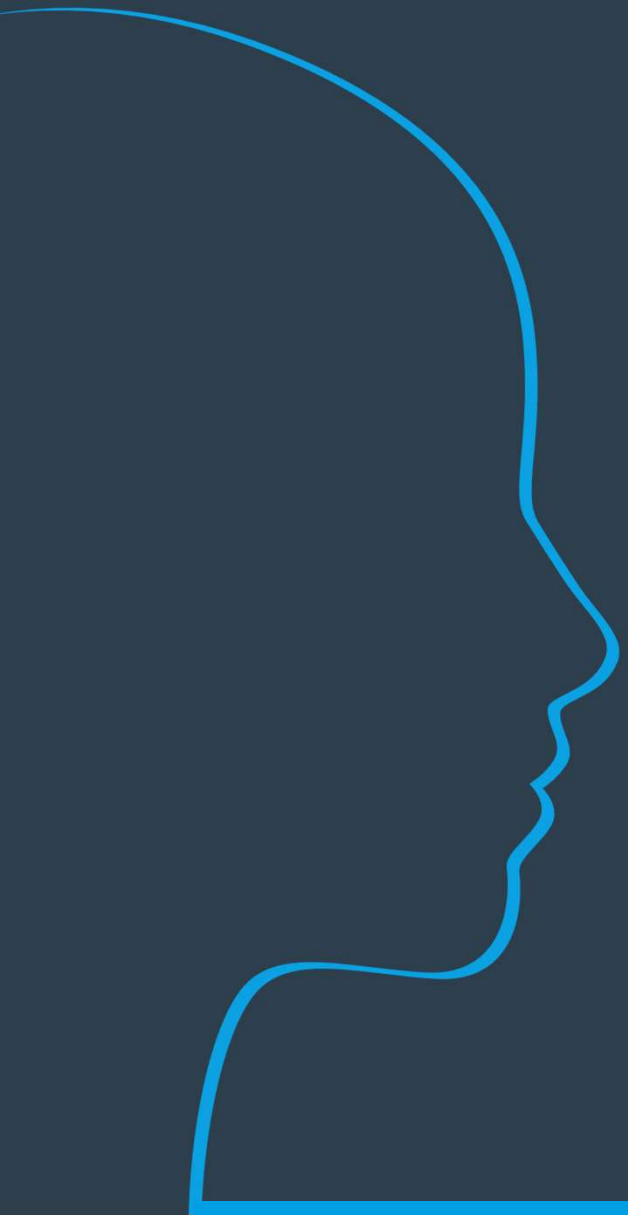


MAIWALD
INTELLECTUAL PROPERTY

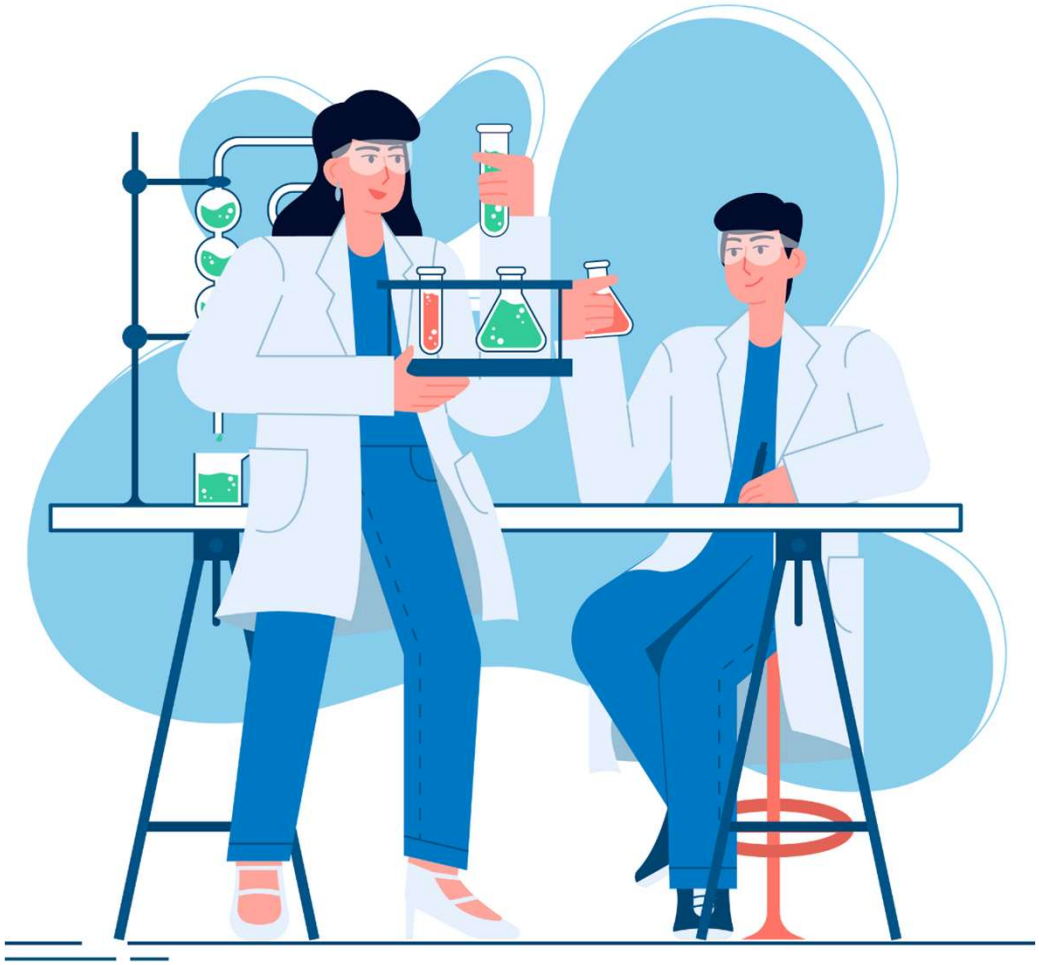
SPC MANUFACTURING & STOCKPILING WAIVER

Legal requirements, opportunities and risks of the SPC Waiver - Regulation (EU) 2019/933

Dr. Marco Stief, LL.M. (University of Chicago)

