COVID-19 疫苗專利豁免擴大至診斷與治療方法？

～歹戲拖棚的無奈～

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摘要

去（2022）年 12 月 17 日，世界貿易組織針對是否將 COVID-19 之疫苗專利豁免擴大至診斷與治療方法一事，做出展延決議期限的決定。其實同年 6 月疫苗專利豁免的部長會議決議本就無實質內容，因為多數內容僅在釐清《與貿易有關之智慧財產權協定》第 31 條既有的適用彈性；即使表面上增加了 5 年內強制授權疫苗可出口的豁免，不過原本已有的第 31 條之 1 早已規定在符合一定條件下，強制授權產品得以出口，故 6 月決議並未真正豁免什麼重要的義務。在這樣的背景下，12 月未進一步擴大這並無實質意義的豁免，也不令人意外，遑論診斷與治療方法的專利範圍為何，難以確定，豁免的必要性也不明確。問題是疫情遲遲未散，逕行否決擴大豁免案恐使已搖搖欲墜的世界貿易組織被反全球化者進一步污名化。藉尋求更多的資料為由以拖待變，或許是更合理的解決方法。因為待疫情隨時間過去而逐漸趨緩，無豁免必要更昭然若揭，屆時問題也就迎刃而解。

壹、前言

世界貿易組織（World Trade Organization, WTO）在去（2022）年 6 月第 12 屆部長會議（Twelfth WTO Ministerial Conference）中通過了 COVID-19 疫苗之專利豁免決議[1]。然而，對於此項豁免是否應擴大至相關的診斷（diagnostics）與治療方法（therapeutics），會員間未取得共識，因此決定最遲於疫苗專利豁免決議通過起 6 個月內決定之[2]。問題是半年後，到了同年 12 月 17 日，會員仍無法於期限屆滿前做成擴大豁免的決議[3]；不少會員表示需要更多資料以判斷擴大豁免之

[1] WTO, Ministerial Decision on the TRIPS Agreement, para. 1, WTO Doc. WT/MIN(22)/30, WT/L/1141 (June 22, 2022) [hereinafter Covid-19 Waiver].
[2] *Id.* para. 8 ("No later than six months from the date of this Decision, Members will decide on its extension to cover the production and supply of COVID-19 diagnostics and therapeutics.").
[3] *Members to Stretch Deadline on Extending TRIPS Decision to COVID Diagnostics, Therapeutics*, WTO (Dec. 16, 2022), https://www.wto.org/english/news_e/news22_e/trip_15dec22_e.htm.

必要性，故最終做出無限期展延此決議期限的結論[4]。

本文先檢視疫苗專利豁免決議之背景與其真實意涵，再分析無法擴大專利豁免範圍之原因，最後說明 12 月展延決議之目的以為結論。

貳、疫苗專利豁免決議之真實意涵

一、實為釐清既有規範已含的解釋彈性

論及6月疫苗專利豁免決議，表面上雖是對於COVID-19疫苗生產與供應所須之專利，豁免「適格會員[5]」有關《與貿易有關之智慧財產權協定（Agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS）》第31條強制授權之部份要件，諸如「事先無需盡相當努力向專利權人提出授權請求」、「授權下所製造之產品可出口至其他適格會員」等[6]。然而，究其實質內容，不過是進一步釐清會員於TRIPS第31條、第31條之1（已允許符合一定條件時出口強制授權下製造之產品）之條文中本即含有的解釋彈性[7]。

由此可見，上述疫苗專利豁免決議可有可無。既然如此，為何第 12 屆部長會議將之視為重要成果？

二、避免 WTO 被污名化

6 月部長會議正處全球疫情嚴峻狀況未緩、且疫苗供應也未達充份或普及之

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[4] *E.g.*, The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, *Discussion Paper on the Possible Extension of TRIPS Decision to Diagnostics and Therapeutics*, *Informal Meeting of the Council for TRIPS 6 December 2022*, para. 10, WTO Doc. RD/IP/51 (Dec. 5, 2022).

[5] 所謂的「適格會員」雖涵蓋所有開發中國家會員，但鼓勵現已具備 COVID-19 疫苗製造能力之開發中國家會員，作出不利用此項決議之拘束性聲明，如中國即已聲明不會利用此項決議之豁免。Covid-19 Waiver, *supra* note 1, para. 1; *Record in Accordance with Footnote 1 of the Ministerial Decision on the TRIPS Agreement of 17 June 2022 (WT/L/1141)*, para. 1, WTO Doc. IP/C/W/690 (June 22, 2022).

