

PREPARED ORAL STATEMENT OF
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IN ITC INVESTIGATION 332-996, ON COVID-19 DIAGNOSTICS AND
THERAPEUTICS: SUPPLY, DEMAND, AND TRIPS AGREEMENT FLEXIBILITIES
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In this prepared statement, we address the critical need for governments to compel trade secret information sharing (including “know how” and confidential information that may not rise to the level of a protectable trade secret) for developing and equitably distributing affordable pandemic vaccines. We observe that: (1) the failure to compel trade secret sharing led to large numbers of avoidable deaths that might have been prevented during the COVID-19 pandemic, and more avoidable deaths will foreseeably occur in future pandemics absent such compelled sharing; (2) there is no restriction by the TRIPS Agreement for governments to compel such sharing (although it would be better to adopt an international requirement to require such sharing in the pending pandemic treaty); (3) there is ample existing domestic authority to already require such sharing; and (4) what is currently lacking is the political will to exercise existing authorities and to push for international *requirements*. Importantly, the foregoing means that the discussion of “waivers” and “flexibilities” in regard to TRIPS obligations is largely beside the point, as such waivers are neither necessary nor sufficient as a matter of law to address actual health needs.

We hope that our testimony will help generate the needed political will to address these problems head-on, before more people unnecessarily die around the world. We need to follow the “Golden Rule” – treating others as we would like to be treated – rather than to prioritize vaccine, therapeutic, and other medical-product access to our own citizens, whenever other people around the world are *more likely than we are* to die or suffer without such access. Further, doing so both will reduce the likelihood of generating new pandemic disease variants overseas that cause even more harm to our own citizens and will minimize economic costs to society – in amounts that will dwarf any compensation that can and should be paid for compelling such trade secret, know-how, and confidential information sharing.

1. The Failure to Compel Sharing and Vaccine Nationalism Led to Avoidable Deaths.

First, the failure to compel trade secret sharing – and the initial pre-purchase by technology-rich and wealthy nations and the related hoarding of limited vaccine supplies for the domestic citizenry of those nations – led to large numbers of avoidable but unavoids deaths around the world. Recent modeling based on excess mortality rates by Oliver Watson, et al., *Global impact of the first year of COVID-19 vaccination: a mathematical modelling study*, 22 *The Lancet* 1293 (Sept. 2022), showed as follows regarding avoidable deaths that were not avoided (without analyzing the effects on variant production).

[F]rom mid-2021 onwards those countries with access to plentiful vaccine supply opted for mass vaccination of the adult population, later including children and subsequent boosting to maintain high levels of protection given the waning in

vaccine efficacy and the emergence of new variants of concern. This approach has resulted in vast inequalities in global vaccine distribution.

To reduce inequality, a fair allocation mechanism for COVID-19 vaccines was developed through the COVID-19 Vaccines Global Access (COVAX) facility, with a key target of achieving 20% vaccine coverage for the countries covered by its Advance Market Commitment (AMC) through COVAX-secured doses by the end of 2021....

Model-based estimates have . . . been developed to obtain a more complete estimate of the pandemic to date . . .

Notably, the shortfall of the COVAX target in several regions *was estimated to have resulted in an additional 156 900 (95% CrI 147 800–165 400) deaths* (table 3). Although these deaths constituted a small proportion of the total deaths averted globally, *these avertable deaths were concentrated in 25 low-income countries*, which we predict would have averted an additional 81 750 (95% CrI 75 430–88 200) deaths across low-income countries by reaching 20% coverage, representing an additional 45% of deaths averted (table 3).

We evaluated the impact of the first year of COVID-19 vaccination, revealing how vaccinations have more than halved the potential global death toll due to COVID-19, with an estimated 19.8 million deaths from COVID-19 averted as a result of vaccination, based on excess mortality estimates of the impact of the pandemic. . . . If the 40% target, per country, from WHO had been met, we estimated a further increase in deaths averted, mainly focused in lower-middle-income countries and low-income countries....

[T]he results of this analysis still provide a comprehensive and thorough assessment of the impact of COVID-19 vaccination, revealing the substantial impact that vaccines have had and the millions of lives that are likely to have been saved during the first year of vaccination. Despite this, more lives could have been saved if vaccines had been distributed more rapidly to many parts of the world and if vaccine uptake could have been strengthened worldwide.

