

High prices, poor access: What is Big Pharma fighting for in Brussels?

Chapter 4. Patent extensions: helping keep drug prices high for longer

Monopoly prices for longer threaten access to affordable medicines

Supplementary protection certificates (SPCs) are extensions to a patent, and like patents, they give the holder a monopoly on a drug. This means they are the only ones who can make and sell it, and therefore can set the price as high as they like. For example a preventative HIV treatment called Truvada made by US firm Gilead, shows how SPCs are geared towards corporate profits rather than public health. In France Gilead was granted a highly controversial SPC on Truvada, which non-profit group AIDES estimates will cost the French public health system an additional €815 million, directly threatening the country's preventive HIV policy.¹ SPCs are an EU invention, and can be awarded to pharmaceutical (or plant protection) products to “offset the loss of patent protection... due to the compulsory lengthy testing and clinical trials” required to obtain marketing approval.² Intended to woo pharma firms to the European market by promising more time supposedly to 'recoup' R&D investments, SPCs are granted by national patent offices. Patents normally last 20 years; SPCs can extend them by five. Weak criteria for SPCs however, means they are often routinely given, delaying the entry of generic competitors and the consequent drop in price. As Médecins Sans Frontières (MSF) points out, by prolonging monopolies, “SPCs lead to unaffordable medicines prices that prevail for longer periods of time – threatening the sustainability of national healthcare systems and delaying patients' access.”³

A faulty rationale

The very rationale for SPCs is faulty: Big Pharma companies are earning huge returns on drugs, not struggling to recoup their R&D costs. Monopoly drug prices do not reflect development costs, rather, they often exceed them wildly, whilst pharma companies are spending more on share buybacks and dividend payments than they are on R&D (see Box 1). As MSF explains, broad IP rules “facilitate the so-called 'evergreening' strategies of pharmaceutical companies”, that is they help extend market monopolies and maintain high rates of profit for longer, for example by filing multiple patents on a single medicine.⁴ Finally, the notion that companies need to be compensated for the time taken by the marketing authorisation process – necessary to determine a medicine's safety and efficacy – is itself highly questionable. Not least since companies often prolong this “by failing to provide quality data” or respond to queries in a timely way. But also because, as AIDES notes, the 20 years of patent protection was never intended as an effective 20 years of monopoly, only “to provide a sufficient period

of monopoly on the market” whilst also “covering the various steps of the R&D process”, which it already does.

The distracting debate

Public health advocates like MSF argue that SPCs should be abolished.⁵ Yet at the EU level, the debate around SPCs has not focused on such fundamental questions – as how they prevent access to affordable medicines, or whether the rationale for their existence is even justifiable. Instead, the lobby battle in Brussels has merely focused on how SPCs distort competition. The generics industry has long argued that SPCs have the unintended effect of disadvantaging European generics manufacturers vis-a-vis their non-EU counterparts. EU firms cannot manufacture generic or biosimilar medicines for export to countries without an SPC (or where one has expired), but companies based elsewhere can. And, they argue that it is a competitive disadvantage to be unable to start making a drug whose SPC is due to expire, so that they are ready to enter the market on the day it expires in an EU country, whilst manufacturers from elsewhere can be. The idea of an SPC manufacturing waiver – allowing EU generics firms to manufacture an SPC-protected drug solely for export to a third country without an SPC – was designed to level the playing field for EU and non-EU generics firms. The Commission’s 2015 Single Market Strategy first floated the idea, and the Parliament, in 2016, “urged the Commission to introduce and implement before 2019 an SPC manufacturing waiver”.⁶ Numerous studies, a public consultation and an impact assessment later, and the Commission published its proposal in May 2018. A pitched lobby battle between Big Pharma and generics characterised this process, with wins and losses on both sides. For many public health groups, however, the SPC manufacturing waiver barely scratches the surface of the real changes needed; as Dimitri Eynikel from MSF notes, it “primarily seeks to rebalance the competing commercial interests of originator and generic pharmaceutical industries in Europe” not address the issue of access to affordable medicines.⁷

