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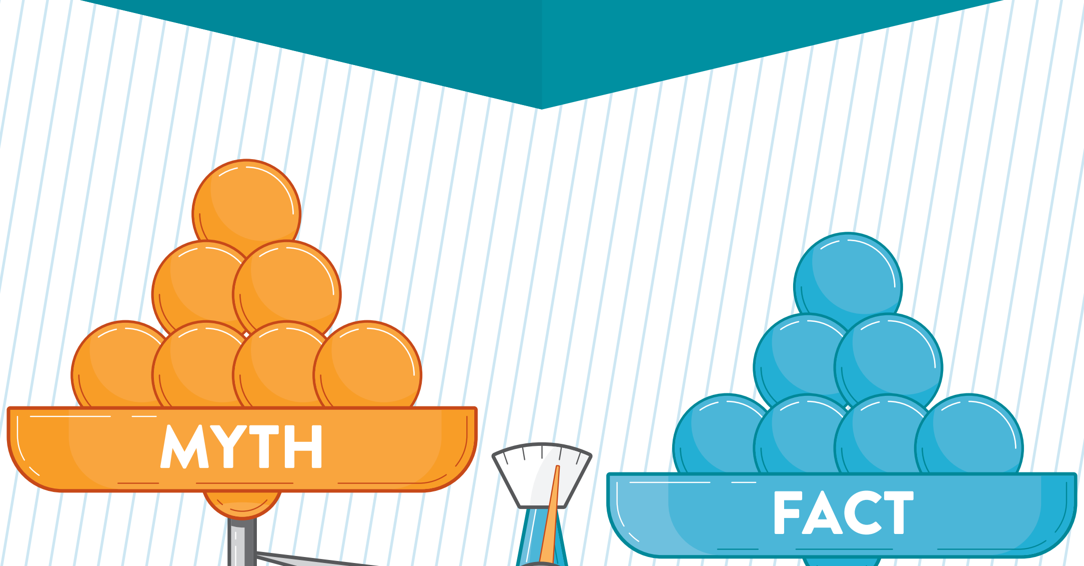
SPC WAIVER

SETTING THE RECORD STRAIGHT



DID YOU KNOW?

Countries with the highest level of IP right protection for pharmaceuticals, including SPC, attract the lion's share of R&D investments[1].

The SPC regime also exists in the USA and Japan, global leaders in pharmaceutical innovation and the EU's main competitors in this area[2].

China is currently considering the introduction of an SPC regime to increase its global attractiveness for pharmaceutical R&D investments[3].

Illustrating the economic value of the EU's SPC regime, research has shown that the reduction of IP rights results in job losses. One particular study evaluated the reduction of the SPC to lead to the loss of more than 120,000 jobs[4].

Generic companies employ 160.000 employees[5].
Innovative pharmaceutical companies employ 745,000 people and generate three to four times more employment indirectly[6]. Innovative companies also invest an estimated €35 billion in R&D per year in Europe.

90% of EU trade stems from IP right-intensive industries, generating a trade surplus of €96b per year for the EU[7].

[1] US Chamber International IP Index. 'The roots of innovation' (2017); OECD database (accessed 2017).
[2] Preamble of Regulation No 469/2009, paragraph (3); Explanatory Memorandum of Council Regulation (EEC) concerning the creation of an SPC for medicinal products. 11 April 1990.
[3] — State Council of China of 12 April 2018 presided by Premier Mr. Li Keqiang ("Breaking News on New Policies of Innovative Drugs in China", Lexology)
— General Office of the Communist Party of China "The Opinion on [...]Encouraging the Innovation of Drugs and Medical Devices 8 Oct. 2017.
[4] Europe Economics "Cost to European Patented Medicines Sector of Switch to Canadian Patent Extension Framework" March 2018
[5] Medicines for Europe, "Who we are".
[6] EFPIA, "The pharmaceutical industry in figures" (2017)
[7] EUIPOI. 'Intellectual Property Rights-intensive industries and economic performance in the EU' (2016)

1

MYTH: The SPC waiver does not erode or change Intellectual Property (IP) protection in any way[a].

FACT: By allowing manufacturing during the exclusivity period, the SPC waiver would in fact be rolling back on the level of IP rights granted to innovators.

2

MYTH: Reducing IP rights would accelerate access to medicines[b].