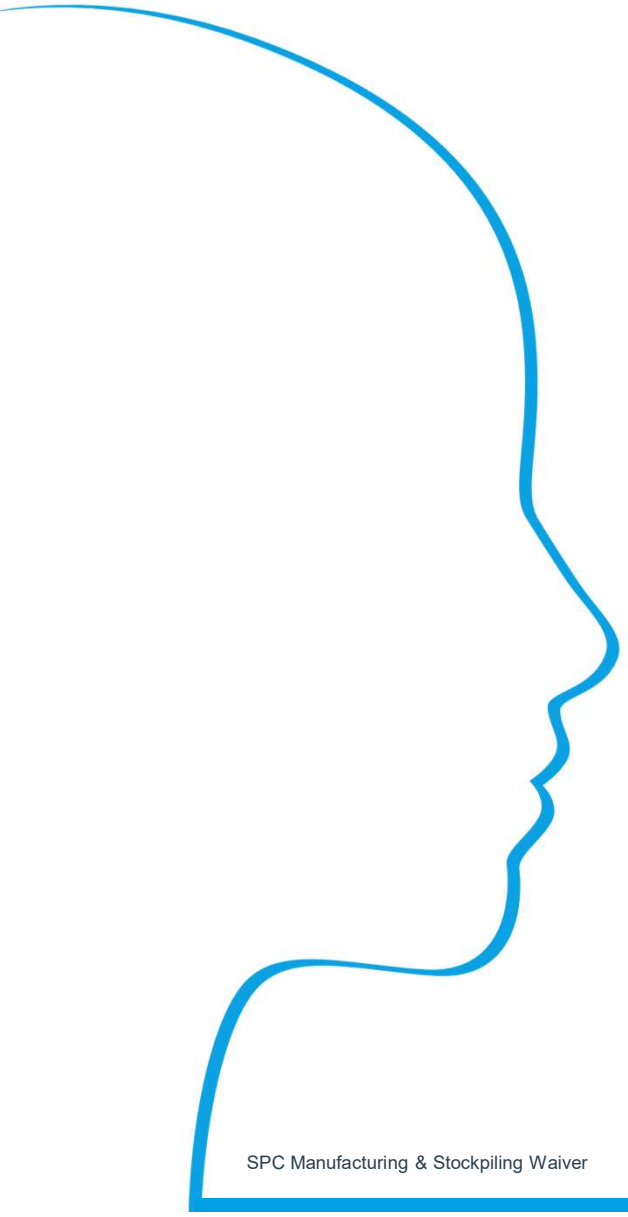
SPC MANUFACTURING & STOCKPILING WAIVER AGENDA

1. The SPC waiver at a glance
2. Scope of the SPC Waiver
3. Notification obligations
4. Documentation obligations
5. Labeling obligations
6. Discussion



MATERIALS AND FURTHER INFORMATION

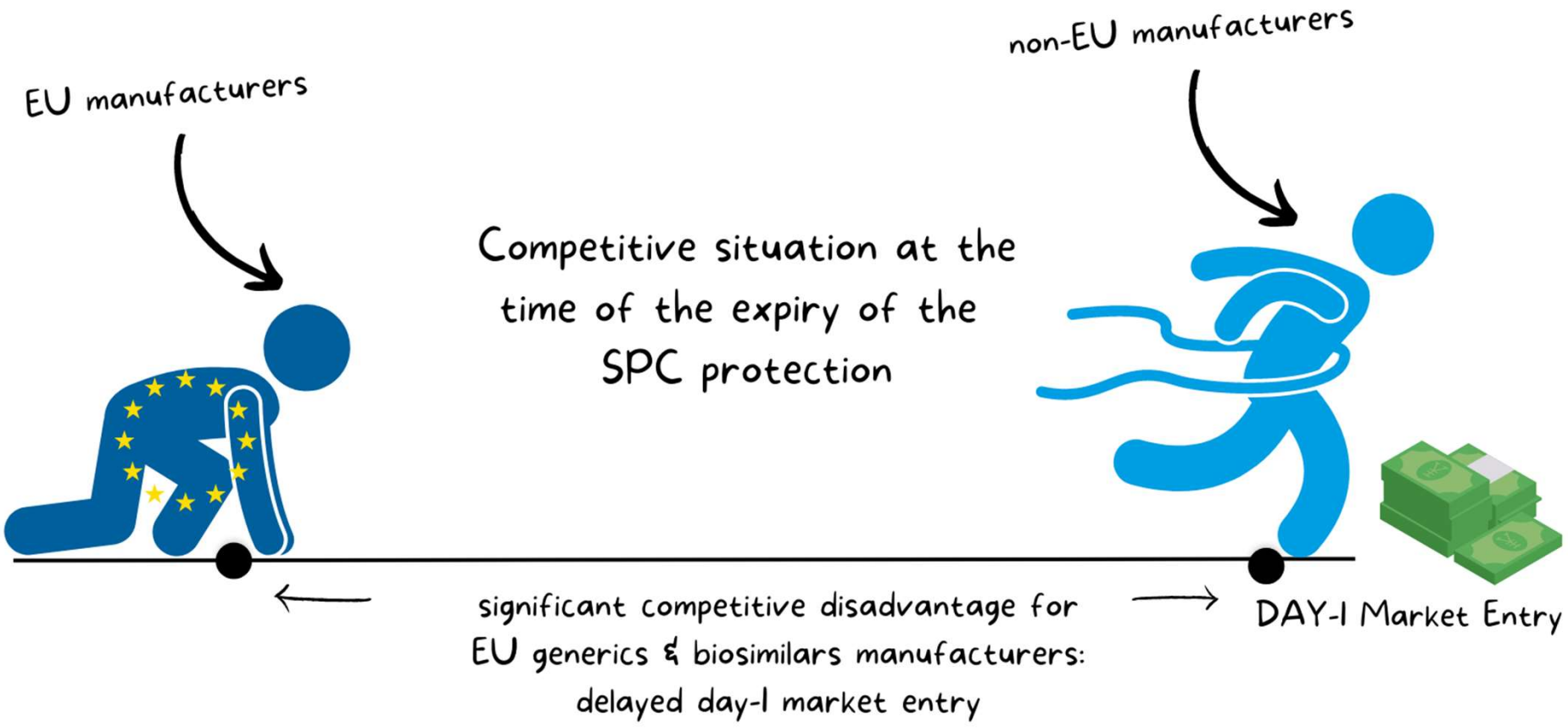
- SPC Waiver: Regulation (EU) 2019/933, Impact Assessment
- EU Pharma Package: Unitary SPC, SPC Regulation (recast)
- Medicines for Europe: Industry Report (June 2023), Intro Video; (212) Medicines for Europe policy vision on the SPC manufacturing waiver - YouTube
- Articles + Blogs
  - Management IP, Risk of SPC waiver counterattack makes generics extra cautious
  - Kluwer Patent Blog, Analyzing the use of the SPC waiver provisions and its reach outside the EU
  - IIC 2019, 971 Analysis of the SPC waiver regulation by Vidal-Quadras
  - JUVE Patent, Formycon and Janssen Biotech put EU SPC waiver to the test in Munich / Samsung Bioepis and Simmons repel Janssen infringement claims over SPC waiver



01

THE SPC WAIVER AT A GLANCE

THE PROBLEM AT THE TIME OF EXPIRY OF THE SPC PROTECTION



THE PROBLEM AT THE TIME OF EXPIRY OF THE SPC PROTECTION

(4) The absence [...] of any exception to the protection conferred by the certificate has had the unintended consequence of preventing makers of generics and biosimilars established in the Union from making generics and biosimilars in the Union, even for the purpose of export to third-country markets in which protection does not exist or has expired. Likewise, makers are prevented from making generics and biosimilars for the purpose of storing them for a limited period before the expiry of the certificate. [...]

(5) Those circumstances put makers of generics and biosimilars established in the Union **at a significant competitive disadvantage in comparison with makers based in third countries that offer less or no protection.** [...]