Big Pharma furious at even minor change to SPC

Patent-holding, name-brand drug ‘originator’ companies such as Novartis, GSK, and Pfizer have furiously lashed out at the SPC manufacturing waiver, even though it does not even alter the monopoly period provided by an SPC (so it doesn’t actually reduce their ‘reward’). EFPIA’s Nathalie Moll, for example, writes in Euractiv that the SPC manufacturing waiver sends a “damaging signal” that Europe is weakening its IP framework, whilst its competitors develop theirs, which could lead to a “perfect storm of disinvestment in R&D in Europe”.⁸ This is the usual big business argument that if you regulate us in ways we don’t like, we’ll up sticks and leave. In a letter to Commissioner Beinkowska in February 2018 EFPIA said it had “reviewed various studies” and concluded an SPC manufacturing waiver could result in a negative EU trade balance.⁹ But the “various studies” EFPIA cites as evidence are without exception funded or commissioned by Big Pharma. Namely, a report by consultancy firm Pugatch Consilium which was “commissioned by” AbbVie, F. Hoffmann – La Roche, and the US Chamber of Commerce”,¹⁰ a study by QuintilesIMS study, funded by EFPIA,¹¹ and a report by the Office for Health Economics (OHE), also commissioned and funded by EFPIA.¹² In its letter, EFPIA does not mention any of these links.

Coordinated lobby efforts

EFPIA's letter shares language with a host of other letters sent to the Commissioner from various national association members of EFPIA (Swedish LIF and Polish INFARMA) and EuropaBio (Belgian BIO.BE), which are scattered with near-identical phrasing.¹³ This cluster of apparently co-ordinated letters emphasise different, but converging elements of Big Pharma's messaging. Arguments and tactics that are also used by other, interconnected groups in their lobbying against an SPC manufacturing waiver, include:

'A threat to jobs, growth, and patients': INFARMA told the Commission any adjustment to "existing IP incentives" could be "to the detriment" of jobs, growth and patients' health in Europe. EBE also warned of job and investment losses, and lobby firm G+, on behalf of AbbVie ("in close coordination with" EFPIA), said "weakening" patent protection will undermine jobs, investments, and patient access.

'It will hurt small and medium size enterprises': EBE argued that an SPC manufacturing waiver "would be unfair" to EU biopharma SMEs which "larger companies" increasingly rely on "to secure their product pipelines".¹⁴ But EBE does not represent SMEs' interests; its members are the biggest of Big Pharma companies, with pockets full of the monopoly profits from SPCs.¹⁵ Biotech lobby ICBA said "weakening the SPC" will "damage the viability" of European biotech SMEs, as SPCs provide 'certainty' to investors ("venture capitalists and larger companies").¹⁶ ICBA's letter was signed by EuropaBio – which represents many Big Pharma firms – and nine of EuropaBio's members.¹⁷ EUCOPE, the association for pharma SMEs, claimed the Commission had "shown a fundamental disregard" for SMEs' interests by "prioritising the input of larger market players". This is despite the fact that Big Pharma also objected to the waiver, and that EUCOPE shares many large corporate members with EFPIA (Chiesi, for example, sits on the board of both).¹⁸ EUCOPE's members also include lobby firms with Big Pharma clients, such as Fipra (hired by EFPIA, Pfizer and Novartis) and Covington (hired by EFPIA, UCB and MSD).¹⁹ Yet EUCOPE repeatedly tried to distance itself from Big Pharma, which often develops new drugs by buying or licensing molecules from smaller biotech firms (or buying the firms).²⁰

