

# SPC manufacturing and stockpiling waiver—part 1

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## Abstract

This two-part article analyzes and discusses the legal requirements of, as well as the opportunities and risks associated with the SPC Manufacturing and Stockpiling Waiver as introduced by EU Regulation 2019/933. The introduction of the SPC Manufacturing/Stockpiling Waiver on July 1, 2019 opened up opportunities for generics and biosimilars companies established in the EU to manufacture and stockpile medicinal products before expiry of the respective SPC, either for export to third countries or for timely Day-1 market entry in the EU. But unlike, for example, the bolar exemption, application of the SPC Waiver is dependent upon compliance with specific notification, due diligence and labeling obligations. Although introduced more than four years ago, there is still considerable legal uncertainty surrounding the application of the SPC Waiver, something recent court decisions in Germany and The Netherlands have exacerbated rather than clarified. In this first part, the policy background of the Regulation is explained and the territorial and temporal scope of the SPC Waiver is examined. In the second part of the article, to be published in the next edition of the Journal of Intellectual Property Law and Practice Vol.(...) Issue (...) I will take a close look at the material scope and core components of the waiver, particularly as it relates to privileged acts and the conditions under which the waiver is applicable

## A. Introduction

Described as ‘a double-edged sword’ for the generics industry,<sup>1</sup> the Supplementary Protection Certificate Waiver (SPC Waiver) as introduced in the European Union (EU) by Regulation 2019/933 has been a bone of contention in the pharmaceutical industry since its inception. As it is evident from its recitals, the main goal of the Regulation was to establish a ‘level playing field’ for EU-based generics and biosimilars companies competing with manufacturers from third countries where no SPC protection existed. An exemption from the scope of SPC protection was needed to allow EU-based manufacturers of generics and biosimilars to launch manufacturing for timely market entry before the expiry of the relevant SPC protection, so as to be able to effectively compete with their counterparts in third countries. Even before Janssen against Formycon came before the District Court of Munich last October, concerning the highly lucrative biosimilar ‘Stelara’, the SPC waiver had already been the subject of litigation between originators and generics manufacturers. Most cases ended in confidential settlements between the litigating parties. The Munich ruling was followed by a decision of the District Court of the Hague in January 2024 in proceedings again initiated by Janssen against another biosimilar manufacturer. The Dutch court disagreed with their German colleagues on the interpretation of a key provision of the Regulation, namely the extent of the information generics and biosimilars manufacturers are obliged

to provide to the certificate holder under Article 5 (5) lit. e) of the Regulation.

Central to Regulation 2019/933 is the notion of allowing EU-based manufacturers to carry out manufacturing and other necessary related acts before the expiry of SPC to guarantee a timely market entry both in EU and in third countries. However, there are strings attached to the SPC exemption, as the manufacturers need to comply with different temporal and territorial restrictions as well as additional notification, documentation and labelling obligations, depending on whether they manufacture for EU countries, and under specific circumstances for the European Economic Area (EEA) countries (stockpiling waiver) or for third countries (manufacturing waiver). In practice, the SPC waiver resembles a kind of *sui generis* compulsory licence where no remuneration is involved but which is contingent on other formalities being observed, instead of an *ipso iure* exemption like the Bolar exemption.<sup>2</sup> Due to ambiguous operative clauses, redundant

<sup>2</sup>cf Miguel Vidal-Quadras, ‘Analysis of EU Regulation 2019/933 on the SPC Manufacturing Waiver Exception’ [2019] IIC 971, 997: ‘In fact, none of the exceptions that have been recognised for third parties in the patent laws requires any communication to the patent office from the person who carries out acts falling within the scope of the patent claims. There is no link between the patent holder and the person who benefits from the application of an exception’.

Cf also European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Romandini, R., Kur, A., Walz, A. et al, *Study on the Legal Aspects of Supplementary Protection Certificates in the EU—Final report*, Publications Office of the European Union (2018), <<https://data.europa.eu/doi/10.2873/680006>> 313f, discussing the SPC waiver as compulsory licence or exception contingent on formalities other than remuneration (accessed 10 May 2024).

<sup>1</sup>Managing IP, Rory O'Neill, 21 July 2022, Risk of SPC waiver counterattack makes generics extra cautious.

recitals, a rather byzantine law-making process with much to-ing and fro-ing between the EU legislative organs that resulted in patchwork legislation, not to mention a paucity of relevant case law, legal uncertainty regarding the application of the waiver persists.

This article, which will be published in two parts, aims to provide a systematic analysis of the SPC waiver provisions and address questions that arise in its practical application. The first part of the article examines the purpose and policy background of Regulation 2019/933 (section B). It also addresses the territorial application of the Regulation directly within the EU and indirectly in the EEA (B.I.1) and discusses the question of extraterritorial application of foreign IP rights in terms of the obligations under the manufacturing waiver (B.I.2). It also explains the transitional period outlined in Regulation 2019/933 (B.II). The first part of the article concludes (B.III) with a delineation of the roles of different persons and entities as defined in the Regulation with a particular focus on the interrelation between makers and third parties.

## B. The SPC waiver under Regulation (EU) 2019/933

SPC protection in the EU unintentionally led to significant competitive disadvantages for EU-based generics and biosimilars manufacturers compared to non-EU manufacturers, which the EU sought to tackle by introducing the so-called 'SPC waiver' under Regulation 2019/933.<sup>3</sup> SPC protection aims to offset the loss of effective patent protection as a consequence of necessary but lengthy testing, clinical trials and marketing authorization procedures, and thus provide the pharmaceutical industry with appropriate incentives to innovate. An SPC takes effect at the end of the term of the basic patent, and can generally be granted for up to 5 years, although the average duration of SPCs granted in the EU is 3.5 years.<sup>4</sup> Since, according to Article 5 of Regulation (EC) 469/2009, a SPC 'confer[s] the same rights as conferred by the basic patent', the monopoly resulting from the basic (reference) patent is extended and enables its holder to prevent competitors from practising the invention including *inter alia* manufacturing the medicinal product offering it for sale, storing it, etc. in those Member States in which an SPC has been granted.<sup>5</sup> Thus, at the time of expiry of the SPC, only non-EU manufacturers were able to immediately have their products, which had been manufactured and stored outside of the EU, imported into the EU market. European generics and biosimilars manufacturers, on the other hand, could only start 'building up production capacity' after expiration of the

respective SPCs, since under European patent law<sup>6</sup> even manufacturing as such, regardless of the destination of future products, was considered an infringement<sup>7</sup> of the SPCs in question.

The absence of a provision such as the SPC waiver resulted in a significantly delayed day-1 market entry for EU-based generics, and especially biosimilars, manufacturers, since manufacturing of advanced biologics is, because of the inherent variabilities, technically highly complex<sup>8</sup> and particularly time-consuming. This translated into a significant strategic disadvantage over manufacturers based outside the EU in countries with no similar protection or no protection at all, since the market for generics and biosimilars is characterized by a strong 'first mover' effect: in the EU, generics firms entering one year after the first generics entrant often only succeed in capturing up to 11 per cent of the first entrant's market share.<sup>9</sup> Even though the decline in prices for biosimilars is not as steep as in the case of generics, the 'first-mover' effect is considerable, since later market entrants have difficulty in gaining market share without reducing prices further.<sup>10</sup> For biosimilars, studies show that, in 2016, the first biosimilars to reach the market captured over 70 per cent market share, while second and third biosimilar entrants captured 30–40 per cent and 5–22 per cent market share, respectively.<sup>11</sup>

Notably, the Regulation explicitly warns of existential threats to EU manufacturers of generics and biosimilars, as well as the EU internal market as a whole, unless changes are made in the legal regime: This includes the 'loss of potential new business opportunities for makers of generics and biosimilars' and 'possibly diminishing related investments and hampering job creation within the Union'.<sup>12</sup> The EU would risk substantially weakening its position as a hub for pharmaceutical development and manufacturing.<sup>13</sup>

Recitals 7–8 of the Regulation explain the purpose behind the Regulation. Its aim is to ensure the timely entry of generics and biosimilars into the Union market after expiry of the corresponding SPC in order to increase competition, reduce prices and ensure the sustainability of national healthcare systems and also guarantee that patients in the Union have better access to affordable medicines.<sup>14</sup> To this end, generics and biosimilars manufacturers should be allowed to make and store products (essentially stockpile) in a Member State pending expiry of the certificate, for the purpose of entering the market of any Member State immediately upon expiry of the corresponding certificate ('EU day-1 entry').