A recent letter (at <https://app.box.com/s/016uv7schj901mdchxm64gt9ckli81w9>), signed by many dignitaries, noted an even higher rate of deaths that could have been avoided – about one every 24 minutes – had medicines been distributed more equitably around the world. That figure was based on estimates made in a different paper published in Nature Medicine (at <http://tracking.vuelio.co.uk/tracking/click?d=yGN1ZNFNwrjdWTtu3Yv1P69jguYL5vxRBZbzP5Epl-UIEHWdpDAmLtBb85hoHuRPwiZF1TqQPLZAIBMMsw1SPzBLqN2sqD3bfJxeHrXSeUsBHF6dMRk4iywYStwl9uMPp0D6vbWIT8W69Nbs921FWjWTDbf-DXlnHGfapR7XOWem0>) estimating about 1.3 million more avoidable but unavoids deaths occurred in 2021 than would have occurred with more equitable vaccine distribution (even without regard to increasing production). See Donato Mancini, Vaccine inequality blamed for boosting global Covid death toll, Financial Times (Mar. 10, 2023).

We note that there were and remain significant problems with distribution mechanisms and health care systems in the developing world, which made and will continue to make the task of equitable distribution much more difficult than otherwise. These limitations need to be addressed *in advance* of the next major pandemic. Importantly, *these limitations should not be an excuse for refusing to share trade secrets* when the medical needs around the world are not going to be adequately addressed absent sharing (even if that failure is only a timing issue until total manufacturing can be geared up). We have utilized this approach in the past, providing vaccines where they are most needed e.g., to front-line workers in Africa dealing with Ebola and Marburg. We need to take the same approach to prioritizing vaccine distribution to the epicenters of the outbreaks, and to the public health first-responders, rather than to those at relatively low risk. Even aside from the moral imperative to “do the right thing,” such action may also reduce risks at home from subsequent variant development.

2. The TRIPS Agreement Does Not Restrict Compelled Trade Secret Sharing, But Waivers Will Not Impose The Needed, Worldwide Requirements To Act.

We have already submitted to the ITC in this investigation our draft law review article. It is soon to be published in the *Hastings Law Journal* under the title “Compelling Trade Secret Sharing.” That article explains in detail why the TRIPS Agreement does not prevent governments from compelling trade secret sharing. Simply put, the TRIPS Agreement provisions in Article 39 are directed at “unfair” commercial activities. Nothing in the Agreement addresses what actions governments can take regarding private conduct or information in order to protect public health. In fact, Article 39.3 contains an express exclusion for public health needs from its required protections.

Additionally, traditional interpretive methods compel the conclusion that by expressly excluding compulsory licensing of trademarks and by regulating compulsory licensing of patents, but by simultaneously not addressing compulsory licensing of trade secrets or (in TRIPS parlance) “undisclosed information,” the Agreement leaves countries free to issue compulsory licenses to share such trade secrets. To the extent it were relevant under international treaty interpretation principles, moreover, the drafting history of the TRIPS Agreement provides no basis to restrict the clear textual lack of prohibition on compelling trade secret sharing. In sum, there simply is no restriction on governments abilities to compel such sharing.

As our article and the above indicates, such sharing is critically needed at early stages of pandemic diseases, when manufacturing supplies of vaccines will be limited and when scale-up of production is critically important. Although biologics and pharmaceutical companies will argue that voluntary licensing solves this problem and resulted in rapid scale up of COVID-19 vaccines, numerous requests from reputable generics manufacturers early in the pandemic to voluntarily license their technologies were rejected or ignored. See Ashley Furlong, *Big vaccine makers reject offers to help produce more jabs*, *Politico* (May 14, 2021). Thus, it is likely that licensing (or other forms of sharing) will need to be compelled to gear up R&D, regulatory approvals, and production more rapidly in the next pandemic. Importantly, reasonable compensation can and should be provided for such uses.