FACT: Robust standards of **IP protection enable investments in R&D** needed to develop innovative treatments. Greater investments in healthcare accelerates access to medicines[c].

3

MYTH: Reducing the scope of the SPC will accelerate the launch of generic products in the EU.

FACT: Today, generic products can legally be launched in the EU on day one after the expiry of exclusive rights.

4

MYTH: An SPC waiver would increase the EU's trade balance[a].

FACT: The shift to exporting low-priced generics instead of high-value treatments would reduce the value level of European trade[e].

5

MYTH: The SPC waiver would generate thousands of jobs in Europe[d].

FACT: Leading economists contested this claim in a number of critical reviews[e]. According to one study, the SPC waiver would lead to significant annual job losses (direct job losses 4,500-7,700; indirect job losses 19,000-32,000) in the innovative industry and to a decrease of investments in R&D (€215m-€363m)[f].

6

MYTH: The SPC waiver will allow generic manufacturers to produce in the EU[g].

FACT: The most sophisticated part of manufacturing drugs is the production of the active substance (as opposed to packaging). The active substance is often and increasingly sourced from outside the EU where manufacturing costs are lower[h]. The SPC waiver will not change the ability of generic companies to source APIs from outside the EU.

7

MYTH: Biosimilar manufacturers welcome the introduction of an SPC waiver.

FACT: The majority of biosimilar products are produced by innovative companies[i]. These companies support a system that promotes innovation and allows competition after expiry of exclusivity.

FINAL WORD:

THERE ARE NEARLY 7,000 MEDICINES IN DEVELOPMENT TODAY.
74% ARE POTENTIALLY FIRST IN CLASS AND 100% ARE BASED ON STRONG IP RIGHTS.

References:

[a] Medicines for Europe, "Supplementary Protection Certificate (SPC) Manufacturing Waiver Benefits & Myths" (October 2017).
[b] Medicines for Europe, The impact of SPC manufacturing waiver on jobs, competitiveness, & patient access to medicines (February 2018).
[c] IFPMA, EFPIA, PhRMA and JPMA, Contribution: the value of intellectual property for access to medicines (February 2016).
[d] Medicines for Europe, The impact of SPC manufacturing waiver on jobs, competitiveness, & patient access to medicines (February 2018).
[e] Office of Health Economics (OHE), Review of CRA's Report "Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe" (January 2018).
[f] Pugatch Consilium, "UNINTENDED CONSEQUENCES: How introducing a manufacturing and export exemption to SPCs would weaken global standards of IP protection and result in direct losses to Europe's research-based biopharmaceutical industry." (October 2017)
[g] Medicines for Europe, The impact of SPC manufacturing waiver on jobs, competitiveness, & patient access to medicines (February 2018).
[h] Zion Market Research, Worldwide trends in active pharmaceutical ingredient market size will reach USD 213.84 Billion by 2021 (April 2018).
[i] European Medicines Agency's European Public Assessment Reports data base.

A QUICK REFRESHER:

As part of the Single Market Strategy review, the European Commission is proposing an "SPC manufacturing waiver". This would allow generic manufacturers to produce a pharmaceutical product during the exclusivity period granted by the SPC.

A better way to describe the waiver would be to call it a "manufacturing exemption". The term "waiver" indicates the willingness of the property holder to relinquish exclusive rights.

SPC

THE SUPPLEMENTARY PROTECTION CERTIFICATE IS

an extension of the patent term to *partially* compensate innovators for the substantial patent time lost during the lengthy clinical tests and trials required to secure regulatory approval.

SPCs are a critical part of the European Intellectual Property rights framework. They have played a key role in the development of innovative medicines for European patients. At the end of the SPC, these innovative medicines become generic.

HOW DOES IT WORK? TWO CASES TO ILLUSTRATE

PATENT FILED	PRODUCT ON THE MARKET	PATENT EXPIRES
8 YEARS Time for product development	12 YEARS Time for commercialisation of patent	3 YEARS SPC Max Term

15 years maximum from first marketing authorisation in the EU/EEA

PATENT FILED	PRODUCT ON THE MARKET	PATENT EXPIRES
10 YEARS Time for product development	10 YEARS Time for commercialisation of patent	5 YEARS SPC Max Term

15 years maximum from first marketing authorisation in the EU/EEA*

* ECIPE Policy Brief #4/2017 based on Pharmaceutical Compliance Monitor (2013).