從國際評論淺談歐盟補充保護證書制度導入醫藥品製造免責之現況與未來

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壹、前言

貳、歐盟補充保護證書制度導入製造免責

參、從國際評論分析歐盟補充保護證書之製造免責

肆、淺談歐盟補充保護證書之製造免責的現況與未來

伍、結語

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本文相關論述僅為一般研究探討，不代表任職單位之意見。

摘要

歐盟規章 No 469/2009 修法前，歐盟補充保護證書到期前不得製造或儲存學名藥及生物相似藥，造成歐盟學名藥及生物相似性藥發展劣勢。為此，提出歐盟規章 No 2019/933，即製造免責。對此政策，在歐盟及國際引發熱烈討論，本文蒐集補充保護證書導入製造免責評論，將評論內容依法制面、實務面、成效面說明以提供各界評估參考。

關鍵字：補充保護證書制度、歐盟規章 No 2019/933、製造免責
Supplementary Protection Certificates(SPC)、Regulation (EC) No 469/2009、Manufacturing Waiver

壹、前言

歐盟補充保護證書（Supplementary Protection Certificates, SPC）類似專利權期間延長（patent term extension, PTE），SPC 立法目的係為鼓勵到歐盟從事醫藥品研發，原專利到期後授予額外特別（sui generis）保護來提供其充分有效保護。長期以來，SPC 營造利於醫藥創新之優勢，激勵研發者到歐盟研發新藥，尤其是需長期、高成本來研發之罕見疾病用藥及兒科用藥，更在歐盟蓬勃發展。然而，提供醫藥專利權人優渥保護，卻也造成歐盟學名藥（generic drug）或生物相似藥（biosimilar）市場面臨到前所未有之競爭劣勢。為緩解該競爭劣勢，歐洲執行委員會（European Commission, EC）於 2018 年 5 月 28 日最初公布 SPC 導入製造免責（Manufacturing Waiver 或 SPC Wavier 或 SPC Exemption，下稱 SPC 製造免責）草案[1]，為出口目的而製造受 SPC 保護之醫藥品，不再構成侵權。對此政策，在歐盟境內及國際上引發熱烈討論，有些報導表示質疑且否定，有些報導表示支持。而歐盟 SPC 製造免責實施迄今，尚未有任何援用 SPC 製造免責之公開，或許從國際評論及相關報導，可略見可能原因，並帶來不同省思。

貳、歐盟補充保護證書制度導入製造免責

SPC 類似 PTE，惟其本質不同於 PTE 立法目的，係補償醫藥品、農藥品或其製法發明專利，須依法取得上市許可而無法實施發明之期間。具體說明，歐盟規章 No 469/2009[2]（下稱歐盟規章 No 469/2009）前言（Recital）第 (3) 點[3]明定，醫藥品，特別是經過長期、昂貴研發之成果，除非法規能提供其**足夠保護**，否則

[1] 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 (https://ec.europa.eu/docsroom/documents/29462) Publication date: 2018/05/28 (last visited May 13, 2023).

[2] Regulation (EC) No 469/2009(https://www.legislation.gov.uk/eur/2009/469/contents) (last visited May 13, 2023).

[3] (3)Medicinal products, especially those that are the result of long, costly research will not continue to be developed in the Community and in Europe unless they are covered by favourable rules that provide for **sufficient protection** to encourage such research.

將不會在歐洲共同體繼續開發。同法前言第 (9) 點[4] 進一步明定，SPC 授予之保護期限應能提供**足夠有效保護**。為此，專利和證書持有人應能夠從所涉藥品首次獲得在共同體市場之上市許可日起享有最多 15 年獨占權。正如其名，SPC 立法目的，係在原專利權到期後提供額外特別（sui generis）保護，以提供足夠有效保護。至於補充保護證書之權利範圍，同法第 5 條[5] 規定，證書應授予與基礎專利相同之權利，並應受到相同限制及義務。同法第 4 條[6] 規定，SPC 授予之保護，係在基礎專利保護範圍內，該藥品許可上市所涵蓋之該產品及其在 SPC 屆期前被許可之**任何用途**。同法第 1(b) 條[7] 指出，產品係為藥品所含有效成分（active ingredient）或其組合。

