

2024-03-25「WTO MC13談判議題進展與成果研討會」

# TRIPS豁免決議與後疫情時代的大流行病國際規範發展

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WORLD TRADE  
ORGANIZATION



World Health  
Organization

# WTO, TRIPS與公共衛生



# TRIPS強制授權規範與公共衛生

## TRIPS Art. 31:

- Where the law of a Member allows for other use of the subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
  - (b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by a Member in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable.....
  - (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use; .....

# TRIPS出口強制授權規範與公共衛生

## TRIPS Art. 31bis

- 1. The obligations of an exporting Member under Article 31(f) shall not apply with respect to the grant by it of a compulsory licence to the extent **necessary for the purposes of production of a pharmaceutical product(s) and its export to an eligible importing Member(s)** in accordance with the terms set out in paragraph 2 of the Annex to this Agreement.....

## Annex to the TRIPS Agreement

- 1. For the purposes of Article 31bis and this Annex:
  - (a) **“pharmaceutical product”** means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address the public health problems as recognized in paragraph 1 of the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2). It is understood that active ingredients necessary for its manufacture and diagnostic kits needed for its use would be included;

# TRIPS出口強制授權的程序規範

- 2. The terms referred to in paragraph 1 of Article 31bis are that:
  - (a) the eligible importing Member(s) has made a notification to the Council for TRIPS, that: .....(ii) confirms that the eligible importing Member in question, other than a least-developed country Member, has established that it has insufficient or no manufacturing capacities in the pharmaceutical sector for the product(s) in question in one of the ways set out in the Appendix to this Annex; and .....
  - (b) the compulsory licence issued by the exporting Member under the system shall contain the following conditions: .....
  - (c) the exporting Member shall notify the Council for TRIPS of the grant of the licence, including the conditions attached to it.....

# 國際貿易與公共衛生



# WTO會員的正反意見

## 支持豁免意見



- ☐ 智慧財產保護阻礙抗疫物資取得
- ☐ 自願授權模式有其極限
- ☐ 出口強制授權程序過於繁雜
- ☐ 疫苗係由公共資金資助，屬公共財

## 反對豁免意見



- ☐ 智慧財產保護有其鼓勵創新價值
- ☐ 自願授權與強制授權已足夠
- ☐ 藥品取得並非只是智慧財產議題
- ☐ 豁免範圍與期間難以明確界定

# COVID-19與TRIPS豁免提案

	2020提案	2021修正案	2022決議
豁免TRIPS條文	第2篇第1、4、5及7節及第3篇	第2篇第1、4、5及7節及第3篇	第28條第1項
豁免智慧財產權類型	著作權、產業設計、專利權、未公開資料之保護	著作權、產業設計、專利權、未公開資料之保護	專利權
涵蓋產品或技術範圍	與預防、抑制及治療COVID-19疫情有關者	與預防、抑制及治療COVID-19疫情有關的健康產品及技術	製造及供應COVID-19疫苗而需實施之專利保護標的



# 2022 TRIPS豁免決議

- 1. Notwithstanding the provision of patent rights under its domestic legislation, an eligible Member may limit the rights provided for under Article 28.1 of the TRIPS Agreement by authorizing the use of the subject matter of a patent required for the production and supply of COVID-19 vaccines without the consent of the right holder to the extent necessary to address the COVID-19 pandemic, in accordance with the provisions of Article 31 of the Agreement, as clarified and waived in paragraphs 2 to 6 below.....
- 3. Members agree on the following clarifications and waiver.....:
  - (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, .....

# 2022 TRIPS豁免決議

- 5. For purposes of transparency, as soon as possible after the adoption of the measure, an eligible Member shall communicate to the Council for TRIPS any measure related to the implementation of this Decision, including the granting of an authorization
- 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.

# 2022 TRIPS豁免決議的實益

## 解釋面向

- 肯認COVID-19屬於國家緊急情事，可豁免TRIPS針對強制授權所設的事前取得授權的程序要求
- 但會員國依杜哈部長宣言本有權利自行認定個案情境是否構成國家緊急情事

## 豁免面向

- 豁免強制授權須主要用以供應國內市場的要件，從而擴大出口強制授權的空間
- 會員國固然本可依TRIPS第31-1條辦理出口強制授權，但依此豁免決議辦理出口強制授權僅須由進口國辦理通報，可減省程序成本

# TRIPS豁免決議的爭議

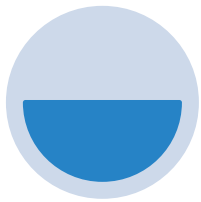
## 法制面

- 既有TRIPS規定與杜哈部長宣言即允許各國自行認定緊急情事與強制授權基礎，TRIPS豁免決議的突破有限
- 既有TRIPS規定即允許出口強制授權，TRIPS豁免決議的突破有限

