# 1NC

## 1

### OFF

#### The WTO has been seen as ineffective but has the opportunity to bounce back with strong international buy in

Ngozi Okonjo-Iweala, 20, Reviving the WTO, https://www.brookings.edu/opinions/reviving-the-wto/, Brookings, Ngozi Okonjo-Iweala is a nonresident distinguished fellow with the Africa Growth Initiative in the Global Economy and Development program at Brookings. She is an economist and international development expert with over 30 years of experience.

The World Trade Organization is in the news mostly for the wrong reasons nowadays. Many people regard it as an ineffective policeman of an outdated rulebook that is unsuited for the challenges of the twenty-first-century global economy. And WTO members generally agree that the organization urgently needs reforming in order to remain relevant. Recent months have brought further challenges. The WTO’s appellate body, which adjudicates trade disputes among member countries, effectively [ceased functioning](https://www.project-syndicate.org/commentary/world-trade-organization-revive-appellate-body-by-shang-jin-wei-and-xinding-yu-2019-12) last December amid disagreements regarding the appointment of new judges to the panel. And in May 2020, Director-General Roberto Azevêdo [announced](https://www.nytimes.com/2020/05/14/business/wto-chief-roberto-azevedo.html) that he would step down at the end of August, a year before his current term was due to end. Whoever Azevêdo’s successor is will face a major challenge. Since its establishment in 1995, the WTO has failed to conclude a single trade-negotiation round of global trade talks, thus missing an opportunity to deliver mutual benefits for its members. The Doha Development Round, which began in November 2001, was supposed to be concluded by January 2005. Fifteen years later, WTO members are still debating whether the Doha process should continue. Some think it has been overtaken by events, while others want to pursue further negotiations. The WTO has so far delivered disappointingly few other notable agreements as well, apart from the [Trade Facilitation Agreement](https://www.wto.org/english/tratop_e/tradfa_e/tradfa_e.htm), which entered into force in February 2017, and the 2015 [decision](https://www.wto.org/english/thewto_e/minist_e/mc10_e/briefing_notes_e/brief_agriculture_e.htm) to eliminate all forms of agricultural export subsidies. Meanwhile, some of its members have worked together on a raft of much broader regional trade deals that cover pressing issues such as the digital economy, investment, competition, the environment, and climate change. The Doha Development Round, which was intended to modernize the WTO’s rulebook, covers very few of these topics. And even some of the organization’s existing rules can easily be circumvented, thereby upsetting the balance of rights and obligations among members. During the current COVID-19 crisis, for example, some countries have imposed questionable export controls on medical supplies and food products in order to mitigate shortages. But despite these challenges, the WTO has not been a “failure.” Rather, it has built upon the successes of its predecessor, the General Agreement on Tariffs and Trade, which entered into force in 1948. The rules-based multilateral trading system that began with GATT has contributed immensely to global economic growth over the last seven decades, by reducing average tariffs and steadily eliminating non-tariff barriers. As a result, living standards have improved in most countries. Moreover, rules-based global trade has helped to underpin peace and security, because trading partners are more likely to resolve differences through negotiations than through armed conflict. Nonetheless, WTO members today recognize the need to reboot the organization for the 21st century. Developed countries believe that they have shouldered the burden of trade liberalization for far too long, and that developing countries should shoulder more obligations if they are in a position to do so. Least-developed and low-income developing countries, meanwhile, say that WTO rules are hampering their efforts to grow and modernize their economies. Over the last two decades, international trade has become a bogeyman for critics who blame it for the economic woes some countries face. But trade is not a zero-sum game: Rights and obligations can be balanced, as the evolution of global and regional trading rules since 1948 has shown. The question facing the WTO and its members now, therefore, is how to make progress and reach mutually beneficial agreements. All members should participate in this endeavor, because that is the only way the organization can regain its credibility and carry out its rule-making function. New negotiations must therefore take account of members’ varying levels of economic development, and aim—as ever—to reach fair and equitable agreements. Other crucial priorities for the WTO include enhanced transparency, in the form of timely notifications of countries’ trade measures, and an effective dispute-settlement system that commands the confidence of all members. A moribund WTO does not serve any country’s interest. An effective, rules-based international trade system is a public good, and failure to revive it will undermine governments’ efforts to pull the global economy out of the recession caused by the COVID-19 pandemic. The WTO has an irreplaceable role to play in transforming countries’ economic prospects and the lives of people around the world. Although the current crisis has brought the organization’s deteriorating health into sharp focus, its further decline is not inevitable. In a world economy already imperiled by COVID-19, we must now apply the antidote—members’ political will, determination, and flexibility—needed to revive it.

