantive changes in the conditions for granting an SPC.

Opposition

- Within 2 months from the publication of the examination opinion, any person may file an opposition with the EUIPO, Art. 15 Sec. 1 uSPC Regulation, Art. 26 Sec. 1 SPC Regulation;
  - No grant before expiry of opposition period, Art. 18 uSPC Regulation, Art, 32 Sec. 1 SPC Regulation;
  - Opposition has suspensive effect, Art. 18 uSPC Regulation, Art, 32 Sec. 1 SPC Regulation;
- Grounds for opposition are that the conditions for grant are not met, Art. 15 Sec. 2 uSPC Regulation, Art. 26 Sec. 2 SPC Regulation;
- Opposition panel (1 examiner from the EUIPO, 2 examiners from different competent national authorities) not previously involved in the examination, Art. 15 Sec. 5 uSPC Regulation, Art. 26 Sec. 5 SPC Regulation;
- Opposition decision within 6 months unless the complexity of the case requires longer, Art. 15 Sec. 10 uSPC Regulation, Art. 26 Sec. 9 SPC Regulation.

Appeal

- At the EUIPO within 2 months from the notification of the decision, Art. 28 Sec. 3 uSPC Regulation, Art. 29 Sec. 3 SPC Regulation;
  - Also against negative examination opinion;
- Reasons for appeal within 4 months from the notification of the decision, Art. 28 Sec. 3 uSPC Regulation, Art. 29 Sec. 3 SPC Regulation;
- Appeal has suspensive effect, Art. 28 Sec. 2 uSPC Regulation, Art. 29 Sec. 2 SPC Regulation;
- Board of Appeal has 3 to 5 members;
- Appeal on points of law against decisions of the Board of Appeal to the General Court of the European Union within two months, Art. 28 Sec. 6 uSPC Regulation, Art. 29 Sec. 6 SPC Regulation.

Grant and rejection

- uSPC: EUIPO, Art. 18 uSPC Regulation;

- SPC applied for in centralised procedure: competent national authority in each designated Member State, Art. 32 SPC Regulation;
  - National authority may deny grant if basic patent has lapsed/was limited in the Member State or marketing authorisation has been withdrawn, Art. 32 Sec. 3 SPC Regulation.

Invalidity

- uSPC:
  - Application for declaration of invalidity of a uSPC can be filed by any person with the EUIPO, Art. 23 Sec. 1 uSPC Regulation;
  - Admissible as long as no final decision of the EUIPO or other competent court between the same parties on the same subject and cause of action has become final, Art. 23 Sec. 6 uSPC Regulation;
  - Decision shall be issued within 6 months unless the complexity of the case requires a longer period, Art. 23 Se. 10 uSPC Regulation;
  - Declaration for invalidity has ex tunc effect, Art. 23 Sec. 12 uSPC Regulation;
  - Counterclaim for invalidity of a uSPC possible as well, Art. 24 uSPC Regulation;

- SPC granted in centralised procedure:
  - Invalidity proceedings against „classical“ SPCs granted in centralised procedure before competent courts, Art. 20 Sec. 4, Art. 15 Sec. 2 SPC Regulation;

- No change in grounds for invalidity.

Oral hearings and costs

- Oral hearings possible if expedient:
  - Oral hearings before the examination panel, opposition panel and invalidity panel are not public, Art. 41 Sec. 2 uSPC Regulation, Art. 44 Sec. 2 SPC Regulation;
  - Oral proceedings before the Boards of Appeal are generally public, Art. 41 Sec. 3 uSPC Regulation, Art. 44 Sec. 3 SPC Regulation;

- Costs:
  - Losing party in opposition proceedings (including appeal proceedings) has to bear the fees and essential costs of the other party, Art. 48 Sec. 1 uSPC Regulation, Art. 51 Sec. 1 SPC Regulation;
  - In case of partial defeat different cost apportionment possible.

Misc

- Combined applications for uSPC and SPC in centralised procedure are possible (Art. 32 uSPC Regulation; Art. 39 SPC Regulation);

- Priority over national applications, Art. 20 Sec. 2:
  - When the basic patent is an EP or UP and the marketing authorisation for the product has been granted through centralised procedure, filing of national SPC applications for the product is not possible in the Member States in which the basic patent is in force;

- Paediatric extension possible for uSPC and SPC.

