

Abel+Imray

FICPI Open Forum Vienna

The SPC Manufacturing Waiver

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The SPC Waiver

- + What is it?
- + Why has it been created?
- + How will it operate?
- + What safe guards are in place?
- + When will it start?
- + Is it a good thing?



What is it?

- + It is not a “Waiver”!
- + Dictionary:
 - “refrain from insisting on or using (a right or claim)”
- + The SPC waiver is not a freely given up right by the right-holder. The legislation removes a right.
- + Other languages are more accurate:
 - “Ausnahmeregelung für die Herstellung”
 - “dérogation pour la fabrication”
 - “esonero per la fabbricazione”

What is it?

- + It is a limitation on the acts that can be prevented by an SPC:
 - SPC cannot be enforced against a party manufacturing in the EU for export to outside the EU.
 - SPC cannot be enforced against a party manufacturing or making other preparations for launch in the EU in the last 6 months of the SPC's term

Why has it been created?

- + To redress the perceived relative disadvantage of generics producers in the EU compared to those outside:
- + For example:
 - Patent and extensions have expired in Canada, but SPC still in force in EU
 - Manufacturers in Canada or India can compete for Canadian market, but manufacturers in the EU cannot
 - Manufacturers in Canada or India can prepare product for launch in EU after expiry of EU SPCs, but manufacturers in the EU cannot
- + The waiver is intended to put EU-based manufacturers on a level footing with those based outside the EU

How will the waiver operate?

- + Set down in Regulation 2019/933 of 20 May 2019
- + Mostly, it amends Art 5 of the SPC Regulation (469/2009) creating two classes of exemption:
 - The making of a product, or a medicinal product containing that product, for the purpose of export to third countries.
 - The making, no earlier than six months before 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 medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate.
- + In both cases, the waiver includes related acts strictly necessary for the making or storing

How will the waiver operate?

- + As first step, the maker must notify the SPC holder and the national IP office three months before starting the acts that would otherwise be an infringement.
- + A standard form has been provided in ANNEX-Ia to the regulation:

How will the waiver operate?

+ Standard Form:

ANNEX -Ia

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

Tick the appropriate box	<input type="checkbox"/> New notification <input type="checkbox"/> Update of an existing notification	
(a) Name and address of the maker	...	
(b) Purpose of making	<input type="checkbox"/> Export <input type="checkbox"/> Storing <input type="checkbox"/> 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	...	
	...	
	...'	

How will the waiver operate?

- + Logo is to be applied:

'ANNEX -I

Logo

This logo shall appear in black and in such a size as to be sufficiently visible.



- + Maker has an obligation to ensure any person in a contractual relationship is fully informed
- + National IP office shall publish the notification as soon as possible

When will it start?

- + The Waiver does not apply to SPCs that took effect before 1 July 2019
- + For certificates applied for before 1 July 2019 but not coming into effect after 1 July 2019, the Waiver applies from 2 July 2022
- + For all certificates applied for after 1 July 2019, the Waiver applies immediately

The obligatory Brexit slide

- + Will the Waiver happen in the UK in the event of a 'no deal' Brexit?
- + Probably yes
- + The UK Government has published draft legislation using the same text as the EU Regulation but with 'the Union' replaced with 'the UK and the Isle of Man'
- + For the UK, the EU will then be 'export' and vice versa



Is the waiver a good thing?

- + It is a removal of previous rights, so a net loss for originators
- + Is the balance different for 'biologics'?
 - Complicated products that currently only originators can make
 - Does the ability to export biologics give a boost to EU pharma?
- + Does waiver increase the value of 'secondary' patents?
- + Or, will the effect of the waiver be smaller than the Commission expects?

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Thank you!

Any questions?