#### Intellectual property rights cannot be discriminated on the basis of field, or place of invention

WTO <https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm>, Article 27.1, Section 5 on patents, World trade Organization, WTO, Part II — Standards concerning the availability, scope and use of Intellectual Property Rights

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [(5)](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#fnt-5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

#### The WTO’s appellate body no longer exists to mediate disputes, without immediate buy in by states, and no mechanism to make disobedient states obey, the system collapses

Horton, 08/3, Lessons from Trump’s assault on the World Trade Organization, https://www.chathamhouse.org/2021/08/lessons-trumps-assault-world-trade-organization, Chatham House – International Affairs Think Tank, Communications Manager; Project Lead, Common Futures Conversations

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.

#### A major country operating outside WTO consensus wrecks global trade norms

Bacchus 20 [James Bacchus, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida, 12-16-2020, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, [https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines]/Kankee](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines%5d/Kankee)

In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the last thing the WTO needs is another debate over perceived trade obstacles to public health. Unless WTO members reach a consensus, the multilateral trading system may be further complicated by a delay like that in resolving the two‐​decades‐​old dispute between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious “North‐​South” political struggle definitely would not be in the interest of the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19. Background In early October 2020, India and South Africa asked the members of the WTO to waive protections in WTO rules for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the “prevention, containment or treatment of COVID-19 … until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”1 India and South Africa want to give all WTO members freedom to refuse to grant or enforce patents and other IP rights relating to COVID-19 vaccines, drugs, diagnostics, and other technologies for the duration of the pandemic. In requesting the waiver, India and South Africa have argued that “an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.” They have said that “as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”2 Later in October, the members of the WTO failed to muster the required consensus to move forward with the proposed waiver. The European Union, the United States, the United Kingdom, and other developed countries opposed the waiver request.3 One WTO delegate, from the United Kingdom, described it as “an extreme measure to address an unproven problem.”4 A spokesperson for the European Union explained, “There is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID‐​19‐​related medicines and technologies.”5 In the absence of a consensus, WTO members have decided to postpone further discussion of the proposed waiver until early 2021. Balancing IP Rights and Access to Medicines Not New to WTO This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease. Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”6 It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions. 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 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

#### Collapse of the WTO triggers an inevitable global war

Raymond J. Waldmann, Corporate Counsel & Secretary for AuBeta Networks Inc and former vice president of international relations and as director of government affairs for The Boeing Company & assistant U.S. Secretary of Commerce for international economic policy (1981-83) and chair of the Seattle Host Committees for the 1999 WTO Ministerial Meeting, “WORLD TRADE ORGANIZATION IMPORTANT TO CITIZENS OF CITY AND STATE, Seattle-Post Intelligencer, 5/11/99,

The answer is simple: Because trade matters to the U.S. economy, to Washington state and to Seattle and because the WTO matters to trade. The Geneva-based WTO is the only global body dedicated to developing international trade rules. From the U.S. perspective, the WTO is our voice and vote for dealing with trade issues. The WTO provides the rules-based system of international trade on which we rely. Members negotiate agreements ensuring that:-- Countries may not raise their tariffs or other border taxes whenever they feel like it, and thereby exclude American products from their markets; -- Countries may not impose unjustified technical barriers such as inspection requirements on U.S. wheat, apples and other agricultural products just to protect their home markets, nor may they favor products from specific countries; -- Countries may not allow or encourage piracy of intellectual property, thereby protecting our software and computers, books and films, CDs and tapes;-- Countries are restricted from violating the rules on subsidies and export assistance, and flooding the world with government-subsidized products whose prices we could not match.Trade is not a panacea for the political, economic and social problems of the world. But it is a force for peace and cross-cultural contact. Countries are less likely to go to war against their trading partners than they are against strangers. The WTO furthers the process of protecting against commercial skirmishes and potential trade wars by forging agreement among nations on trade protocols. Without the WTO, trade would be too dangerous a proposition for countries to leave to their trade ministries, and eventually trade disputes could become national security issues. A non-WTO world would more closely resemble the international economy before World War II, where countries used trade as tools of foreign policy, and international commerce was a pawn of aggressor states. As Franklin D. Roosevelt's former secretary of state Cordell Hull said, "When goods do not cross borders, armies do."

