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INTELLECTUAL PROPERTY, VOLUNTARY LICENSING AND TECHNOLOGY TRANSFER

COMMUNICATION FROM THE UNITED KINGDOM

The following communication, dated 14 July 2023, is being circulated at the request of the United Kingdom.

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1 INTRODUCTION

1. The COVID-19 pandemic's health, economic, and social impacts continue to be felt, particularly in developing and least developed countries, three years on from the World Health Organisation's announcement of a public health emergency of international concern (PHEIC).[1] The pandemic has highlighted longstanding debates, particularly those concerning equitable access to health products and technologies, and the role of the multilateral trading system, including the TRIPS Agreement, to achieve equitable access.

2. The World Trade Organisation (WTO) has been a forum for extensive discussion on the pandemic response, particularly within the TRIPS Council. Here, Members continue to examine the role of intellectual property (IP) and access to COVID-19 health products and technologies. While positions diverge, Members share the objective of improving equitable access for all to products, both now and in the future.

3. In the context of the pandemic's continued impacts, there is a need to reflect on both successes and shortcomings of the global pandemic response and make meaningful progress towards collective future pandemic preparedness. In particular, the pandemic illustrated a growing need to identify how trade can help facilitate voluntary licensing and/or technology transfer partnerships as part of collective efforts to address pandemic preparedness and equitable access concerns. The cross-cutting nature of the topic requires involvement from various stakeholders and careful consideration of the needs of developing countries and least-developed countries.

4. A key outcome of the pandemic response has been the establishment of many new voluntary licensing and/or technology transfer partnerships between pharmaceutical companies and generic manufacturers for COVID-19 health products and technologies. The WIPO Patent Landscape reports on COVID-19 vaccines and therapeutics[2,3] highlight the diversity and range of the successful collaborations seen globally during the pandemic. Examples include, but are not limited to, collaborations like AstraZeneca, Oxford University, and the Serum Institute of India; Pfizer-BioNTech; as well as partnerships via the Medicines Patent Pool (MPP) for COVID-19 therapeutics.

5. The United Kingdom has long championed use of voluntary licensing and technology transfer, as have other Members. These partnerships not only contributed to the rapid scaling up of production for essential COVID-19 products, helping improve access, including pricing, and availability, but also represent the importance of international collaboration during times of a PHEIC.

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[1] https://www.who.int/news/item/30-01-2020-statement-on-the-second-meeting-of-the-international-health-regulations-(2005)-emergency-committee-regarding-the-outbreak-of-novel-coronavirus-(2019-ncov)

[2] https://www.wipo.int/publications/en/details.jsp?id=4589

[3] https://www.wipo.int/publications/en/details.jsp?id=4658

6. While these partnerships have clearly made a successful contribution to expanding access to COVID-19 products, there has been criticism of their not being a silver bullet, primarily due to not all manufacturers being able to secure voluntary licensing and/or technology transfer partnerships. We must also acknowledge the growing discourse and ideas on the role of trade and technology transfer taking place within the WTO from other Members and the need for a pragmatic way forward.

2 OBJECTIVE

7. The United Kingdom considers there to be strong merit in examining the factors influencing and underpinning the formation of these partnerships and for Members to share experiences on how more partnerships may be formed as a further step to achieving equitable access to health products and technologies. Together, Members should look systematically at collective experience to inform our future approach.[4]

3 IP SYSTEMS, THE TRIPS AGREEMENT, AND VOLUNTARY LICENSING

8. The multilateral intellectual property (IP) framework was instrumental in the COVID-19 response. Prior to COVID-19 being declared a PHEIC, the framework helped incentivise and resulted in the development of innovative, safe, high quality and effective health products and technologies for the treatment, prevention, and containment of COVID-19 by providing rightsholders and other stakeholders with confidence to invest in R&D activity, e.g., mRNA platform technology.