<sup>6</sup>Now harmonized under Art 26f UPCA for the Contracting Member States of the Unified Patent Court.

<sup>7</sup>Cf BGH GRUR 1951, 452 [454]; Peter von Czettritz/Christian Kau, 'Ergänzende Schutzzertifikate: Herstellungsprivileg als neue Ausnahmeregelung' [2018] GRUR-Prax 396, 397; Scharen, *Patentgesetz: PatG, Gebrauchsmustergesetz, Patentkostengesetz* (Georg Benkard, Klaus Bacher eds, 11th edn, C.H.Beck 2015, Munich, Bavaria, Germany) PatG, ch 9 para 10.

<sup>8</sup>Arnold G. Vulto, Orlando A. Jaquez, 'The process defines the product: what really matters in biosimilar design and production?' (2017) 56 *Rheumatology* (Oxford), p iv14–iv29, <<https://doi.org/10.1093/rheumatology/kex278>>.

<sup>9</sup>European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, Fischer, R., Débarbat, G., Koustoumpardi, E. et al, *Assessing economic impact of changing exemption provisions during patent and SPC protection in Europe*, Publications Office (2017) <<https://data.europa.eu/doi/10.2873/673124>> (accessed 10 May 2024). A number of studies support the existence of a 'first-mover advantage' effect for generic products. See Sharjarzadeh et al (2015), Yu and Gupta (2008), Hollis et al (1991).

<sup>10</sup>Cf Commission, 'Impact Assessment of Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products' COM(2018) 317 final, 18f.

<sup>11</sup>QuintilesIMS, 'The Impact of Biosimilar Competition in Europe' (May 2017) 6 <[https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017\\_V9.pdf](https://www.medicinesforeurope.com/wp-content/uploads/2017/05/IMS-Biosimilar-2017_V9.pdf)> (accessed 5 February 2024).

<sup>12</sup>Regulation (EU) 2019/933 (n 3) Recital 6.

<sup>13</sup>Regulation (EU) 2019/933 (n 3) Recital 30.

<sup>14</sup>Regulation (EU) 2019/933 (n 3) Recital 7.

<sup>3</sup>Cf Regulation (EU) 2019/933 of the European Parliament and of the Council of 20 May 2019 amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products [2019] OJ L135/1, Recitals 4–5; cf. for the legislative history and a discussion of the studies mentioned in the Impact Assessment: Robert Wenzel, *Supplementary Protection Certificates (SPC): A Handbook* (Stief ed, 2nd edn, Munich, Bavaria, Germany, C.H.BECK2021) ch K.

<sup>4</sup>European Commission, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs, *Study on the economic impact of supplementary protection certificates, pharmaceutical incentives and rewards in Europe—Final report*, Publications Office (2018). <<https://data.europa.eu/doi/10.2873/886648>> (accessed 10 May 2024). A study analysing the combined effect of pharmaceutical incentives in Europe.

<sup>5</sup>Margaret Kyle, 'Economic analysis of supplementary protection certificates in Europe' (2017) <[https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products\\_en](https://single-market-economy.ec.europa.eu/industry/strategy/intellectual-property/patent-protection-eu/supplementary-protection-certificates-pharmaceutical-and-plant-protection-products_en)> (accessed 10 May 2024) > Luxembourg: European Commission: 'The share of medicinal products having an SPC in at least one Member State increased from 75% in the early 1990s to 86% in 2017.'

This would serve the general interests of the Union by strengthening EU-based supply chains for medicines.<sup>15</sup> The availability and security of supply chains is a matter of critical importance to the EU, something that gained significant attention during the Covid-19 pandemic.<sup>16</sup> In May 2023, a Belgian initiative supported by the majority of EU countries including France and Germany submitted a non-paper asking the EU to ‘take more drastic steps to improve the security of medicines supply’.<sup>17</sup> The non-paper decried the EU’s increasing dependence on imports from a few manufacturers and regions for its medicines supply.<sup>18</sup> This matter is currently addressed by the Commission’s Draft Regulation as part of the revised EU Pharma Package including stronger obligations on marketing authorization holders to notify of potential or actual shortages and marketing withdrawals and to offer their marketing authorization for transfer to another company before withdrawal.<sup>19</sup>

Furthermore, EU-based generics and biosimilars should be allowed to make, in the Union, products, or medicinal products containing those products, for the purpose of export to third country markets in which protection does not exist or has expired. In this regard, the EU aims at creating ‘a level playing field between makers [of generics and biosimilars] established in the Union and third-country makers’.<sup>20</sup> The overarching aim of the Regulation is to foster the competitiveness of the EU, to enhance growth and job creation in the internal market and to contribute to a wider supply of medicines by preventing relocation and allowing EU-based generics and biosimilars to compete ‘on fast-growing global markets where protection does not exist or has already expired and [...] on the Union market upon expiry of the certificate’.<sup>21</sup> It is worth emphasizing that the Regulation mainly addresses EU-based manufacturers of generics and biosimilars by seeking to prevent their ‘relocation’ due to the absence of the waiver under the previous legal regime.<sup>22</sup> However, the Regulation also seeks to attract new investments from Union (or thirdcountry) based manufacturers who maintain development phases in third countries. This is evident in the assessment criteria of the Regulation, as the Commission should evaluate *inter alia* ‘whether making that was

previously taking place outside of the Union would be moved to within Union territory’.<sup>23</sup>

Central to the nature of the waiver, which privileges certain acts that would otherwise require the consent of the SPC holder, which acts are contingent on the fulfilment of certain obligations on the part of the privileged party, thus the ‘maker’, is the balancing of the interests of generics and biosimilars and those of the SPC holders. The Regulation articulates this conflict as follows: ‘The Union should strike a balance between restoring a level playing field between those makers and ensuring that the essence of the exclusive rights of holders of certificates (“certificate holders”) is guaranteed in relation to the Union market’.<sup>24</sup> More precisely, a carefully calibrated balance should harmonize ‘the impact of the exception on research and production of innovative medicines in the Union by certificate holders’ and ‘the different interests at stake, in particular as regards public health, public expenditure and, in this context, access to medicines within the Union’.<sup>25</sup> These interests include the right to property (Article 17) and the right to health care (Article 35) enshrined in the EU’s Charter of Fundamental Rights.<sup>26</sup> For this, the SPC Waiver should ‘not go beyond what is necessary and appropriate in the light of the overall objective of this Regulation’.<sup>27</sup>

## 1. Territorial scope of application

### 1. Direct application in the EU and modified indirect application in the EEA subject to national legal provisions and decisions of the EEA Joint Committee

According to Article 288 of the Treaty on the Functioning of the European Union (TFEU) Regulation 2019/933 is directly applicable in the EU and with some modifications also in the EEA, although in the latter case, national legal provisions<sup>28</sup> play a role. The Official Journal of the European Union characterized Regulation 2019/933 as a ‘text with EEA relevance’, meaning that it can be considered to be incorporated to the EEA Agreement.<sup>29</sup> Regulation 2019/933 was incorporated into the EEA Agreement by Decision of the EEA Joint Committee.<sup>30</sup> Since Liechtenstein does not grant SPCs, it is excluded from the Regulation’s scope of application.<sup>31</sup> The Decision of the EEA Joint Committee further changed the date of entry into force of Regulation 2019/933 regarding the three EEA EFTA States - Iceland, Liechtenstein and Norway states. Instead of 1 July 2019, the date of entry into force of the Decision of the EEA Joint Committee is relevant, ie 10 June 2022.<sup>32</sup> Iceland already adopted the SPC waiver provisions in 2021 by amending Article

<sup>15</sup> Regulation (EU) 2019/933 (n 3) Recital 8.