2 | Union Compulsory Licence

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Background of the proposal

- Conflict in status quo:
  - Regulation patchwork: Currently, compulsory licensing of patents in the EU is fragmented, as every member state has its own legislation on compulsory licensing
  - Cross-border value chains: Many value and supply chains operate across Europe

- Problem (highlighted by the COVID-19 pandemic): Difficulties to obtain compulsory licences covering the entire value chain

Aims of the proposal

- Before this background the Commission has presented a draft Regulation for a Union compulsory licence

- The proposal aims at…
  - Providing an effective tool in crisis times as a last resort when voluntary agreements do not work
  - Ensuring an appropriate territorial reach of compulsory licensing to cover cross-border supply chains
  - Complementing the EU crisis mechanisms that have been and are being established

Requirements + general conditions

- Main requirements for grant of a Union compulsory licence:
  - Art. 4 → Activation or declaration of crisis mode or emergency mode listed in Annex to Regulation
  - Need for Compulsory licence in context of this crisis or emergency, in particular due to shortage of crisis-relevant products

- General conditions governed by Art. 5:
  - Non-exclusive and non-assignable licence
  - Scope of licence shall be limited to
    - purpose for which compulsory licence is granted and the scope and duration of the crisis or emergency mode
    - territory of the Union
  - Compulsory licence for patent also covers SPC based on this patent

ANNEX - Crisis or emergency modes referred to in Article 4 and competent advisory bodies as referred to in Article 6(2) are listed below:

Union crisis or emergency mechanism	Crisis mode or emergency mode	Competent Advisory Body
1. Regulation XXX/XX of the European Parliament and of the Council establishing a Single Market Emergency Instrument and repealing Council Regulation (EC) 2679/98 [COM(2022) 459]	**Single Market emergency mode** activated by means of a Council implementing act [Article 14 of Regulation XXX/XX] [COM(2022) 459]	**Advisory Group** [Article 4 of Regulation XXX/XX] [COM(2022) 459]
2. Regulation (EU) 2022/2371 of the European Parliament and of the Council of 23 November 2022 on serious cross-border threats to health and repealing Decision No 1082/2013/EU	**Public health emergency at Union level** formally recognized by means of a Commission implementing act [Article 23 of Regulation (EU) 2022/2371]	**Health Security Committee** [Article 4 of Regulation (EU) 2022/2371]
3. Council Regulation (EU) 2022/2372 of 24 October 2022 on a framework of measures for ensuring the supply of crisis-relevant medical countermeasures in the event of a public health emergency at	**Emergency framework** activated by the adoption of a Council Regulation [Article 3 of Regulation (EU) 2022/2372]	**The Health Crisis Board** [Article 5 of Regulation (EU) 2022/2372]

Procedure

- Procedure is initiated by Commission (Art. 6 Sec. 1)

- Involvement of advisory body (Art. 6)
  - Advisory body shall provide opinion to Commission with regard to need for Union compulsory licence and its conditions (Art. 7 Sec. 1)

- Involvement of right holder (Art. 7 Sec. 3)
  - Assessment of possibilities to reach a voluntary licence agreement (lit. a)

- If requirements for Union compulsory licence are met, the Commission grants it by means of an implementing act (Art. 7 Sec. 7)

- Judicial review: Implementing acts are subject to judicial review by CJEU but there are no specific provisions in draft regulation in that regard

Effects of Union compulsory licence

- Permission for the licensee to exploit the protected invention within the scope of the licence
- Suspension of data exclusivity and market protection, where applicable (Recital (14) and Art. 80 para. 4 of new Directive (EU) No XXX/XX [COM(2023)192])
- Remuneration of right holder (Art. 9: shall not exceed 4% of gross revenue generated through activities under compulsory licence)

Export

- In general, export of products manufactured under Union compulsory licence shall be prohibited (Art. 11)

- Exception for pharmaceutical products:
  - Regulation (EC) No. 816/2006 already provides the possibility of national compulsory licences for export of medicines to non-EU countries with health problems
  - According to the present proposal, this regulation will be amended to the effect that the Commission may grant a compulsory licence where the activities of manufacture and sale for export spread across different Member States and would therefore require compulsory licences for the same product in more than one Member State.