'It's incompatible with trade policy': LIF told the Commission that "patent exemptions" are incompatible with its trade policy. EUCOPE elaborated that since the "EU is trying to enforce its IP standards" globally, by promoting SPCs in trade talks with Mexico, and winning a WTO case against a stockpiling exemption in Canada, an SPC manufacturing waiver goes "against EU trade policy".²¹ G+, representing AbbVie further warned that the Commission's draft proposal "already raised concerns in the United States, triggering deliberations about Section 301 measures." This refers to the US' annual reports identifying trade barriers (including IP laws) to US companies. Both the US Chamber of Commerce (which co-commissioned the Pugatch report with AbbVie) and PhRMA (EFPIA's sister US group) lobbied the US to include the EU in its IP 'Watch List' over the pharma incentives review and SPC manufacturing waiver. The US Chamber warned that these "IP-degrading initiatives" could trigger "a race to the bottom in weakening global IP standards".²² PhRMA meanwhile asked the US to "seek

assurances” that the incentives review “will not result in measures to weaken” IP. And it seems they were successful at getting the US to stick its oar in. In October 2018, Brussels’ news outlets reported that the “U.S. Permanent Mission to the EU is holding a meeting with EU officials and IP attachés” to discuss the Commission’s SPC manufacturing waiver proposal, under the Chatham House Rule (meaning that no information on who said what can be reported publicly).²³

'It is incompatible with 'Better Regulation': EFPIA, INFARMA and G+, representing AbbVie, all invoked the Commission’s big business-friendly and deregulatory so-called ‘Better Regulation’ agenda in their arguments.²⁴ EUCOPE went further, sending the Commission a document setting out “10 principles of Better Regulation the Commission has failed to respect”.²⁵ These include not considering “an industry self-regulation model”, the benefits of which are “explicitly recognised” in the Commission’s Better Regulation Toolbox.

'It ignores the benefits of self-regulation': EUCOPE urged the Commission to consider “successful voluntary industry agreements that achieve equal aims”.²⁶ By failing to do so, it argued, “the Commission is undermining the very credibility of its actions.” A bold claim, given that Parliament had mandated the Commission to legislate for an SPC manufacturing waiver! LIF also berated the Commission for omitting “less intrusive mechanisms” like “soft-law” in its consultation.

'It will have dire effects... according to industry-funded studies': G+, on behalf of AbbVie (which co-commissioned the Pugatch study with Roche), sent the Commission materials full of references to Big Pharma-funded studies about how bad an SPC manufacturing waiver would be, including the Pugatch and EFPIA-QuintilesIMS studies.²⁷ AmCham EU and ICBA referred to the Pugatch study as disproving its benefits,²⁸ and EBE – in which AbbVie and Roche both hold important positions – also cited it.²⁹ Meanwhile, when lobbying the US to intervene, PhRMA cited the Pugatch and EFPIA-OHE studies, plus a study commissioned by EuropaBio,³⁰ as “debunking” the “belief” that an SPC manufacturing waiver would level the playing field for generics.³¹

'It's an unnecessary concession to a thriving generics industry': G+, on behalf of AbbVie, told the Commission that “there is no market failure” as the generics industry is thriving, a sentiment echoed by EBE. ICBA said an SPC manufacturing waiver would “favour of IP-infringing copycat products”.³² EUCOPE meanwhile berated the Commission for the “undue rush” between the public consultation and the proposal, implying the “evidence-light and politically driven” proposal was a “foregone conclusion” thanks to “a well-orchestrated campaign from the generic industry”.³³

Generic industry’s wins and losses

Throughout the process, the generics industry lobbied intensely for the waiver, which is in its commercial interests.³⁴ When the US got involved the EU lobby group for the generics industry, Medicines for Europe, responded by accusing it of “interfering in an EU domestic policy matter by trying to manipulate and influence the current debate” and to “convey the position of the US

commercial bodies”.³⁵ Medicines for Europe fought tirelessly for an SPC manufacturing waiver with provisions to stockpile for 'day-one' market entry, but they also made it clear they were not challenging the legitimacy of SPCs.³⁶ When the Commission's proposal did not include 'day-one entry', and delayed the date it would take effect for 10-15 years, Medicines for Europe – complaining that it would “not have any positive impact” as it would “hardly be used”³⁷ – were told by DG Sante that the proposal was “a reflection of different interests”.³⁸ So Big Pharma's ferocious lobbying – including growing pressure from increasingly mobilising US lobby groups³⁹ – *did* yield significant successes – though it did not derail the waiver altogether.⁴⁰