9. Once the pandemic was declared, previously developed technologies and products were repurposed to urgently respond to the spread of COVID-19. The production of COVID-19 products was scaled up through the various voluntary licensing and/or technology transfer partnerships mentioned earlier, and data provided by the WIPO Patent Landscape reports on COVID-19 vaccines and therapeutics. It is the TRIPS Agreement, as the international minimum standards agreement for IP, which plays an integral part in providing a constructive means to structure and enable the formation of these partnerships.

10. A voluntary arrangement, whereby IP and know-how is transferred from the right holder to a manufacturer on mutually agreed terms, has numerous advantages as a model for upscaling production of health products and technologies. It creates a sound basis for long-lasting, beneficial relationships and incentives to produce and disseminate new inventions, such as life-changing vaccines. Where possible, a range of options, such as voluntary licensing including non-exclusive forms, should be promoted to maximise the scope of a licence scope and therefore to increase opportunity for equitable access.

11. An inherent benefit of a balanced IP system and successful voluntary licensing partnerships are their contribution to the innovation ecosystem through making public information on innovations, allowing innovation to be disseminated for further development, and the confidence it provides to IP rightsholders to collaborate between institutions and internationally, and dedicate resources to innovative activity which benefits the public.

12. There are multiple factors to consider when considering eligibility for a voluntary licensing agreement. Existing technical capacity and experience is important, alongside a relationship of trust and transparency. Another equally key element is the protection and enforcement of IP rights, which provides confidence to the entity entering a business relationship that their IP will not be infringed and, if it is, that legal recourse for infringement is available. Voluntary arrangements provide a means of consolidating the confidence which the IP framework provides.

13. Demand generation for the product itself is a fundamental success criterion. Several factors contribute to this including, but not limited to, ensuring a country can diagnose the disease in question and has the willingness and infrastructure to treat it; and ensuring willingness from the government or purchaser to procure the product.

[4] Paragraph 23 and 24, Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics, https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True

14. While the TRIPS Agreement's substantive obligations provide confidence for entities to form voluntary partnerships, it contains a specific provision focused on increasing technology flows, which may be beneficial in supporting equitable access if the enterprise holds technology related to health products and technologies.

15. As mandated by Article 66.2, *"Developed country Members shall provide incentives to enterprises and institutions in their territories for the purpose of promoting and encouraging technology transfer to least-developed country Members in order to enable them to create a sound and viable technological base"*.[5]

16. Recognising the critical lessons that all Members must learn from the COVID-19 pandemic, WTO Members should clarify and build upon the effective role which the multilateral IP framework has played in the global pandemic response by further examining the framework's relationship with voluntary licensing and technology transfer partnership formation.

4 IP, VOLUNTARY LICENSING, AND TECHNOLOGY TRANSFER

17. Contained within some, but not all, voluntary licensing arrangements is the transfer of technology and know-how, often protected via IP, which is a necessary component required to scale up production. For example, technology transfer can feature as part of contract manufacturing partnerships.

18. There are multiple factors to consider when assessing if a manufacturer is eligible for technology transfer. Protection and enforcement of IP is only one factor in the formation of partnerships. This paper focuses on IP and, therefore, is within the TRIPS Council's competency to examine further. Other WTO fora of relevant competency would likely benefit from exploring other factors and their connection to the formation of partnerships in closer detail.

19. Such factors may include, but are not limited to, the availability of sustainable manufacturing capacity; sustainable market demand underpinned by policy and demand forecasting which create incentives for licensees and/or generic companies; experience of manufacturing the relevant product; the availability of skilled personnel; adherence to harmonised regulatory standards including those recognised internationally; rule of law being established and enforced supportive of an innovation-friendly environment; being a trusted partner demonstrating behaviour conducive to trust-based relationships; and clear economic development priorities which promote technology transfer and inward investment for continual development. While overlap with IP may exist in these factors, they are not the core focus of the TRIPS Council's remit or competency.

