BIA position on WHO pandemic preparedness accord

September 2023

UK BioIndustry Association

Introduction and summary

The BioIndustry Association (BIA) is the voice of the innovative life sciences and biotech industry, enabling and connecting the UK ecosystem so that businesses can start, grow and deliver world-changing innovation. The BIA's membership includes innovative start-ups, scaling businesses and established life sciences companies, all of which routinely utilise intellectual property (IP), and specifically patents, to secure and protect investment in innovation either on their own behalf or on behalf of their global client base. The survival and success of life sciences companies, especially SMEs, and their ability to develop life-saving medicines and vaccines, is inextricably linked to the value attributed to their IP rights and their ability to predictably enforce those rights in the countries in which they operate.

We are therefore very concerned about the WHO CA+ zero draft, which risks undermining the vital global mission to strengthen our collective ability to respond to future pandemics. Our concerns cover three main areas:

1. The zero draft of the WHO CA+ contains a **damaging and false narrative of the role of IP in pandemic preparedness, prevention and response**. IP is vital in the research, development and production of medicines, vaccines and technologies to the benefit of public health. BIA urge the UK Government to take an evidence-based approach to discussing IP-related matters and not to weaken innovators' IP rights through this treaty, as IP rights give collaborating parties the ability and confidence to share information openly and rapidly.
2. Article 7 of the WHO CA+ commits innovators to **transfer technology and know-how** relevant to the manufacturing of pandemic-related products and encourages innovators to grant licenses to manufacturers to use their know-how. The scope of know-how, and whether it includes confidential information and trade secrets, is unclear. Any development of measures that promote and incentivise relevant transfer of technology and know-how for production of pandemic-related products, while encouraged, should be based on a voluntary nature and enabled by strong IP rights that provide confidence for rights owners.
3. Implementing a **Pathogen Access and Benefit Sharing (PABS)** system for pathogens with pandemic potential runs the risk of delaying the rapid sharing of pathogens and development of countermeasures, running counter to its very intention.

With this in mind, we urge the Government to take into consideration the significance of IP in the life sciences as it prepares its position and engages with other nations on the WHO CA+ zero draft and other international pandemic preparedness initiatives. We ask that the Government carefully considers the role of strong IP rights in enabling technology transfer and the sharing of know-how, and be aware of the pitfalls of access and benefit sharing (ABS) mechanisms for genetic resources and their impact on innovation, a topic BIA has engaged on in relation to the Convention of Biological Diversity (CBD)'s Nagoya Protocol on ABS of genetic resources, for many years.

1. Damaging and false narrative of the role of IP in pandemic preparedness, prevention and responses

The BIA and its members are committed to playing a key role in response to pandemics and other public health concerns by working collaboratively to ensure quick and safe global access to diagnostics, vaccines and therapies. Among other declarations, this is evidenced by our commitment to the 100 Days Mission jointly adopted by the Government and life sciences industry[1].

At no stage during the COVID-19 pandemic has IP been the barrier to global equitable access to vaccines and treatments. In fact, IP has been crucial in the development of the vaccines and therapeutics for COVID-19 by incentivising the investment in the technology and skills that were able to be harnessed at record speed to develop them.

The zero draft of the WHO CA+ contains a **damaging and false narrative of the role of IP in pandemic preparedness, prevention and response**. IP is vital in the research, development and production of medicines, vaccines and technologies to the benefit of public health, and IP rights should not be weakened through this treaty.

IP rights provide a direct incentive to invent in the first place. They encourage continued R&D in companies, enabling biopharma companies to do research *secure* in the knowledge that they can get IP rights to protect results and ultimately recoup their R&D investment. In addition, the disclosure function of patents means that any knowledge created is publicly shared. This means that the existence of IP-protected innovations encourages competitors to find their own alternative solutions. This accelerates innovation and results in more solutions being developed for public benefit.

Waiving or loosening IP rights was not the solution to the COVID-19 pandemic and will not be the solution to the timely and equitable access, production and distribution of future pandemic-related health technologies and know-how. On the contrary, it will make it much harder to respond to the next pandemic by discouraging investment in innovation and inhibiting collaboration.

We urge the Government to adopt an evidence-based approach to discussing IP-related matters in the context of the WHO CA+ and not to weaken innovators' IP rights through this treaty. We recommend seeking the guidance and advice of the UK IPO and WIPO where it is well-understood that IP, rather than inhibiting innovation, 'provides a vehicle for lifesaving medicines and breakthrough technologies to get to market, …helps research across the life sciences to create impact…and [provides] a means for distributing groundbreaking discoveries to places where they are needed the most'[2].

