## Innovation DA Generic

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

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Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

**Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.**

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As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

## **WTO ILaw DA**

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

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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

#### Interpretation – topical affirmatives must defend reduction of intellectual property rights for medicines

#### Medicine is treatment for illness or injury

Cambridge Dictionary 21 [Cambridge Dictionary, 2021, <https://dictionary.cambridge.org/us/dictionary/english/medicine>] //Lex AKo

[treatment](https://dictionary.cambridge.org/us/dictionary/english/treatment) for [illness](https://dictionary.cambridge.org/us/dictionary/english/illness) or [injury](https://dictionary.cambridge.org/us/dictionary/english/injury), or the [study](https://dictionary.cambridge.org/us/dictionary/english/study) of this:

#### Violation – Data exclusivity are not IPP for medicine.

Thrasher 21 Thrasher, Rachel. “How Data Exclusivity Laws Impact Drug Prices:” *Global Development Policy Center Chart of the Week How Data Exclusivity Laws Impact Drug Prices Comments*, 25 May 2021, [www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data](http://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data)-exclusivity-laws-impact-drug-prices/. // Lex AKo

**Data exclusivity is a form of intellectual property protection that applies specifically to data from** pharmaceutical **clinical trials. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law.** Data exclusivity operates independently of patent protection and **can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection.** Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. **Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms**. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use,” it does not require exclusivity rules that block the registration of generic products.

#### Clinical trials are a study for medicine to then get protected, but not medicine themselves

Review [Institutional Review, "Clinical Trials," <https://www.phrma.org/policy-issues/Research-Development/Clinical-Trials>] //Lex AKo

A clinical trial is a carefully designed study which tests the benefits and risks of a specific medical treatment or intervention, such as a new drug or a behavior change (e.g., diet). Once researchers have completed a rigorous screening and preclinical testing process, the company files an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA). This application allows the investigational medicine to be tested in human volunteers in clinical trials.

#### Vote Neg –

#### 1] Limits – their model justifies defending ANY INTELLECTUAL PROPERTY PROTECTION outside of medicines which – A] incentivizes the aff for a race to the margins and pick topics like this aff that have little to no lit base which also guts education. B] shifts an unfair prep burden to prep hundreds of affs compared to the generics that the AC has to answer