BREIFING

Waiver of Intellectual Property Rights relating to COVID-19 health technologies

On 2 October 2020, South Africa and India submitted a joint proposal to the TRIPS (Trade Related Aspects of Intellectual Property Rights) Council at the World Trade Organisation (WTO), titled "Waiver from certain provisions of the TRIPS agreement for the prevention, containment and treatment of COVID-19". The UK Government rejected the text on the Waiver at the TRIPS Council meeting on 15th-16th October saying that it was not necessary whilst also stating that existing measures to overcome Intellectual Property (IP) barriers would suffice. This briefing sets out some key rebuttals against the Government's position.

What would it mean if it was granted?

The Waiver would allow all WTO members to choose to not grant or not enforce patents and other IP related to COVID-19 drugs, vaccines, diagnostics and other technologies until widespread vaccination is in place globally, and the majority of the world's population has developed immunity. Specifically the Waiver Proposal applies to Section 1 (copyrights and related rights), 4 (industrial design), 5 (patents) and 7 (protection of undisclosed information) of Part II of the TRIPS Agreement. The proposed waiver would be applicable only to COVID-19 health technologies. It does not suggest a waiver from all TRIPS obligations, nor does it suggest a waiver beyond what is needed for COVID-19 prevention, containment and treatment.

Why is it needed?

The UK government has recognised that 'no one is safe until everyone is safe' and to form a sustainable global response to COVID-19 all countries need to have equitable access to safe and effective diagnostics, treatments and vaccines. Intellectual property rights can lead to monopolies which restrict further research, manufacturing scale-up and can lead to price gouging all of which impede access, particularly for countries with smaller health budgets. A few organisations and a handful of WTO member states, including from the UK representative at the TRIPS Council meeting, have said that IP is not a barrier to accessing COVID-19 tools. However evidence from the COVID-19 response so far, and many other public health issues throughout history from the AIDS crisis in the 2000s to cancer drugs today, clearly shows that IP does restrict access (see examples below). This situation will only get worse unless governments intervene.

N95 respirator masks

IP barriers, including patents, have exacerbated the shortages of N95 respirator masks for healthcare workers in hospitals around the world. The respirator is protected by hundreds of patents owned by the US government, the multinational company '3M', paper and healthcare companies, individuals and universities. In March 2020, the Governor of Kentucky in the United States called on 3M to release its patent for the N95 respirator so that more manufacturers could start producing it. The company has not released its patents to date.

Ventilator Valves

A shortage of ventilator valves globally led to engineers in northern Italy using a 3-D print to reverse engineer the component in March 2020 after the manufacturer refused to share the blueprint. The valves have helped save many lives. They cost about $2-3 each to produce, compared to $11,000 per valve from the manufacturer, and can be manufactured in a

fraction of the time. The engineers received hundreds of requests for their 3D-printed valves, but did not share their digital print file more widely due to possible legal and medical issues. See MSF's technical briefing for more examples of where IP has presented a barrier to accessing life-saving health technologies.

Medicines for cancers, hepatitis C and cystic fibrosis

The issue of high priced medicines has become a global problem affecting low, middle and high income countries alike. For example here in the UK over the last few years a breakthrough hepatitis C medicine has had to be rationed on the NHS due to its high cost, cancer patients have had to crowd-fund and campaign for treatments that haven't been available on the NHS and cystic fibrosis patients have had to wait over 3 years to access a new therapy as the pharmaceutical company refused to lower the price to something our health system could afford.

Why can't existing solutions overcome IP barriers

Responding to COVID-19 effectively cannot rely only on addressing IP barriers on a national level. Many countries lack immediate manufacturing capacity for essential parts for a product, for example raw materials, so removing IP barriers on one component in one country alone will not be sufficient. Likewise, countries that have the capacity to produce a finished product would need to ensure that there are no restrictions for them to export the product to any other countries in need.

Existing solutions such as voluntary licenses from pharmaceutical companies are piecemeal at best, as we've seen from Gilead's behaviour with remdesivir . Other solutions such as governments utilising the flexibilities within the TRIPS agreement to override patent monopolies can still play a role, but again these have territorial restrictions and are granted on a product by product and country by country basis.

Will the Waiver hamper innovation?

Never has there been a weaker case for the granting of monopoly-based incentives for biomedical innovation. Firstly because it is governments and philanthropic resources that are funding a huge proportion of the research and development of COVID-19 drugs and vaccines, not just the pharmaceutical industry. Over US$12 billion of public funds has been poured into the research and development (R&D), clinical trials and manufacture of six front-runner candidate COVID-19 vaccines. Therefore the common justification from the industry to charge a high-price to recoup R&D is unjustified. Secondly, because no company has the manufacturing capacity to meet global demand, granting a patent-based monopoly will hinder the knowledge sharing that is essential for scaling-up manufacturing capacity to ensure sufficient supply. In general, monopoly-based incentives do not deliver for public health and there is growing support for alternative incentives which don't lead to high prices.

Would the Waiver be applied to all countries?

Yes, all countries would be able to use the waiver. However, countries could choose not to enforce it domestically while other member states can implement it.

What is the process for the Waiver being passed?

The waiver proposal will be discussed at the TRIPS Council meeting on 20th November and 10th December. A decision on the Waiver could be reached at the General Council Meeting of the WTO on 17th December. If the General Council cannot come to a decision, the proposal will be decided at the WTO ministerial currently pencilled in for June 2021.