歐盟規章 No 469/2009 修法前，SPC 享有與基礎專利相同之權利，SPC 保護範圍不存在任何例外情況，造成歐盟境內製藥商在 SPC 到期之前，不得製造或儲存學名藥及生物相似藥以預作準備，也不得出口到沒有相關保護規定之國家，導致歐盟境內製藥商在學名藥及生物相似藥市場面臨競爭劣勢。為此，提出歐盟規

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4 (9)The duration of the protection granted by the certificate should be such as to **provide adequate effective protection**. For this purpose, the holder of both a patent and a certificate should be able to enjoy an overall maximum of 15 years of exclusivity from the time the medicinal product in question first obtains authorisation to be placed on the market in the Community.

5 Article 5 Effects of the certificate
Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.

6 Article 4 Subject matter of protection
Within the limits of the protection conferred by the basic patent, the protection conferred by a certificate shall extend only to the product covered by the authorisation to place the corresponding medicinal product on the market and for any use of the product as a medicinal product that has been authorised before the expiry of the certificate.

7 Article 1 Definitions
For the purposes of this Regulation, the following definitions shall apply:
(a) ‘medicinal product’ means any substance or combination of substances presented for treating or preventing disease in human beings or animals and any substance or combination of substances which may be administered to human beings or animals with a view to making a medical diagnosis or to restoring, correcting or modifying physiological functions in humans or in animals;
(b) ‘product’ means the active ingredient or combination of active ingredients of a medicinal product

章 No 2019/933[8] 以修正歐盟規章 No 469/2009，歐盟規章 No 469/2009 第 5 條第 2 項[9] 新增免責規定，包含有：

(1) 在 SPC 保護期間，以出口到歐盟境外國家為目的而製造受保護之產品或含有該產品的醫藥品，並不構成侵權；

(2) 在 SPC 到期前 6 個月內，為了儲存以便 SPC 到期之後立即在歐盟成員國上市而製造受保護之產品或含有該產品的醫藥品，亦不構成侵權。

為確保 SPC 持有人之權益，同法第 5 條第 2(b) 項[10] 新增通知規定，欲使用免責之仿製藥商，須透過適當及文書方式，通知製造所在地之專利局以及 SPC 持有人；且該通知須在該製造開始前至少 3 個月，或在該製造之前，有任何受 SPC 保護所禁止之第一個相關行為開始前至少 3 個月，以較早者為準。同法第 5 條第 5

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8 Regulation (EU) 2019/933 (https://www.legislation.gov.uk/eur/2019/933/contents) (last visited May 13, 2023).

9 Article 5 Effects of the certificate

1. Subject to the provisions of Article 4, the certificate shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations.
2. By way of derogation from paragraph 1, the certificate referred to in paragraph 1 shall not confer protection against certain acts which would otherwise require the consent of the holder of the certificate (“the certificate holder”), if the following conditions are met: the acts comprise:(i)the making of a product, or a medicinal product containing that product, **for the purpose of export** to third countries; or (ii)any related act that is strictly necessary for the making, in the Union, referred to in point (i), or for the actual export; or (iii)the making, no earlier than six months before the expiry of the certificate, of a product, or a medicinal product containing that product, **for the purpose of storing** it in the Member State of making, in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate; or (iv)any related act that is strictly necessary for the making, in the Union, referred to in point (iii), or for the actual storing, provided that such related act is carried out no earlier than six months before the expiry of the certificate.

10 (b)the maker, through appropriate and documented means, notifies the authority referred to in Article 9(1) in the Member State in which that making is to take place, and informs the certificate holder, of the information listed in paragraph 5 of this Article no later than three months before the start date of the making in that Member State, or no later than three months before the first related act, prior to that making, that would otherwise be prohibited by the protection conferred by a certificate, whichever is the earlier.

