## 1

#### Biopharma R&D is surging, but it’s shaky because of productivity levels – now is not a time to let up

Adams 5/19 [Ben Adams, Ben Adams is a business, science and healthcare journalist, 5-19-2021, "Biopharma R&D 'surged' in 2020, but trial productivity levels a mixed bag: report," FierceBiotech, <https://www.fiercebiotech.com/biotech/biopharma-r-d-surged-2020-but-trial-productivity-levels-a-mixed-bag-report>] // WW LD

A major global pandemic was not enough to stop surging rates of biopharma research and development, but trial productivity still remains below the long-term average. That is according to a new report out by CRO analytics firm IQVIA, which found that funding for early- and late-stage R&D, as well as deals, jumped last year regardless of the pandemic, while aggregate R&D spend for the top 15 companies “reached a record high.” It also found that, overall, clinical trial activity recovered from midyear 2020 to levels above 2019–even without factoring in COVID-19 trials, which clearly didn’t exist the year before. Total trials reached 4,686, more than 300 extra than 2019 and an 8% rise, with 985 in phase 3, 1,880 in midstage testing and 1,821 in phase 1. But there is more complexity here: There was an increase in the clinical trial productivity index, i.e., the way IQVIA measures how these trials are doing, but in 2020 it found this was mostly due to an improvement in phase 3 trials, widening the gap with phase 1 trials, “which score significantly lower with this index.” When it comes to midstage tests, trials “have consistently been above the overall index” as success rates have been trending up and durations have been trending down, “even as complexity has been rising in phase 2 as rising numbers of endpoints and eligibility criteria are attributes of these trials.” Overall, however, productivity “remains below historic levels,” the report found, as success rates are below the long-term average. This is because the complexity of trials is generally increasing, as are study durations in many diseases, IQVIA’s authors note. Looking at the pipeline of pharma, IQVIA saw that growth in the late-stage pipeline continued in 2020, bringing total expansion to 43% since 2015, as cancer drugs reached record-high numbers. Growth in the early-stage pipeline, including next-generation biotherapeutics, paused in 2020, however. RELATED: The top 10 pharma R&D budgets in 2020 The dismal lack of diversity in clinical trials also continued: African Americans or races identified as Black account for 13.4% of the U.S. population, while the clinical trials used to approve new medicines had a median participation of only 3% in the past six years and “were under-representative 79% of the time from 2015 to 2020,” IQVIA said. Persons of Asian descent are also estimated to comprise 6.5% of the U.S. population, but again, only in 2015 was the median above this threshold, and 52% of trials in the past six years that were used by the FDA to approve medicines had under-representative participation. “The growth in research and development driven by new oncology drugs, new funding and strategic investments is a testament to the resilience and strength of the innovative, global biopharmaceutical industry,” said Murray Aitken, executive director of the IQVIA Institute for Human Data Science, in an accompanying release. “Faced with significant disruptions and the need to reprioritize research and development, the global life sciences industry has demonstrated its ability to meet and even exceed expectations for new and better lifesaving therapies and vaccines.”

#### Patents foster innovation

Grabowski et al 15 [Henry G. Grabowski, Joseph A. DiMasi, and Genia Long, February 2015, "The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation," https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047] // WW DL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6 As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13 University licensing trends have generated debate. For instance, there have been recent proposals to encourage the federal government to “march in” and require a university to license a patent or enforce reduced pricing or other terms. 14 The percentage of approved drugs with public-sector patents is relatively small. 15 Nevertheless, if the government exercised its march-in rights in this way, that action could have adverse effects on technology transfer activities and early-stage company investment, particularly if it were to disrupt existing expectations of grantees, licensees, and investors. 12 There have been four petitions to the NIH requesting it to exercise march-in rights on behalf of the federal government; none has been granted. 16

#### Biotech relies on innovation from pharma

Cooper 6 [Garth JS Cooper, independent medical scientist at the University of Auckland, “Fates Intertwined,” March 2006, <https://library.wur.nl/WebQuery/file/cogem/cogem_t4505194e_001.pdf>] //recut WW LD

Biotechnology and pharmaceuticals are inextricably intertwined. Although biotech companies often rely upon the resources of larger pharma companies, the converse is also true. Among other things, biotechs require funding, validation, and access to expertise and markets. Big pharma continues to need ideas and products, and places to outsource risk. The pharmaceutical industry faces uncertainties driven by falling innovation 1,2, its relevance to reducing the global burden of disease , and the equity of access to its products3. If biotechs are not embraced by pharma—they cannot be copied —then as competitors they will increasingly come to dominate the industrial nexus. The issues of both industries need to be addressed together. Apart, biotech and pharma will continue to struggle with the self-determining issues that they currently confront. Working together, the fabric of these industries will be transformed and the world of human therapeutics will flourish.