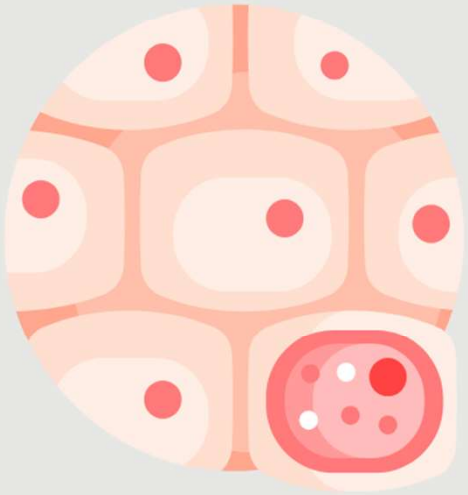
(6) **Without intervention, the viability of makers of generics and biosimilars established in the Union could be threatened**, with consequences for the Union's pharmaceutical industrial base as a whole. [...]

(7) **The timely entry of generics and biosimilars into the Union market is important, particularly in order to increase competition, to reduce prices and to ensure that national healthcare systems are sustainable and that patients in the Union have better access to affordable medicines**. [...]

15%
less than

The USA dominates the market with 40%, China surpassed the EU, now holding 20%, while the EU less than 15%

25%



Biologics represented 25% of the pharma-ceutical market value in 2022.

56%

In 2018, 56% of medicines by volume supplied in the EU were generics or biosimilars.

70%

For biosimilars, the first products to enter the market dominate, capturing over 70% of market share in 2016.

6-10
billion EUR

Increase in EU pharmaceutical trade balance over 10 years for a sample representing 32% of the relevant market.

20.000
additional jobs

Projection of over 20,000 additional jobs for that increase in pharmaceutical trade

8-10.6
billion EUR

Estimated increase of EU exports of generics and biosimilars over 10 years for a sample representing 32% of the relevant market.

1.1
billion EUR

Savings to the public health budget over 3 years due to faster market entry of generics and biosimilars

PRIOR LEGAL REGULATION

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INTELLECTUAL PROPERTY

Phase	Activity under SPC protection	Allowed?	Legal basis
Before approval	Research: acts for experimental purposes relating to the subject matter of the patented invention	✅	Research privilege according to § 11 No. 2 PatG
	Production for the purpose of obtaining an MA	✅	Bolar exception according to § 11 No. 2b PatG
	Stability, BE, clinical studies, etc. for approval	✅	
	Preparation and submission of a generic dossier	✅	
After approval	Manufacture of products, including related acts, for export to non-EU countries without patent/SPC protection	🚫	SPC Regulation (EC) No. 469/2009
	Manufacture and storage of products including related acts for a Day 1 launch within the EU	🚫	SPC Regulation (EC) No. 469/2009

PRIOR LEGAL REGULATION

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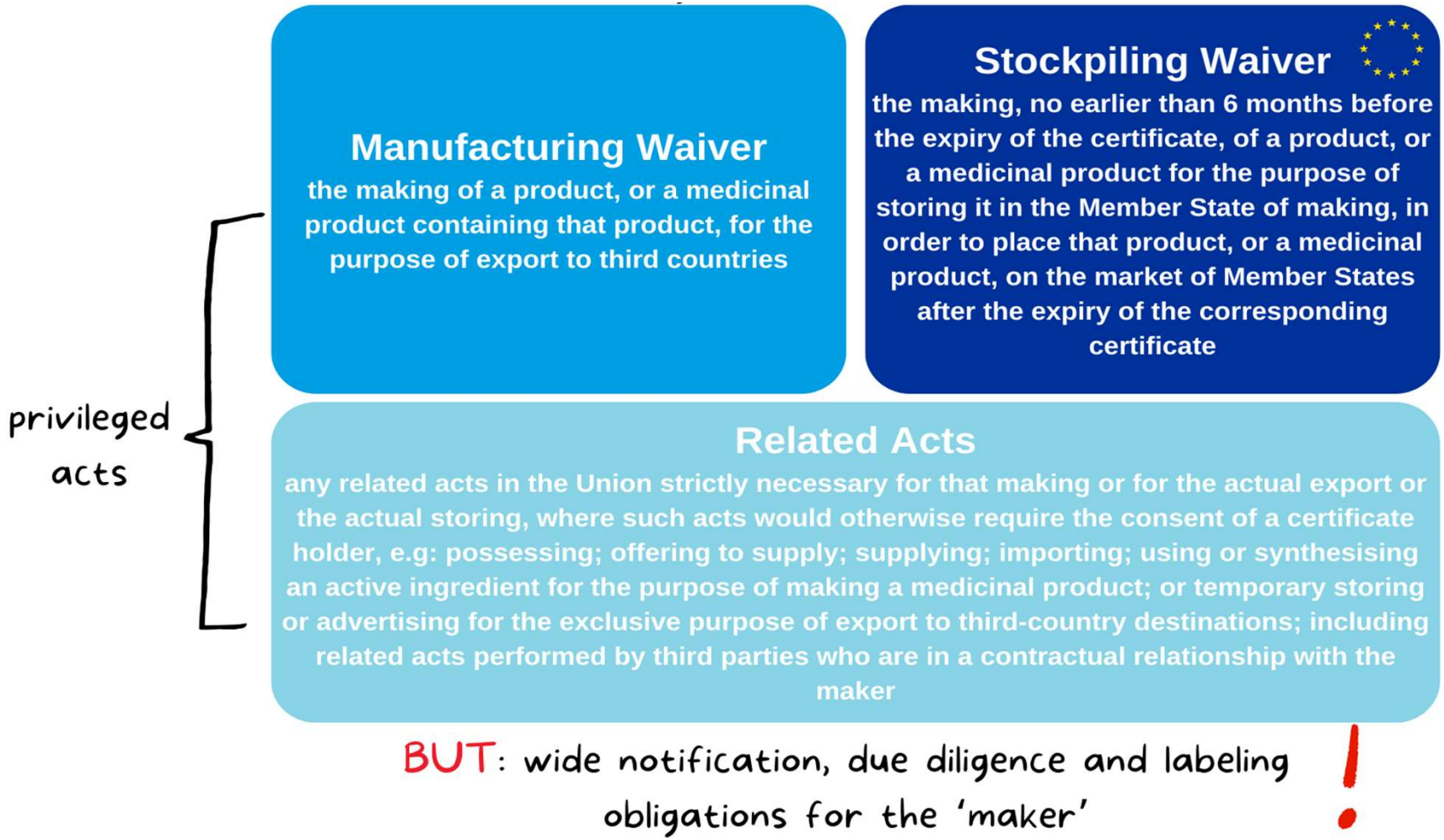
	Production for the purpose of obtaining an MA	✅	Bolar exception according to § 11 No. 2b PatG
	Stability, BE, clinical studies, etc. for approval	✅	
	Preparation and submission of a generic dossier	✅	
After approval	Manufacture of products, including related acts, for export to non-EU countries without patent/SPC protection	✅	SPC Manufacturing Waiver Art. 5 (2) (a) (i) (ii)
	Manufacture and storage of products including related acts for a Day 1 launch within the EU	✅ 6 months	SPC Stockpiling Waiver Art. 5 (2) (a) (iii) (iv)

THE SCOPE OF APPLICATION OF THE SPC WAIVER



02

SCOPE OF THE SPC WAIVER

SCOPE OF THE SPC WAIVER (1)

SPC Manufacturing Waiver for export outside the EU Art. 5 (2) (a) (i) (ii)

privileges the making of a product, or a medicinal product containing that product, for the purpose of export to third countries; or any related act that is strictly necessary for the making, in the Union, or for the actual export;"

Stockpiling Waiver for day-1 entry in the EU Art. 5 (2) (a) (iii) (iv)

privileges the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, for the purpose of storing it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or any related act thereto.