項[11]規定通知項目，包括有，仿製藥商名稱及地址；製造目的（為出口、儲存或兩者兼有）；製造所在會員國（如有較早第一相關行為，則為該行為發生所在會員國）；前述會員國專利局授予之 SPC 證書號碼；對於出口到第三國之藥品，要提供第三國上市授權編號或等效授權編號。此外，為防止仿藥品重新進入或移轉到歐盟境內，同法第 5 條第 2(d) 項[12]規定，以出口為目的而製造的產品及其外包裝必須有其附錄 I 所示 EU export 之標誌（如圖 1）。

圖 1　歐盟規章 No 469/2009 附錄 I 標誌

同法第 5 條第 10 項[13]規定，SPC 製造免責適用於 2019 年 7 月 1 日（含）之後提出申請之 SPC，效力不及 2019 年 7 月 1 日之前生效之 SPC；至於 2019 年 7 月 1 日前提出申請之 SPC，於 2022 年 7 月 2 日起才有適用。以三類 SPC 圖示說明其適用製造免責之情形（如圖 2）：

[11] 5.The information to be provided by the maker for the purposes of point (b) of paragraph 2 shall be as follows: (a)the name and address of the maker; (b)an indication of whether the making is for the purpose of export, for the purpose of storing, or for the purpose of both export and storing; (c)the Member State in which the making and, if applicable, also the storing is to take place, and the Member State in which the first related act, if any, prior to that making is to take place; (d)the number of the certificate granted in the Member State of making, and the number of the certificate granted in the Member State of the first related act, if any, prior to that making; and (e)for medicinal products to be exported to third countries, the reference number of the marketing authorisation, or the equivalent of such authorisation, in each third country of export, as soon as it is publicly available.

[12] (d)in the case of products, or medicinal products containing those products, made for the purpose of export to third countries, the maker ensures that a logo, in the form set out in Annex -I, is affixed to the outer packaging of the product, or the medicinal product containing that product, referred to in point (a)(i) of this paragraph, and, where feasible, to its immediate packaging;

[13] Paragraph 2 shall apply to certificates that are applied for on or after 1 July 2019. Paragraph 2 shall also apply to certificates that have been applied for before 1 July 2019 and that take effect on or after that date. Paragraph 2 shall only apply to such certificates from 2 July 2022. Paragraph 2 shall not apply to certificates that take effect before 1 July 2019.

