# **Production CP**

**The United States federal government should:**

**- substantially increase production and global distribution of the COVID-19 Vaccine, specifically providing all necessary vaccines to India and South Africa, and**

**- cooperate with allies to achieve increased production and global distribution of the COVID-19 Vaccine.**

**That comparatively solves better – IP rights don’t hinder vaccine cooperation, but manufacturing capacity is the current constraint.**

Hans **Sauer 6-17** [(Deputy General Counsel, Biotechnology Industry Organization.) “Web event — Confronting Joe Biden’s proposed TRIPS waiver for COVID-19 vaccines and treatments” https://www.aei.org/wp-content/uploads/2021/06/210617-Confronting-Joe-Bidens-proposed-TRIPS-waiver.pdf?x91208&x91208] TDI

But contrary to what Lori said, **there are genuine real problems in the supply chain** that are **not caused by patents**, that are simply caused by the unavailability and the constraints on existing capacity. There is in this world such a thing as maxed-out capacity that just can’t be increased on a dime. It’s not all due to intellectual property. This is true for existing vaccines as well as for vaccine raw materials. There are trade barriers. There are export restrictions that we should all be aware of and that we need to work on. And there are very real political, I think, interests in finding an explanation for how we got to this place that absolve governments around the world from their own policy decisions that they made in the past. In the United States, again, it was the declared policy of the previous administration, as well as this one, that we would vaccinate healthy college kids and go all down the line and offer a vaccine to everybody who wants it before we start sharing any with grandmothers in Burkina Faso. That was the policy. You can agree with it or disagree with it, but that was policy. We had export restrictions in place before a lot of other countries did. And that, too, contributed to unequal access of vaccines around the world. Another thing that was predictable was that politicians and governments around the world who want to be seen as proactive, on the ball, in control, for a long time were actually very indecisive, very unsure about how to address the COVID problem, which has so many dimensions. Vaccines are only one of those. But with respect to vaccines, not many governments took decisive action, put money on the table, put bets on multiple horses, before we knew whether these vaccines would work, would be approved. And it was governments in middle-income countries who now, I think, justifiably are concerned that they’re not getting fast enough access, who didn’t have the means and who didn’t have the decision-making structure to place the same bets on multiple horses, if you will, that were placed in the relatively more wealthy, global North and global West. But there is, I think, a really good and, with hindsight, predictable explanation of how we got to this place, and I think it teaches us something about how to fix the problem going forward. **So why will the waiver not work**? Well, first of all, with complex technology like vaccines, Lori touched on it, reverse engineering, like you would for a small molecule drug, is much more difficult if not impossible. But it depends very much more than small molecule drugs on cooperation, on voluntary transfer of technology, and on mutual assistance. We have seen as part of the pandemic response an unprecedented level of collaborations and cooperation and no indication that IP has stood in the way of the pandemic response. **The waiver proponents have found zero credible examples of where IP has actually been an obstacle,** where somebody has tried to block somebody else from developing a COVID vaccine or other COVID countermeasure, right? It’s not there. **Second, the myth of this vast global capacity to manufacture COVID vaccines that somehow exists** **out there is unsubstantiated** and frankly, in my opinion, untrue. But there is no such thing as vast untapped, idle capacity that could be turned around on a dime to start making COVID vaccines within weeks or even months. This capacity needs to be built; it needs to be established. And at a time when time is of the essence to beat this pandemic, starting capacity-building discussions is helpful, but it won’t be the answer to beat this pandemic. It will be the answer if we do everything right to beating the next pandemic. And if we learn any lesson of this, and then I will stop, is that the COVID waiver as well as the situation in which we find ourselves — if anything, it’s a reminder that we definitely have to take global capacity-building more seriously than we did in the past. That is true for the global North, as well as for middle-income countries — all of whom have to dedicate themselves much more determinedly to pandemic preparedness. And there’s a need to invest both in preparedness and in public health systems that hasn’t happened in the wake of past pandemic threats. This is what we will need to do. We will need to reduce export restrictions, and we will need to rededicate ourselves to preparing for the next pandemic. As far as this pandemic goes, **there are 11 vaccines around the world that are already being shot into arms, only four of which come from the global North. How many more vaccines do we want?** I don’t know, maybe 11 is enough if we start making more of them. But there are manufacturers around the world who know how to do this — including in China, including in India, and including in Russia. All developed their homegrown vaccines, apparently without interference by IP rights, right? **So let’s make more of those. I think that’s going to be the more practical and realistic answer to solving the problem**. And we need to lean on governments to stop export controls and to dedicate themselves to more global equity.

