Briefing note on supplementary protection certificates

Threatening access to affordable medicines across the European Union

Since the requirement of patent protection on pharmaceutical products through the World Trade Organization's Agreement on Trade-Related Aspects of Intellectual Property Rights (the TRIPS Agreement) in 1995, there has been enormous pressure for all countries, including across the European Union, to further restrict the legal and policy channels that are beneficial to safeguarding access to generic medicines.

Supplementary protection certificates (SPCs) are one such example of an additional monopoly right, intended to expand monopoly protection for medicines beyond the twenty-year patent term. By prolonging the monopolies of originator pharmaceutical companies, SPCs lead to unaffordable medicines prices that prevail for longer periods of time – threatening the sustainability of national healthcare systems and delaying patients' access to lifesaving medical innovation.

Presently, the European Commission is reviewing the SPC mechanism established by Regulation EC No. 469/2009. As civil society organisations working on access to medicines and public health[*], we have witnessed the detrimental impact of some intellectual property rules on access to affordable medicines. We recommend that the European Commission focus this enquiry on how SPCs contribute to high medicines prices and therefor undermine universal access to treatments patients need. We recommend that the European Commission abolish the SPC mechanism, and refrain from encouraging SPCs and similar mechanisms through free trade agreements.

How supplementary protection certificates unfairly expand monopoly protection for new medicines and result in unaffordable medicine prices for longer periods of time

Prolonged exclusivity through SPCs has consistently delayed the availability of generic and biosimilar medicines in Europe, upsetting the balance between the commercial interests of pharmaceutical companies and the public interest of patients across Europe. For example, as shown in Table 1, generic versions of some key antiretroviral medicines for the treatment of HIV/AIDS have been widely used in other countries for the past 10 years; however, they remain unavailable in Europe – even after the expiration of primary patents – due primarily to the extension of exclusivity through SPCs.

Table 1: Generic versions of key antiretroviral medicines for treatment of HIV/AIDS unavailable in Europe due to SPCs

Medicine	European patent expires	SPC extension	Generics available in global market since
abacavir/lamivudine	Mar 2016	Dec 2019	2006
Atazanavir	Apr 2017	Apr 2019	2008
Raltegravir	Oct 2022	Jan 2023	2015

[*] For a list of co-signing organisations, see the letter to the commission on the open submission on supplementary protection certificates for medicinal products in the European Union.

Broad intellectual property rules facilitate the so-called ‘evergreening’ strategies of pharmaceutical companies. Evergreening strategies are employed by pharmaceutical companies to extend market monopolies through a variety of means, including filing multiple patents on one medicine or pursuing prolonged patent terms. The broad and ambiguous scope of SPCs enables and reinforces evergreening strategies. First, multiple SPCs can be issued for the same product. SPCs for the same product can be granted to multiple companies if each company has a patent on the product. The issuance of multiple SPCs for the same product can also be used by a single company to expand its monopoly. Companies link their strategy for patenting minor changes to old medicines as closely as possible to their strategy for applying for an SPC on those minor changes. This allows companies to avoid generic competition and to charge higher prices to patients and governments for longer periods of time, even as affordable and equivalent generic and biosimilar versions of new medicines have been launched outside of the European Union. The lack of SPCs in these other countries means that generic competition can be initiated. Earlier generic competition is all the more critical, since dramatic price reductions due to generic competition can take a few years.

Table 2 (below) demonstrates the specific impact that SPCs have had on the price of medicines used to treat HIV and AIDS, cancer, and hepatitis C by comparing the prices of such products in 10 European countries with the prices of generic and biosimilar versions of the same products in India. For example, due to an additional monopoly granted by SPCs, there was a 10-year delay for European countries to import or produce generic versions of imatinib mesylate, a medicine used to treat leukaemia. Even the lowest current generic price of imatinib mesylate in 10 European countries is up to three times more expensive than the equivalent generic price in India, where generic competition began much earlier.