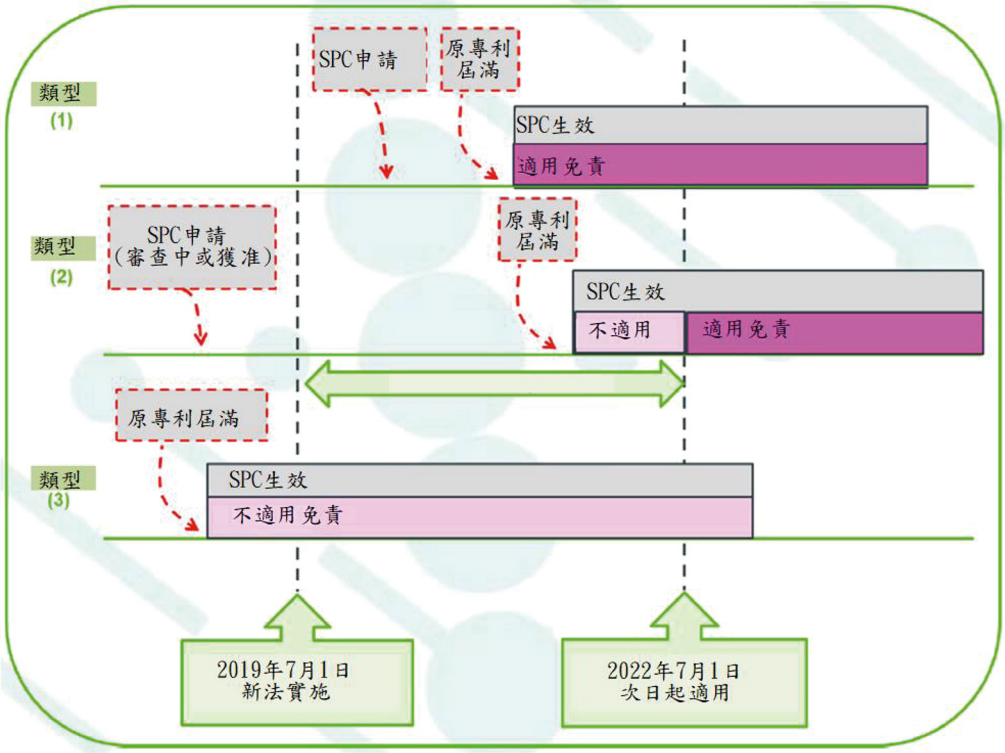

圖 2　三類 SPC 適用免責情形 [14]

參、從國際評論分析歐盟補充保護證書之製造免責

國際上對於歐盟 SPC 製造免責評論不斷，尤其對於 SPC 製造免責之法制合法性，提出諸多疑問，包括有 SPC 是否屬於專利權？SPC 製造免責是否合於與貿易有關之智慧財產權協定（Agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS）第 30 條 [15] 規範，未不合理抵觸專利權之正常使用，且未不合理損害專利所有權人之合法權益？SPC 製造免責是否合於 TRIPS 第 27 條 [16]

[14] 圖片修改自 https://www.biagaladinner.org/static/406c4fd9-c462-4b0d-addaa71bd56b4a77/3d3fdac5-c3ee-4249-bff7aa52127b54ca/BIA%20guide%20to%20the%20SPC%20manufacturing%20waiver.pdf.pdf.（最後瀏覽日 2023/05/13）

[15] 第三十條授予權利之例外會員於考量第三人合法利益下，得對所授予專利權為例外規定，但該例外規定並未不合理抵觸專利權之正常使用，且未不合理損害專利所有權人之合法權益。

[16] 第二十七條可予專利之標的 1. 在符合本條第二項及第三項規定之前提下，所有技術領域之發明應可取得專利，無論為物品或方法，惟需具備新穎性、進步性及可為產業上利用。在符合第六十五條第四項、第七十條第八項，及本條第三項規定之前提下，專利之取得及專利權之享有，不得因發明地、技術領域、或產品是否為進口或在本地製造，而有歧視。

規範，專利之取得及專利權之享有，不得因發明地、技術領域、或產品是否為進口或在本地製造，而有歧視？對此疑問，歐盟表示 SPC 係在原專利權到期後提供之額外特別保護，並不適用 TRIPS 協定。相關評論文獻[17]詳細分析，在探討 SPC 製造免責是否違反 TRIPS 協定前，首要釐清係 SPC 不同於 PTE，SPC 非屬於專利權，不會落入 TRIPS 協定規範之範圍，SPC 製造免責當然不會違反 TRIPS 協定。儘管如此，SPC 製造免責正式施行後，在 2020 年 2 月 WTO 貿易政策檢討期間，仍有多國對此提出質疑，認為恐有違反 TRIPS 規定之疑慮，可能削弱歐盟對智慧財產權之保護。

國際上對於 SPC 製造免責之實務可行性，亦提出諸多質疑，例如實務上恐因難以區分該產品是否係為出口至第三國而製造？歐盟將如何防止 SPC 免責規定被濫用等。此外，相關評論文獻[18]表示，儘管歐洲執行委員會有研議各種保障措施及澄清方式，例如，由學名藥商直接通知 SPC 持有人以及在訴訟案件中誰承擔舉證責任之澄清，但在 SPC 製造免責中未有詳盡且細節規定，恐導致實施後會遇到許多問題。甚至有相關評論報導[19]消極表示，SPC 製造免責可能需要至少十年時間累積足夠法律判例，才能夠填補、釐清現行 SPC 製造免責規定模糊之處。另有報導[20]表示，SPC 製造免責存在著不確定性，學名藥商擔心一旦提出免責使用通知，不知道原研藥商會不會對其提出相關警告或訴訟？不確定 SPC 涵蓋之藥品有沒有受到次要專利之保護，以至於有侵權之疑慮？

儘管實施前，歐洲執行委員會於 2017 年 10 月 5 日公開發表“評估在歐洲專利和 SPC 保護期間改變免責條款的經濟影響（Assessing the economic impacts of

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17 Analysis of EU Regulation 2019/933 on the SPC Manufacturing Waiver Exception, Miguel Vidal-Quadras, IIC (2019) 50:971–1005. (https://link.springer.com/article/10.1007/s40319-019-00860-7) (last visited May 13, 2023).