SCOPE OF THE SPC WAIVER (2)

Maker Art. 1 lit. f Regulation (EC) No. 469/2009 means

- The person established in the Union, on whose behalf making of a product or making of a medicinal product for the purpose of export to third countries, occurs.

Product Art. 1 lit. b Regulation (EC) No. 469/2009 means the active ingredient or combination of active ingredients of a medicinal product.

Medicinal product Art. 1 lit. a Regulation (EC) No. 469/2009 means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals

SCOPE OF THE SPC WAIVER (3)

Related acts Art. 5 (2) (a) (ii) (iv)

means any act in the Union, which is strictly necessary for the making or the actual export/storing if such act would otherwise require the consent of a certificate holder.

Recital 9: Strictly necessary **related acts** include (non-exhaustive list)

- Possessing, supplying, offering to supply, importing, using or synthesising an active ingredient for the purpose of making a medicinal product containing that product.
- Temporary storing or advertising for the exclusive purpose of exporting to third-country destinations.
- **Related acts performed by third parties** who are in a contractual relationship with the maker.

SCOPE OF THE SPC WAIVER (4)

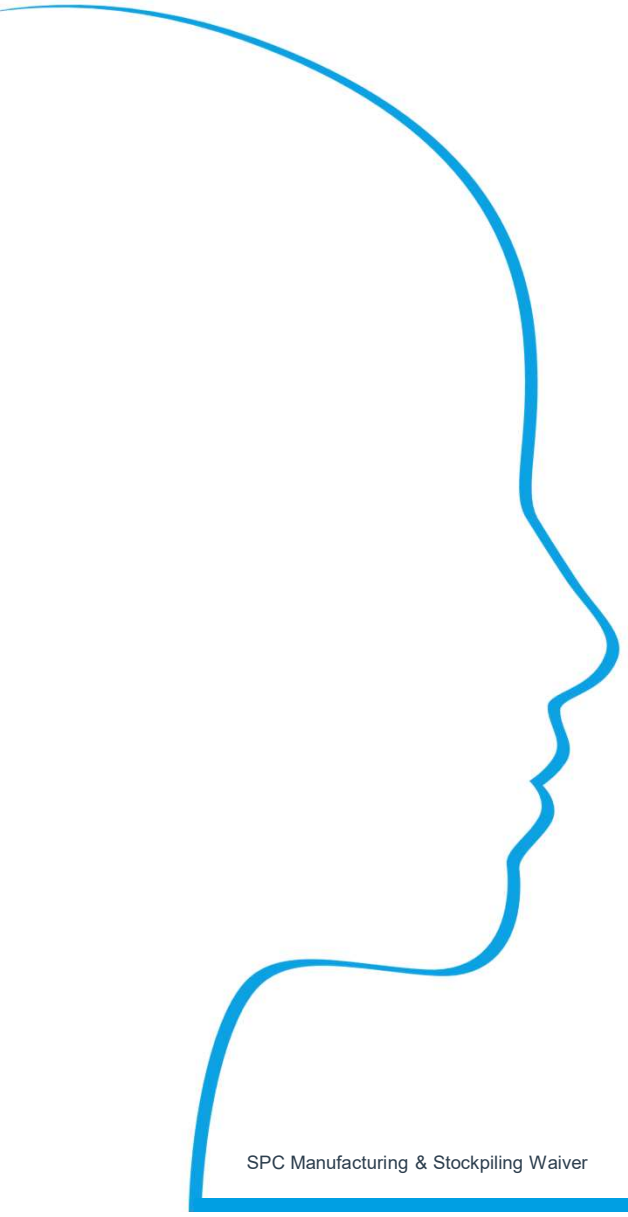
Recital 11: acts **not covered** (numerus clausus) by the exemption

- Placing a product or a medicinal product containing that product on the market of a Member State, which is made for the purpose of export to third countries.
- Storing a product or a medicinal product containing that product with a view to EU day-one entry on the market of a Member State where a certificate is in force, either directly or indirectly after export.
- Re-importation of such a product or a medicinal product containing that product into the market of a Member State in which a certificate is in force.

SCOPE OF THE SPC WAIVER (4)

Recital 11: acts **not covered** (numerus clausus) by the exemption

- Any act or activity for the purpose of import of products or medicinal products containing those products into the Union merely for the purposes of repackaging and re-exporting.
- Any storage of products or medicinal products containing those products for any purposes other than those set out in the Regulation.



03

NOTIFICATION OBLIGATIONS

NOTIFICATION OBLIGATIONS (1)

In order to invoke the SPC waiver, the manufacturer must fulfill several notification obligations to the SPC holder and the competent authorities. These notifications must be made no later than 3 months before the start of manufacture in that Member State, or no later than 3 months before the first related act is carried out (...), **whichever is earlier**.

NOTIFICATION OBLIGATIONS (2)

Pursuant to Art. 5 (5) the following information shall be given by the maker (Annex Ia of the Regulation provides for a template). Such information will be published in the patent register:

(a) the name and address of the maker;

(b) an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing;

(c) the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place;

NOTIFICATION OBLIGATIONS (3)

Pursuant to Art. 5 (5) the following information shall be given by the maker (Annex Ia of the Regulation provides for a template). Such information will be published in the patent register:

(d) the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; and

(e) for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, **as soon as it is publicly available**.

ANNEX -Ia

Standard form for notification pursuant to points (b) and (c) of Article 5(2)

Tick the appropriate box	☐ New notification ☐ Update of an existing notification	
(a)Name and address of the maker	…	
(b)Purpose of making	☐ Export ☐ Storing ☐ Export and storing	
(c)Member State in which making is to take place and Member State in which first related act (if any) prior to making is to take place	Member State of making	…
	(Member State of first related act (if any))	…
(d)Number of certificate granted in the Member State of making and number of certificate granted in Member State of first related act (if any) prior to making	Certificate of Member State of making	…
	(Certificate of Member State of first related act (if any))	…
(e)For medicinal products to be exported to third countries, reference number of marketing authorisation, or the equivalent of such authorisation, in each third country of export	…	
	…	
	…	