Relationship to national compulsory licence regimes

- Proposed Union compulsory licence does not replace national compulsory licence regimes but supplements them in order to be able to effectively tackle EU-wide crises or emergencies

- Interesting difference:
  - In contrast to e.g. German compulsory licence proceedings which are initiated by the licence seeker as applicant against the right holder as defendant, the procedure for the grant of a Union compulsory licence is formally initiated by the Commission which, in collaboration with the advisory body, has to select the potential licensee

3 | Bolar exemptions

Bolar Exception: Status quo

Principle currently set out under Art. 10(6) of Directive 2001/83/EC:

Conducting the necessary studies and trials
with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements
shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.

Practical issues and aims of the revised rules:

- Implemented on a member state bases, the current rules lead to a fragmented application by the national courts in practice
- Unclear legal framework leads to uncertainties
- Revised rules aim strengthening legal certainty, the market and competition

Bolar Exception: Draft of Art. 85 Directive on medicinal products (1)

Objective (1): p. 17

Increased competition from earlier market entry of generic and biosimilar medicinal products

The **‘Bolar exemption’** (under which studies can be carried out for subsequent regulatory approval of generics and biosimilars during the patent or supplementary protection certificate protection of the reference medicinal product), will be **broadened in scope and its harmonised application in all Member States ensured**. In addition, **procedures for the authorisation of generics and biosimilars will be simplified**: as a general rule, risk management plans will no longer be required for generic and biosimilar medicinal products, considering that the reference medicinal product already has such a plan. The interchangeability of biosimilars with their reference medicinal products is also better recognised based on accumulated scientific experience with such medicinal products. In addition, the act provides an incentive for repurposing off-patent, added value medicinal products. This supports innovation, resulting in a new therapeutic indication that offers significant clinical benefit in comparison with existing therapies. Taken together, these measures will **facilitate earlier market entry of generics and biosimilars, thus increasing competition and contributing to the objectives of promoting affordability of medicinal products and patient access**.

Bolar Exception: Draft of Art. 85 Directive on medicinal products (2)

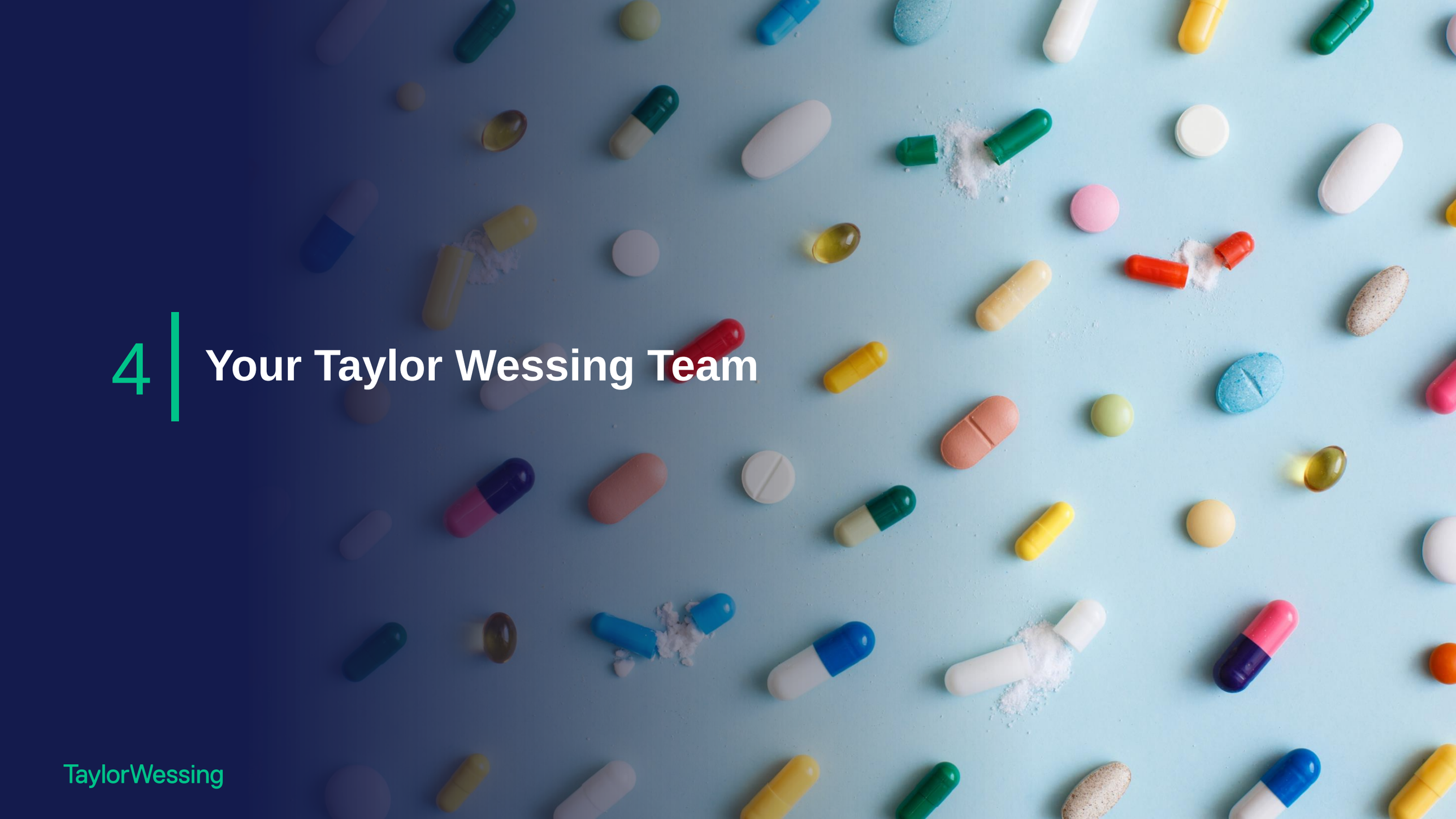
Objective (2): recitals 63 et seq.