[6] Covid-19 Waiver, *supra* note 1, para. 3 ("...(a) An eligible Member need not require the proposed user of the subject matter of a patent to make efforts to obtain an authorization from the right holder as set out in Article 31(b)...(b) An eligible Member may waive the requirement of Article 31(f) that authorized use under Article 31 be predominantly to supply its domestic market and may allow any proportion of the products manufactured under the authorization in accordance with this Decision to be exported to eligible Members....").

[7] 若會員有緊急情況或其他極為急迫之情形，或其係以公共非商業為目的之使用，會員根據 TRIPS 第 31（b）條，本無需事先盡相當努力向專利權人提出授權請求。Agreement on Trade-Related Aspects of Intellectual Property Rights, art. 31(b), Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, 1869 U.N.T.S. 299, 313. 對於不具足夠醫藥製造能力之會員，2005 年增修、後於 2017 年生效的 TRIPS 協定第 31 條之 1，也規定會員得以在通知 TRIPS 理事會確切之藥品授權（包含其種類、數量與期間等相關資訊）的情況下，免除 TRIPS 第 31（f）條禁止出口之義務。*Id*. art. 31*bis*(1).

際。雖然主要疫苗專利藥廠皆已宣示在疫情期間不會主張相關專利[8]，故供需失衡並非疫苗專利，而是其他原因所致（除了全球及時產量不足外，尚包含各國物流、基礎建設與相關規範等未予以配合）[9]，但以印度、南非為首提案要求全面豁免疫苗、診斷與治療方法專利的會員國卻誤指相關專利才是問題之主因[10]。

在這樣的時空背景，與其直接駁斥印度、南非等的不當指責，製造立場的對立，不如以疫苗專利「豁免」案的形式做成決議。不但可以相當程度地給予印度、南非等國下台階，同時更可在 WTO 之回合談判缺乏進展之際，以此做為 WTO 之談判成果，顯現 WTO 仍有作為，並避免有心者之不當炒作，進一步污名化 WTO。

三、擴大豁免決議之以拖待變

既然有上述之政治考量，為何 6 月部長會議決議未將印度與南非等所主張之診斷與治療方法專利一併豁免？理由是完全不知究竟要豁免何種診斷與治療方法之專利。COVID-19 疫苗皆為疫情後所研發，若有專利也是相當明確；再加上如前所述，主要疫苗專利藥廠皆聲明不於疫情期間利用該相關專利營利，故即使豁免專利的保護也不致對醫藥產業有不當衝擊。但是關於診斷與治療方法之專利，到底涵蓋哪些範圍，即使提案國也難以確認，在這種情況下，如何評估對醫藥或相關產業之衝擊？冒然決議豁免，只會引發適用之爭議，故當時做出六個月後再行決議的結論，希望以時間換取解決問題的空間[11]。

參、無法擴大專利豁免範圍之原因

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[8] *Inequity of COVID-19 Vaccines Grows 'More Grotesque Every Day'–WHO Chief*, U.N. (Mar. 22, 2021), https://news.un.org/en/story/2021/03/1087992; *AstraZeneca COVID-19 Vaccine Authorised for Emergency Use by the World Health Organization*, ASTRAZENECA (Feb. 15, 2021), https://www.astrazeneca.com/media-centre/press-releases/2021/astrazeneca-covid-19-vaccine-authorised-for-emergency-use-by-the-world-health-organization.html#!; *Statement by Moderna on Intellectual Property Matters During the COVID-19 Pandemic*, MODERNA (Oct. 8, 2020), https://investors.modernatx.com/Statements--Perspectives/Statements--Perspectives-Details/2020/Statement-by-Moderna-on-Intellectual-Property-Matters-during-the-COVID-19-Pandemic/default.aspx.

[9] Communication from Mexico and Switzerland, *TRIPS Council Discussion on COVID-19 Therapeutics and Diagnostics: Evidence and Questions on Intellectual Property Challenges Experienced by Members*, para. 3, WTO Doc. IP/C/W/693 (Nov. 1, 2022) ("This involves issues with logistics and distribution, which are not IP-related, but that need to be addressed. The Access to COVID-19 Tools Accelerator (ACT-A) Working Group Paper on Therapeutics and Diagnostics noted that recurring challenges for access to therapeutics and diagnostics are regulation, manufacturing, allocation, funding, procurement and deployment, forecasting, and demand.").