Annex Ia of Regulation 2019/933

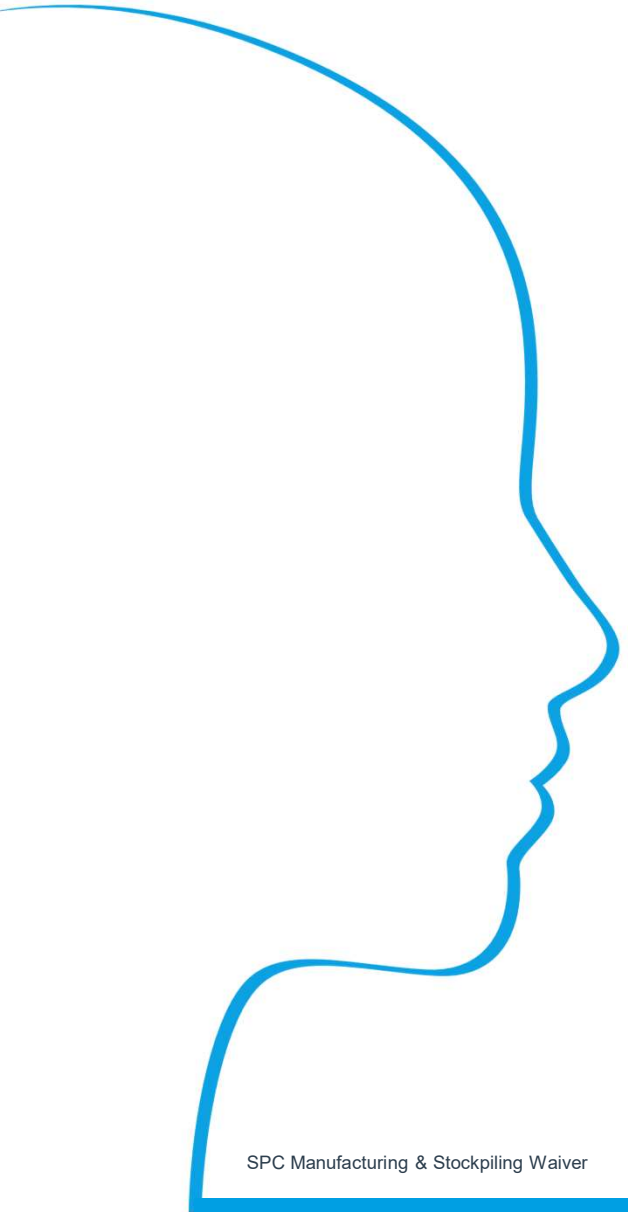
NOTIFICATION OBLIGATIONS (4)

Recital 14: "*The information should be updated as and when appropriate*."

Recital 15: The information communicated to the certificate holder must be limited to what is "necessary and appropriate" for the SPC holder to assess if its rights are respected, and "should not include confidential or commercially sensitive information"

Criticism:

- none of the exceptions in patent law recognized for third parties (not related to the patentee) require a notification of the privileged party to the patent office
- no link between the patent holder and privileged party from the application of an exception
- Obligation to notify a competitor = significant competitive disadvantage