(63) It is *currently possible for applicants for marketing authorisation of generic, biosimilar, hybrid and bio-hybrid medicinal products to conduct studies, trials and the subsequent practical requirements necessary to obtain regulatory approvals for those medicinal products during the term of protection of the patent or Supplementary Protection Certificate (SPC) of the reference medicinal product, without this being considered patent or SPC infringement*. The application of this limited exemption is however **fragmented across the Union** and it is considered necessary, in order to facilitate the market entry of generic, biosimilar, hybrid and bio-hybrid medicinal products that rely on a reference medicinal product, to clarify its scope in order to ensure a harmonised application in all Member States, both in terms of beneficiaries and in terms of activities covered. **The exemption must be confined to conduct studies and trials and other activities needed for the regulatory approval process, health technology assessment and pricing reimbursement request, even though this may require substantial amounts of test production to demonstrate reliable manufacturing. During the term of protection of the patent or SPC of the reference medicinal product, there can be no commercial use of the resulting final medicinal products obtained for the purposes of the regulatory approval process**.

(64) It will allow, inter alia, to **conduct studies to support pricing and reimbursement as well as the manufacture or purchase of patent protected active substances for the purpose of seeking marketing authorisations during that period, contributing to the market entry of generics and biosimilars on day one of loss of the patent or SPC protection**.

Bolar Exception: Draft of Art. 85 Directive on medicinal products (3)

Art. 85 of Directive on medicinal products for human use (draft) *Exemption to the protection of intellectual property rights* (repealing Directives 2001/83/EC and 2009/35/EC)	Art. 10(6) of Directive 2001/83/EC – Community code relating to medicinal products for human use – (as amended by Directive 2004/27/EC)
Patent rights, or supplementary protection certificates under the [Regulation (EC) No 469/2009 - OP please replace reference by new instrument when adopted] shall **not be regarded as infringed** when a **reference medicinal product is used for the purposes of**:	
(a) studies, trials and **other activities** conducted to generate data for an application, for: (i) a marketing authorisation of generic, biosimilar, hybrid or bio-hybrid medicinal products and for subsequent variations; (ii) **health technology assessment** as defined in Regulation (EU) 2021/2282; (iii) **pricing and reimbursement**.	Conducting the necessary studies and trials with a view to the application of paragraphs 1, 2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products.
(b) the activities conducted exclusively for the purposes set out in point (a), may cover the **submission of the application for a marketing authorisation** and the **offer, manufacture, sale, supply, storage, import, use and purchase of patented medicinal products or processes, including by third party suppliers and service providers**.	
This exception shall **not cover the placing on the market** of the medicinal products resulting from such activities.	