[10] Communication from India and South Africa, *Waiver from Certain Provisions of the TRIPS Agreement for the Prevention, Containment and Treatment of COVID-19*, para. 9, WTO Doc. IP/C/W/669 (Oct. 2, 2020) ("There are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients.").

[11] *See* Covid-19 Waiver, *supra* note 1, para. 8.

經過 6 個月的了解與討論，豁免之必要性仍不明確，因為在治療方法方面，已有充份的自願授權藥品；而在診斷方面，需求早已隨著疫情趨緩大幅減少。至於豁免的範圍也依舊難定，因為許多治療用藥本無專利保護，縱有專利，有的原本是用於治療 COVID-19 以外的其他疾病。以下分別詳細說明。

一、市場上已有充份的自願授權治療藥品

誠如墨西哥與瑞士在 TRIPS 理事會討論是否應擴大豁免時所指出：截至 2022 年 10 月，已有 138 項雙邊或藥品專利池（Medicines Patents Pool, MPP）下的自願授權協議，涵蓋 127 國之藥物開發商與 MPP 下之公司，被授權公司得以在免權利金的條件下，生產治療 COVID-19 的藥品並建立生產據點[12]。默沙東（MSD）、輝瑞（Pfizer）、塩野義（Shionogi）與吉立亞（Gilead）皆已就各項治療 COVID-19 藥品簽訂此類協議[13]。換言之，治療藥品的專利根本不會妨礙此類藥品之供應。事實上，自願授權協議中針對 COVID-19 所開發的治療藥品，現今也不具有供需失衡的問題，因為各製藥公司相關產能利用率不到 50%；各政府與非政府組織所採購的此類用藥，實際使用於病患之比例也不到 1/3[14]。

二、疫情趨緩下診斷方法的需求減少

[12] Communication from Mexico and Switzerland, *supra* note 9, paras. 4, 5 ("As of 11 October 2022, 138 bilateral or Medicines Patents Pool-based voluntary licensing agreements comprising some of the most highly demanded treatments, have been signed between innovators and companies all over the world enabling them to join this fight by producing therapeutics. These agreements cover more than 127 countries collectively.…The MPP-licenses are royalty-free. Thanks to these agreements, 191 production sites for COVID-19 therapeutics exist worldwide.").

[13] *Id*. para. 5; *Molnupiaravir (MOL)*, MED. PAT. POOL (Oct. 2021), https://medicinespatentpool.org/licence-post/molnupiravir-mol; *Nirmatrelvir*, MED. PAT. POOL (Nov. 2021), https://medicinespatentpool.org/licence-post/pf-07321332; *Ensitrelvir Fumaric ACID*, MED. PAT. POOL (Oct. 2022), https://medicinespatentpool.org/licence-post/ensitrelvir; *Voluntary Licensing Agreements for Remdesivir*, GILEAD, https://www.gilead.com/purpose/advancing-global-health/covid-19/voluntary-licensing-agreements-for-remdesivir?_sm_au_=iVV3rM63ZjssVkHrvMFckK0232C0F (last visited Feb. 24, 2023). 吉立亞，或譯吉利德，2014 年於臺灣公司登記名稱為香港商吉立亞醫藥有限公司。外國公司登記基本資料：香港商吉立亞醫藥有限公司，經濟部商業司，2022 年 10 月 31 日，https://findbiz.nat.gov.tw/fts/query/QueryCmpyDetail/queryCmpyDetail.do?objectId=SEM1NDM3Njg2MA==&banNo=54376860&disj=01049FADEAB348230B63595B07310695&fhl=zh_TW（最後瀏覽日：2023 年 2 月 24 日）。

[14] *See* Communication from Mexico and Switzerland, *supra* note 9, para. 2 ("...Pfizer would be able to produce 120 million doses of its Paxlovid therapeutic in 2022. The contracted supply stood in August 2022 at only 41.5 million doses, i.e. at 35% of the production capacity. The situation is similar with MSD's Molnupiravir, where demand amounted to a mere 45% of the company's production capacity. Governments and NGOs have purchased 35 million COVID-19 treatments for LMIC for 2022 but have only been able to administer 10 million as of September this year.").