#### WTO cred solves wars that go nuclear.

Hamann 09 [Georgia; 2009; J.D. Candidate, Vanderbilt University Law School; “Replacing Slingshots with Swords: Implications of the Antigua-Gambling 22.6 Panel Report for Developing Countries and the World Trading System,” VANDERBILT JOURNAL OF TRANSNATIONAL LAW, http://www.jogoremoto.pt/docs/extra/duqJ53.pdf] Justin

Both Antigua and the U.S. claimed the resolution of the arbitration as a victory.99 In reality, the decision reached a midpoint between the respective countries’ positions, establishing a victory for the evolution of the international trading system itself. Voluntary compliance with WTO rules and procedures is of the utmost importance to the international trading system.100 Given the increasingly globalized market, the coming years will see an increase in the importance of the WTO as a cohesive force and arbiter of disputes that likely will become more frequent and injurious.101 The work of the WTO cannot be overstated in a nuclear-armed world, as the body continues to promote respect and even amity among nations with opposing philosophical goals or modes of governance.102 Demagogues in the Unites States may decry the rise of China as a geopolitical threat,103 and extremists in Russia may play dangerous games of brinksmanship with other great powers, but trade keeps politicians’ fingers off “the button.”104 The WTO offers an astounding rate of compliance for an organization with no standing army and no real power to enforce its decisions, suggesting that governments recognize the value of maintaining the international construct of the WTO.105 In order to promote voluntary compliance, the WTO must maintain a high level of credibility.106 Nations must perceive the WTO as the most reasonable option for dispute resolution or fear that the WTO wields enough influence to enforce sanctions.107 The arbitrators charged with performing the substantive work of the WTO by negotiating, compromising, and issuing judgments are keenly aware of the responsibility they have to uphold the organization’s credibility.108

#### Nuclear war causes extinction – mass starvation and ice age.

**Starr 15** (Steven Starr 15. “Nuclear War: An Unrecognized Mass Extinction Event Waiting To Happen.” Ratical. March 2015. <https://ratical.org/radiation/NuclearExtinction/StevenStarr022815.html>) TG

A war fought with 21st century strategic nuclear weapons would be more than just a great catastrophe in human history. If we allow it to happen, such a war would be a mass extinction event that [ends human history](https://ratical.org/radiation/NuclearExtinction/StarrNuclearWinterOct09.pdf). There is a profound difference between extinction and “an unprecedented disaster,” or even “the end of civilization,” because even after such an immense catastrophe, human life would go on. But extinction, by definition, is an event of utter finality, and a nuclear war that could cause human extinction should really be considered as the ultimate criminal act. It certainly would be the crime to end all crimes. The world’s leading climatologists now tell us that nuclear war threatens our continued existence as a species. Their studies predict that a large nuclear war, especially one fought with strategic nuclear weapons, would create a post-war environment in which for many years it would be too cold and dark to even grow food. Their findings make it clear that not only humans, but most large animals and many other forms of complex life would likely vanish forever in a nuclear darkness of our own making. The environmental consequences of nuclear war would attack the ecological support systems of life at every level. Radioactive fallout produced not only by nuclear bombs, but also by the destruction of nuclear power plants and their spent fuel pools, would poison the biosphere. Millions of tons of smoke would act to [destroy Earth’s protective ozone layer](https://www2.ucar.edu/atmosnews/just-published/3995/nuclear-war-and-ultraviolet-radiation) and block most sunlight from reaching Earth’s surface, creating Ice Age weather conditions that would last for decades. Yet the political and military leaders who control nuclear weapons strictly avoid any direct public discussion of the consequences of nuclear war. They do so by arguing that nuclear weapons are not intended to be used, but only to deter. Remarkably, the leaders of the Nuclear Weapon States have chosen to ignore the authoritative, long-standing scientific research done by the climatologists, research that predicts virtually any nuclear war, fought with even a fraction of the operational and deployed nuclear arsenals, will leave the Earth essentially uninhabitable.