#### Biotech is key to solving food insecurity

Doyle 08 [Alister Doyle, Environment Correspondent, 6-3-2008, "Biotechnology seen as a key to solving food crisis," U.S., <https://www.reuters.com/article/us-food-summit-biotech/biotechnology-seen-as-a-key-to-solving-food-crisis-idUSL0356693120080603>] // WW LD

“Biotechnology is one of the most promising tools for improving the productivity of agriculture and increasing the incomes of the rural poor,” U.S. Agriculture Secretary Ed Schafer said. “We are convinced of the benefits it offers to developing countries and small farmers,” he told a U.S.-led briefing on the sidelines of the June 3-5 summit seeking ways to combat high food prices when climate change may aggravate shortages. Some green groups say genetically-engineered crops threaten biodiversity while many European consumers are wary of eating products dubbed by critics as “Frankenfoods”. Schafer said biotechnology, including genetically-modified organisms (GMOs), could help produce more food by raising yields and producing crops in developing nations that are resistant to disease and pests. “Genetic engineering offers long-term solutions to some of our major crop production problems,” said Philippine Agriculture Minister Arthur Yap. But he said that it was not a panacea for all of his country’s agricultural problems. ADVERTISEMENT Progress being made in the Philippines included research into rice and coconuts resistant to disease, he said. “We’re also working on virus-resistant papaya, papaya hybrids with a longer shelf life that should be ready for market in 2009,” he said. Climate change could aggravate production around the world with more droughts, floods, disruptions to monsoons and rising sea levels, says the U.N. Climate Panel. In Africa alone, 250 million people could face extra stress on water supplies by 2020. COTTON Burkina Faso Agriculture Minister Laurent Sedogo said the African country had worked with U.S. agriculture group Monsanto to battle pests that blighted the cotton crop. ADVERTISEMENT “We are about to plant 15,000 hectares” of a new crop that was resistant to pests, he said. That would also cut down on the use of pesticides that could damage the health of farmers. The World Bank and aid agencies estimate that soaring food prices could push as many as 100 million more people into hunger. About 850 million are already hungry. Bangladesh said that it was going ahead with efforts to make crops able to survive floods and more salinity in the soil. A cyclone last year “is a wake-up call for all of us”, said C.S. Karim, an adviser to Bangladesh’s agriculture ministry. “It shows the vulnerability of Bangladesh. “

#### Food insecurity causes extreme hardships

Cribb ‘10 [Julian, principal of JCA, fellow of the Australian Academy of Technological Sciences, “The Coming Famine: The¶ Global Food Crisis and What We Can Do to Avoid It”, pg 10] // recut WW LD/WWVL

The character of human conflict has also changed: since the early 1990S, more wars have been triggered by disputes over food, land, and water than over mere political or ethnic differences. This should not surprise US: people have fought over the means of survival for most of history. But in the abbreviated reports on the nightly media, and even in the rarefied realms of government policy, the focus is almost invariably on the players—the warring national, ethnic, or religious factions—rather than on the play, the deeper subplots building the tensions that ignite conflict. Caught up in these are groups of ordinary, desperate people fearful that there is no longer sufficient food, land, and water to feed their children—and believing that they must fight ‘the others” to secure them. At the same time, the number of refugees in the world doubled, many of them escaping from conflicts and famines precipitated by food and resource shortages. Governments in troubled regions tottered and fell. The coming famine is planetary because it involves both the immediate effects of hunger on directly affected populations in heavily populated regions of the world in the next forty years—and also the impacts of war, government failure, refugee crises, shortages, and food price spikes that will affect all human beings, no matter who they are or where they live. It is an emergency because unless it is solved, billions will experience great hardship, and not only in the poorer regions. Mike Murphy, one of the world’s most progressive dairy farmers, with operations in Ireland, New Zealand, and North and South America, succinctly summed it all up: “Global warming gets all the publicity but the real imminent threat to the human race is starvation on a massive scale. Taking a 10—30 year view, I believe that food shortages, famine and huge social unrest are probably the greatest threat the human race has ever faced. I believe future food shortages are a far bigger world threat than global warming.”2° The coming famine is also complex, because it is driven not by one or two, or even a half dozen, factors but rather by the confluence of many large and profoundly intractable causes that tend to amplify one another. This means that it cannot easily be remedied by “silver bullets” in the form of technology, subsidies, or single-country policy changes, because of the synergetic character of the things that power it.

## 2

#### CP: The United States of America should declare covid a national emergency <> and issue compulsory licenses for COVID-19 vaccines. Member nations should offer regulatory and legal assistance to nations filing a compulsory license.

#### Compulsory licensing solves access- empirics and past precedent

**Zhuang 2017** (Wei, PhD from the University of Geneva, is currently an associate in the Geneva Office of Van Bael & Bellis. She assists governments in WTO dispute settlement proceedings and advises companies and governments in trade remedy investigations. Prior to joining Van Bael & Bellis, Wei worked in the Legal Affairs Division of the WTO as part of a Secretariat Team on a trade remedy dispute from beginning to end. In addition, she assisted the WTO Secretariat Team in an IP-related dispute, including by contributing to the preliminary rulings. Wei has also gained practical experience as a legal consultant at the United Nations (2010 – 2011), as a legal intern at the International Tribunal for the Law of the Sea (2009) and as an associate judicial officer at the Commission for Discipline Inspection (Muchuan Branch) in China. Wei was also a Marie Curie Fellow with the DISSETTLE (Dispute Settlement in Trade: Training in Law and Economics) Programme; a Visiting Fellow at the Lauterpacht Centre for International Law, University of Cambridge, and a Research Fellow at the Max Planck Institute for IP and Competition Law. Interpreting Patent-Related Flexibilities in the TRIIPS Agreement for Facilitating Innovation and Transfer of ESTs, chapter 6 of *Intellectual Property Rights and Climate Change* Cambridge University Press Pg. 298-304)DR 21

\*\*\*Note: EST= Environmentally Sound Technologies\*\*\*

Even though there are limits to their effectiveness, compulsory licences are considered a valuable tool for governments to facilitate access to medicines through the prevention of patent abuses as well as the “encouragement of domestic capacities for manufacturing pharmaceuticals”. 289 According to the UNDP Human Development Report (2001), after the adoption of the TRIPS Agreement, compulsory licences were initially mainly used in Canada, Japan, the UK and the United States for products such as pharmaceuticals – particularly as a remedy to address anti-competitive practices and prevent higher prices – while no compulsory licence was issued then in developing countries largely due to pressure from Europe and the United States and the fear of long and expensive litigation against the pharmaceutical industry.290 As demonstrated in Section 5.4.1.2, in order to address developing countries’ concern, the 2001 Doha Declaration explicitly reaffirmed the right of countries to issue compulsory licences where necessary, in the interests of public health.