當今市場並無有關 COVID-19 診斷方法專利申請增加的現象，意謂診斷方法之取得無專利卡關的問題[15]。事實上，診斷方法的生產製造門檻並不高，多數不具有專利或是專利早已過期，故會員國內有相當多公司正積極生產相關的診斷產品[16]。不只是供應無虞，甚至隨著疫情趨緩，此類診斷方法的全球需求正逐漸減少[17]。在這種情況下，究竟要豁免何種診斷方法專利？以及豁免的必要性皆成問題。

三、治療 COVID-19 的藥品認定範圍困難

檢視現今 COVID-19 的治療方法，多數係採取早已廣泛使用的藥品，以控制呈現出來的發燒、呼吸道症狀[18]。由於多數 COVID-19 患者病情較輕，得以在家中修養康復，故這些控制症狀的非處方藥（over-the-counter medicines）就成為普遍採取的治療方法[19]。這類非處方藥如乙醯胺酚（Tylenol）[20]，過往即被用於治療 COVID-19 以外的其他疾病[21]。若僅是其得以用來緩和 COVID-19 的症狀，而使之不受專利保護，是否豁免範圍有過大之嫌[22]？

肆、結語

或許有以為，即使未有實質豁免必要，就如法炮製 6 月部長會議決議作法，以「豁免」案的形式包裝一份僅是重申 TRIPS 第 31 條、第 31 條之 1 適用彈性的內容，難道不可行？鑑於診斷與治療方法存在無專利或專利已過期的產品，以

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[15] The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, *supra* note 4, para. 12 (“With regard to "diagnostics": the proponents did not indicate that there is also an increased number of patent applications in relation to "diagnostics" being filed in patent offices of WTO Members. It seems to us that patents are not a problem with regard to the availability and accessibility of "diagnostics".”).

[16] *Id.* para. 23 (“Since the threshold for entering into the production of many IVD products are not high and since many IVDs do not have patents involved or the respective patents have expired, there are many companies actively engaging in producing such products in many Members.”).

[17] Communication from Mexico and Switzerland, *supra* note 9, para. 3 (“Global demand for tests has reduced and there is no evidence to suggest that supply is constrained relative to actual demand.”).

[18] The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, *supra* note 4, para. 27 (“COVID-19 therapeutics include a certain wide range of medicinal products. Some of them are also used to manage the symptoms.”).

[19] *Id*. para. 28 (“Since most people with COVID-19 have mild illness and can recover at home, managing symptoms with over-the-counter medicines is the commonly adopted approach.”).

[20] Tylenol（國內譯為泰諾）係專利已過期的原廠藥，國外開架式藥局常見；國內開架式藥局常見的則為成分相同的學名藥「普拿疼」。普拿疼有三種你認識嗎？，德芳保健藥妝，2021 年 9 月 12 日，https://www.defangmall.com/Article/Detail/61610?lang=zh-TW（最後瀏覽日：2023 年 2 月 24 日）。

[21] The Separate Customs Territory of Taiwan, Penghu, Kinmen and Matsu, *supra* note 4, para. 28 (“Examples of medicines to manage symptoms include acetaminophen (Tylenol) or ibuprofen (Motrin and Advil)...These medicines are used for different diseases.”).

[22] *Id*. para. 20 (“...merely requiring that the diagnostics and therapeutics must be related to COVID-19 is not sufficient, because there could be too wide of a range of medicines and medical devices which could be considered COVID-19-related....”).

及原專利係為治療非 COVID-19 之疾病而存在的情形，冒然言豁免，只會造成適用的疑義。

基於上述 6 個月討論所得資訊，不擴大豁免或許是更合理的解決方法。然而，目前疫情尚未達完全消弭的程度，為避免少數提案會員國與反全球化者之曲解，將逕行否決擴大豁免案標籤為 WTO 罔顧公衛需求，顯然無法符合國際醫藥產業的期待而逕行否決擴大豁免案。

因此，去年 12 月 17 日展延決議期限的目的，便是續行拖字訣，既不做成否決擴大的決議，也不決定後續展延的期限。表面上是尋求更多的資料以判斷豁免的必要性與其確切的範圍，實質上則是待疫情消弭無蹤，俾無豁免必要之事實昭然若揭後，處理此議題之壓力也就不復存在。