<sup>16</sup> Commission, ‘Commission Staff Working Document-Structured Dialogue on the security of medicines supply’ (2022) <[https://health.ec.europa.eu/system/files/2022-10/mp\\_vulnerabilities\\_global-supply\\_sw\\_d\\_en.pdf](https://health.ec.europa.eu/system/files/2022-10/mp_vulnerabilities_global-supply_sw_d_en.pdf)> (accessed 4 September 2023). Cf Carlo Martuscelli ‘EU capitals propose Chips Act for medicines’ Politico (2 May 2023) <<https://www.politico.eu/article/eu-capitals-propose-chips-act-medicines-big-pharma/>> (accessed 4 September 2023); cf also Marco Stief/Boris Bromm, ‘Lieferengpässe in der Arzneimittelindustrie – Ursache, Gründe und Lösungsansätze am Beispiel des Corona Virus (Teil 1 [Part 1])’ [2020] PharmR 250; cf Marco Stief/Boris Bromm, ‘Lieferengpässe in der Arzneimittelindustrie – Ursache, Gründe und Lösungsansätze am Beispiel des Corona Virus (Teil 2 [Part 2])’ [2020] PharmR 460.

<sup>17</sup> ‘Non-paper – improving the security of medicines supply in Europe – (BE, AT, NL, LU, HU, CZ, ES, FR, DE, EE, SI, RO, LV, LT, EL, MT, PL, IT, PT)’ (Politico, 2 May 2023), <<https://www.politico.eu/wp-content/uploads/2023/05/02/Non-paper-security-of-medicines-supply-02.05.23.pdf>> (accessed 5 February 2024).

<sup>18</sup> Ibid, 1 ‘In 2019, globally more than 40% of APIs were sourced from China. Furthermore, almost all API producers depend on China for intermediate inputs, even if they are located in another country. Next to the geographic concentration, there is also a concentration of manufacturing sites: for more than 50% of APIs globally, less than 5 CEP1 manufacturers exist. As a result, Europe (and the world) depend on a few manufacturers for a large bulk of their medicines supply.’

<sup>19</sup> Commission, ‘Regulation of the European Parliament and of the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006’ COM (2023) 193 final, ch X, Availability And Security Of Supply Of Medicinal Products; cf Article 119 and Recital 139, Article 24 (4).

<sup>20</sup> Regulation (EU) 2019/933 (n 3) Recital 9; cf Regulation (EU) 2019/933 (n3) Recitals 5, 9, 28, 29.

<sup>21</sup> Regulation (EU) 2019/933 (n 3) Recital 30, cf Regulation (EU) 2019/933 (n3) Recital 8.

<sup>22</sup> Regulation (EU) 2019/933 (n 3) Recital 30.

<sup>23</sup> Regulation (EU) 2019/933 (n 3) Recital 28.

<sup>24</sup> Regulation (EU) 2019/933 (n 3) Recital 5.

<sup>25</sup> Regulation (EU) 2019/933 (n 3) Recital 28.

<sup>26</sup> Cf Regulation (EU) 2019/933 (n 3) Recital 30.

<sup>27</sup> Ibid.

<sup>28</sup> See Sec 62a of the Norwegian Patents Act and Art 65a of the Icelandic Patents Act, respectively.

<sup>29</sup> Through the EEA Agreement, the EU Member States and the EEA EFTA States, thus Iceland, Liechtenstein and Norway, have created a shared European Economic Area (EEA), which permits participation in the common internal market and thus access to the four EU freedoms: free movement of goods, services, capital and people with common competition and state aid rules. The EEA Joint Committee, which includes representatives of the EEA EFTA States and of the European Commission, decides on the incorporation of acts into the EEA Agreement which are directly legally binding upon decision of the EEA Joint Committee and implementation on behalf of the EFTA states or they will have to be first incorporated into national law of the EEA EFTA states according to their respective constitutional provisions to be legally binding, cf. Art 103f of the EEA Agreement.

<sup>30</sup> Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 amending Annex XVII (Intellectual property) to the EEA Agreement [2022/1897].

<sup>31</sup> Regulation (EU) 2019/933 (n 3) Recital 2.

<sup>32</sup> Ibid Art 1 (3).



65a of its Patents Act No. 17/1991 after enacting Act No. 1460/2021, which entered into force on 1 July 2021—independently of the amendments to the EEA Agreement.<sup>33</sup> Although the process for incorporating the waiver into Norwegian law was lengthier, the SPC waiver is now in force in Norway. On 20 December 2022, the Norwegian Parliament passed the amendment to Section 62a of the Norwegian Patents Act implementing the waiver, which duly entered into force on 1 February 2023.<sup>34</sup> So in effect this means that where Regulation 2019/933 refers to EU or Member States, these now include the EEA EFTA Member States of Norway, Iceland and Liechtenstein. Even though Liechtenstein is excluded from the application of SPC-relevant legislation, it still forms part of the EEA. Especially given the fact that Liechtenstein confers no SPC protection, acts that would need to have been privileged by the SPC waiver elsewhere can take place in its jurisdiction in absence of any relevant IP protection.

## 2. No extraterritorial application in third countries

SPC-waiver-related litigation has addressed the question of effect of foreign IP rights on the application of the SPC manufacturing waiver. Therefore, it is important to clarify that the SPC waiver regulation has (apart from the territorial application discussed above) no extra-territorial application in third countries and vice versa, ie that IP protection in third countries or the lack thereof has no extraterritorial effect in the EU.<sup>35</sup> Based on Recital 18 of Regulation 2019/933, which states that ‘it should be the responsibility of the maker [...] to verify that protection does not exist or has expired in a country of export [...]’, certificate holders have argued that privileged manufacturing in the EU can only commence after relevant IP protection has expired in the third country where export is intended.<sup>36</sup> Furthermore, some legal scholars argue that infringement of IP protection in a third country may constitute an infringement in the EU.<sup>37</sup> However, this approach implies an impermissible extraterritorial effect of IP protection that conflicts with the internationally applicable territoriality principle<sup>38</sup> of IP rights.

<sup>33</sup>Jiří Slavík, ‘Analysing the use of the SPC waiver provisions and its reach outside the EU’, (Kluwer Patent Blog, 17 October 2022) <[https://patentblog.kluweriplaw.com/2022/10/17/analysing-the-use-of-the-spc-waiver-provisions-and-its-reach-outside-the-eu/#\\_ftn6](https://patentblog.kluweriplaw.com/2022/10/17/analysing-the-use-of-the-spc-waiver-provisions-and-its-reach-outside-the-eu/#_ftn6)> (accessed 8 February 2024).

<sup>34</sup>cf Lars Erik Steinkjer and others, ‘SPC manufacturing waiver has entered into force in Norway’, (Wikibrog/Rein, 3 February 2023) <<https://www.wr.no/aktuelt/spc-manufacturing-waiver-has-entered-into-force-in-norway>> (accessed 8 February 2024).

<sup>35</sup>Konstanze Richter, ‘Formycon and Janssen Biotech put EU SPC waiver to the test in Munich’ [Landgericht München I, Case reference: 21 O 12030/23] [Juve Patent, 26 Oktober 2023] <<https://www.juve-patent.com/cases/formycon-and-janssen-biotech-put-eu-spc-waiver-to-the-test-in-munich/>> (accessed 8 February 2024).

<sup>36</sup>cf Medicines for Europe, ‘Review of the SPC Manufacturing Waiver: a First Industry Report’, (Medicines for Europe, June 2023) 8 <<https://www.medicinesforeurope.com/2023/06/13/review-of-the-spc-manufacturing-waiver-a-first-industry-report/>> (accessed 8 February 2024), with reference to Janssen Biotech Inc -V- Amgen Technology [Ireland] Unlimited Company 2023/1328 P.