Big Pharma's fear-mongering narrows the scope for change

Despite Big Pharma's efforts, the European Parliament suggested amendments to the Commission's proposal that included stockpiling provisions. However negotiations with the Council diluted the period that these would apply, and brought changes that may pave the way for more litigation from Big Pharma towards generics firms.⁴¹ But the February 2019 agreement on the draft SPC manufacturing waiver nonetheless seems to represent a 'win' for the generics industry and a 'loss' for Big Pharma. Certainly EFPIA complained the manufacturing waiver was a “gamble” that would turn Europe from “a knowledge-based region at the cutting edge of research, development and medical innovation to a Europe that is not competitive on the global R&D stage and fails to attract future investments”.⁴² Yet it is exactly this impression – that the SPC manufacturing waiver is a huge loss for Big Pharma – that is problematic. Big Pharma's tirade of lobbying and fear-mongering has depicted it as a massive industry setback, when in reality, it does not even reduce the period of monopoly protection.⁴³ Yet Big Pharma's exaggerated 'sky-is-falling' message has narrowed the scope for real change of the current paradigm, which is designed to serve the interests of big companies' shareholders, to one that has access to new, better, and needed medicines at its heart. By fighting so hard against such a small reform, Big Pharma has deflected from the deeper issues at stake, and attempted to constrict the political space for debate.

This is illustrated by the way the Commission rushed to reassure the SPC manufacturing waiver's detractors. DG Grow reassured its critics that the “EU is actively trying to convince its trade partners... to upgrade or introduce IPR regimes similar to our own, including as regards SPC-like protection, something we recently succeeded in achieving in Canada”.⁴⁴ It also said the Commission was taking into account Big Pharma-funded studies,⁴⁵ and “by no means” intends to “weaken the exclusive rights that SPC holders enjoy in respect of the marketing of innovative medicines in the EU”.⁴⁶ It is only the “unintended side effects” on the generics industry's global competitiveness that the waiver is intended to address. A narrow ambition indeed, from the perspective of public health and access to medicines. Yet, it seems clear that the Commission – despite being told by the Council that the whole edifice of pharmaceutical incentives and rewards needs reviewing – “remains fully committed to strong IPR and SPC protection and enforcement, both in the Single Market and in third countries”.⁴⁷

All of this leaves us to wonder whether Big Pharma, far from bemoaning the SPC manufacturing waiver, is in fact congratulating itself for so far stemming the tide of more transformative change. For the sake of public health, it is vital that policy-makers, particularly the upcoming new Parliament and Commission, do not consider this minor tweak to a patent extension a sufficient follow up to the ground-breaking Dutch Council conclusions. A continued critical conversation, with scope for real, public-interest, regulatory changes, is urgently needed. (See Chapter 7 for further recommendations).