In order to enable countries with insufficient manufacturing capacity in the pharmaceutical sector to benefit from the compulsory licensing system, the WTO General Council adopted the Decision of 30 August 2003 on the implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health (the so-called paragraph 6 system).291 This decision essentially expanded the TRIPS flexibilities, involving two waivers: (1) with respect to the exporting country, a “waiver” of obligations to use the authorised compulsory licence predominantly for the supply of the domestic market under Article 31(f); and (2) with regard to the importing country, a waiver of the adequate remuneration requirement under Article 31(h) when remuneration is paid in the exporting Member. “Where a compulsory licence is granted by an exporting Member under the system set out in this Decision, adequate remuneration pursuant to Article 31(h) of the TRIPS Agreement shall be paid in that Member taking into account the economic value to the importing Member of the use that has been authorised in the exporting Member”. 292

In 2005, WTO Members agreed to make the waivers permanent by amending the TRIPS Agreement.293 With the approval of two-thirds of the WTO Members, the amendment entered into force on 23 January 2017. As the very first legal amendment to a WTO multilateral agreement, it was said to have shown that “[M]embers are determined to ensure the WTO’s trading system contributes to humanitarian and development goals”. 294 Likewise, such amendment could be extended to address other global concerns such as climate change in accordance with the WTO’s sustainable development objective and Articles 7 and 8 of the TRIPS Agreement.

In effect, the compulsory licensing system established within the WTO framework is not a panacea, but rather a legal guarantee of rights and ability to make effective use of compulsory licences. Since the adoption of the Doha Declaration, a number of developing countries (e.g., Thailand, Brazil, Ecuador, India and Indonesia) have issued compulsory licences to lower the price of patented medicines such as HIV/AIDS drugs.295 Additionally, in 2007, Rwanda became the first country without sufficient manufacturing capacities to use the WTO “paragraph 6 system” to import Apo-TriAvir from Apotex, a Canadian firm.296 Commentators note that since the Doha Declaration was adopted in 2001, the threat of compulsory licenceshas motivated multinational companies to “voluntarily make proactive efforts to realistically make their drugs accessible**”** either through dramatically lowering the price or by offering voluntary licences on favourable terms.297 Meanwhile, many countries have successfully used the threat of compulsory licences as leverage in drug price negotiations with pharmaceutical companies.298

#### It’s goldilocks - protects patents while allowing urgent access – the perm or the aff shatters IP protections which crushes innovation while the CP strikes an accepted balance

**Bacchus 2020** (James, Adjunct Fellow, Cato Institute, former U.S. Representative (D-FL), and former Chairman, World Trade Organization’s Appellate Body. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” *Cato* <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#balancing-ip-rights-access-medicines-not-new-wto> December 16, 2020)DR 21

As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”[7](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref7) But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.[8](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref8)

After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”[9](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref9) In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.[10](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref10) In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.[11](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref11)

Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance **struck by the members of the WTO** between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

Does a Novel Virus Present Novel Issues?

Now comes the COVID-19 crisis. In the debate over the proposed COVID-19 waiver, mostly we have heard the usual arguments, all of them reminiscent of the HIV/AIDS debate. The pharmaceutical companies in the global vaccine chase have been quick to express their opposition to the proposed waiver of IP rights for the pandemic’s duration. They have warned that allowing their COVID-19 vaccines to be copied without their permission through recourse to compulsory licensing “would undermine innovation and raise the risk of unsafe viruses.”[12](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref12)

The reaction of most nongovernmental health organizations and other global advocacy groups to these arguments is summed up in the Access Campaign’s response: “Since the start of the pandemic, pharmaceutical companies have continued with their ‘business‐​as‐​usual’ approaches either by maintaining rigid control over their proprietary IP rights or by pursuing secretive and monopolistic commercial deals and excluding countries affected by COVID-19.”[13](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref13)

What we have not heard in the waiver debate is any clear explanation from waiver advocates of why they believe that the right to compulsory licensing that they already possess will prove insufficient to ensuring access to COVID-19 vaccines.

In requesting a broad waiver of IP rights to COVID-19 vaccines, India and South Africa maintained that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available” under existing WTO rules. They also noted that a “particular concern for countries with insufficient or no manufacturing capacity” is that the 2017 amendment that permits countries that produce generic medicines under compulsory license to export all of those medicines to least‐​developed countries that lack their own manufacturing capabilities will lead to a “cumbersome and lengthy process.”[14](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref14)

India and South Africa did not offer any further explanation or any evidence to support these assertions. In an effort at an explanation, two Canadian university professors contended, “The TRIPS flexibilities are important policies but they are not perfect. Rules allowing compulsory licensing apply only on a case‐​by‐​case and product‐​by‐​product basis. This slows down the ability of countries to scale up production of needed COVID-19 products.”[15](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref15) But this is advocacy, not evidence. At the time, this point was purely prospective; it was a prejudgment before any COVID-19 vaccine had been given final approval or reached the market.