<sup>37</sup>Peter von Czetztritz/Christian Kau, ‘Ergänzende Schutzzertifikate: Herstellungsprivileg als neue Ausnahmeregelung’ [2018] GRUR-Prax 396, 397; Grabinski, Benkard, *Europäisches Patentreibereinkommen—EPÜ* (Ingo Beckendorf, Jochen Ehlers eds, 4th edn, C.H.BECK 2023) EPÜ ch 63 para 114d-115c.

<sup>38</sup>Regarding the territoriality principle see Roberto Romandini/Alexander Klicznik, ‘The Territoriality Principle and Transnational Use of Patented Inventions – The Wider Reach of a Unitary Patent and the Role of the CJEU’ [2013] IIC 524, 530 and therein cited: Curtis A. Bradley, ‘Territorial Intellectual Property Rights in an Age of Globalism’ [1997] 37 Virginia Journal of International Law 505, 506sq. <[https://scholarship.law.duke.edu/faculty\\_scholarship/1187/](https://scholarship.law.duke.edu/faculty_scholarship/1187/)> (accessed 8 February 2024); Alexander Peukert, ‘Territoriality and Extraterritoriality in Intellectual Property Law’ in Günther Handl, Joachim Zekoll, Peer Zumbansen (eds) *Beyond Territoriality: Transnational Legal Authority in an Age of Globalization*, *Queen Mary Studies in International Law* (Brill Academic Publishing, 2012) 189–228, 2 sq. <<https://ssrn.com/abstract=1592263>> (accessed 10 May 2024); see also Opinion of Advocate General Jääskinen, 29 March 2012, Case C-5/11—Criminal proceedings against

Rendering the effect of the waiver contingent on whether IP protection exists in third countries lacks sound basis in IP law.<sup>39</sup> The export to third countries as such, or in other words the import into third countries, does not require the consent of the EU SPC holder, even if the same person is the holder of IP protection in the third country. The SPC waiver solely concerns activities in the EU.<sup>40</sup> An SPC will not be granted for the domestic manufacturing of a medicinal product intended for export, since the approval for the target market is under the jurisdiction of a foreign authority and does not fall under the definition of approval according to Directive 2001/83/EG or 2001/82/EG, as per Article 3 lit. b) of the SPC Regulation. The position of the certificate holder is not adversely affected in economic terms by domestic manufacturing for export, because the SPC is specifically designed to compensate for the time lost by the patent owner in the domestic market because of the time taken to get the medicinal product through the examination and grant process. Manufacturing purely for export does not impact on the domestic market and is therefore not related to the distribution of the domestically approved medicinal product.

Infringement of IP in a third country can be sanctioned according to the applicable law in that third country independently of the application of EU law.<sup>41</sup> For example, preparatory acts, like advertising aimed at a third country, which is explicitly privileged in the EU under Recital 9 of Regulation 2019/933, may constitute infringement of the applicable IP laws in the country of export.<sup>42</sup> To require that manufacturing in the EU can only commence after the expiry of relevant IP protection in third countries, which is a rather extreme version of this view, would effectively deprive the SPC waiver of its *raison d’être*, and thus perpetuate the disadvantages experienced by EU-based manufacturers compared to their counterparts in third countries, where such restrictions do not apply.<sup>43</sup>

Furthermore, such a requirement has no basis on the operative provisions of Regulation 2019/933 and could not be based solely on Recital 18 either. The CJEU has held that an ambiguous or incomplete provision shall be interpreted according to the objectives it pursues, and the national courts should consider the legislative purpose behind the law.<sup>44</sup> To this end, the CJEU usually refers to the relevant recitals in the preamble along with preparatory documents and legislative proposals.<sup>45</sup> According to the CJEU, the recitals cannot be referenced to derogate the operative terms.<sup>46</sup>

Titus Donner; CJEU Case C-192/04—Lagardère v SPRE 2005 ECR I-7199, para 46; cf Legal Provisions eg for the USA, 35 U.S.C. § 154(a)1 and § 271(a); for the UK, see Sec 60 Patents Act 1977.

<sup>39</sup>cf Kühnen, Kühnen, *Handbuch der Patentverletzung* (15th edn, Carl Heymanns Verlag 2023) pt A V, ch 8 [Mittelbare Patentverletzung] para 592, who requires a so-called ‘double domestic connection’ for indirect patent infringement.

<sup>40</sup>cf Regulation (EU) 2019/933 (n 3) Recital 13: ‘Effective and proportionate safeguards should apply in relation to the exception in order to increase transparency, to help the holder of a certificate enforce its protection in the Union and check compliance with the conditions set out in this Regulation, and to reduce the risk of illicit diversion onto the Union market during the term of the certificate. (...)’.

<sup>41</sup>cf Kühnen, *Handbuch der Patentverletzung* (n 39) pt A V, ch 7 [Benutzungshandlungen] para 326.

<sup>42</sup>Regarding the US, see 35 U.S.C. 271(a), cf Lucas S Osborn, ‘Ripple Effects in the Law: The Broadening Meaning of an “Offer to Sell” in Patent Law’ (2014) 17 Stan Tech L Rev 549 <[https://scholarship.law.campbell.edu/fac\\_sw/98](https://scholarship.law.campbell.edu/fac_sw/98)> (accessed 12 February 2024).

<sup>43</sup>cf Regulation (EU) 2019/933 (n 3) Recital 8.

<sup>44</sup>Case 26/62, van Gend & Loos v Nederlandse Administratie der Belastingen [1963] m.n. 27; cf Karl Larenz/Claus-Wilhelm Canaris, *Methodenlehre* (3rd rev edn, Springer, Munich, Bavaria, Germany 2001) 153.

<sup>45</sup>Llio Humphreys and others, ‘Mapping Recitals to Normative Provisions in EU Legislation to Assist Legal Interpretation’ (2015) International Conference on Legal Knowledge and Information Systems <<https://icr.uni.lu/leonvanderortte/papers/jurix2015.pdf>> (accessed 1 September 2023).

<sup>46</sup>Case C-162/97, Nilsson et al, para 54, 1998, E.C.R. I-07477; and Case C-344/04, IATA, ELFAA v Department for Transport, § 76.

When a recital is inconsistent with the operative terms, effect is given only to the latter.<sup>47</sup> The CJEU affirms that the recitals can only be used to interpret ambiguous provisions, but they cannot restrict the scope of unambiguous provisions.<sup>48</sup> In the words of the CJEU, 'the terms of a Recital cannot be used to give a particular construction to a provision which the terms of that provision would not otherwise bear'.<sup>49</sup> Therefore, recitals in general, including Recital 18 of Regulation 2019/933, do not exert an independent normative effect.<sup>50</sup>

It is questionable whether the wording of the second sentence of Recital 18 would even meet the standards outlined in the EU Joint Practical Guide regarding drafting of recitals.<sup>51</sup> According to this guide for drafting EU legislation, the operative terms, the so-called 'enacting terms', 'should lay down rules, and include provisions setting out the information (for example: the scope and the definitions) necessary to understand and apply those rules correctly'.<sup>52</sup> The guide goes on to say: '[A]nything else is superfluous: desires, intentions and declarations do not belong in the enacting terms of a binding act'.<sup>53</sup> On the other hand, the primary function of recitals in EU law is to explain the essential objective pursued by the respective legislative act. They give effect to Article 296 TFEU, which stipulates that all legal acts must state the reasons on which they are based. According to the EU Joint Practical Guide for drafting EU legislation, the purpose of the recitals is to set out concise reasons for the main provisions of the operative terms in non-mandatory language, without reproducing or paraphrasing them.<sup>54</sup> In other words, the recitals should contain the motivation or 'statement of reasons for the adoption of the act'.<sup>55</sup> The EU Joint Practical Guide further recommends specific elements of the recitals: '(a) a succinct statement of the relevant points of fact and of law; (b) the conclusion that it is therefore necessary or appropriate to adopt the measures set out in the enacting terms; and (c) the historical context of the act'.<sup>56</sup> Thus, no mandatory element can be autonomously derived from Recital 18.