[1] See https://www.gov.uk/government/publications/joint-statement-on-delivering-the-100-days-mission/joint-statement-from-the-uk-government-cepi-ifpma-abpi-bia-bio-and-dcvmn-on-delivering-the-100-days-mission

[2] See https://www.wipo.int/pressroom/en/articles/2023/article_0005.html?utm_source=WIPO+Newsletters&utm_campaign=19cb1fbac4-DIS_PRESS_EN_300523_01&utm_medium=email&utm_term=0_-e43393f8c2-%5BLIST_EMAIL_ID%5D

2. Transfer of technology and know-how

Just as with developing treatments and vaccines through R&D, the manufacturing and distribution of pandemic-related products present novel scientific and innovative challenges, given the cutting-edge nature of many of the technologies. In addition, they present tremendous logistical, regulatory and management challenges.

The production of pandemic-related treatments and vaccines therefore does not merely require knowing the 'recipe' and methodology, but the appropriate equipment, raw materials, skill set and expertise to apply the methodology correctly to manufacture the product to the same safety and efficacy standards as produced by the original developer and manufacturer. Regulators around the world need confidence that the products are the same as those which received original approval for safety and effectiveness. Some of this is protected IP, but much of it is know-how of highly expert individuals, developed over a lifetime, that is not easily or quickly replicated or taught. IP rights ensure that collaborations on developing and manufacturing these products across the world are safe and effective[3].

Weakening or waiving IP rights will not ease or increase the transfer of technology and know-how. On the contrary, IP enabled collaboration and coordination among innovators and manufacturers during the COVID-19 pandemic by enabling the up-front sharing of technologies and know-how. Removing IP protection would have made it impossible in the case of COVID-19 to innovate so quickly, as it would have made knowledge and technology sharing unduly risky. Innovators would not have been able to share their knowledge without the security of IP, as it creates the trust which is necessary to work with strangers. As a result, companies were able to complete technology transfer and have medicines produced with a speed that had not been previously seen.

Any development of measures that promote and incentivise relevant transfer of technology and know-how for production of pandemic-related products, while encouraged, should be based on a voluntary nature, a position supported by the Government[4]. Since the beginning of the COVID-19 pandemic, 177 collaborations were created to manufacture and commercialise COVID-19 treatments, including 93 voluntary licensing agreements, of which 80 are active in developing countries (as of October 2022)[5]. There is no evidence that mandatory or compulsory agreements are effective, and indeed they are rarely used. Therefore, while we support the overall aim of Article 7 of the WHO CA+, emphasis must be placed on the voluntary nature of any mechanism to incentivise access to and transfer of technology and know-how.

Know-how ranges from trade secrets to general knowledge and skills. The value, and protection, of know-how is determined by limitations to its accessibility. Once know-how is shared, it is difficult to enforce any restrictions on its 'use' or isolate the application of the know-how to a specific area. In manufacturing, this includes process skills and techniques which may be applicable to the manufacture of other products, which could include non-pandemic related products which lie outside the scope of the intended use of the know-how or technology. Any measure that encourages the transfer of technology and sharing of know-how needs to be based on a high level of trust between the parties and would need to be backed up with the appropriate requirements to enforce restrictions on the use of that technology or know-how.

[3] See https://377da495-a7a0-44e0-a16f-dde7e79abeae.filesusr.com/ugd/159979_71b651acbd27478baeeb22f6eddf9f24.pdf

[4] See https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=q:/IP/C/W704.pdf&Open=True

[5] See https://healthpolicy-watch.news/pharma-shares-covid-19-volunary-licensing-lessons/

Lastly, and importantly, it is unclear how far the transfer of existing know-how on manufacturing will aid responsiveness in a future pandemic situation. Highly specialized manufacturing facilities of the type needed to respond to the next pandemic, and a distinct pathogen, take many years to build. This means that transferring technology and know-how without the facilities in place to adopt them is ineffectual to a most rapid pandemic response. The complexity of manufacturing vaccines was exemplified by setting up additional manufacturing capacity for the AstraZeneca COVID-19 vaccine in Leiden, the Netherlands, in 2021 which despite the Netherland's strong manufacturing capacity and standards was a lengthy and difficult process.

Better, faster responsiveness is unlikely to be achieved through 'time-bound waivers of intellectual property rights that can accelerate or scale up manufacturing of pandemic-related products during a pandemic'[6], or through mandated technology transfer and know-how. To solve the issue of responsiveness, the focus should be placed on equitable product distribution, and the building of capacity for local specialised production and manufacturing capacity in the long-term.

3. Pathogen Access and Benefit Sharing (PABS)

The WHO CA+ seeks to introduce an access and benefit sharing mechanism for pathogens (PABS) with pandemic potential. For many years, the BIA has warned of the negative impact of ABS mechanisms for genetic resources and the digital sequence information thereof, most notably in relation to the Nagoya Protocol[7]. An ABS mechanism for pathogens runs the risk of delaying the timely and rapid identification and sharing of pathogens, inhibiting research and the development of life-saving treatments. This has been analysed in depth in an independent report on Global Disease Surveillance and Pathogen Sharing[8].