## 政策面

- 豁免產品與技術範圍僅限於COVID-19疫苗，不足以完整因應疫情
- 豁免智慧財產權範圍僅限於專利權，其他貿易限制仍可能存在

# 擴大TRIPS豁免決議至「診斷與治療藥品」的爭議

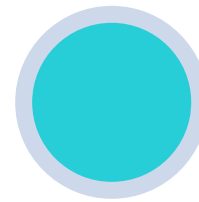


## 贊成方

全球抗疫產品與技術仍  
掌握於已開發國家，分  
配不均衡

自願授權與捐贈數量仍  
不足

COVID-19 仍未消失，  
仍須診斷與治療藥品



## 反對方

相關診斷與治療藥品已  
有充足生產，並無短缺

採取強制授權可能降低  
投資人投資生產的誘因

診斷與治療藥品應回歸  
個案事實判斷是否有出  
口強制授權的必要

# 第13屆部長會議宣言

- 22. We recall the Declaration in MC12 on the "WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics" and take note of the work done in relevant WTO Councils and Committees, as reflected in the General Council report in document WT/MIN(24)/8. We encourage the relevant WTO bodies to continue their work as directed by the Declaration, based on Members' submissions, to review and build on all the lessons learned and the challenges experienced during the COVID-19 pandemic, to build effective solutions in case of future pandemics in an expeditious manner. We also note the work of the WTO Secretariat in supporting this work with data, analysis, and technical cooperation, including through trilateral cooperation with the World Health Organization (WHO) and the World Intellectual Property Organization (WIPO), and cooperation with other relevant international organizations, and encourage it to continue doing so going forward, as appropriate.

# TRIPS豁免決議的談判發展評論

- **時空限制**：COVID-19的迫切性已不如以往，討論範圍應由「COVID-19」相關藥品轉移至更廣泛的防疫物資，但也更增加談判複雜性
- **議題限制**：防疫物資取得所涉者不僅專利權或智慧財產權，也涉及其他貿易面向（特別當相關物資的進出口涉及第三地轉運時）
- **管制限制**：如何避免出口強制授權被使用於脫法用途仍無妥善對策
- **法制限制**：TRIPS豁免決議相較於既有TRIPS出口強制授權規定突破有限，談判實益有限

**就有效衡平分配全球防疫物資而言，強化TRIPS豁免決議不必然是適合的場合**

# WHO Pandemic Treaty的努力方向

## Article 9. Research and development

- 6. Each Party shall develop national policies to:
  - (a) include provisions in government-funded research and development agreements for the development of pandemic-related products that promote timely and equitable global access to such products during public health emergencies of international concern and pandemics.....; and
  - (b) publish relevant terms of government-funded research and development agreements promoting equitable and timely access to such products during a pandemic emergency.

## Article 10. Sustainable and geographically diversified production

- 1. The Parties commit to achieving a more equitable geographical distribution and scaling up of the global production of pandemic-related products, and increasing sustainable, timely, fair and equitable access to such products, as well as reducing the potential gap between supply and demand during pandemics.



# WHO Pandemic Treaty的努力方向

## Article 11. Transfer of technology and know-how

- 1. In order to enable sufficient, sustainable and geographically-diversified production of pandemic-related products each Party, taking into account its national circumstances, shall:
  - (a) promote and otherwise facilitate or incentivize the transfer of technology and know-how for both pandemic-related and routine health products, including through the use of licensing and collaboration with regional or global technology transfer partnerships and initiatives, and in particular for the benefit of developing countries and for technologies that have received public funding for their development; .....
- 2. The Parties shall develop and strengthen, as appropriate, mechanisms coordinated by WHO with the participation of other relevant technology transfer mechanisms as well as other relevant organizations, to promote and facilitate the transfer of technology and know-how for pandemic-related products to geographically diverse research and development institutes and manufacturers, particularly in developing countries, through the pooling of knowledge, intellectual property, know-how and data to all developing countries.

# WHO Pandemic Treaty的努力方向

- 3. During pandemics, in addition to the undertakings in paragraph 1 of this Article, each Party shall:
  - (a) encourage holders of relevant patents regarding pandemic-related products, in particular those who received public funding, to forgo or otherwise charge reasonable royalties to developing country manufacturers for the use, during the pandemic, of their technology and know-how for the production of pandemic-related products; and
  - (b) consider supporting, within the framework of relevant institutions, time-bound waivers of intellectual property rights to accelerate or scale up the manufacturing of pandemic-related products to the extent necessary to increase the availability and adequacy of affordable pandemic-related products.
- 4. The Parties that are WTO Members recognize that they have the right to use to the full, the flexibilities inherent in the TRIPS Agreement as reiterated in the Doha Declaration on the TRIPS Agreement and Public Health of 2001, which provide flexibility to protect public health including in future pandemics, and shall fully respect the use thereof by others.
- 5. Each Party shall, as necessary and appropriate, review and update its national legislation in order to ensure the implementation of such flexibilities referred to in paragraph 4 of this Article in a timely and effective manner.

# 結語

- 目前的TRIPS豁免決議不論適用產品範圍或豁免義務範圍均相對有限，可能不足以達到推動TRIPS豁免決議以有效衡平分配防疫物資的初衷
- 於WTO推動防疫物資豁免相關智慧財產權規範的政治可行性恐怕不高
- 就有效衡平分配防疫物資的目的而言，過度允許各國使用強制授權制度豁免相關智慧財產權規範，可能引起濫用疑慮，以及引發類似囚徒困境的資源搶奪
- 有效衡平分配全球防疫物資需要的可能是國際統合行動(包括全球或區域層面)，而非各國個別行動
- 強調國際統合行動或許符合我國立場，有助我國實質參與國際衛生活動





謝謝聆聽 敬請指教！