Before such a sweeping waiver of IP rights is taken up, it should first be demonstrated that the option of compulsory licensing and other flexibilities under the current trade rules will not suffice. At this point, the developed countries that have opposed the waiver are correct. There is no evidence of the need for such a waiver. Action by the WTO should be contemplated only if, and when, the current flexibilities in WTO rules prove to be inadequate. Should that happen, any such action should be no broader than necessary to address the global medical need.

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for … profitability in decision‐​making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”[16](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref16)

This view is myopic. **Subordinating IP rights temporarily** to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.[17](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref17) To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs?

With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded.

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion.

The primary justification for granting and protecting IP rights is that they are incentives for innovation, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”[18](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18) The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth **in the 21st century is increasingly** ideas‐​based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation.

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus **preventing** the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19)

As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”[20](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref20) This fault line is much on display in the WTO rules on IP rights. These rules **recognize that “intellectual property rights are private rights”** and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐​related intellectual property rights.”[21](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref21) Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

## 3

#### Congress doesn’t have the support to pull out from the WTO now, but more agreements that perceptually favor China changes that

Johnson ’20 [Keith, senior staff writer for Foreign Policy, “U.S. Effort to Depart WTO Gathers Momentum”, 05-27-2020, https://foreignpolicy.com/2020/05/27/world-trade-organization-united-states-departure-china/]//pranav

Frustration with hyperglobalization, China’s “economic imperialism,” and a seemingly broken world trading system is boiling over into serious calls for the United States to withdraw from the World Trade Organization (WTO)—which would have potentially disastrous implications for the country if carried out. For the first time since 2005, lawmakers from both parties and both houses of Congress are pushing to pull the United States out of the trading body it helped create and which was the culmination of decades of postwar efforts to boost free trade and economic integration. By law, the United States has a chance to vote every five years on staying inside the WTO, but staying on board was such a no-brainer in recent years that no such resolution was even presented. But this year—powered by a rise in economic nationalism, growing concern about China, and frustration with two decades of paralysis at the WTO—the knives on Capitol Hill are out, to the delight of some of the trade hard-liners in the White House. “The WTO has been a disaster for the United States,” said Rep. Peter DeFazio, an Oregon Democrat, who introduced House legislation to withdraw this month. “No trade regime can last when it no longer serves the people of the countries who are part of it,” said Sen. Josh Hawley, a Missouri Republican, in a recent Senate floor speech after introducing his own resolution to leave. “Our interests and those of the WTO diverged long ago.” It’s doubtful that the measures could secure enough votes for passage in either chamber, and a tight legislative calendar makes the push for withdrawal doubly hard to pull off. But the rush for the exit is still a serious indication of deep and growing dissatisfaction with how global trade has evolved, highlighted by the vulnerability of cross-border supply chains that have begun to come apart under the stress of the COVID-19 pandemic. If the United States were to pull out of the system it helped build, the implications would be dire. Other countries would be able to discriminate against U.S. goods and services with no limits. Tariffs would almost certainly rise and export markets shrink. Meanwhile, others like China and the European Union would increasingly be in a position to write the rules of the future economy, from data protection and privacy to intellectual property and state subsidies. “We’d have no rights, and we’d lose a seat at the table,” said Wendy Cutler, a former U.S. trade negotiator now at the Asia Society. Why the big push now? For years, different aspects of the global trading system have stirred concern and at times anger in the United States and other countries; the WTO has essentially been stuck in place since the collapse of its last big negotiating round in 2008. For years, economists have debated the impact of the so-called “China shock” on U.S. jobs and manufacturing, and some evidence has shown that the competition from low-wage Chinese labor and the rapid movement of U.S. companies offshore hit the U.S. middle class harder than many economists expected. For years, Republicans have railed against international organizations—from the WTO to the International Criminal Court—that they see as encroaching on U.S. sovereignty. Now, all those forces have come together in a kind of imperfect storm. “I think the confluence of factors—the WTO’s credibility, China’s accession and all the outsourcing, and then the general animosity toward international organizations—they’re all in play,” Cutler said. For proponents of withdrawal, like Hawley, it’s mostly about China taking advantage of an open global trading system to get a leg up on countries like the United States that mostly try to play by the rules. “I think [China] is a principal factor” in the push to leave the WTO, Hawley told Foreign Policy in a recent interview. Beijing’s ability to claim special privileges inside the WTO as a so-called “developing” country, despite boasting the world’s second-largest economy, has powered its rise at the expense of countries like the United States, he said.

#### There’s bipartisan Congressional hatred for the plan – they view it as a giveaway of American tech to China.

Lopez 5/19 [Ian, Senior Reporter @ Bloomberg Law, “China Will Steal U.S. Vaccine IP Via Waiver, GOP Senators Say”, 05-19-2021, Bloomberg Law, https://news.bloomberglaw.com/health-law-and-business/china-will-steal-u-s-vaccine-ip-via-waiver-gop-senators-say]//pranav