- 1 AIDES, Appendix I – Legal arguments, https://www.aides.org/sites/default/files/Aides/bloc_telechargement/Aides%20CJEU%20CCP%20Appendix%20December%202017.pdf
- 2 DG Grow, SPCs, https://ec.europa.eu/Growth/industry/intellectual-property/patents/supplementary-protection-certificates_en
- 3 (MSF, Briefing note on SPCs: Threatening access to affordable medicines across the European Union, September 2017, <https://msfaccess.org/briefing-note-supplementary-protection-certificates-spcs>
- 4 The “broad and ambiguous” scope of SPCs means multiple SPCs can be issued for the same product, or for the same product to multiple companies. Firms also mirror their strategy of patenting minor changes to old medicines with applications for SPCs on those minor changes. MSF, 2017 *ibid*.
- 5 MSF, Open submission on SPCs, September 2017, https://issuu.com/msf_access/docs/open-submission-on-spcs
- 6 EP legislative train, SPC regulation, <http://www.europarl.europa.eu/legislative-train/theme-deeper-and-fairer-internal-market-with-a-strengthened-industrial-base-products/file-supplementary-protection-certificate-for-medicinal-products>
- 7 Dimitri Eynikel, EU Parliament Calls for Regular Evaluation of SPC System, 24/01/19, <https://dimitrismusings.wordpress.com/2019/01/24/european-parliament-calls-for-regular-evaluation-of-spc-system-including-its-effect-on-access-to-medicines-in-europe/>
- 8 *Euractiv*, Protecting the spark, avoiding the storm, By Nathalie Moll | EFPIA, 29/11/18, <https://www.euractiv.com/section/health-consumers/opinion/protecting-the-spark-avoiding-the-storm/>
- 9 Grow docs, EFPIA Response 13-02-18. EFPIA wrote to DG Grow again in March 2018, promising to have “identified a possible option that could be supported by all stakeholders involved”, expressing its hope that it could “be considered in the final stages of decision making”. Letter from EFPIA to DG Grow 19-03-18
- 10 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, 2017, http://www.pugatch-consilium.com/reports/Unintended_Consequences_October%202017.pdf
- 11 QuintilesIMS, Assessing the impact of proposals for a SPC Manufacturing Exemption in the EU, 2017, <https://www.efpia.eu/publications/downloads/efpia/assessing-the-impact-of-proposals-for-a-supplementary-protection-certificate-spc-manufacturing-exemption-in-the-eu/>
- 12 OHE, Review of CRA’s Report “Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe”, Consulting Report for EFPIA, 2018, <https://www.ohe.org/publications/review-cra%E2%80%99s-report-%E2%80%9CAssessing-economic-impacts-changing-exemption-provisions-during>
- 13 Grow docs, Letter from BIO.BE 13-03-18; Letter from LIF 26-01-18; INFARMA letter 11-04-18; EFPIA 13-02-18
- 14 Documents released from DG Sante (hereafter ‘Sante docs’), Annex V attachment, EBE View on the SPC Manufacturing Waiver, 02/08/18
- 15 GSK, Bayer, Lilly, Sanofi, etc. EBE, Membership, <https://www.ebe-biopharma.eu/membership/>
- 16 Grow docs, Letter from BIOTECCanada Document 11-01-18 International Council of Biotechnology Associations (ICBA)
- 17 ASSOBIOTEC, Association of German Biotechnology Companies, BIO.be, BIODeutschland, BiolIndustry Association, Finnish BiolIndustries, HollandBIO, Portugal’s Biotechnology Industry Organization, Swiss Biotech Association
- 18 EUCOPE, Executive Board, <https://www.europe.org/people/>, EFPIA, Board, <https://www.efpia.eu/about-us/who-we-are/>, as of January 2019.
- 19 Transparency Register, Fipra, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=58746194306-23>, last modified on: 08/11/2018;
- 20 Covington, <http://ec.europa.eu/transparencyregister/public/consultation/displaylobbyist.do?id=083671317381-0>, last modified on: 25/01/2019
- 21 Eg EUCOPE said that while “big pharma” can divest” from high-risk areas, SMEs and “start-up biotech will struggle”. Grow docs, Letter from EUCOPE 16-02-18
- 22 EUCOPE correspondence with DG Grow and DG Sante.