#### Outweighs and turns case

[1] reversibility

[2] magnitude

[3] turns suffering

## 2

### OFF

#### Interpretation – if the affirmative reads both a Role of the Judge and Role of the Ballot as ways to frame offense, they must specify which one comes first and how each interacts with each other in the 1AC

#### Violation – they didn’t

#### Vote negative for Critical Engagement – absent specification the NC doesn’t know what types of offense to read to link under their multiple frameworks. Even if we somehow link offense under one, the 1AR can shift and moot the NC, and we still don’t know how each interacts with each other ie. does the ROTB influence the ROTJ. There are a couple impacts –

#### [1] Movement building – a) Dogmatism DA – Absent specification we can’t discuss countermethods of solving the affirmative which kills solvency and causes polarization b) Legitimacy DA – If NC’s don’t know how to link offense that means your ROTB or ROTJ becomes a NIB that the NC will have to frame out of which is bad because the nuances of the affirmative never get discussed

#### [2] Education – only my model allows debaters to rigorously test the affirmative and learn the literature through countermethods, anything else excludes offense and ends in commodification of literature for the ballot. Independently, not specifying is bad for novice inclusion because they won’t know how to engage with the affirmative and lose everytime – inclusion is a voter you can’t debate if you can’t participate

#### Framing is that they can’t use their aff to take out theory a) that proves the abuse of the shell they should have specified and that’s shifting b) truth testing – we couldn’t rigorously test the aff so we don’t know if it’s true c) form v content distinction – the shell criticizes the ability to read the framing in the first place

#### Voters – Fairness is a voter since debate is a competitive activity that intrinsically requires an equal shot at winning. Education is a voter since it’s the reason schools fund debate and its ultimate impact.

#### DD – a) to deter future abuse, b) otherwise they could just kick and go for the positive time tradeoff on theory, c) the round has been skewed so theory is the only fair place to vote d) DTA doesn’t make sense because it indicts you as a norm

#### CI – a) reasonability requires judge intervention because I don’t know where your BS meter is, and b) reasonability creates a race to the bottom since it motivates debaters to use increasingly unfair strategies and get away with them by playing defense on theory c) collapses because you garner offense based on the brightline d) footnoting because saying “oh lets be reasonable just this once” even if it’s a better norm means we never get the norming potential of the shell e) the bl is catered to your situation not the best situation f) race to the bottom because we never find better norms and think everything is reasonable

#### No RVIs – a) It’s illogical to vote for you for being fair, rounds without theory would be irresolvable b) It incentivizes you to bait theory and win off a scripted CI which means infinite abuse c) you have the 2ar to blippily extend rvis which kilsl substance education

## 3

### OFF

#### Interpretation: “medicines” is a generic bare plural. The aff may not defend WTO member nations reducing intellectual property protections for a subset of medicines.

#### The upward entailment test and adverb test determine the genericity of a bare plural

Leslie and Lerner 16 [Sarah-Jane Leslie, Ph.D., Princeton, 2007. Dean of the Graduate School and Class of 1943 Professor of Philosophy. Served as the vice dean for faculty development in the Office of the Dean of the Faculty, director of the Program in Linguistics, and founding director of the Program in Cognitive Science at Princeton University. Adam Lerner, PhD Philosophy, Postgraduate Research Associate, Princeton 2018. From 2018, Assistant Professor/Faculty Fellow in the Center for Bioethics at New York University. Member of the [Princeton Social Neuroscience Lab](http://psnlab.princeton.edu/).] “Generic Generalizations.” Stanford Encyclopedia of Philosophy. April 24, 2016. <https://plato.stanford.edu/entries/generics/> TG

1. Generics and Logical Form

In English, generics can be expressed using a variety of syntactic forms: bare plurals (e.g., “tigers are striped”), indefinite singulars (e.g., “a tiger is striped”), and definite singulars (“the tiger is striped”). However, none of these syntactic forms is dedicated to expressing generic claims; each can also be used to express existential and/or specific claims. Further, some generics express what appear to be generalizations over individuals (e.g., “tigers are striped”), while others appear to predicate properties directly of the kind (e.g., “dodos are extinct”). These facts and others give rise to a number of questions concerning the logical forms of generic statements.