Senate Republicans are calling on top Biden administration officials to walk back support of an international plan to waive Covid-19 vaccine IP protections, calling the decision a “giveaway” to China and India that will only promote “vaccine nationalism.” Countries like China that regularly steal U.S. intellectual property began urging the World Trade Organization to waive IP rights “almost immediately after these vaccines were proven to work,” Sens. Thom Tillis (R-N.C.) and Tom Cotton (R-Ark.) wrote in a Wednesday letter to Commerce Secretary Gina Raimondo and U.S. Trade Representative Katherine Tai. “These nations are falsely claiming that granting such a waiver would speed the development of new vaccine capacity. Nothing could be further from the truth,” they said in the letter, obtained by Bloomberg Law. Senators d Chuck Grassley (R-Neb.), Mike Lee (R-Utah), and Dan Sullivan (R-Alaska) are among the letter’s backers, according to a Republican staffer. The letter comes amid a heightening debate over whether the U.S.'s backing of a waiver would help expedite global vaccine manufacturing and distribution. “It is not surprising that China, India, and South Africa want to steal our intellectual property and medical technology,” the senators wrote. “What is surprising is that an American president, especially one who claims to be a ‘jobs’ president, would force American companies to give their medical technology and manufacturing processes to foreign adversaries like China.” A proposal before the WTO—set out by South Africa and India last year and supported by dozens of other countries—would waive obligations on the protection of IP rights for the duration of the pandemic. ‘America’s Interests Last’ Key to the debate is whether patents and other IP are an obstacle to global Covid-19 immunization. Proponents of the waiver plan—which include some Democrats and nonprofits—say it’s a step in the right direction, and, taken with other steps like increased manufacturing capacity, could help with faster world vaccination. U.S. support could help get other countries on board with global distribution while spurring efforts to ramp up vaccine production capabilities in nations struggling to immunize their populations, proponents say. Opponents say it’s bad for innovation and does little to get vaccines to those in need while opening the door to IP theft from competing countries. Among those in the latter camp are Tillis, who led a legislative effort to strengthen patent rights; former U.S. Patent and Trademark Office Director Andrei Iancu; and Sen. Chris Coons (D-Del.), who has previously criticized the idea of waiving rights around Covid-19 vaccines. “The reason why there are not enough vaccine doses at this time is simple: the supply chain lacks the technological capacity,” the letter said. “At best, all The President’s giveaway to China and India and others will do is to foster uncoordinated vaccine nationalism, as countries jump in to try to coerce technology transfer and manufacturing locally.” Tai earlier this month announced the Biden administration’s support of the IP waiver, following pressure from a group of more than 100 House Democrats, led by Rep. Jan Schakowsky (D-Ill.). Piecemeal IP licensing agreements can’t keep pace with the scope and speed of the pandemic, while temporarily waiving rights could promote technology access and sharing for vaccine production without spurring trade sanctions, they argue. House Republicans quickly followed suit, writing their own letter to Tai in opposition. The senators in their letter posed a series of questions over the details and economic impact of waiving vaccine IP rights. They called for a list and descriptions of all U.S. meetings with foreign officials about the waiver plan. They also asked if the Biden administration is considering waiving domestic IP enforcement, and whether support of the waiver is “premised on China, Russia, South Africa, India, or any other nation state supporting other foreign policy priorities of the Administration,” according to the letter. “Simply put, the Biden Administration’s support for a TRIPS waiver puts America’s interests last and China’s interests first,” the senators said.

#### Withdrawal collapses global trade

Hopewell & Horton 08-03 [Kristen Hopewell is the Associate Professor and Canada Research Chair in Global Policy at the University of British Columbia, and Ben Horton is the Communications Manager; Project Lead, Common Futures Conversations, "Lessons from Trump’s assault on the World Trade Organization," 08-03-2021, https://www.chathamhouse.org/2021/08/lessons-trumps-assault-world-trade-organization]//pranav

What has this episode revealed about the strength of multilateral institutions such as the WTO, in the face of spoiling tactics from major powers? The WTO is unique amongst international institutions because it has a powerful enforcement mechanism – the dispute settlement system. However, the fundamental vulnerability is that if powerful states like the US and others won’t participate in the system and be bound by its rules, they quickly risk becoming irrelevant. And that’s the situation we’re in right now with the appellate body crisis, where, without a functioning mechanism to ensure that WTO rules are enforced, the entire system of global trade rules risk collapsing. Ironically, the United States has been the leader of the liberal trading order for the past 70 years, but since Trump, it has become its leading saboteur. What are the implications of a permanent collapse of the international trading system? The very real danger from such a breakdown is a return to what we saw in the 1930s. In response to the outbreak of the Great Depression, you had countries imposing trade barriers, blocking imports from other state, and a general escalation of tit-for-tat protectionism. This response wound up not only exacerbating the effects of the depression itself but has also been credited by some as paving the way for the outbreak of the second world war. The reason why institutions like the WTO were created in the first place was to prevent a recurrence of the 1930s protectionist trade spiral. The danger now – if those rules become meaningless and unenforceable – is the institutional foundations of postwar economic prosperity could unravel, throwing us back into economic chaos and potentially political disorder. What does the WTO’s future look like under new director-general Dr Okonjo-Iweala?

## Case

#### **Vote neg on presumption – the aff can’t solve any of their impacts**

Garde et al 5-6 [Damian Garde , Helen Branswell , and Matthew Herper May 6, 2021, 5-6-2021, "Waiver of patent rights on Covid vaccines may be mostly symbolic, for now," STAT, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] // WW LD

The U.S.’s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it’s likely to be more of a symbolic milestone than a turning point in the pandemic. For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don’t magically produce vaccines. Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022. Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said. “My take is: By itself, it will not get us much benefit in increased manufacturing capacity,” Yadav said. “But as part of a larger package, it can.” That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents. Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.” Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production. “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said. In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.” As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, “handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine.” Conversely, the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea “flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery.” Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It’s highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company. But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave. Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: “What do we need to do?” Said Love: “If you really think this is a big emergency, ‘what do we need to do’ should be the question, not just saying we can’t do anything.” That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.