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# **Substandard Drugs DA**

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#### **Brink: 10% of all drugs in developing countries are substandard; Breman 19**

Breman, Joel (C. Dr. Breman was educated at the University of California, Los Angeles; Keck School of Medicine, University of Southern California (USC); and the London School of Hygiene and Tropical Medicine. He trained in internal medicine at the USC-Los Angeles County Medical Center, infectious diseases at the Channing Laboratory, Harvard Medical School, and epidemiology at CDC. He is Senior Scientist Emeritus, NIH and President-Elect, the American Society of Tropical Medicine and Hygiene. Dr. Breman worked on smallpox eradication, measles control, and disease surveillance as a CDC assignee to Guinea, Burkina Faso (Upper Volta), and WHO, Geneva. Following the eradication of smallpox, Breman returned to CDC where he worked on malaria treatment, epidemiology and control in Africa. In 1995, he followed his wife, an environmental lawyer, to Washington, DC, to become Director, Program in Emerging Infectious Diseases, Fogarty International Center, NIH.)**. “**It's time to stop murder by counterfeit medicine.” *STAT*, 2019, May 7, <https://www.statnews.com/2019/05/07/stopping-murder-counterfeit-medicine/> Accessed 30 Aug. 2021.

**Each year, more than 250,000 children with malaria and pneumonia, common illnesses in poor countries, do not survive after treatment with fake and substandard drugs.** While poor quality drugs targeting older individuals are also entering global markets, the World Health Organization says “it is very difficult to quantify [their] impact.” Such useless or harmful drugs once went by the confusing designation “substandard/spurious/falsely labeled/falsified/counterfeit medical products.” A recent move by the WHO aims to simplify this by separating them into three categories: falsified medical products deliberately misrepresent their identity and are distributed with criminal intent substandard medical products fail to meet quality standards unregistered or unlicensed medical products have not been assessed or approved **According to the WHO, 1 in 10 medical products in developing countries is falsified or substandard. The personal and public health tolls are huge, as is the economic burden — up to $200 billion annually.** **Poor-quality antimicrobials are most often found in low-income countries.** In addition to failing to treat infection, **they also contribute to the evolution of antimicrobial resistance, which British researchers have estimated could kill up to 10 million people a year by 2050.** But counterfeit medications in virtually every therapeutic class, from blood pressure pills to treatments for cancer and vaccines, are made and distributed by unscrupulous criminals. **In countries with poor pharmaceutical control systems, such drugs can be made in illicit facilities inside or outside the country and enter the supply stream because no FDA-like system exists for inspection or approval. Expensive analytic equipment generally isn’t available, while simple, accurate, and inexpensive testing systems for use in the field, at pharmacies, and at the point of care remain out of reach in virtually all poor countries. To make matters worse, many countries do not have laws to define and enforce regulations addressing crimes related to counterfeit or substandard medicines, nor do the have well-defined judicial actions once criminals are suspected or identified.**

#### **Link: IP protections are a essential barrier to fight counterfeit medicine and substandard drugs; Lybecker, 16**

Lybecker, Kristina M (C. Dr. Kristina M. Lybecker is an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. She has testified numerous times on the economics of the importation of Canadian drugs and the risks of pharmaceutical counterfeiting. Dr. Lybecker has also worked with US Food and Drug Administration, PhRMA, and the World Bank, on a variety of issues relating to the economics of innovation and international trade policies.) “Counterfeit Medicines and the Role of IP in Patient Safety.” IPWatchdog.com | Patents &amp; Patent Law, IPWatchdog, 27 June 2016, [www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/](http://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/).