In any case, the wording of Recital 18 neither establishes an enforceable duty under Regulation 2019/933, nor a requirement upon which the application of the waiver depends. According to the Cambridge Dictionary, 'should' is used 'most commonly to talk about what is ideal or best thing to do in a situation' and 'to give advice and make suggestions'.<sup>57</sup> In contrast, 'shall' is used in very formal contexts to give commands.<sup>58</sup> Accordingly, 'should, not shall' is used for advice and suggestions.<sup>59</sup> This corresponds with the German wording of Recital 18, 'sollte dafür verantwortlich

sein, sich zu vergewissern', which uses the verb 'sollten' instead of 'müssen' to express, according to the Duden Dictionary, that a certain behaviour is required, desired, right, beneficial or actually expected, but not obligatory.<sup>60</sup> Any prudent company should of course conduct a so-called freedom-to-operate (FTO) before launching a product, especially in a foreign market. Inadequate or faulty FTO analyses frequently result in infringement of IP rights, which can be enforced according to the applicable law, but it does not have any effect on the application of the SPC waiver.

In this regard, the legislative history of this provision needs to be considered. The clear intention of the European legislator was not to establish such an enforceable duty under Regulation 2019/933, as is clearly explained in the Third Revised Proposal.<sup>61</sup> 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 not included this suggestion as, *inter alia*, it is not the role of a court in the Union to investigate the legal situation of the product to be exported in third countries. Hence, the European legislator consciously and explicitly decided to omit such a reference in the operative terms, thereby opting not to include such a constitutive requirement.

The question of whether foreign IP rights are relevant for the application of Regulation 2019/933 cannot be conflated with principles of international private law, among other things the question of the competent court and the applicable law. At the present time, when questions relating to international jurisdiction in matters of IP law arise, the primary framework used in the EU is the Brussels I Regulation. Under Article 4 (1) of the Brussels I Regulation, defendants residing in an EU Member State are generally subject to the jurisdiction of the courts in that State (referred to as the general jurisdiction of the defendant). Consequently, legal actions can also be initiated in the general jurisdiction of the defendant's domicile for acts of infringement that occur in another state. The ability to bring infringements occurring in other countries before a domestic court, in accordance with the provisions of the Brussels I Regulation, offers the significant advantage of being able to address multi-jurisdictional offenses in a single legal proceeding.<sup>62</sup> Regarding IP infringement, the principle of *lex loci protectionis* of Article 8 (1) of Rome II Regulation apply, namely the law of the country for whose territory IP protection is claimed. A reasonable plaintiff would claim IP protection for the country where IP protection has actually been granted.<sup>63</sup> In the case of infringement of a pharmaceutical patent in the USA by a company having its seat in Germany, the said company can be sued before German courts, although the German courts would need to apply US patent law to determine the fact of infringement. Even if courts are generally reluctant to apply foreign law, this is legally possible.

However, transnational patent litigation is no longer common, even in theory. For the sake of clarity, reference must be made to the *GAT v Luk*<sup>64</sup> judgment of the CJEU and Article 24 (4) of Brussels I Regulation that generally overruled transnational patent litigation regarding the validity of patents granted outside of the court's

<sup>47</sup>Slaughter and May, 'Introduction to the legislative processes for European Union Directives and

Regulations on financial services matters' (April 2014) <<http://www.slaughterandmay.com/media/1934583/introduction-to-the-legislative-processes-for-european-union-directives-and-regulations-on-financial-services-matters.pdf>> (accessed 1 September 2023).

<sup>48</sup>Case C-244/95, P. Moskof AE v Ethnikos Organismos Kapnou, 1997 E.C.R. I-06441.

<sup>49</sup>Case C-412/93, Société d'Importation Edouard Leclerc-Siplec v TF1 Publicité SA and M6 Publicité SA.

<sup>50</sup>*Ibid.*

<sup>51</sup>cf European Union, 'Joint Practical Guide of the European Parliament, the Council and the Commission for persons involved in the drafting of European Union legislation' (2015) 31 <<https://eur-lex.europa.eu/content/techleg/KB0213228ENN.pdf>> (accessed 1 September 2023).

<sup>52</sup>European Union, 'Joint Practical Guide' (n 51) 38.

<sup>53</sup>*Ibid.*

<sup>54</sup>European Union, 'Joint Practical Guide' (n 51) 31.

<sup>55</sup>*Ibid.*

<sup>56</sup>*Ibid.*

<sup>57</sup>Cambridge Dictionary, Should, <<https://dictionary.cambridge.org/grammar/british-grammar/Should>> (accessed 1 September 2023).

<sup>58</sup>Cambridge Dictionary, Shall <<https://dictionary.cambridge.org/grammar/british-grammar/shall>> (accessed 1 September 2023).

<sup>59</sup>*Ibid.*

<sup>60</sup>Duden, Sollen <<https://www.duden.de/rechtschreibung/sollen>> (accessed 1 September 2023).

<sup>61</sup>3rd Revised Proposal, Council of the European Union, Brussels, 22 November 2018, 14647/18, 3.

<sup>62</sup>Drexler, *Münchener Kommentar zum BGB*, Vol 13 (8th edn, C.H.BECK 2021) Rome II VO pt 6 ch 2 Art 8 para 11.

<sup>63</sup>*Ibid.*

<sup>64</sup>CJEU, Case C-4/03, ECLI:EU:C:2006:457—Gesellschaft für Antriebstechnik mBH & Co KG (GAT) v Lamellen und Kupplungsbau Beteiligungs KG (LuK).

jurisdiction. This is compatible with the opinion of the Council of the European Union as documented in the Third Revised Proposal.<sup>65</sup>

According to Article 24(4) Brussels I Regulation, the courts of a Member State have exclusive jurisdiction concerning the registration or validity of patents granted in their own national jurisdiction. In a general sense, Article 24(4) seeks to secure jurisdiction for certain matters by designating courts closely connected to the proceedings in both substance and legal aspects.<sup>66</sup> This is especially important in the context of patents, where the aim is to ensure that these cases are handled by specialized courts.<sup>67</sup> Exclusive jurisdiction is deemed necessary due to the specialized nature of patent law, coupled with the existence of specific judicial protection systems in various countries.<sup>68</sup> The requirement for exclusive jurisdiction is further underscored by the involvement of national administrative authorities in the patent-granting process.<sup>69</sup> The CJEU ruled in *GAT v LuK* that the exclusive jurisdiction provided for by Article 24(4) should apply whatever the form of the proceedings in which the issue of a patent's validity is raised: by way of an action or a defence, or at whatever stage in the proceedings.<sup>70</sup>

However, regarding Recital 18, it might be assumed when applying EU law that according to Regulation 2019/933 an infringement of foreign IP law simultaneously constitutes infringement of EU IP law; this could only be based on Regulation 2019/933 and not on international private law. As such, no interpretation method of Regulation 2019/933 allows for such a conclusion. Otherwise, such a consequence could easily lead to abusive practices; for instance, a company claiming that an infringement of any IP right, eg a copyright, in an exotic foreign jurisdiction constitutes infringement of an SPC granted in the EU. SPCs are *sui generis* rights and thus cannot be compared with other foreign IP rights, since SPCs do not fall under the scope of application of the Agreement on Trade-Related Aspects of Intellectual Property Rights Agreement.<sup>71</sup> Even if there were such an FTO-related duty, it could entail practical challenges for the maker in proving the absence of relevant rights in third countries beforehand, since the certificate holder, usually the IP-rights holder in the third countries, is in a better position to provide such proof. It goes without saying that this hypothetical duty would be bound up with immense legal uncertainty for the maker.