#### The Plan can’t solve COVID - Lack of key supplies – conceded in cx that they don’t have the resources

Tepper 21 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK’s jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline’s plant at Barnard Castle to be put into vials for distribution. “The first hurdle is showing it works and we don’t have that hurdle any more,” Erck said. But he added there were others still to overcome. “There’s the media that the cells have to grow in,” Erck said. “You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count.” Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. “We started working on our part of the supply chain in summer last year,” he said. “We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled.” Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK’s vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: “We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags. We typically run out at 16 weeks to get a custom bioreactor bag out to a customer.” He said ABEC was still managing to fulfil orders at roughly that rate. “The bag manufacturing capacity can’t meet demand right now,” he added. “And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time.” ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and “vaccine nationalism” by operating on four continents, with 20 facilities in nine countries. “One year ago, we had exactly zero manufacturing capacity,” Erck said. “We’re self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands.” There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports.

#### Only IPRs can check back against counterfeit production – key to solving crisis.

FIFARMA 4/28. “This Is How We Fight Counterfeit Medicines with Intellectual Property.” FIFARMA, 28 Apr. 2021, fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/.

This is how we fight counterfeit medicines with Intellectual Property There is a threat to health security that is present in every country in the world: counterfeit medicines. These may appear as a promise to cure any disease, but they contain excessive, insufficient or no doses of the active ingredient that treats the disease. Counterfeit medicines also include stolen drugs, drugs that have been stored in poor conditions or are expired, so they may be ineffective or may be contaminated. In the end, the only goal of counterfeit medicines is to make money, regardless of the consequences they may have on people’s health. In fact, according to the World Health Organization (WHO), this business represents more than $30 billion dollars in low- and middle-income countries. Recently, EFPIA did a podcast where it deepens the relationship between the decrease in the distribution of counterfeit medicine and Intellectual Property. You can find it in the following link: [Fighting the fakes – what’s industry’s role?](https://shows.acast.com/19-conversations/episodes/fighting-the-fakes-whats-industrys-role) Why does this relationship occur? Counterfeit medicines are more present where there is less strict regulatory control, where there is a lack of basic medicines, where there are unregulated supply chains, where medicines are priced very differently in the market, where intellectual property is not protected, and where no attention is paid to quality assurance. Therefore, this is a transversal issue to different sectors outside the health industry. It is necessary for different actors to be part of the solution. Decision-makers can create campaigns to inform people about the existence of these medicines. They must go hand in hand with regulatory agencies, as they are the ones that control the entry of medicines into countries. Likewise, the pharmaceutical industry must take action, since they are the ones who research and manufacture products. Thus, the international Fight The Fakes campaign, supported by FIFARMA, aims at raising awareness regarding the dangers of counterfeit medicines. Each actor must play a role, however, without partnerships and collaboration between different parties, it is difficult to fight the problem. Moreover, there are other tools that contribute to the elimination of these threats to public health, such as Intellectual Property (IP). The role of IP In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate. On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines. In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP. Also, IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines. Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products. This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection. On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem. Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

#### Counterfeit drugs lead to drug resistant diseases - turns the aff

**Jahnke, 19** (Art Jahnke, Art Jahnke began his career at the Real Paper, a Boston area alternative weekly. He has worked as a writer and editor at Boston Magazine, web editorial director at CXO Media, and executive editor in Marketing & Communications at Boston University, where his work was honored with many awards., 1-14-2019, accessed on 8-17-2021, Boston University, "How Substandard and Counterfeit Drugs Drive Drug-Resistant Infections", https://www.bu.edu/articles/2019/how-bad-drugs-turn-treatable-diseases-deadly/)