1.1 Isolating the Generic Interpretation

Consider the following pairs of sentences:

(1)a.Tigers are striped.

b.Tigers are on the front lawn.

(2)a.A tiger is striped.

b.A tiger is on the front lawn.

(3)a.The tiger is striped.

b.The tiger is on the front lawn.

The sentence pairs above are prima facie syntactically parallel—both are subject-predicate sentences whose subjects consist of the same common noun coupled with the same, or no, article. However, the interpretation of first sentence of each pair is intuitively quite different from the interpretation of the second sentence in the pair. In the second sentences, we are talking about some particular tigers: a group of tigers in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), some individual tiger in ([2b](https://plato.stanford.edu/entries/generics/#ex2b)), and some unique salient or familiar tiger in ([3b](https://plato.stanford.edu/entries/generics/#ex3b))—a beloved pet, perhaps. In the first sentences, however, we are saying something general. There is/are no particular tiger or tigers that we are talking about.

The second sentences of the pairs receive what is called an existential interpretation. The hallmark of the existential interpretation of a sentence containing a bare plural or an indefinite singular is that it may be paraphrased with “some” with little or no change in meaning; hence the terminology “existential reading”. The application of the term “existential interpretation” is perhaps less appropriate when applied to the definite singular, but it is intended there to cover interpretation of the definite singular as referring to a unique contextually salient/familiar particular individual, not to a kind.

There are some tests that are helpful in distinguishing these two readings. For example, the existential interpretation is upward entailing, meaning that the statement will always remain true if we replace the subject term with a more inclusive term. Consider our examples above. In ([1b](https://plato.stanford.edu/entries/generics/#ex1b)), we can replace “tiger” with “animal” salva veritate, but in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) we cannot. If “tigers are on the lawn” is true, then “animals are on the lawn” must be true. However, “tigers are striped” is true, yet “animals are striped” is false. ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) does not entail that animals are striped, but ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) entails that animals are on the front lawn (Lawler 1973; Laca 1990; Krifka et al. 1995).

Another test concerns whether we can insert an adverb of quantification with minimal change of meaning (Krifka et al. 1995). For example, inserting “usually” in the sentences in ([1a](https://plato.stanford.edu/entries/generics/#ex1a)) (e.g., “tigers are usually striped”) produces only a small change in meaning, while inserting “usually” in ([1b](https://plato.stanford.edu/entries/generics/#ex1b)) dramatically alters the meaning of the sentence (e.g., “tigers are usually on the front lawn”). (For generics such as “mosquitoes carry malaria”, the adverb “sometimes” is perhaps better used than “usually” to mark off the generic reading.)

#### It applies to “medicines” – 1] upward entailment test – “reduce intellectual property protections for medicines” doesn’t entail reducing protections for aids, because it doesn’t prove that we should derestrict other beneficial tech, 2] adverb test – member nations “ought to usually reduce intellectual property protections for medicines” doesn’t substantially change resolutional meaning, 3] predicate level – the rez is an individual level predicate not a stage level because moral obligations in ought statements are long-lasting as opposed to fleeting phases

#### **Violation – they only defend diabetes medicine**

#### Vote neg:

#### 1] Limits – you can pick anything from COVID vaccines to HIV/AIDS to random biotech to insulin treatments and there’s no universal disad since each one has a different function and implication for health, tech, and relations – explodes neg prep and leads to random medicine of the week affs which makes cutting stable neg links impossible. PICs don’t solve – it’s absurd to say neg potential abuse justifies the aff being flat out not T, which leads to a race towards abuse. Limits key to reciprocal engagement since they create a caselist for neg prep.

#### 2] TVA – read the aff as an advantage to a whole rez aff.

#### T outweighs 1ar theory – a) norms – topic for 2 months, theory can be anytime b) if I was abusive it was because you forced me into it

## Case

### Adv

#### A vaccine waiver greenlights counterfeit medicine – independently turns Case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### Patents are not the limiting factor – 95% of insulin patents expired in 2016

Kaplan MA 16

Warren A. Kaplan, (MA works in Department of Global Health), 7-19-2016, "The global intellectual property ecosystem for insulin and its public health implications: an observational study," Journal of Pharmaceutical Policy and Practice, [https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8 //](https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8%20//) AW