04

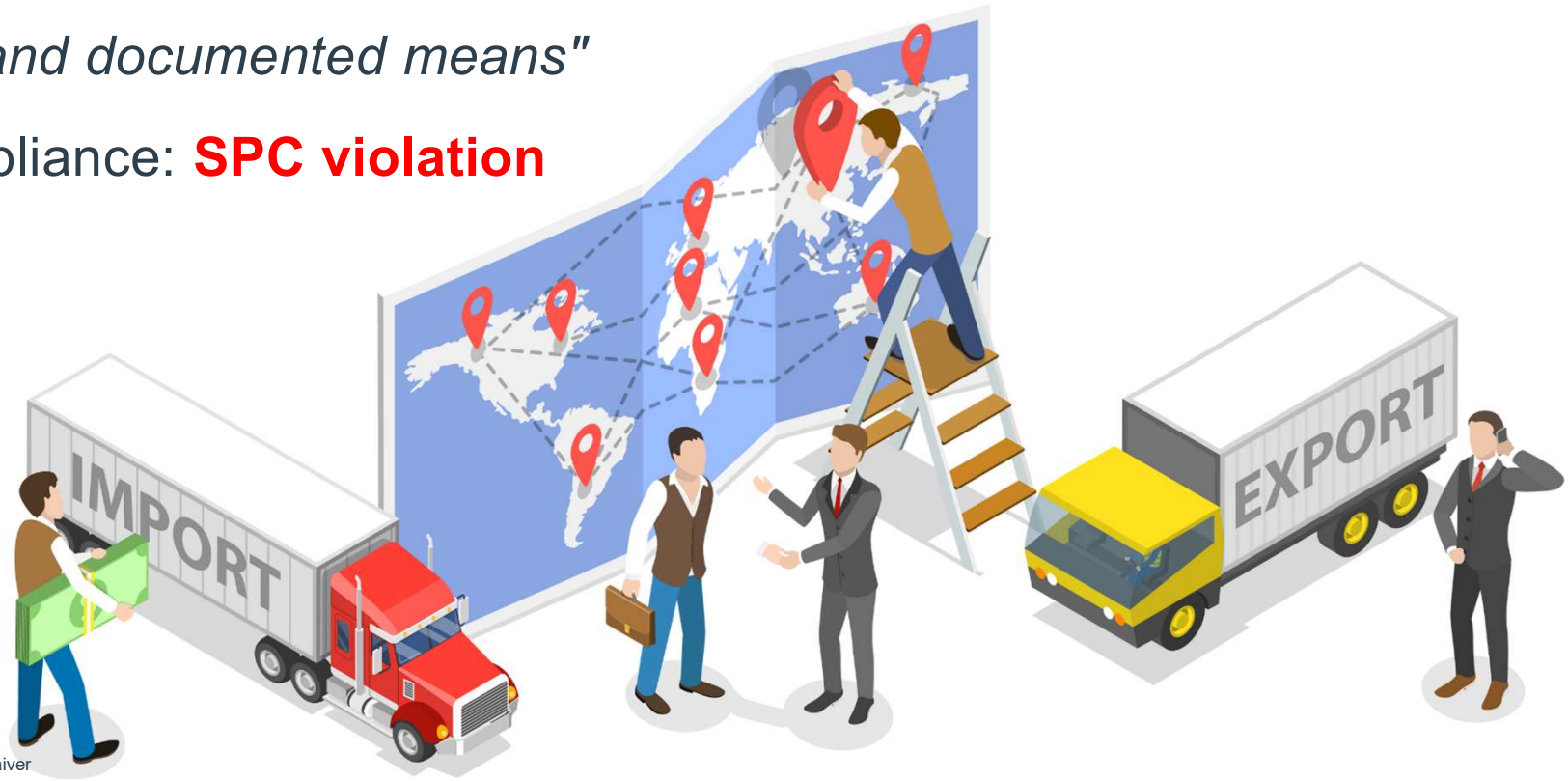
DOCUMENTATION OBLIGATIONS

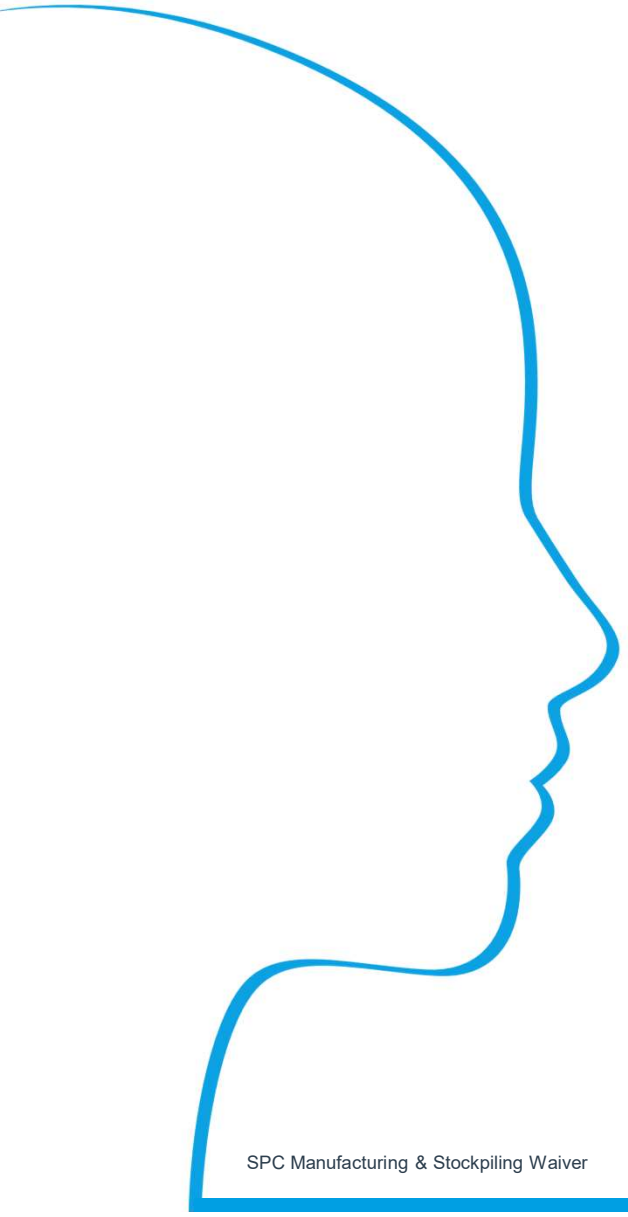
DOCUMENTATION OBLIGATIONS

The manufacturer has a **documentation obligation** towards its contractual partners in accordance with Art. 5 (9) Regulation (EU) 2019/933:

"by appropriate and documented means"

Risk of non-compliance: **SPC violation**





05

LABELING OBLIGATIONS

LABELING REQUIREMENTS (1)

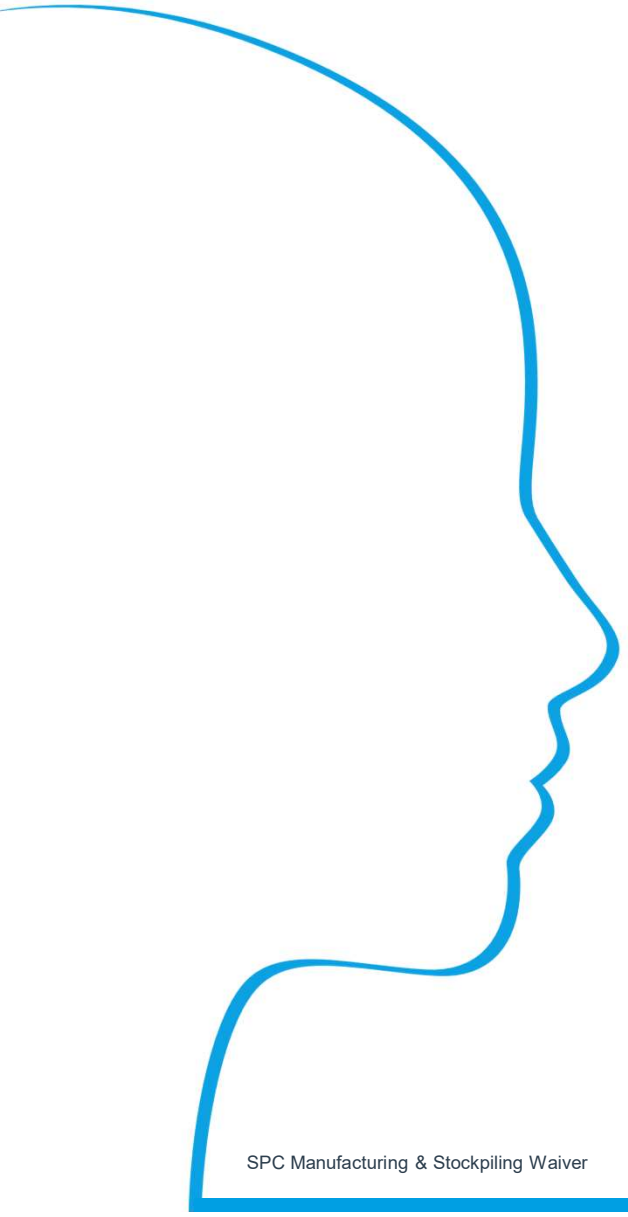
- According to Art. 5 para. 2 lit. d, the Regulation stipulates that the manufacturer shall ensure that a logo in the form described in Annex I is affixed to the outer packaging of the product intended for export to third countries or of the medicinal product containing this product and, where feasible, to the immediate packaging;

- The label (Annex 1) must be in **black color** and in be affixed in a size that is sufficiently visible:

- According to Art. 5 para. 8, manufactured medicinal products intended for export to third countries may not bear an active unique identifier within the meaning of Commission Delegated Regulation (EU) 2016/161.

LABELING REQUIREMENTS (2)

- No case law on when non-feasibility is deemed to exist
- Risk for the manufacturer, who bears the burden of proof for non-feasibility if only the "outer packaging" is labeled.



06

OPEN QUESTIONS

OPEN QUESTIONS

1. Interpretation of the term "third country" in relation to the manufacturing waiver in Art. 5(2) lit (a) (i) ?
2. What exactly is meant by the term "any person having a contractual relationship with the manufacturer" according to Art. 5 (9) of the Regulation?
3. How is the 6-month period of the stockpiling waiver calculated if the (national) SPCs expire at different times within the EU?
4. What is meant by Member State of making within the meaning of Art. 5 para. 2 lit. a (iii)?

OPEN QUESTIONS

5. IP Status in export countries - what is meant by Recital 18 sentence 2?

"[…] ***It <u>should</u> be the responsibility of the maker*** *established in the Union* ***<u>to verify that protection does not exist</u>*** *or has expired* ***<u>in a country of export</u>****, or whether that protection is subject to any limitations or exemptions in that country."* *(Rec. 18, 2nd sentence)*

OPEN QUESTIONS

5. IP Status in export countries - what is meant by Recital 18 sentence 2?

Third Revised Proposal (Brussels, 22 November 2018, 14647/18) :

"While noting that it is obviously not the intention of the proposal to encourage the infringement of IP rights in third countries, ***the Presidency has <u>not</u> included this suggestion as, inter alia, it is <u>not the role of a court in the Union to investigate the legal situation of the product to be exported in third countries.</u>***"

OPEN QUESTIONS

6. What information must the manufacturer disclose in relation to an intended export to third countries?

- Recent cases in Munich and The Hague address Article 5(5)(e) of the SPC Regulation regarding information on exporting third countries.
- Originally, the Draft Regulation required disclosing intended third countries, but it was amended to only require the MA reference number after publication.
- In the final version, Art. 5(5)(e) reads:

> „[…] *the reference number of the marketing authorization [….] in each exporting 3rd country* ***as soon as it is publicly available***".