18 An export-only exception to pharmaceutical patents in Europe: should United States follow suit?, Nature Biotechnology. 2019, Vol. 37, No. 1 (https://www.nature.com/articles/nbt.4324) (last visited May 13, 2023).

19 Risk of SPC waiver counterattack makes generics extra cautious, Rory O'Neill July 21, 2022 (https://www.managingip.com/article/2adxpw95mqfh1hiqyyj9c/risk-of-spc-waiver-counterattack-makes-generics-extra-cautious) (last visited May 13, 2023).

20 SPC waiver: generics getting ready ahead of time, Charlotte Kilpatrick,2020/07/30 (https://www.managingip.com/article/2a5cx783ao223eeyu1dds/spc-waiver-generics-getting-ready-ahead-of-time) (last visited May 13, 2023).

changing exemption provisions during patent and SPC protection in Europe）”研究報告[21]表示免責對於歐盟經濟所帶來效應保守估計[22]，到 2025 年將為歐盟製藥行業帶來淨額額外銷售額 73 至 95 億歐元；為歐盟製造業帶來就業增長 13 至 16%（增加 2 至 2.5 萬個就業機會）；為歐盟活性藥物成分淨銷售額增加 2.543 億歐元並提供 2,000 個相關工作機會；為歐盟醫療系統節省藥品支出可達 4-8%（約 31 億歐元）。然而，國際上對於 SPC 製造免責之實施成效，亦提出不同見解。舉例而言，相關評論報導[23]表示，對於生物相似性藥品而言，一般需要至少 9-12 個月製造準備，因此，SPC 製造免責僅提供 6 個月準備期並不足夠，無法帶來實益。另相關評論文獻[24]甚至分析，歐盟所預期欲達成成效並不一定會實現。原因在於，事實上，對於某些新藥來說，出口市場可能太小，或者是，進入某些海外市場之法律和物流之障礙可能太高。再者，若存在有吸引力之出口國家，原研藥商可透過在這些國家布局新藥相關專利，以回應免責對其所造成影響。

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[21] Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe, Corporate author(s): Charles River Associates, Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (European Commission) (https://op.europa.eu/en/publication-detail/-/publication/6e4ce9f8-aa41-11e7-837e-01aa75ed71a1/language-en) (last visited May 13, 2023).

[22] With respect to the SPC export waiver to third countries, considering the impact on both EU-based innovators and generics and biosimilars, we estimate that in our base case scenario, it could result in net additional sales of € 7.3 billion to € 9.5 billion by 2025 for the EU-based pharmaceutical industry. These results translate into an EU manufacturing employment increase of 13% to 16% (20,000 to 25,000 additional jobs), assuming no change in worker productivity. Additional savings in EU spending on pharmaceuticals of 4–8% could materialise from a timelier introduction of generics and biosimilars in European markets following SPC expiry in Europe. These numbers are lower bounds as the effects are estimated on a sample of 117 non-biological and 17 biological molecules.

[23] SPC waiver: generics getting ready ahead of time, Charlotte Kilpatrick,2020/07/30 (https://www.managingip.com/article/2a5cx783ao223eeyu1dds/spc-waiver-generics-getting-ready-ahead-of-time) (last visited May 13, 2023).

[24] An export-only exception to pharmaceutical patents in Europe: should United States follow suit?, Nature Biotechnology. 2019, Vol. 37, No. 1. (https://www.nature.com/articles/nbt.4324) (last visited May 13, 2023).