Global insulin patents Most patents on insulin products in the world have already expired by 2015 yet many markets continue to be dominated by the brand-name versions marketed by original patent-holders. Figure [1](https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8#Fig1) plots the percentage of all OB/HC granted patents on insulin remaining in force in any given year (based on a 20 year-from-filing patent life (black markers), and shows how relatively quickly the Eli Lilly, Novo and Pfizer insulin OB/HC patents are expiring compared to Sanofi. We confirm that after 2016, between about 5–20% of Pfizer, Eli Lilly and Novo Nordisk patents listed in the OB/HC remain un-expired and these percentages rapidly dimish, except for those of Sanofi who appears to have listed OB/HC patents whose expirations would extend well into 2030 and beyond (i.e., derived from a patent application filed in 2010).

#### It is not IP that is limiting Insulin’s availability, it is corrupt trial processes

Peccoud 18

Jean Peccoud (professor at colorado state), 9-13-2018, "After a century, insulin is still expensive – could DIYers change that?," Conversation, [https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822 //](https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822%20//) AW

Patents don’t make insulin expensive [Discovering and developing drugs is expensive](https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/). Patents help drug companies recoup the costs from their investments by granting them a monopoly for a limited time. Once the patent expires, competing companies can begin producing generics: off-brand versions of a patented drug. This healthy competition drives [prices down](https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM609808.pdf). So why, with the original patent long-expired, is there still no affordable generic insulin? Don’t let yourself be misled. The insulin for purchase today is not the same insulin used to treat diabetic patients nearly 100 years ago. That insulin came primarily from animals. Today, insulin is brewed up by microbes that have been [genetically engineered](https://www.fda.gov/downloads/AboutFDA/WhatWeDo/History/ProductRegulation/UCM593496.pdf) with the gene for human insulin. Insulin pumps are one of the newer ways to administer the drug to diabetic patients. [AP Photo/Mark Zaleski](http://www.apimages.com/metadata/Index/Insulin-Legislation/75bd28fc8ed840c3802727306873cce0/1/0) And insulin is seldom injected with an old-fashioned syringe and needle anymore. Now there are insulin pens, pumps, test strips and other devices that improve the quality of life for diabetic patients. Pharmaceutical companies have also modified the chemical formula to produce faster-acting or longer-lasting insulins. With each of these inventions came a new patent. But the benefits of these “improved” insulins [are debatable](https://doi.org/10.2337/dc13-2915), and there’s nothing preventing competing companies from selling older, long off-patent versions of insulin. So [what’s the holdup](https://doi.org/10.1016/j.tibtech.2018.07.009)? Regulations keep insulin expensive Insulin is a [biologic drug](https://theconversation.com/biologics-the-pricey-drugs-transforming-medicine-80258), which means it’s produced by a living organism, not a chemical reaction. This process, called biomanufacturing, is [more inconsistent](https://doi.org/10.1177/1932296813516958) than chemical synthesis of non-biologic drugs like aspirin. Making reliable biologic drugs is a little like winemaking. Even though the winemaker carefully follows a well-established process, minute differences will affect the final product. It’s always wine, but some vintages are better than others and tasting the wine is the only way to evaluate the final product. So if a new company wants to make insulin, that insulin has to be tested on patients in expensive clinical trials. Bringing a biologic drug to market can cost as much as [$250 million](https://doi.org/10.4161/mabs.3.2.15005). No company can afford that lump if it can’t file for a patent to recoup the investments. That’s why there’s only [one “generic” insulin](https://www.businessinsider.com/insulin-cheaper-generic-2016-12) available so far. It’s [made by a company](https://www.basaglar.com/en/) that was already a major player in the insulin market, and it’s only 15 percent cheaper than the patented version. By comparison, most non-biologic generic drugs cost [80 percent less](https://doi.org/10.1056/NEJMms1411398) than the original. Obviously, regulations are important for keeping insulin safe, but at what cost? [Ten percent of people](https://doi.org/10.2337/dc12-0257) living with diabetes in the U.S. are uninsured, and there are nearly 10,000 crowdfunding campaigns related to insulin on the site GoFundMe alone. Stories about diabetic patients ending up hospitalized or worse because they [tried to ration their insulin](https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/) are all-too common. Could big pharma eventually be cut out of the process by