OPEN QUESTIONS

6. What information must the manufacturer disclose in relation to an intended export to third countries?

- Recital 17: "„[…] *the notification should be updated without delay by including the number of that marketing authorization or equivalent*."
- Munich district court required specifying MA in notification to be effective.
- The Hague court supported submitting notifications without it.
- In a nutshell, the Munich Court argued that the originators would need to be able to check whether their rights are infringed, while the Hague Court emphasized fair competition and confidentiality protection as emphasized in the legislative history.

OPEN QUESTIONS (4)

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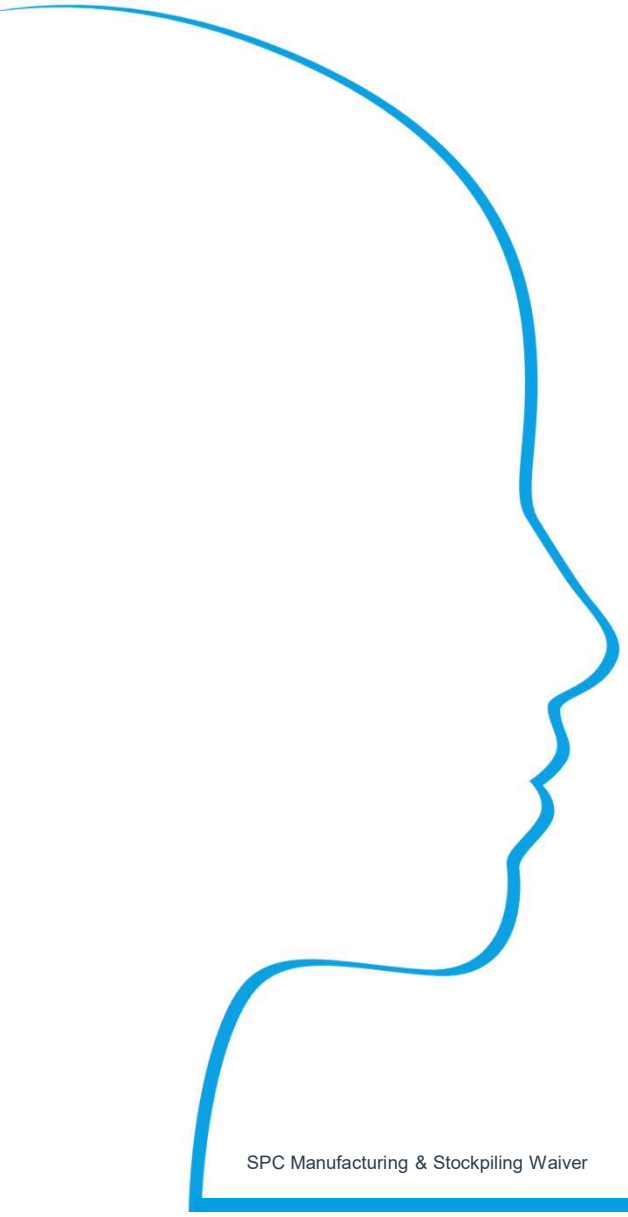
7. How long is **storage** permitted **under the manufacturing waiver**?

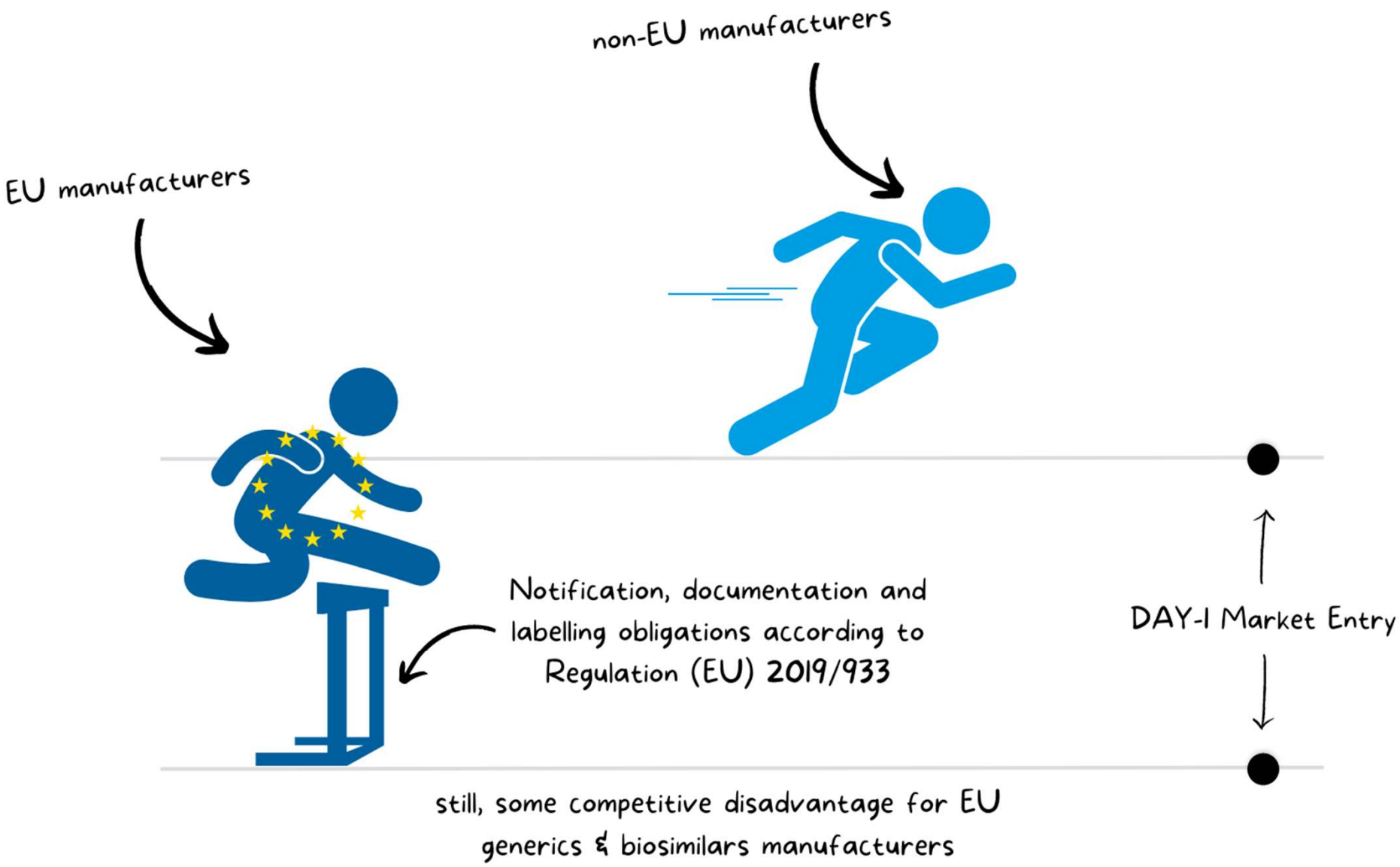
- The Regulation's operative part does not specify a time limit for storage under the export waiver.
- Recitals and legislative history indicate no intention for time limits on storage duration.
- The manufacturing waiver wasn't meant to have time limits for storage duration, only for the initiation of acts.
- Labeling requirements mitigate the risk of diversion by ensuring products under the export privilege cannot be placed on the EU market.
- The risk of diversion is addressed through labeling requirements, as highlighted in the Impact Assessment