Muhammad Zaman learned at an early age that one did not shop for medicine at the convenient neighborhood pharmacy. In Pakistan, where he grew up, the safer thing to do was walk the extra mile to a pharmacy whose drugs were known to be high quality. Four decades later as a Boston University professor of biomedical engineering and materials science and engineering, Zaman was reminded of the dangers of low-quality drugs in his native country when he learned that more than 200 people in the city of Lahore died after being treated with an adulterated version of a hypertension drug. That event, in 2012, altered the course of Zaman’s research. Now, he focuses on the global problem of “substandard drugs,” poorly made medicines containing ingredients that are either ineffective or toxic. His most recent discovery has startling implications for our understanding of drug resistance: a low-quality version of rifampin, a broad spectrum antibiotic typically used as the first line of defense to treat tuberculosis, can greatly contribute to the development of drug-resistant infections. The findings, published in Antimicrobial Agents and Chemotherapy, are particularly pressing because drug-resistant TB is an increasing problem worldwide. Of the 10 million new cases of tuberculosis in 2016, about 600,000 were rifampin resistant, requiring second-line treatments which come with increased toxicity. “There had not been a definitive study showing that lack of [antibiotic] quality leads to resistance,” says Zaman, who is also a Howard Hughes Medical Institute Professor of Biomedical Engineering and International Health. “Now we are sure that it does, and it does with TB, a global problem that has become stubbornly hard to resolve.” “We had always thought of this a scientific issue, but now it is also an ethical issue.”Muhammad Zaman Zaman says substandard drugs, as well as drugs that are deliberate counterfeits, are all too common in developing nations. A recent survey by the World Health Organization found that in low- and middle-income countries, one in ten medicines is substandard or falsified. One contributing factor could be that government enforcement of safe manufacturing practices is feeble or nonexistent. In Pakistan, for example, a country of nearly 200 million people, only a handful of federal inspectors monitor the quality of drug manufacturing. Across sub-Saharan Africa, things are no better. A recent World Health Organization (WHO) study written in part by Paul Newton, an adjunct professor at BU School of Public Health, found that substandard antimalarials killed more than 120,000 children under the age of five in 2013. Another WHO study, conducted in 2008, found that 64 percent of antimalarial drugs tested in Nigeria were substandard. When the same study looked at antimalarials in Cameroon, Ethiopia, Ghana, Kenya, Nigeria, and Tanzania, it found that 28 percent of 267 samples were substandard. Zaman says it’s impossible to know how many deaths globally are caused by substandard drugs because people don’t usually die immediately. They could die, as the Lahore victims did, from a toxic reaction, or they could die from the disease that the drug was supposed to cure. Or, says Zaman, he and other scientists have long speculated that they could die for a third reason: adulterated medicines could encourage the development of drug resistance, rendering the disease incurable with standard treatments. Although that possibility had been considered for years, Zaman and Zohar Weinstein teamed up to finally put the hunch to the test. In the lab, Zaman and Weinstein, a postdoctoral researcher in biomolecular pharmacology who’s nearly finished with her medical degree as well, conducted several tests with rifampin to learn if a degraded form of the TB drug could build drug resistance in bacteria. They first ran a series of in vitro tests pitting rifampin against E. coli, sometimes referred to as the workhorse bacteria of laboratories because its rapid doubling time makes it ideal for such studies. The researchers exposed the bacteria to gradually increasing doses of rifampin, which suppresses RNA transcription in bacteria, leading to cell death. They then ran the same tests with rifampin quinone, the most commonly found form of degraded rifampin. Within a week, they observed that the bacteria became significantly more resistant to the drug. Next, the researchers repeated the experiment, swapping out E. coli for a strain of tuberculosis called M. smegmatis, selected because it has a conveniently short doubling time of two hours, while the more common strain of tuberculosis has a doubling time of about one day. After two weeks, the M. smegmatis also began to show signs of resistance. “We found that over five days, E. coli exposed to [rifampin quinone] became up to 64 times more resistant to rifampin,” says Weinstein. “And over 22 days, M. smegmatis became up to 100 [times] more resistant to rifampin.” “You could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to resistance.”Muhammad Zaman Zaman and Weinstein had expected such responses, but they didn’t expect to find such a powerful resistance. In fact, once the bacteria gained resistance, no amount of standard rifampin would kill them. The researchers also looked for another indicator of rifampin resistance: a genetic mutation in a gene called rpoB. What they discovered was alarming. “We found that the majority of bacteria exposed to [rifampin quinone] also had mutations in this gene, even though they had never been exposed to the standard drug,” says Weinstein. In other words, the degraded drug wasn’t just failing to cure the disease, it was cultivating cross-resistance to the high-quality, standard product. In that sense, says Zaman, bad drugs can become doubly dangerous. “That [observation] was very revealing,” says Zaman. “It changed the equation, because we had always thought of this a scientific issue, but now it is also an ethical issue. We usually think of the spread of resistant TB in two ways. We say you got it because you were exposed to resistant TB, maybe you were living with someone with resistant TB. The second way is you got it because you were supposed to take drugs and you didn’t adhere to the program. But what this study reveals is that you could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to [treatment] resistance.” “While it is well established that subtherapeutic doses of medicines play a role in antimicrobial resistance, this is, as far as I know, the first demonstration of how substandard medicines directly drive the emergence of resistance genes in pathogens,” says Michael Levy, vice president of USP’s Quality Institute, which researches the influence of substandard drugs on health outcomes. USP is a nonprofit organization that sets drug quality standards that are legally recognized in the US and are also used in more than 140 other countries. Zaman’s next steps will be threefold. First, he plans to test the quality of drugs that are available in the community hospitals of several low-income countries, looking specifically for the presence of rifampin quinone, the degraded form of rifampin. Second, he plans to work with researchers at the National Emerging Infectious Diseases Laboratories (NEIDL) on a mouse model to study the resistance mechanism in vivo. Third, he says he hopes to expand his work to investigate adulterated forms of other commonly used, high-impact antibiotics. Meanwhile, patients around the world are still being prescribed substandard antibiotics every day. “The patient may be doing everything he or she is supposed to do and still become resistant [to treatment],” Zaman says. This work was supported by National Institute of General Medical Sciences and USP.