## II. Temporal scope of application and transitional period

Article 5 (10) of the amended SPC Regulation in combination with Recitals 26 and 27 of Regulation 2019/933 prescribe the temporal scope of application of the SPC waivers. Accordingly, to safeguard the rights of certificate holders, the SPC waiver does not apply to a certificate that has already taken effect at the date of entry into force of the Regulation, namely 1 July 2019. Instead, the exemption should only apply to certificates that are applied for on or after the date of entry into force of the Regulation. Since a certificate can only come into effect at the end of the term of the basic

patent, which can be a relatively long time after the date of filing the application for the certificate, the SPC waiver also covers a certificate that was applied before the date of entry into force of the Regulation, but has not yet taken effect before that date, irrespective of whether or not that certificate was granted before that date. In this case, the exemption should apply only from 2 July 2022 to a certificate that takes effect from the date of entry into force of this Regulation. The progressive temporal scope of application should ensure that the exemption is applied to such a certificate, depending on the date on which it takes effect and on its duration. Such application provides for a reasonable period of transition for certificate holders to adapt to the changed legal context, while ensuring that makers of generics and biosimilars can benefit effectively, without excessive delay, from the exemption.

Regarding the application of Regulation 2019/933 in EEA-EFTA countries, not 1 July 2019, but 10 June 2022 is the relevant date, ie the date of entry into force of the Decision of the EEA Joint Committee.<sup>72</sup> Since Iceland's national SPC waiver provisions entered into force quite soon after the EU Regulation itself, Iceland included similar, yet shorter, transitional provisions as compared with the EU ones: As of 2 July 2022, the waiver applies to SPCs entering into force on 1 July 2021, and later if an SPC application has been filed prior to that date.<sup>73</sup>

Recital 27, introducing the exemption on the basis of the filing date of the application for a certificate, is intended to promote uniformity and limit the risk of disparities. Typically, an applicant for a certificate files an application at approximately the same time in each Member State in which the certificate is being applied for. However, due to differences in national procedures for the examination of applications, the date of grant of the certificate might vary significantly, which results in disparities in the legal situation of the applicant in the Member States in which the certificate is being applied for.

## III. Personal scope of application: maker, third parties and the certificate holder

It is essential to define the scope of the Regulation as it applies to particular persons or entities in order to determine what rights and obligations can be attributed to each party. The Regulation addresses three categories of person: the maker, third parties and the certificate holder. While the term 'certificate holder' is unambiguous, the terms 'maker' and 'third parties' deserve a closer look due to their interrelationship and given the fact that both terms can only be attributed alternatively.

### 1. 'Certificate holder'

Elaboration is hardly necessary here, especially because under Article 11 (1) lit. a) of Regulation (EC) No 469/2009, the name and address of the certificate holder are published by the competent authority granting the SPC in question.

### 2. 'Maker'

The term 'maker' as used in the SPC Waiver Regulation is important. The 'maker' is the person who triggers application of the waiver and essentially takes advantage of the privileged acts, on condition that they fulfil all the information, due diligence and labelling obligations. The distinction between 'third parties' and

<sup>65</sup>3rd Revised Proposal, Council of the European Union, Brussels, 22 November 2018, 14647/18, p.3.

<sup>66</sup>Paul England, 'Cross-border actions in the CJEU and English Patents Court – ten years on from *GAT v LuK*' [2017] GRUR Int 293, 294 sqq.

<sup>67</sup>*Ibid.*

<sup>68</sup>*Ibid.*

<sup>69</sup>*Ibid.*

<sup>70</sup>CJEU, Case C-4/03, ECLI:EU:C:2006:457—Gesellschaft für Antriebstechnik mBH & Co KG (*GAT*) v Lamellen und Kupplungsbau Beteiligungs KG (*LuK*).

<sup>71</sup>cf Miguel Vidal-Quadrás, 'Analysis of EU Regulation 2019/933' (n 2) 979sq.

<sup>72</sup>Decision of the EEA Joint Committee No 197/2022 of 10 June 2022 amending Annex XVII (Intellectual property) to the EEA Agreement [2022/1897], Art 1 (3).

<sup>73</sup>Jiří Slavík, 'Analysing the use of the SPC waiver provisions and its reach outside the EU' (n 33).



'maker' is also highly relevant when, in the course of litigation, the certificate holder claims that the designated 'third parties' are in fact 'makers' and must abide by the obligations of Regulation 2019/933. Pursuant to Article 1 (1) (f) of SPC Regulation ((EC) No 469/2009) "'maker" means the person, established in the Union, on whose behalf the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out'. Thus, the Regulation requires that the maker be established in the Union and that the making of a product, or a medicinal product containing that product, for the purpose of export to third countries or for the purpose of storing, is carried out on that person's behalf. However, upon closer inspection, questions arise.

## 2.1 Do only generics and biosimilars companies qualify as 'maker'?

To begin with, it is questionable whether 'maker' may only be a generics and biosimilars company, since the recitals only use the term 'maker' in the context of generics and biosimilars. Then again, recitals have no independent legal effect; they can only act complementary/secondary to the operative terms. The European legislator could have included the term 'generics or biosimilars company' in the operative terms to avoid any ambiguity as to its limited personal scope. Since the broader term 'maker' was chosen instead, it appears more likely that no such restriction was envisioned, and that the mention in the recitals of only 'generics and biosimilars' merely reflects the focus of the European legislator upon this sector, but does not support the conclusion that originators were to be excluded from the granted privileges. A more restrictive interpretation would also not serve the other legitimate aims of the Regulation, namely, to facilitate a timely entry into the EU market of cheaper pharmaceuticals after the expiry of the corresponding SPCs, to lower public health care costs and to boost pharmaceutical manufacturing with the ultimate aim of preventing or minimizing medicines shortages. These aims can, of course, be achieved by competitors who are originators but intend to bring a generic pharmaceutical into the EU market. Nevertheless, such a restriction would be arbitrary. The roles of a generic and originator company often overlap depending on the pharmaceutical in question; many originators maintain generics branches, while many generics companies, especially biosimilars, conduct innovative research.<sup>74</sup> This is also compatible with the EU Commission's characterization of EU-based manufacturers in the Draft Proposal:<sup>75</sup> 'Whether they have their headquarters in the Union or in a non-EU country, and including generics/biosimilars subsidiaries of innovative pharmaceutical companies.' Therefore, while the recitals only refer to 'generics and biosimilars', any pharmaceutical company that plans to bring to the market a generic or biosimilar medicinal product in relation to the corresponding SPC is eligible as maker regardless of its overall portfolio.

<sup>74</sup>cf Commission, 'Commission Staff Working Document, Impact Assessment Accompanying the document Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products', SWD(2018) 240 final, 12: 'Today, the classical boundaries between originators and generics/biosimilars manufacturers are more blurred. Some originators have branches devoted to generics (e.g. Novartis/Sandoz, Pfizer and Merck KGaA are the top sellers of unbranded products in the EU) and some traditional generic manufacturers are developing innovative or high value-added generics and biosimilars (eg Mylan, Dr Reddy's or Teva)'. <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2018:240:FIN>> (accessed 12 February 2024).

<sup>75</sup>Commission, 'Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No 469/2009 concerning the supplementary protection certificate for medicinal products' COM(2018) 317 final, see there fn 11 <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A317%3AFIN>> (accessed 12 February 2024).

## 2.2 'Established in the Union'

For a definition of 'established in the Union', reference can be made to Article 49 (1) sentence 2, and Article 54 TFEU. According to Article 49 (1) sentence 2 TFEU, the freedom to secondary establishment applies only for 'nationals of any Member State established in the territory of any Member State'. Article 54 (1) TFEU extends the applicability of the right to establishment to legal persons which can prove a specific Union nexus:

Companies or firms formed in accordance with the law of a Member State and having their registered office, central administration or principal place of business within the Union shall, for the purposes of this Chapter, be treated in the same way as natural persons who are nationals of Member States.