肆、淺談歐盟補充保護證書之製造免責的現況與未來

對於 SPC 製造免責，外界多數認為原研藥商持反對立場，而學名藥商、生物相似性藥商持贊成立場。事實上，有報導[25]推翻這般認知，歐盟境內學名藥商及原研藥商（共計 30 家）民意調查顯示，有高達 30% 原研藥商支持 SPC 製造免責，不意外的是，所有學名藥商都支持 SPC 製造免責。探究其原因在於，歐盟境內只有少數製藥業者係完全研發新藥，大多數製藥業者擁有學名藥或生物相似性製藥部門，或者是其集團內有學名藥公司，舉例而言，Novartis 係原研藥商，其子公司 Sandoz 則係學名藥商。因此，原研藥商對於學名藥或是生物相似性藥開發也有興趣，會支持 SPC 製造免責並不意外。除此之外，歐盟境內少數之完全研發新藥的製藥業者表示，他們長期專注於疫苗藥品研發，事實上，沒有學名藥商或生物相似性藥商能在短期內躍升成為競爭對手，因此支持 SPC 製造免責。

探究 SPC 製造免責之現況，歐盟境內製藥業者，不論是學名藥商、生物相似性藥商或是原研藥商，多數係支持 SPC 製造免責，支持者表示，SPC 製造免責有很多優點，具體而言，可以更早進入不同市場與歐盟境外公司競爭、提高供應鏈與製造地點分配之靈活性、歐盟國家人民可以廣泛受益。此外，歐盟製藥業者表示，現況存在的事實問題是，想要在印度及中國大陸找到有能力製造生物相似性藥品的人才極困難，因此，在 SPC 製造免責生效前，歐盟製藥業者需要承擔移轉員工或長期派任到外國製藥基地之高價人事費用，而 SPC 製造免責實施，可以有效節省相關花費。

探究 SPC 製造免責之未來，民意調查顯示，SPC 製造免責實施後將會面臨最大挑戰係「管理通知」及「管理免責使用之監控」，所述「管理通知」係指原研藥商必須對主張 SPC 製造免責使用之學名藥商所提通知，進行組合管理、接收及後續對應處理；所述「管理免責使用之監控」則指原研藥商後續所為監控，以確保學名藥商確實遵循 SPC 製造免責之相關規定。此外，未來可預見，原研藥商

[25] Poll: SPC waiver backed by some innovators, Patrick Wingrove, 2019/08/28. (https://www.managingip.com/article/2a5bqtj8ume32iy7sh91c/poll-spc-waiver-backed-by-some-innovators) (last visited May 13, 2023).

會積極開發申請次要專利[26]，藉此作為阻擋競爭對手使用 SPC 製造免責之工具。另有報導[27]指出，實務上，若製造前未通知，原研藥商通常很難察覺，學名藥商已經開始生產製造其 SPC 保護之藥品；一旦履行製造前通知，此有助於原研藥商察覺到有採取法律訴訟之機會，原研藥商不但可以利用通知所提供之訊息，更加容易監控學名藥商活動，使得學名藥商可能會因不屬於免責範圍之次要專利，而被提訴。因此，學名藥商對於 SPC 製造免責所反饋之風險，須做足準備，格外審慎思量、謹慎行事。想要運用 SPC 製造免責之學名藥商正面臨著微妙平衡，提出 SPC 製造免責使用，或多或少自承了專利侵權，並且為其帶來了相當程度之風險；相較之下，原研藥商也承受相當程度之風險，當其次要專利不夠強大時，也無法對學名藥商所提 SPC 製造免責來進行反競爭。或許正因如此，SPC 製造免責實施迄今，仍未查詢到有公開[28]學名藥商或生物相似性藥商提出免責使用。

為評估 SPC 製造免責成效，歐盟規章 No 469/2009 新增第 21a 條評估規定[29]，在第 5 條第 10 項所述日期後不晚於 5 年內，並且每 5 年 1 次，委員會應對第 5 條第 2-9 項及第 11 條進行評估，以評估該等法條之目標是否已達成，並向歐洲議會、理事會及歐洲經濟和社會委員會，提交有關主要調查結果報告。除了評估以出口為目的之例外製造外，應特別考量，以儲存為目的之例外製造，在醫藥取得及公

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[26] Last week's most read: SPC waiver may drive innovator investment in secondary patents and litigation, Patrick Wingrove, 2019/05/09 (https://www.managingip.com/article/2a5bqtj8ume32ix9jxbls/last-weeks-most-read-spc-waiver-may-drive-innovator-investment-in-secondary-patents-and-litigation) (last visited May 13, 2023).