#### Multiple alt causes to high drug prices and limited access

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The Panel Is Poised To Ignore Real Access Problems The Panel’s misguided focus on patents has led the U.S. State Department to encourage the Panel to abandon its “narrow mandate” and instead focus on actual obstacles that stand in the way of persons obtaining life-saving drugs. Echoing the WHO, the State Department has pointed to four main reasons that the developing world lacks access to healthcare: (1) an inability to select and use medicines rationally; (2) unaffordable drug prices; (3) unreliable health and supply systems; and (4) inadequate financing. **None of these barriers are directly related to patents**. First, irrational drug use is a serious barrier to access. The WHO defines “irrational use” as any use that is not “appropriate to [patients’] clinical needs, in doses that meet their own individual requirements, for an adequate period of time, and at the lowest cost to them and their community.” Two recent studies conducted in Africa illustrate this problem. One study conducted at Kapiri Mposhi District Hospital in Central province, Zambia found a high prevalence of irrational drug use. Fifty percent of 680 patient records surveyed showed some form of inappropriate drug use. And a study in Sudan found that 73% of participants reported to have acquired and used medication without a prescription at least a month prior to the study. Second, there is no doubt that affordability is a barrier to access. But patent protections are not to blame. In fact, patents do not protect the vast majority of essential medicines, which the WHO defines as “those drugs that satisfy the health care needs of the majority of the population.” 350 of these 375 “essential medicines” are available in generic versions and are thus sold at a much lower price point. Moreover, data shows that patent-holding companies do not frequently make use of patent laws in developing countries, even where they could. Moreover, **patent rights do not explain the high cost of drugs in the developing world.** The WHO itself points out that **taxes, tariffs** and other government policies play a significant role in keeping drug prices high in emerging markets. And, in fact, reports have concluded that excessive tariffs and taxes on imported medicines **may inflate the cost of medicines by up to one-third.** When combined with taxes on medicines, government-imposed levies account for an additional 55% in India; 40% in Sierra Leone; 34% in Nigeria; and 29% in Bangladesh. In any event, contrary to the Panel’s suggestion, patent protections ultimately help keep the costs of drugs low. To be sure, patented drug prices will often decline only after a patent expires. But the decline in price after patent expiration is not evidence that the drug manufacturer charged too much for the product. To the contrary, the decline in price of a formerly patented medicine is consistent with an efficient market. Patents expire after a certain period of time fixed by law. As economists have explained, during this period, prices will reflect both the costs of production and the company’s research and development costs. The exclusivity period that the patent creates attracts investment, which enables the innovator company to recoup its research and development costs. Once the patent expires, other companies may create generics that are priced lower. But these lower costs reflect the fact that copycat companies only need to recoup production costs, not research and development. In other words, a patent’s provision of an opportunity for an innovator company to recover costs enables it to produce the medicine in the first place. And the patent’s eventual expiration allows for robust competition that drives prices down. Third, as many experts point out, structural and economic barriers are a significant barrier to access to medicine in the developing world. Poor infrastructure and weak healthcare systems plague third-world countries. Several countries’ medical centers are located in remote areas that may only be reached through impassable roads. Also, many drugs and vaccines must be stored at certain temperatures. But many developing countries lack reliable electricity and sanitary facilities to enable proper storage. In India, for example, a quality-control study followed a series of vaccine vials through the supply-chain delivery process. The study found that 76 percent of the vaccines could not be used because they were stored in substandard storage facilities. Fourth, experts also acknowledge that developing countries tend to underinvest in health. In 2001, for example, African leaders met in Abuja, Nigeria, and pledged to allocate 15 percent of their national budgets to health. The 2015 DATA Report found, however, that between 2011 and 2013, just eight of the 47 countries for which there was data available spent 15 percent or more on health: Uganda, Rwanda, Malawi, Swaziland, Nigeria, Ethiopia, Liberia, and Togo. Twenty countries did not reach even the 10 percent level. If anything, patent protections could incentivize further investment in health in these countries. \* \* \* The UN has a real opportunity to address the critical issue of healthcare access. As it stands now, however, it seems poised to do more damage than good.

#### Reducing IP protections isn’t the silver bullet to vaccine distribution – lack of technical knowledge and expertise and export restrictions constrain the process

de Bolle and Obstfeld 5/12, Monica, senior fellow at the Peterson Institute for International Economics, Maurice, nonresident senior fellow at the Peterson Institute, Peterson Institute for International Economics, “Waiving patent and intellectual property protections is not a panacea for global vaccine distribution”, <https://www.piie.com/blogs/realtime-economic-issues-watch/waiving-patent-and-intellectual-property-protections-not>, Accessed 6/27/21 VD

The second, and arguably more intractable, challenge is technical: Even if they overcome IP obstacles and get permission to produce vaccines, less prosperous countries lack the know-how, facilities, and trained personnel to produce them. Despite the abysmal decades-long record of vaccine distribution in those countries, existing TRIPS flexibilities have done nothing to improve the situation. A smoother IP waiver process might help, but only as a component of a broader effort. True, patent protection is the main obstacle to creation of generic small-molecule drugs, which chemists can synthesize. But other major obstacles exist for vaccines, which are biologics. For the latter category of drugs, an identical product requires an identical production technology, with most steps categorized as hard-to-replicate trade secrets rather than patentable innovations. Thus, Moderna announced in October 2020 that it would not enforce its COVID-19-related patents during the pandemic. But this step, however laudable, is of limited immediate help to would-be producers of a "generic" version of the Moderna vaccine. Without precisely replicating all steps of Moderna's production process, including the many quality controls, a generic version would have untested immunogenicity (the ability to induce the body to generate an immune response) and thus would require extensive clinical trials before release. Production glitches—such as those that afflicted the Janssen/Johnson & Johnson vaccine in the United States—could prompt widespread vaccine skepticism, damaging pandemic control efforts. The replication hurdle is especially high for the new and more sophisticated messenger ribonucleic acid (mRNA) vaccines, which have proven most effective against SARS-CoV-2 (the virus that causes COVID-19) and which are likely to provide the most adaptable platforms for the vaccines of the future. The genetic vaccines produced by Pfizer-BioNTech and Moderna require considerable technical knowledge and sophisticated techniques to generate a version of the viral spike protein that elicits a strong immune response.1 Therefore, from a biological standpoint, patent and IP waivers alone cannot resolve the existing lack of capacity in most countries to produce genetic vaccines at scale locally. A final challenge is that vaccine supply chains are intricate and global in scope. Different stages of vaccine manufacturing are spread across different parts of the globe, with various countries supplying key inputs and equipment. Patent and IP waivers cannot resolve export restrictions that these countries may decide to impose—and in fact have imposed—throughout the pandemic. Nor can poor countries with production waivers easily integrate into global supply chains. At the moment, current production capacity and quality standards continue to constrain global supply.