07

WRAP-UP

WRAP UP


non-EU manufacturers
EU manufacturers
Notification, documentation and labelling obligations according to Regulation (EU) 2019/933
DAY-1 Market Entry
still, some competitive disadvantage for EU generics & biosimilars manufacturers

more than 50%

Over half of responding companies have utilized at least one SPC manufacturing waiver.

Business Impact

Majority of respondents rated the impact on their business between 6 to 9 out of 10.

Positive Effects when Waiver is used

SPC Waiver Usage

25 ✓

24 ✗

Companies decided to manufacture in Europe for 25 products but not for 24 products.

600 million €

One company invested EUR 600 million and created 300 new manufacturing jobs.

Medicines for Europe, Review of the SPC Manufacturing Waiver: a First Industry Report June 2023

Q&A

WRAP-UP

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Managing IP

Risk of SPC waiver counterattack makes generics extra cautious

Rory O'Neill July 21, 2022

The EU's landmark SPC waiver has taken full effect, but generics still have plenty of legal obstacles to navigate

"double-edged sword"

"DELICATE BALANCING ACT"

"It will change the game a bit."

"YOU COULD PUT OUT THE FLAME WHILE IT'S STARTING BEFORE IT GOES INTO FULL BLAST".

THANK YOU FOR YOUR TIME AND ATTENTION

Dr. Marco Stief
stief@maiwald.eu

Dr. Marco Stief, LL.M. (University of Chicago)

Marco Stief is a partner in the Maiwald law firm and head of the legal department. His expertise covers all aspects of intellectual property, with a focus on industrial property rights and advising on contractual matters with a technical background.

Marco Stief has nearly 25 years of experience in international and national patent infringement cases and also regularly advises companies on complex IP transactions and a wide range of technology agreements. He also advises on issues of competition law, employee invention law and the infringement of trade secrets.

Marco Stief is a lecturer at the Technical University of Dresden, the Technical University of Munich and the University of Marburg. He is the editor and/or author of numerous specialist publications, including the "*Handbuch des Patentrechts*" (published in German and English) and editor and co-author of the "*Rechtshandbuch Chemie-, Pharma- und Life-Sciences-Patente*“, editor and co-author of the „*Supplementary Protection Certificates (SPC)*“ handbook and co-editor and co-author of the „*Contract Manual – Pharma and Life Sciences*“.

In the course of his career, Marco Stief has received numerous awards from JUVE, Chambers, Legal 500, MIP IP Stars, IAM 300 (World's Leading IP Strategists) and IAM 1000 (World's Leading IP Litigators), WirtschaftsWoche and many others. Best Lawyers/Handelsblatt has repeatedly recognized him as one of "Germany's Best Lawyers" and Who's Who Legal as one of the top 6 German patent lawyers.

Dr. Marco Stief, LL.M. (University of Chicago)
Partner | Rechtsanwalt (Attorney at Law)
Vertreter vor dem EPG (UPC)

Maiwald GmbH | Elisenhof, Elisenstraße 3 | D-80335 München
T +49 (0)89 747266-0 | D +49 (0)89 747266-281 |
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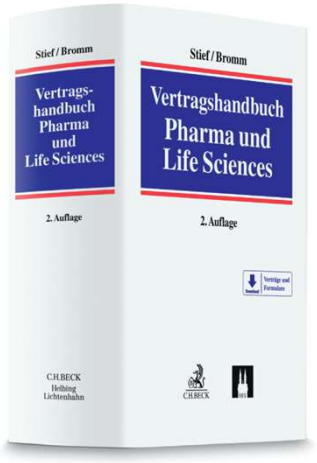

Stief / Bromm
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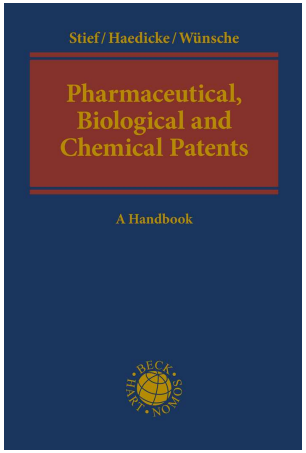

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C.H.BECK. ISBN 978-3-406-64855-7; April 2024
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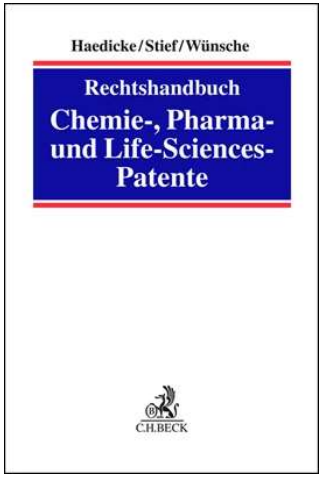

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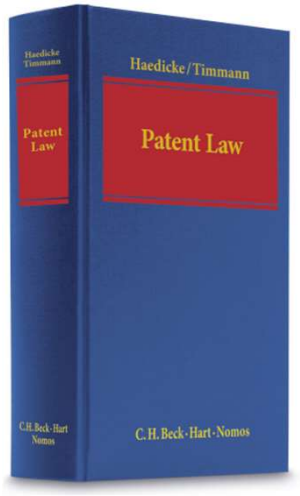
“*Legal Handbook Chemical, Pharmaceutical and Life Sciences Patents*”
Hardcover
1st edition, 350 pp, 2023
C.H.BECK
ISBN 978-3-406-78599-3



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2nd edition, LXXV, 1761 pp, 2020
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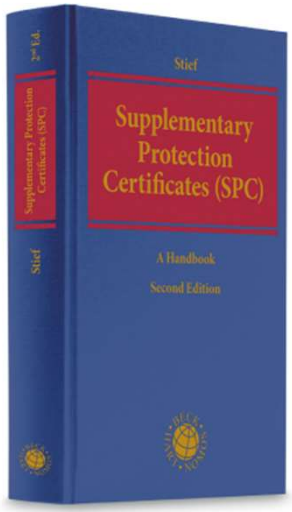

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Maiwald Patentanwalts- und Rechtsanwaltsgesellschaft mbH
Dr. Marco Stief, LL.M., Elisenhof, Elisenstraße 3 | 80335 Munich
T +49 (0)89 747 266 0 | stief@maiwald.eu | mail@maiwald.eu

www.maiwald.eu