[27] Risk of SPC waiver counterattack makes generics extra cautious, Rory O'Neill, 2022/07/21. (https://www.managingip.com/article/2adxpw95mqfh1hiqyyj9c/risk-of-spc-waiver-counterattack-makes-generics-extra-cautious) (last visited May 13, 2023).

[28] Notifications by exporting WTO members. (https://www.wto.org/english/tratop_e/trips_e/public_health_notif_export_e.htm) (last visited May 13, 2023).

[29] Article 21a Evaluation
No later than five years after the date referred to in Article 5(10), and every five years thereafter, the Commission shall carry out an evaluation of Article 5(2) to (9) and Article 11 in order to assess whether the objectives of those provisions have been achieved, and present a report on the main findings to the European Parliament, the Council and the European Economic and Social Committee. In addition to evaluating the impact of the exception of making for the purpose of export, special account shall be taken of the effects of making for the purpose of storing in order to place that product, or a medicinal product containing that product, on the market of Member States after the expiry of the corresponding certificate on access to medicines and on public health expenditure, and of whether the waiver and in particular the period provided for in point (a)(iii) of Article 5(2) is sufficient to achieve the objectives referred to in Article 5, including public health.

共衛生支出上所產生之影響。即，SPC 製造免責未來能否達成所預期之效果，仍有待日後每 5 年 1 次評估報告，始能得知。

伍、結語

國際對於歐盟 SPC 製造免責評論雷聲大雨點小，實施之前公布草案當時引發最多正負面評論，相對地實施之後相關評論反而少見。首波適用 SPC 製造免責，係新法實施前已獲准 SPC 之原專利權尚未到期者，其自去（2022）年 7 月 1 日起適用免責。合理推論，有些 SPC 已開始能被歐盟學名藥商或生物相似性藥商主張免責，惟迄今，筆者並未能查到援用 SPC 製造免責之相關公開，或許可從國際評論略見其可能原因。

SPC 製造免責實施之前，最多評論是關於 SPC 製造免責之法制合法性，儘管支持者表示，SPC 係原專利到期後所授予額外特別保護，本質上不同於 PTE 屬於專利權，SPC 製造免責不會違反 TRIPS 規定；然而反對者表示[30]，未來不排除 SPC 製造免責會提交世界貿易組織爭端解決機制之可能性。其次，關於 SPC 製造免責之實務可行性亦廣受討論，歐盟境內學名藥商表示，SPC 製造免責立法初衷良好，但對使用者來說，卻不容易駕馭，因為 SPC 過於複雜，歐盟境內不同國家 SPC 到期日不同，主張 SPC 製造免責，須特別留意不要侵犯了國家權益；而 SPC 製造免責之使用，就如同刀之兩刃，使用者或許可從中獲取利用，然不可忽視，其反撲所帶來訴訟風險。最後，外界持續關注的是，關於 SPC 製造免責後續所帶來之衍生效應，例如，學名藥商、生物相似性藥商因主張 SPC 製造免責之使用，引發原研藥商提起相關訴訟會隨之增加；又例如，原研藥商會加強申請其專利藥品相關之次要專利，並且到出口市場之國家進行相關專利布局，以有效阻擋 SPC 製造免責對其所帶來之不利益影響。歐盟補充保護證書期間納入為出口、儲存之製造免責措施，究竟能否為歐盟帶來如預期般之效益，還是帶來不可預期之骨牌效應，仍有待持續觀察。

[30] An export-only exception to pharmaceutical patents in Europe: should United States follow suit?, Nature Biotechnology. 2019, Vol. 37, No. 1. (https://www.nature.com/articles/nbt.4324) (last visited May 13, 2023).