Hence, Article 54(1) stipulates two obligatory conditions in order for companies to be treated in the same way as natural persons with the freedom of establishment: their formation under the law of a Member State and their presence in the European Union.<sup>76</sup> According to settled CJEU case law, 'the location of their registered office, central administration or principal place of business serves as the connecting factor with the legal system of a particular State in the same way as does nationality in the case of a natural person'.<sup>77</sup> The three connecting factors mentioned in Article 54 (1) TFEU are each alternatives to one another. In this way, the Treaty takes account of the different company law situations in the Member States.<sup>78</sup> While the central administration is located at the place of entrepreneurial management (recognizable to third parties), the principal place of business is located at the actual centre of business, ie where the essential human and material resources are concentrated, whereas, the registered office is the statutory seat specified in the articles of association.<sup>79</sup> As the EU Commission suggests in its first Proposal, manufacturers do not need to have their headquarters in the EU to be considered EU-established.<sup>80</sup>

However, maintaining a merely nominal presence by establishing a registered office in a Member State in the Articles of Association alone could ultimately lead to letterbox companies in the Union without any economic link to the internal market.<sup>81</sup> This is because Article 54 does not require that, in addition to the registered office, the head office or the principal place of business be located in a Member State of the Union. Therefore, in addition to a registered office, a real and lasting link with the economy in the Union is also required.<sup>82</sup> Such a link exists if, in addition to the formal registered office, the company concerned already has a secondary establishment in the territory of the Union, but also if the internal market is one of its main outlets or, for example, if the company has made significant direct investments. Natural persons who wish to establish a secondary establishment must even prove, on the basis of the wording of Article 49 (1) sentence 2 TFEU, that they are resident in a Member State in addition to

<sup>76</sup>Jürgen Tiedje, *Europäisches Unionsrecht* (Hans von der Groeben/Jürgen Schwarze/Armin Hatje (eds), 7th edn, Nomos 2015) TFEU Art 54 para 25.

<sup>77</sup>CJEU 270/83, Slg. 1986, 273 Rn. 18—Kom./Frankreich; 79/85, Slg. 1986, 2375 Rn. 13—Segers; C-330/91, Slg. 1993, I-4017 Rn. 13—Commerzbank; C-264/96, Slg. 1998, I-4695 Rn. 20—ICI; C-212/97, Slg. 1999, I-1459 Rn. 20—Centros; cf Forsthooff, *Das Recht der Europäischen Union* (Eberhard Grabitz/Meinhardt Hilf/Martin Nettesheim (eds), 79th EL, C.H.BECK May 2023) TFEU Art 54 para 21.

<sup>78</sup>Forsthooff, *Das Recht der Europäischen Union* (n 77) TFEU Art 54 margin 21.

<sup>79</sup>Korte, *EUV/AEUV: Das Verfassungsrecht der Europäischen Union mit Europäischer Grundrechtecharta* (Christian Callies/Matthias Ruffert (eds), 6th edn, C.H.BECK 2022) TFEU Art 54 para 19.

<sup>80</sup>cf Commission, 'Proposal COM(2018) 317 final' (n 75), see there fn 11.

<sup>81</sup>Jürgen Tiedje, *Europäisches Unionsrecht* (n 76) TFEU Art 54 para 29.

<sup>82</sup>Forsthooff, *Das Recht der Europäischen Union* (n 77) TFEU Art 49 para 59.

their nationality.<sup>83</sup> Accordingly, companies that are established in a Member State but only have a formal registered office in the EU cannot be placed in a better position.<sup>84</sup> The 'General Programme for the abolition of restrictions on freedom of establishment' from the year 1962 therefore states that should these companies have only their registered office within the Community, their activities must show 'a real and continuous link with the economy of a Member State'.<sup>85</sup> This is also consistent with the aforementioned overarching aim of the SPC Waiver Regulation, which seeks to redress disadvantages of EU-based generics and biosimilars companies compared to their competitors in third countries, where no similar protection exists or has elapsed. This requires a stronger link than a mere letterbox company actually based in third countries merely seeking to take advantage of the SPC waiver legal regime. While investing in generics and biosimilars development in the EU could prove a sufficient economic investment, it is at least doubtful whether this would satisfy the requirement of the 'continuous link' as mentioned above. Notwithstanding the aforementioned criteria, the specific circumstances of each case must be taken into account.

### 2.3 'Making [...] is carried out on [their] behalf'

'On behalf' is a broad term that implies a contractual relationship of some kind, according to which the 'third-party' manufactures the medicinal product for the benefit or for account of the 'maker'. Thus, the term 'on behalf' is inextricably bound up with the third parties commissioned to manufacture the product. As can be derived from the wording of the Regulation, paradoxically, the 'maker' does not need to 'make' any product themselves, as long as this product is made on their behalf.<sup>86</sup> In the case of subcontractors who are themselves commissioned with parts of the manufacturing process, the term 'on behalf' becomes blurry. The more complex the sub-levels evolve, the more this muddles the definition of 'maker', especially when the maker tends to be the party that commissions the making but is not itself directly involved in the making. A distinction has to be made between the 'maker' and 'third parties' (see below).

The 'maker' could be defined as the holder of the manufacturing authorization according to Article 40 sqq. of the amended Directive 2001/83/EC.<sup>87</sup> However, this does not sufficiently differentiate between the 'maker' and 'third parties', since both could be holders of a manufacturing authorization: According to Article 40 (2) of the amended Directive 2001/83/EC, such an authorization is required 'for both total and partial manufacture, and for the various processes of dividing up, packaging or presentation'.<sup>88</sup> Apart from this, as previously explained above, the 'maker' does need to manufacture anything themselves so the property of the manufacturing authorization holder is not necessary.

A helpful hint for navigating this confusing territory can be found in the overall system of the Regulation: According to Article 5 (5) lit. e) of Regulation 2019/933, for medicinal products to be exported to third countries, the 'maker' has to provide the reference number of the marketing authorization, or the equivalent of such authorization, in each third country of export, as soon as it is publicly available. It is safe to assume that the person best suited to provide this information is the holder of the marketing authorization themselves. Thus, based on the system of the Regulation, the maker and the holder (or rather the applicant when the marketing authorization has not yet been granted) of the corresponding marketing authorization regarding the specific product must be one and the same person or entity. This interpretation is confirmed by Article 2 (2) of Regulation (EC) No 726/2004 regarding the definition of 'marketing authorization holder', which has elements in common with 'maker': 'The holder of a marketing authorisation for medicinal products covered by this Regulation must be established in the Community. The holder shall be responsible for the placing on the market of those medicinal products, whether he does it himself or via one or more persons designated to that effect'.<sup>89</sup> Both the 'maker' and the marketing authorization holder must be established in the EU and can act via third parties. The SPC waiver privileges acts that ultimately lead to 'placing on the market', either in the EU or in third countries, so the 'maker' 'shall be responsible for the placing on the market of those medicinal products' as well. A more accurate definition of 'maker' can be deduced from the aforementioned: 'making of a product, [...], for the purpose of export to third countries or for the purpose of storing is carried out on behalf of the person responsible for the placing on the market of those medicinal products', in other words, the marketing authorization holder or, where this has not yet been granted, the applicant of the marketing authorization.

### 3. 'Third parties'

As explained above under Section 2.2.2, any privileged acts under Article 5 (2) lit. a) of Regulation 2019/933 can be directly executed by third parties on behalf of the 'maker'.<sup>90</sup> While Recital 9 of the SPC Waiver Regulation provides that the 'exception should also apply to related acts performed by third parties who are in a contractual relationship with the maker', the wording of Article 5 (9) of Regulation 2019/933 that imposes due diligence obligations on the 'maker' related to third parties refers to third parties as 'any person in a contractual relationship with the maker who performs acts falling under point (a) of paragraph 2'. Whereas the operative term and the Recital appear contradictory in this regard, as the Recital limits the privileged acts that can be executed to so-called 'related acts', preference shall be given to the operative term. Therefore, third parties can execute all privileged acts under (2) lit. a) that would otherwise need the consent of the certificate holder.

<sup>83</sup>Jürgen Tiedje, *Europäisches Unionsrecht* (n 76) TFEU Art 54 para 30.

<sup>84</sup>Jürgen Tiedje, *Europäisches Unionsrecht* (n 76) TFEU Art 54 para 30; cf Peter Kindler, 'Der reale Niederlassungsbegriff nach dem VALE-Urteil des EuGH' [2012] EuZW 888.