4 | Your Taylor Wessing Team

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Your Taylor Wessing Team

Verena Bertram's main areas of activity are IT and Life Sciences.

She advises national and international companies and develops strategic solutions for the challenges they face. She represents her clients before the courts and in out-of-court proceedings. She is also involved with patent attorneys in opposition and nullity proceedings before the European Patent Office and the Federal Patent Court.

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Julius Zacharias is a member of the Practice Area Patents Technology & Life Sciences in our Munich office.

He advises national and international clients and represents them in disputes in and out of court. He primarily advises clients from the life sciences sector.

Prior to joining Taylor Wessing as an attorney in 2016, Julius worked as a research fellow at the department for civil law, IP law and competition law (chair of Professor Ohly) at the Ludwig-Maximilians-Universität in Munich.

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Phillip is a Certified Specialist Lawyer for Intellectual Property law and has been handling patent litigation for national and international companies for more than 11 years. He represents clients in the fields of pharma/life sciences, mechanics/automation and IT/electronics.

He also has extensive experience in trade-secret matters, from their creation during the whole life-cycle. Phillip is regularly involved in IP-related arbitration proceedings as well as in drafting and negotiating license and R&D agreements.

Phillip gives lectures for Intellectual Property Law at the Munich Business School, publishes articles on current IP topics on a regular basis and is co-author of several IP-litigation handbooks. He regularly speaks at national and international conferences and seminars on patent law related topics.

Phillip is Vice President of the Software and Integrated Circuit Commission and member of the board of the German Group of the European Practitioners in Intellectual Property (UNION-IP), as well as member of the German Association for the Protection of Intellectual Property (GRUR).

Languages

- German, English

"

"*It is enriching and refreshing to work with him*.', client Legal 500 2023

"*Jan Phillip Rektorschek: Fast feedback and good, clear processing of issues*.", client Legal 500 2021

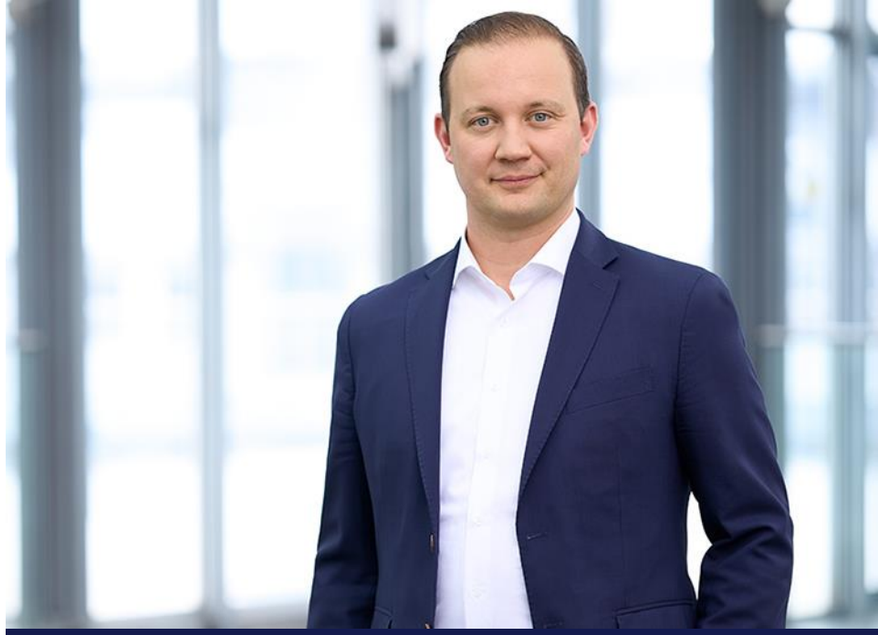
Recommended as "key lawyer", Legal 500 2020 – 2023

Frequently recommended lawyer for Patent Litigation JUVE 2021 – 2022

Highlighted as Best Lawyer for Intellectual Property Law, Best Lawyers in Germany, Handelsblatt 2021 – 2023

"*Taylor Wessing remains true to its focus on life sciences, electronics and IT, in which the newly appointed salary partner Jan Phillip Rektorschek also has special expertise*.", Legal 500 2018

"[…] *Jan Phillip Rektorschek, who specialises in life sciences, electronics and IT, is a rising star*.", MIP IP Stars 2017



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