5 BARRIERS TO EFFECTIVE PARTNERSHIPS

20. The effectiveness of voluntary partnerships may also be affected by trade barriers, including tariff and non-tariff barriers. For example, high applied tariffs and other taxes on pharmaceuticals around the world mean it is often costly to import essential therapeutics to treat patients. Moreover, high applied tariffs on certain inputs to vaccines remain high, which can have a cumulative impact on manufacturing costs.[6]

21. The use of export restrictions can cause significant disruption to global trade, leading to an inequitable and regressive distribution of goods. Applying export restrictions too readily, without clarity or over a prolonged period may have an acute impact on developing countries who rely on imports and have limited capability to scale up domestic production during times of shortage. For example, export restrictions impeded access to COVID-19 vaccine inputs, leading to uncertainty on delivery timeframes by suppliers. They also hindered clinical trials by impeding the movement of critical biological samples from global clinical trials to centralised testing sites.[7]

[5] Paragraph 66.2 of the TRIPS Agreement, https://www.wto.org/english/docs_e/legal_e/trips_e.htm#part6

[6] https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf

[7] https://www.wto.org/english/tratop_e/covid19_e/bottlenecks_update_oct21_e.pdf

22. Wider elements, such as those recognised in the Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics of 17 June 2022[8], may also impact the effectiveness of a partnership.

23. It is important to recognise that not all manufacturing entities in Member jurisdictions have been recipients of voluntary licensing and/or technology transfer partnerships. The TRIPS Agreement has flexibilities built into its architecture, including compulsory licensing in certain situations, to reflect the importance of achieving public health policy objectives. It is critical to recall that existing flexibilities may be utilised by Members, where considered necessary and appropriate, to achieve their public health policy objectives. Where Members feel that they are unable to use the TRIPS Agreement's existing flexibilities, we encourage the sharing of evidence to understand this and discussion on how to navigate potential challenges.

24. It is also important to recall least developed countries' (LDCs) exemption from implementing the TRIPS Agreement's substantive obligations until July 2034 or upon graduation, whichever comes first.

6 ROLE OF WTO AND OTHER STAKEHOLDERS

25. Recognising the growing importance of trade and technology transfer, Members should consider how the WTO can drive forward shared interests on voluntary licensing and technology transfer.

26. The WTO has a role to play in progressing equitable access ambitions through a holistic trade approach. It has experience of progressing this ambition as exemplified by the Ministerial Declaration on the WTO Response to the COVID-19 Pandemic and Preparedness for Future Pandemics of 17 June 2022. The United Kingdom recognises the ongoing work to address trade barriers within the Committee on Market Access (CMA), and the need for coordination across WTO committees.

27. It is evident that voluntary licensing and/or technology transfer is a complex and cross-cutting topic which will require constructive engagement across the WTO Membership. There should be a particular focus on the experiences of and challenges faced by developing and least developed countries to better identify pragmatic next steps.

28. Voluntary licensing and technology transfer is a complex but essential tool for achieving equitable access. WTO bodies of relevant competence, recognising the increasing importance of technology transfer in trade policy limited not only to health, may benefit from examining how their competency may help or hinder the formation of voluntary licensing and technology transfer partnerships.

29. To ensure any discussion is underpinned by evidence, the involvement of external stakeholders with expertise should also be considered, such as the World Intellectual Property Organisation (WIPO) and World Health Organisation (WHO), as part of their ongoing trilateral cooperation. The role of business, civil society, and academia should also be considered. Such discussions could be held as part of thematic sessions organised by TRIPS Council as they relate to IP aspects of a partnership.

30. There is also scope for discussion at the Working Group on Trade and Technology Transfer (WGTTT). It may be used as a forum to address the cross-cutting aspects of policy questions, share experience, explore challenges, and consider possible recommendations on steps that might be taken within the mandate of the WTO, including within TRIPS Council and other forums of relevant competency, to increase technology transfer flows between countries, particularly to developing and least developed countries.