<sup>85</sup>Jürgen Tiedje, *Europäisches Unionsrecht* (n 76) TFEU Art 54 para 30; cf for a mediating view: Korte, *EUV/AEUV: Das Verfassungsrecht der Europäischen Union mit Europäischer Grundrechtecharta* (n 79) TFEU Art 54 para 22.

<sup>86</sup>cf Regulation (EU) 2019/933 (n 3) Recital 14: '(...) It is possible [therefore not necessary] that the maker directly carries out the making'.

<sup>87</sup>A hint can be found in Regulation (EU) 2019/933 (n 3) Recital 25: 'This Regulation does not affect the application of Directives 2001/82/EC and 2001/83/EC, in particular the requirements relating to the manufacturing authorisation of medicinal products made for export'.

<sup>88</sup>cf Commission, 'Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use' OJ L311/67, Art 40 (2): '(...) However, such authorization shall not be required for preparation, dividing up, changes in packaging or presentation where these processes are carried out, solely for retail supply, by pharmacists in dispensing pharmacies or by persons legally authorized in the Member States to carry out such processes'.

<sup>89</sup>cf Commission, 'Proposal for a Regulation of the European Parliament and the Council laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006' COM(2023) 193 final, Art 5 Nr 1: 'The marketing authorisation holder for medicinal products covered by this Regulation shall be established in the Union. The marketing authorisation holder shall be responsible for the placing on the market of those medicinal products, whether done by that marketing authorisation holder or via one or more persons designated to that effect'.

<sup>90</sup>cf Regulation (EU) 2019/933 (n 3, 40).



Based on the wording of the amended Regulation,<sup>91</sup> third parties may execute privileged acts under Article 5 (2) lit. a) on behalf of and in contractual relationship with the ‘maker’. Regarding third parties, reference shall be made to the term ‘contract manufacturer’ in Article 17 of the Commission Delegated Regulation (EU) No 1252/2014: according to Article 17 (1), a manufacturing operation or an operation linked thereto which is to be carried out on behalf of the manufacturer of the active substance by another party (*‘the contract manufacturer’*) shall be the subject of a written contract. Furthermore, the contract shall clearly define the responsibilities of the contract manufacturer with regard to good manufacturing practice. Article 17 (2) provides that the manufacturer of the active substance is responsible for ensuring that operations carried out by a contract manufacturer comply with good manufacturing practice. According to Article 17 (3), a manufacturing operation which has been entrusted to a contract manufacturer shall not be subcontracted to a third party without the written consent of the manufacturer of the active substance. Thus, third parties addressed by the SPC Waiver Regulation are ‘contract manufacturers’ within the meaning of Article 17 of the Commission Delegated Regulation (EU) No 1252/2014, when the ‘maker’ is a manufacturer as well.

This contractual relationship may also exist in the case of group companies depending on their corporate governance structure. Third parties who have a contractual relationship with the maker can be suppliers, clients or subcontractors: a supplier of the manufacturer could be the manufacturer of the active pharmaceutical ingredient or Active ingredient (API), or of an intermediate of that API; a client could be a manufacturer of the medicinal product or a distributor of the pharmaceutical; and a subcontractor could be the person or company that carries out activities such as storage, packaging, transport or export.<sup>92</sup> Third parties can be both primarily and secondarily liable for SPC infringement depending on the specific circumstances of the case, when they exceed the privileged scope of application of the SPC Waiver.

## C. Summary

The SPC waiver introduced by Regulation 2019/933 aims to address competitive disadvantages faced by EU-based generics and biosimilars manufacturers compared to their non-EU counterparts. Based on the recitals, the purpose of the Regulation is to facilitate timely market entry by allowing manufacturing and other strictly related acts before SPC expiry, both for export to the EU and EEA or to third countries. However, conflicts arise due to ambiguous clauses, redundant recitals and a complex legislative process, all of which lead to legal uncertainty.

The territorial scope of Regulation 2019/933 is directly applicable in the EU and has modified indirect application in the EEA, subject to national legal provisions and decisions of the EEA Joint Committee. Liechtenstein, which does not grant SPCs, is excluded from the scope of the Regulation. The SPC waiver is now in force in Norway, Iceland, following amendments to their respective patent laws.

The Regulation does not have extraterritorial application in third countries. Thus, IP protection in third countries, or the

lack thereof, does not affect the application of the SPC waiver in the EU. The requirement for privileged manufacturing in the EU to commence only after relevant IP protection expires in third countries lacks a sound basis in IP law and conflicts with the territoriality principle of IP rights. The legislative history of Regulation 2019/933 reveals the European legislator’s explicit intention not to establish an enforceable duty regarding foreign IP rights. Recital 18, which mentions verifying the absence of IP protection in export countries, does not impose an enforceable duty and cannot be interpreted as doing so. Regarding transnational patent litigation, the Brussels I Regulation and the *GAT v Luk* judgment of the CJEU limit jurisdiction concerning the registration or validity of patents to courts of the Member State where the patent is granted. However, an infringement of foreign IP law does not necessarily constitute infringement of EU IP law, and no interpretation method of Regulation 2019/933 allows for such a conclusion. Such an interpretation could lead to abusive practices and legal uncertainty for EU-based generics and biosimilars companies/manufacturers.

The temporal scope of Regulation 2019/933, outlined in Article 5(10) and Recitals 26 and 27, dictates that the SPC waiver applies to certificates applied for on or after 1 July 2019, the date of entry into force of the Regulation. However, it also covers certificates applied for before this date but not yet in effect, starting from 2 July 2022. This progressive approach allows for a reasonable transition period, ensuring both certificate holders and generics/biosimilars manufacturers can adapt to the changed legal landscape. In EEA-EFTA states, the relevant date for the application of the Regulation is the entry into force of the Decision of the EEA Joint Committee, typically 10 June 2022. Iceland implemented similar transitional provisions, applying the waiver to SPCs entering into force from 1 July 2021 onwards, if an application was filed prior to that date. Recital 27 emphasizes the importance of basing the exemption on the date of the application for a certificate in order to promote uniformity and minimize disparities. Despite potential variations in the grant date due to national procedural differences, this approach ensures consistency in the status of applications across Member States.

The analysis of Regulation 2019/933’s scope as it applies to different categories of person shows the interrelations between makers and third parties. Eligibility as a maker extends beyond generics and biosimilars companies, with the Regulation accommodating any pharmaceutical company intending to bring generic or biosimilar medicinal products to market. However, companies must be established in the EU, meaning they must have a genuine and continuous link with the EU economy beyond merely having a registered office. The primary difference between ‘makers’ and ‘third parties’ is that the former must be the applicant or holder of the marketing authorization. Third parties, such as contract manufacturers or subcontractors, may thus execute privileged acts on behalf of the maker. If a subcontractor, entrusted with specific manufacturing tasks by the maker, engages in activities beyond the scope of their authorization or fails to adhere to the required standards, they can be held liable for direct or indirect SPC infringement.

The second part of this article will undertake a detailed examination of the material scope of the SPC waiver, scrutinizing the privileged acts while considering the temporal, geographical and purposive restrictions of these acts. Furthermore, it will assess the obligations on makers, including notification, due diligence obligations and adherence to labelling requirements, depending on the applicable provisions. The second part will also discuss

<sup>91</sup>cf Commission, ‘Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products’ OJ L 152/1,

Art 5 (9): ‘contractual relationship’; Regulation (EU) 2019/933 (n 3) Art 1 (1): ‘whose behalf’.

<sup>92</sup>Miguel Vidal-Quadras, ‘Analysis of EU Regulation 2019/933’ (n 2) 993.

pending and potential cases involving the SPC waiver. Specifically, it will examine the obligations of generics and biosimilars manufacturers to provide information to the certificate holder, as stipulated in Article 5(5) lit. e). Finally, it will discuss the

assimilation of SPC waiver provisions into the new EU Pharmaceutical Package and conclude with a critical assessment of the regulatory framework and practical ramifications of the waiver.