Table 2: Impact of SPCs on the price of medicines for the treatment of HIV/AIDS, cancer, and hepatitis C

Medicine [*]	European patent expires	SPC extension (France)	Generic/ biosimilar available in global market since	Prices (€) in European countries [†]										Prices (€) in India for generics/ bio-similars [†]
				The Netherlands [I]	Belgium [II]	Luxembourg [III]	U.K. [IV]	Portugal [V]	Denmark [VI]	Hungary [VII]	Norway [VIII]	France	Germany [IX]	
trastuzumab powder for injection From Roche	Jun 2012	Jul 2014	2013 (India)	590	556	1582	456	--	762	561	688	499 [X]	826	**169** [XI] From Mylan, Biocon
sofosbuvir From Gilead	Mar 2028	Jan 2029	2014 (India)	14487	14487	13667	13060	15181	19731	--	16698	9567 [XII]	16809	**210** From Gilead **91** From generic suppliers [XIII]
tenofovir/ emtricitabine (TDF/FTC) From Gilead	Jul 2017	Feb 2020	2007 (India)	535	527	512	398	--	1113	481	604	347 [XIV]	820	**4 – 5** [XV] From Hetero, Strides, Cipla, Aurobindo, Macleods
imatinib mesylate From Novartis or its generic company, Sandoz	Mar 2013	Dec 2016	2003 (India)	2584	984	956	2180	2354	2909	2146	2843	1843[‡] [XVI]	3408	**25** From Natco [XVII] **36** From Cipla [XVIII]
From generic suppliers [§]			→	2241	984	955	--	2354	80	839	--	987	3057	

[*] Product details: trastuzumab powder for injection - 150mg in vial, one vial; sofosbuvir - 400mg tablet, bottle of 28 tablets; tenofovir/emtricitabine (TDF/FTC) - 300/200mg tablet, bottle of 30 tablets; imatinib mesylate - 400mg tablet, bottle of 30 tablets.

[†] Prices rounded to nearest whole euro. The prices indicated are the prices publicly available online as indicated in the references. The prices may not necessarily account for discounts or deals made between governments, pharmacies or hospitals and individual companies.

[‡] Three generic products have been approved in France but not marketed.

[§] The Netherlands, Belgium and Denmark: Accord Healthcare; Luxembourg: Eurogenerics; Portugal: Pharmoz; Hungary: Teva; France: multiple suppliers [XIX]

[I] https://www.medicijnkosten.nl
[II] http://ondpanon.riziv.fgov.be/SSPWebApplicationPublic/nl/Public/ProductSearch
[III] http://www.cns.public.lu/en/legislations/textes-coordonnes/liste-med-comm.html
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[XVIII] http://www.cips.org.in/documents/2015/March/Half-day/Srinivasan.pdf (public sector prices)
[XIX] http://www.lepharmacien.fr/produitafine/medicament/substance/909?page=1

SPCs are in direct conflict with policies for accelerating access to medicines and lack flexibilities for responding to public health needs

The SPC mechanism directly conflicts with mechanisms designed to accelerate the introduction of generic and biosimilar medicines. Under current European Union regulations, there is no linkage between patent status and the regulatory approval process for medicines as patent linkage restricts competition.[1] In addition, Directive No. 2004/27/EC introduced the Bolar exemption,[2] allowing early review and approval of applications from generic producers by the regulatory authorities before the patent terms expire. While these policies aim to accelerate generic and biosimilar entry and thereby reduce medicine prices, SPCs delay the entry of generic and biosimilar alternatives, which is associated with higher prices for new medicines that prevail for longer periods of time.

Furthermore, mechanisms to oppose the granting of SPCs should be bolstered. Third-party observations should be allowed during the examination procedure for SPC applications and an opposition procedure, opened to anyone, should be made available after an SPC is granted.