31. We welcomed the recent WGTTT Chair consultations on how members might better use this forum and seek to engage constructively in conversations that might enrich the broader discussions at the WTO.

[8] https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/WT/MIN22/31.pdf&Open=True

7 CONCLUSION

32. As a first step, Members should consider what experiences of IP's connection with voluntary licensing and/or technology transfer can be brought to the TRIPS Council which could progress discussion. To achieve this, the UK supports suggestions to expand the TRIPS Council agenda item "IP and COVID-19" to include "Pandemic Preparedness". This communication should be used to kick-start a longer dialogue on pertinent policy questions focused on progressing collective efforts for pandemic preparedness which can be incorporated with other WTO forums of relevant competency such as the WGTTT and CMA.

Questions to initially consider include but are not limited to:

a. Noting the importance and prevalence of voluntary licensing and/or technology transfer, how could Members facilitate further voluntary licensing and/or technology transfer?

b. What other factors may affect the successful formation of partnerships?

c. What national and/or international, public and/or private stakeholder experiences could be brought for discussion? For example:

    i. How have domestic policies helped Member's pandemic response efforts?

    ii. Where has a Member successfully incentivised technology transfer?

    iii. Where has an entity in a Member successfully been the recipient of technology transfer and/or voluntary licensing and what were the factors for success?

    iv. Where has an entity in a Member been unsuccessful in forming a partnership – if so, why?

d. What challenges have entities in a Member experienced previously in securing voluntary licensing and/or technology transfer partnerships, and how were they overcome?

e. What challenges are Members currently experiencing in helping facilitate partnerships?

ANNEX A:

EXAMPLES OF SUCCESSFUL VOLUNTARY LICENSING AND/OR TECHNOLOGY TRANSFER PARTNERSHIPS AND THEIR IMPACT

Information contained within this Annex was provided by the Association of the British Pharmaceutical Industry (ABPI) and International Federation for Pharmaceutical Manufacturers and Associations (IFPMA), with other material publicly available from the Medicines Patent Pool (MPP).

Pfizer

1. Reflecting the urgency of the situation, Pfizer's agreement with the MPP was signed in November 2021, before its antiviral had received approval or emergency use authorisation anywhere. The agreement covers 95 countries, and sublicensing agreements for the generic version of Pfizer's oral COVID-19 treatment are in place with a large number of generic partner companies.

2. As of June 2023, Pfizer and BioNTech have shipped 4.6 billion vaccine doses to 181 countries and territories around the world. The partnership between the two companies is an example of the collaboration involved in not only development of COVID-19 vaccines, but also in their manufacturing and distribution.

3. Pfizer and BioNTech had been working together since 2018 on a potential mRNA vaccine for influenza, so there was an existing relationship and trust between the partners. Reflecting the urgency of the situation in March 2020, the two companies signed a Material Transfer and Collaboration Agreement for co-development and distribution of a potential COVID-19 vaccine. This allowed them to immediately start to work together on a range of areas including development and manufacturing, and finalize the details of their partnership at a later date.

4. Under the agreement between the companies, BioNTech retained the IP rights to the vaccine and its related technology. Meanwhile, Pfizer contributed its expertise and capabilities in R&D, regulatory work, production and distribution. This included working with BioNTech to expand manufacturing capacity substantially to enable production at sufficient scale to respond to the pandemic.

5. The work involved investing at risk, including scaling up manufacturing, before knowing whether a vaccine would be successfully approved. With deployment of a new technology, mRNA, at scale for the first time, this also required building supply chains, including supplier networks and cold chain technologies, mid-crisis, from scratch.

6. The manufacturing and supply network for the vaccine comprises over 20 sites in Europe, the US, Brazil and South Africa. It includes both sites operated by the two companies themselves and, critically, sites operated by their contract manufacturing partners.

7. Technology transfer was a key enabler of this scale up. Core elements of this work included training, sharing of know-how, equipment installation, engineering and process qualification tests, and regulatory approvals.