As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and **the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals.** UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] **The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines.** While **patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit** **counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.**

#### **Internal Link: Lack of IP floods markets with dangerous products; Mercurio, 21**

Mercurio, Bryan (C.Bryan Mercurio is the Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.) “The IP Waiver for COVID-19: Bad Policy, Bad Precedent.” *IIC; international review of industrial property and copyright law*, 1-6. 24 Jun. 2021, doi:10.1007/s40319-021-01083-5<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/>

Alan Beattie, writing in the *Financial Times*, believes that even the proponents of the waiver desire this outcome: “having talked to the proponents, [the original proposal] was always a tactical position designed to start a debate, identify possible support and flush out opponents rather than a likely outcome. To that end, it seems to have worked rather well.”[19](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn19) India’s negotiator to the TRIPS Agreement and longtime WTO staffer, Jayashree Watal, agrees, stating the proposal is an “indirect attempt to put pressure on the original manufacturers to cooperate [and license production to companies in their countries]”.[20](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8223179/#Fn20) This view makes sense, as the proponents (and their supporters) have not even pointed to one credible instance where IPRs have blocked the production of a COVID-19 vaccine. Moreover, it is well known that the **leading vaccines** using mRNA **are difficult to reproduce and having the “blueprints” does not guarantee safe and effective production.** Simply stated, if a pastry chef provides instructions on how to bake a cake, the cake they bake is still going to be better than cakes baked by novices using the exact same recipe. **The know-how** and trade secrets **are the key ingredient to the manufacture of quality, safe and effective pharmaceuticals** or vaccines, and not only is it not transferred through compulsory licenses but it is hard to imagine how any government would force the transfer of such information even under a waiver. For this reason, **instead of encouraging production everywhere – including in locations where safety and efficacy standards are virtually nonexistent – and accepting that there will be a flood of substandard vaccines coming onto the world market (with devastating effects) it is much more sensible to find out where potential manufacturing capabilities exist and find ways to exploit them and scale them up.**

#### **Impact: Increased presence of substandard drugs and falsified medicines endangers public health and strengthens antimicrobial resistance; Johnston and Holt, 14**

#### **Johnston, Atholl (C. Clinical Pharmacology, Barts and The London School of Medicine and Dentistry, Queen Mary, University of London, London, UK) and David W Holt (C. Professor David Holt has more than 47 years’ experience in the measurement of drugs as a guide to therapy, and has been responsible for the development of assays used to monitor a wide variety of therapeutic agents. For over 20 years he was the Director of the Analytical Unit at St George’s, University of London, where he was also responsible for the analysis of illicit and prescription drugs for the Unit’s Forensic Toxicology Services provided to HM Coroners, pathologists and law enforcement agencies. He now advises on proficiency testing schemes for the measurement of immunosuppressive drugs, and on problems associated with substandard pharmaceuticals.**

#### **Professor Holt is a frequent speaker on a broad range of issues relating to bioanalytics and clinical toxicology. He is the author of over 400 publications in peer reviewed journals and invited contributions to books. He is a past President of the International Association of Therapeutic Drug Monitoring and Clinical Toxicology and a recipient of the Charles E Pippenger Award for Outstanding Contributions to Therapeutic Drug Monitoring.. “Substandard drugs: a potential crisis for public health.” *British journal of clinical pharmacology* vol. 78,2 (2014): 218-43. doi:10.1111/bcp.12298** [**https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/)

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#### **The WHO defines ‘counterfeit’ drugs as ‘medicines that are deliberately and fraudulently mislabelled with respect to identity and/or source’ [**[**8**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b8)**]. It also states that both branded and generic products may be counterfeited and that ‘counterfeit medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient or too much active ingredient, or with fake packaging’. However, because of the potential misunderstanding of the term ‘counterfeit’ – which, in the context of intellectual property, refers specifically to trademark infringement – the phrase ‘falsified medicines’ is used by some authorities, particularly in Europe. The Commission of the European Communities defines these as ‘medicinal products which are falsified in relation to their identity, history or source. These products … usually contain sub-standard or false ingredients, or no ingredients or ingredients in the wrong dosage, including active ingredients’ [**[**9**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b9)**].**