home brewers cooking up their own medications? [Sanofi Pasteur](https://www.flickr.com/photos/sanofi-pasteur/5283263633), [CC BY-NC-ND](http://creativecommons.org/licenses/by-nc-nd/4.0/) Democratizing insulin production Some people are taking matters [into their own hands](https://doi.org/10.1016/j.tibtech.2018.07.009), tinkering to meet their medical needs. In 2015, patients and hobby scientists launched an initiative known as the [Open Insulin Project](http://openinsulin.org/about-the-project/). As in winemaking, the specific know-how required for insulin production is a guarded secret. The goal of the Open Insulin Project is to figure out a patent-free method and release the information, so that competing companies can manufacture “generic” insulin. Given the cost of regulatory approval, it is more likely that the project could enable patients to “home brew” their own diabetic treatments. There is currently no structure for regulating drugs that are not produced commercially. One report estimates that as many as [2,000 patients have already reverse engineered](https://www.bloomberg.com/news/features/2018-08-08/the-250-biohack-that-s-revolutionizing-life-with-diabetes) their own insulin pumps and electronic monitoring systems. The insulin itself could be next. Is it possible to make biologic drugs like insulin more affordable without compromising safety? One suggestion that has been gaining steam is to [scale down biomanufacturing](https://doi.org/10.1038/nbt.3888). Right now, biologic medicines like insulin are cooked up in giant batches. Ensuring that those batches are consistent and free of contamination is a major challenge. Think about the meat department in your grocery store. Many big-box stores stock hamburger that was ground in a central processing plant and then distributed. If an E. coli outbreak occurs in the plant, it’s going to spread to all of the stores downstream, potentially infecting hundreds or thousands of people. The meat is also exposed to more potential contamination events through storage and transport. And, if contaminated meat is identified in one store, it won’t be immediately clear whether or not all the others are safe. Industrial-scale production – whether of hamburger or drugs – makes it harder to zero in on the source of problems when they occur. [David Tadevosian/Shutterstock.com](https://www.shutterstock.com/image-photo/meat-grinder-industry-775823329) Now, consider a small local butcher who grinds meat in-house. Any safety risk is going to be isolated to the customers of that one store and the source will be obvious. Similarly, producing medications in smaller batches reduces the potential impact of any one safety event. Pharmacy compounding provides [an example](https://doi.org/10.1038/nbt.3888). In compounding, drugs are specially mixed or produced for a very small number of patients. Compounded medications are not subject to clinical trials. If insulin were made in smaller batches, manufacturers might be able to forego clinical trials and use simpler and [less expensive tests](https://doi.org/10.1208/s12248-016-9908-z) to confirm that each batch of insulin produced is safe and comparable to previously approved insulins. It would be like using chemical tests to identify important flavor compounds in two vintages of wine instead of organizing taste tests. [This model](https://doi.org/10.1016/j.tibtech.2018.07.009) could also apply to other expensive biologic drugs such as those that treat cancer, HIV and rheumatoid arthritis. The technology necessary for small-batch insulin production [already exists](http://news.mit.edu/2016/portable-device-produces-biopharmaceuticals-on-demand-0729). [Future research](http://peccoud.org/insulin/) could help automate and streamline small batch medicine production in order to minimize safety risks. The authors describe how biohacking insulin and other biologic drugs have important implications for the future of pharmaceutical drug regulation. The future of medicine The pharmaceutical industry is [ripe for disruption](https://doi.org/10.1016/j.tibtech.2018.07.009). In the coming decades, drugs might be produced in very different settings. Hospitals have already begun [plans to make their own medicines](http://www.latimes.com/business/la-fi-generic-drugs-hospitals-20180906-story.html). DIY biologists could provide patients with the knowledge needed to produce for themselves the drugs their lives depend on. As the industry and regulatory agencies gain more experience with biologic drugs, it is also possible regulations will ease up, lowering the cost of approval. This would enable the emergence of small-scale drug manufacturers that could provide off-brand drugs at a lower cost. One thing is certain, the future of medicine will not be “business as usual.” Biomanufacturing technologies will continue to evolve. These changes could enable [decentralized production of life-saving drugs](https://doi.org/10.1016/j.tibtech.2018.07.009). How the regulatory system and pharmaceutical industry will adjust to that future is yet to be determined.