8. Technology transfer was facilitated by working with partners with strong track records on quality compliance and safety, technical capability, capacity availability; in many cases a prior working relationship was a vital enabler of this work on an accelerated timeline.

MSD

9. In April 2021, prior to the completion of Phase 3 trials for molnupiravir and more than six months before its initial authorisation, MSD entered into non-exclusive voluntary licensing agreements (VLAs) with multiple established Indian generics manufacturers, to facilitate availability of generic molnupiravir in more than 100 low- and middle-income countries (LMICs) following local approvals or emergency authorisation.

10. MSD currently has eight bilateral voluntary licensees producing generic molnupiravir. The selection criteria for these was important, and MSD selected manufacturers that were well known, and used to supplying with high manufacturing quality. Additionally, MSD's agreement with the Medicines Patent Pool (MPP) – MPP's first voluntary license for a COVID-19 medical technology – allows for sublicensing deals for supplies to 106 LMICs.

11. Agreements are operational with more than 20 generic manufacturers from 10 countries (Bangladesh, China, India, Indonesia, Jordan, Kenya, Pakistan, South Africa, South Korea, and Vietnam). Through these non-exclusive VLAs, the MPP sublicenses, and local manufacturing and supply partnerships established with companies in Brazil and China, MSD's voluntary collaborations cover approximately 90 percent of the population in LMICs.

Gilead

12. In May 2020, Gilead signed non-exclusive VLAs for remdesivir with generic pharmaceutical manufacturers based in India, Pakistan, and Egypt to enable them to supply remdesivir to 127 developing countries.

13. Since the beginning of the pandemic, VEKLURY® and generic remdesivir have been made available to over 13 million patients around the world, including 8 million in low- and lower-middle income countries (LLMICs) through Gilead's voluntary licensing programme. Gilead's voluntary licenses for remdesivir remain royalty free.

Eli Lilly

14. Lilly has signed voluntary royalty free license agreements with 8 generic manufacturers for baricitinib. The licensees set the price. Additionally, Lilly announced a donations program making available courses of baricitinib free of charge to least, low, and middle-income countries and made donations to multiple countries, including India.

Shionogi

15. In October 2022, Japanese pharmaceutical company Shionogi, and MPP, signed a voluntary licence agreement for Shionogi's antiviral candidate ensitrelvir fumaric acid (S-217622).

16. Under the terms of the licence agreement between Shionogi and MPP, qualified generic manufacturers that are granted sublicences by MPP will be able to manufacture and supply ensitrelvir to 117 countries, pending regulatory authorisation or approval in those countries. In June 2023, sublicence agreements were signed with three generic manufacturing companies from China; two from India; and one from Vietnam.

17. Shionogi will waive royalties on sales in all countries covered by the agreement while COVID-19 remains classified as a Public Health Emergency of International Concern by the World Health Organization (PHEIC).

AstraZeneca

18. In the early stages of the pandemic AstraZeneca partnered with Oxford University to enable global development, manufacturing and distribution of the vaccine. The result was a COVID-19 vaccine that was developed in under a year. AstraZeneca's approach has been to share technology and know-how with more than 20 experienced vaccine manufacturing organisations in countries where production can be ramped up at scale. For example, their voluntary licensing agreements with the Serum Institute of India (SII) and Fiocruz in Brazil facilitated the scaling-up of manufacturing across the world.

19. AstraZeneca believe this offers a more effective way of scaling up production and supporting innovation, and AstraZeneca's model has enabled them to supply over 3 billion doses to 180 countries around the world. Approximately two thirds of the doses have gone to low and lower middle-income countries. Together with their partners they made a significant impact in terms of global public health. Based on data published in The Lancet and an analysis by Airfinity, AstraZeneca's vaccine is estimated to have saved over 6 million lives in the first

year of vaccination. AstraZeneca was the first and largest contributor in 2020 and 2021 to COVAX, the global initiative for equitable access.