Finally, although patent rights are important issue for rapid development, they are usually much less important than requiring the early disclosure or sharing of needed trade secret information (such as data on and actual samples of pathogens). This is partly because patent rights can be infringed absent injunctive relief, and because patent use can be expressly authorized by governments. For example, numerous lawsuits have been filed by Arbutus-Genevant and by others against Moderna and Pfizer for allegedly infringing patents in developing and producing their COVID-19 vaccines. Had patent rights been enforced by injunction or had the patent uses not been authorized by the U.S. Government, the subject vaccines could not have been made as quickly. Of course, if infringement of valid patent claims is proven, the patent holders can and should be reasonably compensated.

Thus, the TRIPS Waiver is helpful to generate political will and to avoid future retaliation against countries that issue compulsory patent licenses or that authorize infringement to satisfy critical public health needs. But the TRIPS waiver says nothing of trade secret sharing. Several countries, including South Africa, have opened discussion about a similar waiver for trade secrets (based on David Levine's prior work on the subject; see <https://docs.wto.org/dol2fe/Pages/SS/directdoc.aspx?filename=t:/IP/C/W666.docx&Open=True>). Even a trade secret waiver, however, would be unnecessary or insufficient to assure rapid production at scale of vaccines. Nor would the original TRIPS waiver proposal have been necessary or sufficient, although it would have eliminated any need to compensate for such public health uses of patents or trade secrets *as a matter of international law*.

Put simply, no waiver proposal can override national laws previously adopted to implement the TRIPS Agreement, and even in jurisdictions where the waiver might be self-implementing it would not compel any information transfers. Accordingly, a new pandemic treaty must *mandate* such compulsory trade secret and know-how sharing obligations and thus must *require* countries both to adopt such measures *and to exercise them* for worldwide public benefit in a pandemic. The U.S. should be pushing for such language, not resisting it. And not just as a moral matter, as it is possible that we might have a prioritized need for vaccines first produced elsewhere around the world.

3. Ample Authority Already Exists To Compel Such Trade Secret Sharing.

As the article that we submitted demonstrates, numerous authorities already exist to compel such trade secret sharing. These authorities include the Defense Production Act (DPA). The DPA has been used repeatedly in the COVID-19 pandemic to direct not only production priorities and supplies to vaccine manufacturers, but also to require them – or to threaten action that effectively compelled them – to voluntarily license their trade secrets and to transfer to others their know-how and confidential information. Additionally, no action is required to amend international treaty obligations for the U.S. Government (or other governments within and outside the U.S.) to exercise those (or similar) authorities. Finally, as previously noted, actions to compel trade secret sharing are fully compatible with existing international law, whether or not such actions would require compensation under Investor-

State Dispute Settlement treaties. Thus, nothing should prevent the U.S. Government from immediately using its powers to compel the worldwide transfer of technologies to help prepare for the next pandemic.

4. What We Need Is The Political Will To Do The Right Thing.

We now know that voluntary transfers of proprietary trade secrets, know-how, and confidential information have not occurred in the time frames and at the scale needed to avoid worldwide vaccine shortages. Predictably, such sharing will not occur in the future without compulsion. Accordingly, the U.S. Government should act now to compel such sharing. At its core, this is about whether to share our knowledge for human benefit rather than continue to seek to preserve competitive advantages, both commercially and in international trade. We must reconsider the dynamics that put profits and short-term national interests above human lives and long-term national interests.

As Mr. Rogers used to say, “won’t you be my neighbor?” We must answer with a resounding “yes” and end the hoarding of knowledge and pandemic medical products. The best way to do that is to require worldwide sharing by treaty. The U.S. should lead the way in doing so by deed and by word. Our government should exercise existing authorities to compel such sharing and should urge that the WHO pandemic treaty establish a worldwide system for prioritizing *worldwide* production and distribution of pandemic medical products.

The idea of sharing *only* 20% of needed pandemic medical product outputs for health-prioritized worldwide distribution is disturbing, and it also reinforces the post-colonial mindset and competition regime that increasingly fails to serve any modern national interest. Now is the time to act like a real neighbor. It is time to reconsider how intellectual property can serve the greater good to save more lives, particularly at times of intense and historic need. And to do so governments must compel (and should agree by treaty in advance of pandemics to compel) trade secret, know-how, and confidential information sharing.