ABS mechanisms can pose a burden to innovators, as evidenced by the UK's post-implementation review of the Nagoya Protocol[9]. In the context of a pandemic, a fast and well-coordinated response is essential, which is why in March 2022 the UK life sciences industry and Government together committed to deliver the 100 Days Mission: 'the ambition to have safe and effective vaccines, therapeutics and diagnostics within 100 days of an epidemic or pandemic threat being identified'[10]. We have significant concerns that the PABS system would have harmful effects on innovation related to public health, without any counter-balancing positive effects on achieving the goals of the WHO CA+ in easing pandemic preparedness, prevention and response, running counter to its very aim.

Rapid provision of and freedom to utilise physical materials and digital sequence information relating to the COVID-19 virus was and continues to be vital to dealing with its impact. There is no doubt that delays in providing access to the genetic resources relating to the COVID-19 virus and restrictions on or barriers to its use - of the type we have seen relating to physical genetic resources under the implementation of the Nagoya

[6] See https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf
[7] See https://www.bioindustry.org/static/uploaded/b3e57d3f-ca70-42ff-87996ac74d1a5f80.pdf
[8] See https://www.cov.com/en/topics/global-disease-surveillance-and-pathogen-sharing
[9] See https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/1034596/The_Nagoya_Protocol__Compliance__Regulations_2015_post_implementation_review.pdf
[10] See https://www.gov.uk/government/publications/joint-statement-on-delivering-the-100-days-mission/joint-statement-from-the-uk-government-cepi-ifpma-abpi-bia-bio-and-dcvmn-on-delivering-the-100-days-mission

Protocol, which the PABS, and the WHO[11], look to as a suitable ABS model - would have hindered the pandemic response globally. The transactional and as yet legally uncertain approach in the PABS as outlined in the WHO CA+ runs the risk of delaying the open and rapid access to and sharing of pathogens, and the work on vaccines needed to respond to major public health threats caused by pathogens.

We note that 'pathogens with pandemic potential' remain undefined in the WHO CA+. In order to develop a well-functioning PABS that will not hinder innovators in their efforts to quickly identify and share pathogens with pandemic potential, and develop treatments, the WHO will need to clearly define what constitutes such a pathogen. Without such a definition, the certainty and legal clarity that will be required by Article 10 cannot be met. In addition, some pathogens with human pandemic potential are currently covered through the Pandemic Influenza Preparedness (PIP) Framework[12], running the risk of creating overlapping obligations. The PIP could also in future become a specialised instrument under the Nagoya Protocol[13], creating further legal and transactional complexity and opacity.

Importantly, Article 10(d) stating that 'recipients of materials shall not claim any intellectual property or other rights that limit the facilitated access to pathogens with pandemic potential…'[14], and any other clause that hinders the obtaining of IP rights, should be removed from the agreement, as IP does not hinder access to pathogens. As the Government itself stated on 14 June 2023 with regards to the TRIPS agreement and waiver extension, 'more patent applications do not equal restricting access to [pandemic] products and instead are proof that the current IP framework provides confidence to innovators to develop new products. […] Changes that could potentially weaken the ability of this framework to incentivise investment and innovation risk impacting our ability to tackle health emergencies both now and in the future'[15].

Both the role of IP in pandemic preparedness and response, and the role of access and benefit sharing mechanisms for genetic resources and the digital sequence information thereof, are currently being discussed in multiple international fora. This includes the existing obligations under the Nagoya Protocol and its flawed implementation in the UK, the CBD's ongoing discussions on a multilateral benefit sharing mechanism for DSI of non-human genetic resources, the recently agreed BBNJ agreement[16], the ongoing negotiations over the extension of the 2022 TRIPS waiver, and WIPO intergovernmental committee negotiations on a legal instrument relating to IP and genetic resources. It is important to take an evidence-based approach to these discussions, ensure they do not run contradictory to each other, and do not inhibit the innovative efforts of UK life sciences companies that are vital in the UK's pandemic preparedness, prevention and response.

[11] See https://cdn.who.int/media/docs/default-source/documents/nagoya-protocol/nagoya-full-study-english.pdf?sfvrsn=ec2ab49d_12&download=true

[12] See https://www.who.int/initiatives/pandemic-influenza-preparedness-framework

[13] See https://www.absfocalpoint.nl/en/absfocalpoint/internationalinstruments/pip-framework.htm

[14] See https://apps.who.int/gb/inb/pdf_files/inb4/A_INB4_3-en.pdf

[15] See https://www.gov.uk/government/news/uk-statement-on-ministerial-decision-on-the-trips-agreement?utm_medium=email&utm_campaign=govuk-notifications-topic&utm_source=f3c26ad5-571a-4278-ab85-2c9b25a09b0d&utm_content=daily

[16] See https://www.un.org/bbnj/

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