There is no public health justification for supplementary protection certificates

The introduction of SPCs was initially and partly justified in order "to meet the innovative pharmaceutical concern that they were no longer given a fair opportunity to recover their Research and Development efforts and investments".[3] We disagree with this premise. First, studies demonstrate that the expansion of patent and market exclusivity protection on medicinal products worldwide has not addressed unmet medical and public health needs.[4] Instead, the use of patents encourages pharmaceutical companies to prioritise research and development (R&D) that responds only to profitable markets rather than unmet medical needs.[5] Experiences in other countries have also shown that there is no evidence of increased investment, or visible incentive to innovate for novel pharmaceuticals after the introduction of extension of patent terms.[6]

Second, evidence suggests that, in practice, drug prices do not reflect R&D costs – whether claimed or estimated.[7] Reported figures consistently indicate that prices charged by pharmaceutical companies globally significantly exceed the actual cost of R&D.[8] In fact, pharmaceutical companies have too much power to both recover their investments and earn outsized returns for new pharmaceutical products. Recent academic studies illustrate that companies are increasingly allocating revenues from high drug prices to share buybacks and dividends that boost executive and shareholder compensation. This indicates that most companies are earning returns that both accommodate their prior and future R&D investments and also enable them to pay executives and shareholders excessive compensation.[9] In many cases, annual expenditure on share buybacks and dividend payments exceed companies' R&D investments.[10] From 2006 to 2015, Gilead Sciences, the patent holder for sofosbuvir and many antiretrovirals for HIV, spent US$27 billion on share buybacks and dividends, and only US$17 billion on R&D.[11] Over the same 10-year period, 18 large pharmaceutical companies collectively spent US$516 billion on buybacks and dividends, and only US$465 billion on R&D.[12]

SPCs misinterpret the reality of the time span between regulatory process and patent filing

One of the major justifications for introducing the SPC mechanism has been that "the period that elapses between the filing of an application for a patent for a new medicinal product and authorisation to place the medicinal product on the market makes the period of effective protection under the patent insufficient to cover the investment put into the research"[13] and this could "lead to a lack of protection which penalises pharmaceutical research".[14] This assertion is fundamentally flawed. In particular, SPCs increase medicine prices for governments and patients by expanding monopolies if and when regulatory agencies take the requisite time to protect public safety and public health by carefully assessing the safety, efficacy and quality of medicines. Furthermore, the above justification to impose SPCs ignores the role companies themselves often play in prolonging the duration of review – for example by failing to provide quality data or failing to respond to queries regarding dossiers in a timely manner. Any delay in regulatory approval due to a lack of capacity or resources within a drug regulatory agency should be mitigated by empowering regulatory agencies and expanding their resources, rather than providing additional market exclusivity to drug companies that have already benefited sufficiently.

In addition, the evergreening strategy that companies exploit artificially lengthens the time lapse between patent filing and regulatory approvals. Companies normally start filing patent applications early in order to create unjustifiable 'patent thickets'. Many such patent applications are abstract and overly broad, and may not fulfil the patentability criteria that warrant a patent. In this context, companies themselves are to blame for lengthening the duration of delay between the initial patent filing and the actual initiation and completion of the regulatory process. Policy makers should take measures to safeguard against broad patent filings, including introducing stricter patentability criteria and examination practices and allowing companies to capture only a twenty-year monopoly from the initial patent filing. Introducing SPCs is the wrong solution.

Recommendations

Abolish the SPC mechanism: The European Commission should abolish the SPC mechanism from its current legislation, regulations and practices. Provisions related to patent term extension under the European Patent Convention and other bilateral trade agreements to which European Union is a party should be reviewed and suspended in light of ensuring access to affordable medicines.

Stop encouraging SPCs and similar mechanisms, such as patent term extension through free trade agreements: The European Commission must stop pushing for TRIPS-plus provisions in its negotiations of trade agreements with other countries and should remove any previously negotiated provisions in free trade agreements that bind other countries, and the European Commission, to the use of SPC and similar mechanism such as patent term extension.

In the event SPCs remain:

Bolster opposition procedures: Mechanisms to oppose the granting of SPCs should be bolstered. Third-party observations should be allowed during the examination procedure for SPC applications and an opposition procedure, opened to anyone, should be made available after an SPC is granted.

Improve transparency of market exclusivity status: The European Commission should create an easily searchable public database for consumers, procurement agencies, civil society organisations and governments to identify SPCs that have been awarded and the delays to generic competition that such SPCs will cause.

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https://www.msfaccess.org

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