- 23 US Chamber of Commerce 2018 Special 301 Submission <https://politico.us8.list-manage.com/track/click?u=e26c1a1c392386a968d02fdb&id=8df4f47e9f&e=15d0700433>
- 24 *Politico*, IP — Unites States in on the mix on SPCs, 23/10/18; *Euractiv*, EU generics industry slams US ‘intervention’ in SPC manufacturing waiver talks, 23/10/18, <https://www.euractiv.com/section/health-consumers/news/eu-generics-industry-slams-us-intervention-in-spc-manufacturing-waiver-talks/>
- 25 Sante docs. Exchange of emails between DG Sante Services and G+Europe. Nb. DG Sante turned down G+ request for a meeting “due to a heavy schedule” and citing DG Grow being responsible for the issue.
- 26 Grow docs, EUCOPE, 10 principles of Better Regulation the Commission has failed to respect in the review of EU rules on SPCs.
- 27 Grow docs, Letter from EUCOPE Document 24-01-18
- 28 Sante docs. Exchange of emails between DG Sante Services and G+Europe
- 29 AmCham EU et al, Letter to Vice President Katainen, January 12, 2018, https://www.amchameu.eu/system/files/position_papers/european_amcham_letter_on_eu_incentives_review.pdf
- 30 EBE’s Public Affairs Network is chaired by Roche, and its Regulatory & Technical Affairs Network vice-chaired by AbbVie, <https://www.ebe-biopharma.eu/governance/>
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- 32 PhRMA Special 301 Submission 2018, https://www.keionline.org/wp-content/uploads/2018/02/PhRMA_2018_Special_301_Submission.pdf
- 33 Grow docs, Letter from BIOTECCanada Document 11-01-18 ICBA
- 34 Grow docs, Letter from EUCOPE Document 24-01-18
- 35 Grow docs re. Medicines for Europe dated 09-10-17, 09-11-17, 02-10-17, 12-04-18, 03-10-18, 06-11-18, 17-07-16.
- 36 Medicines for Europe, US interference unacceptable in EU legislative proposal for an SPC manufacturing waiver, Brussels - 22 October 2018, <https://www.medicinesforeurope.com/news/us-interference-unacceptable-in-eu-legislative-proposal-for-an-spc-manufacturing-waiver/>
- 37 MfE argued an SPC manufacturing waiver would stimulate EU generic/biosimilar industries “without eroding SPC protection in Europe. Grow docs, Urgent Meeting Request Document 09-10-17 Medicines for Europe
- 38 Grow docs, Letter Medicines for Europe.
- 39 Sante docs, Report meeting Commissioner and Medicines for Europe (17 July 2018), 04/12/2018.
- 40 EPHA, The top 5 issues...2019, *ibid*.
- 41 Individual MEPs also lobbied the Commission both for and against an SPC manufacturing waiver, [DG Grow correspondence with MEP GállPelcz, 10-02-17 (seemingly pro-waiver), MEP Axel Voss, 12-06-18 (seemingly anti-waiver), and MEP Angelika Niebler 06-07-18 (seemingly anti-waiver). Niebler is president of Bavaria Economic Advisory Board (Wirtschaftsbeirat Bayern), whose members include Prof. Dr. Horst Domdey, Managing Director BioM Biotech Cluster Development, who also lobbied DG Grow against the SPC manufacturing waiver [Grow docs, 14-02-18].
- 42 See, eg Patent Strategy, SPC Waiver will save money but increase litigation for generics, 14/03/19, <https://patentstrategy.managingip.com/Articles/15>
- 43 EFPIA, Europe’s gamble with the future of medical innovation, 14/02/19, <https://www.efpia.eu/news-events/the-efpia-view/statements-press-releases/europe-s-gamble-with-the-future-of-medical-innovation/>
- 44 This point is expounded by the Standing Committee of European Doctors, who note that the SPC manufacturing waiver is not intended to (and would not) undermine “the compensation that originator pharmaceutical companies seek for marketing approval delays in Europe”, and that preventing manufacturing for export during the SPC period does not actually “benefit SPC holders in Europe”. [Grow docs, 12-02-18]
- 45 Grow docs, Letter to MEP Niebler 06-07-18
- 46 Grow docs, Letter to EUCOPE 12-03-18
- 47 Grow docs, Letter to MEP Voss 12-06-18
- 48 Grow docs, Letter to MEP Voss 12-06-18