#### **Thus, falsified drugs are highly likely to be of substandard quality, possibly containing no API. However, only a small proportion of substandard drugs are falsified; the rest reach the market as a result of poor manufacturing practices, inadequate quality-control processes, incorrect storage or inappropriate packaging, or a combination of these factors. This can affect both branded and generic drugs. In many cases, the reason why a drug product is substandard (i.e. deliberate falsification or poor manufacturing practice) is not stated or is not known. Whether or not a drug product is substandard because of criminal intent or because of failures in manufacturing, storage, etc. is immaterial to the patient because the impact on their health will be the same, regardless of cause [**[**10**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b10)**]. In this article, we consider the term ‘substandard’ to apply both to legally approved but poor-quality drugs and to falsified drugs, but we focus on the former with regard to reviewing potential solutions.**

#### **Substandard drugs pose a serious health concern from several perspectives (Table ​(Table44 [47,48,51,52,57,59,70,95–104]). Although falsified drugs have perhaps received most of the attention with respect to causing unnecessary deaths, substandard drug manufacture also leads to morbidity and mortality. A formulation with insufficient API may lead to a lack of clinical response, and possibly, death. For example, there are reports of patients failing to respond to antimalarial treatment [95,96] because the drugs contained less than the stated dose of API and, in one reported case, contained more paracetamol than antimalarial agent [95]. In other cases, a reduced therapeutic response has been associated with generic/copy versions of drugs compared with the originator drugs, including antibiotics, tacrolimus and imatinib [70,97,99–102].**

#### **Adverse events also occur due to drug–drug interactions with contaminants, the presence of excess API, contamination with poisonous substances, or allergic reactions to contaminants or substituted excipients. As mentioned above, some of the most extreme cases involve the (possibly deliberate) contamination of medicines with DEG [**[**47**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b47)**,**[**48**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b48)**]. In another case, heparin was found to be contaminated with oversulphated chondroitin sulphate, which was thought to be responsible for the allergic or hypersensitivity-type reactions experienced by a number of patients, some of which proved fatal [**[**51**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b51)**]. At the time of the heparin incident, the oversulphated chondroitin sulphate could not be distinguished from heparin by the standard quality-control tests used. However, the FDA has since implemented changes to the USP standards for heparin, including a new test method that is able to detect such impurities [**[**105**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b105)**].**

#### **There are also adverse societal effects arising from the use of substandard drugs. The inadvertent use of suboptimal doses of drugs is likely to be one of the key factors contributing to antimicrobial resistance and thereby leading to the wider spread of disease. This has been most widely discussed with regard to malaria [**[**106**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b106)**–**[**108**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b108)**]; the repeated administration of subtherapeutic doses of antimalarials will promote the selection and spread of resistant parasites [**[**95**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b95)**,**[**106**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b106)**]. Indeed, artemisinin-resistant malaria has been reported in Cambodia and Thailand [**[**109**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b109)**,**[**110**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b110)**], although the extent to which this can be attributed to the use of substandard drugs is unknown. Likewise, poor-quality antibiotics may contribute to the resistance and spread of diseases such as tuberculosis [**[**23**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b23)**,**[**111**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b111)**,**[**112**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b112)**]. The use and subsequent failure of substandard narrow-spectrum antibiotics may lead to the unnecessary administration of broad-spectrum antibiotics, thus potentially creating further resistance [**[**113**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b113)**]. Substandard antihelminthics have been implicated in the development of drug-resistant human helminths [**[**114**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b114)**], and substandard antiviral drugs are likely to contribute to the evolution of drug-resistant viruses, including human immunodeficiency virus (HIV) [**[**115**](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4137817/#b115)**].**