Microbial Resistance DA

IPR harmonization undermines the ability to market counterfeit drugs.

Ferrill, Spring **2007** (Elizabeth – Law Clerk to the Honorable Liam O'Grady, Magistrate Judge, U.S. District Court for the Eastern District of Virginia, Clearing the Swamp for Intellectual Property Harmonization: Understanding and Appreciating the Barriers to Full TRIPS Compliance for Industrializing and Non-Industrializing Countries, University of Baltimore Intellectual Property Law Journal, p. Lexis-Nexis)
In 1994, the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) was created. n2 TRIPS requires all 150 members n3 of the World Trade Organization (WTO) to provide minimal standards of protection for intellectual property (IP). n4 **TRIPS** is part of the larger WTO framework that **promotes trade liberalization**. n5 Through a series of [*138] agreements designed to lower trade tariffs and eliminate other barriers to trade, the WTO strives to improve standards of living of all members, expand production of and trade in goods and services, and sustain development, especially in developing countries worldwide. n6 Most economists view trade liberalization as a means to wealth maximization. n7 If each country produces what it is best at producing, then output of efficiently produced products is higher worldwide. n8 Hence, countries that are the most efficient producer of a certain good would produce that good and trade with other countries for those goods it produces more efficiently, all without the cost of trade barriers. n9 Yet, countries are reluctant to unilaterally lower their trade barriers. n10 To avoid this problem, the WTO established rules for reciprocal [*139] lowering of trade barriers. n11 In the realm of intellectual property, **harmonization**, defined as the standardization of intellectual property laws, **is analogous to trade liberalization.** If every country were to respect and protect the intellectual property rights of all other countries, inventors and creators would have the maximum incentive to create, mutually benefiting the world. More than a decade after its ratification, there remains tension and widespread noncompliance with **TRIPS**, as many countries **continue to** not **enforce foreign IP rights**, despite the potential benefits of harmonization. **Counterfeiting**, n12 which could be **mitigated by such enforcement, costs the world economy about $ 600 billion annually** and includes a multitude of products, such **as pharmaceuticals**, DVDs, software, toys, spare parts for cars and aircraft, and apparel. n13 This prompts the question of why complying with TRIPS and curbing counterfeiting and pirating has been so difficult over the past decade. There are a number of possible explanations.

That's crucial as Low-quality and counterfeit pharmaceuticals make anti microbial resistance spread globally

Kelesidis '15 (Theodoros Kelesidis – MD @ the University of Athens Medical School, Fellowship @ the UCLA School of Medicine, Specializes in Infectious Diseases. Mathew E. Falagas – MD @ the University of Athens Medical School, MSc in Epidemiology @ Harvard, Adjunct Assistant Professor of Medicine at Tufts University School of Medicine, Boston, Massachusetts, President, Board of Directors, Alfa Institute of Biomedical Sciences (AIBS), Athens, Greece, and Director, Infectious Diseases Clinic of Henry Dunant Hospital. "Substandard/Counterfeit Antimicrobial Drugs," 18 March 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4402958/)
Consequences for the Community **Counterfeit** and/or substandard antimicrobial **medicines** may **promote antimicrobial resistance**. **Emergence of antimicrobial resistance as a result of low-quality antimicrobials has been reported** with antimicrobials that are often used in combination therapy, such as antimalarials (45, 45, 123, 217,–220) and antituberculosis agents (1, 121, 221). The use of substandard products **may lead to underdosing of antibiotics**, **which can increase antimicrobial resistance** (2, 4, 8, 24,

222, 223). **As a result**, in some developing countries **multidrug-resistant bacteria may emerge**, and the development of travel may further promote **the spread of drug-resistant bacteria worldwide** (15, 17, 51). Furthermore, therapeutic failure **prolongs the period of contagiousness and increases the prevalence of infections** from multidrug-resistant pathogens in the community. With regard to malaria, WHO has recommended that if 10% of patients fail treatment, the malaria treatment guidelines should change (224). However, the contribution of substandard/counterfeit medicines to treatment failure for malaria needs to taken into account and addressed in future research studies. Low-quality antimicrobials **may significantly decrease confidence** in the efficacy of certain antibiotics. **Poor-quality antimicrobials may lead physicians to lose confidence** in specific antibiotics and thus to use broad-spectrum antibiotics as the drugs of choice for infections (215, 225). According to the WHO, this may lead to loss of efficacy of relatively inexpensive drugs and will promote the use of more expensive antibiotics that patients in developing countries are not able to afford. The **public confidence in health care systems and in governments may decline significantly**. If **patients** with infectious diseases do not take antimicrobials due to lack of trust in their efficacy, **they remain infectious and pose risks for global public health.**

Disease pandemics threaten extinction.

Dhillon 17 [Ranu, works on building health systems in developing countries and served as an advisor to the president of Guinea during the Ebola epidemic instructor at Harvard Medical School, Harvard Business Review, 3-15-17, "The World Is Completely Unprepared for a Global Pandemic", https://hbr.org/2017/03/the-world-is-completely-unprepared-for-a-global-pandemic]

We fear it is **only a matter of time before** we face a **deadlier and more contagious pathogen**, yet the threat of a deadly pandemic remains dangerously overlooked. **Pandemics now occur with greater frequency, due to** factors such as **climate change, urbanization, and international travel**. Other factors, such as a weak World Health Organization and potentially massive cuts to funding for U.S. scientific research and foreign aid, including funding for the United Nations, stand to deepen our vulnerability. **We also face the specter of novel and mutated pathogens that could spread and kill faster than diseases we have seen before.** With the advent of genome-editing technologies, bioterrorists could artificially engineer **new plagues**, a threat that Ashton Carter, the former U.S. secretary of defense, thinks could **rival nuclear weapons in deadliness**. The two of us have advised the president of Guinea on stopping Ebola. In addition, we have worked on ways to contain the spread of Zika and have informally advised U.S. and international organizations on the matter. Our experiences tell us that the world is unprepared for these threats. We urgently need to change this trajectory. We can start by learning four lessons from the gaps exposed by the Ebola and Zika pandemics. Faster Vaccine Development The most effective way to stop pandemics is with vaccines. However, with Ebola there was no vaccine, and only now, years later, has one proven effective. This has been the case with Zika, too. Though there has been rapid progress in developing and getting a vaccine to market, it is not fast enough, and Zika has already spread worldwide. Many other diseases do not have vaccines, and developing them takes too long when a pandemic is already under way. We need faster pipelines, such as the one that the Coalition for Epidemic Preparedness Innovations is trying to create, to preemptively develop vaccines for diseases predicted to cause outbreaks in the near future. Point-of-Care Diagnostics Even with such efforts, vaccines will not be ready for many diseases and would not even be an option for novel or artificially engineered pathogens. With no vaccine for Ebola, our next best strategy was to identify who was infected as quickly as possible and isolate them before they infected others. Because Ebola's symptoms were identical to common illnesses like malaria, diagnosis required laboratory testing that could not be easily scaled. As a result, many patients were only tested after several days of being contagious and infecting

others. Some were never tested at all, and about 40% of patients in Ebola treatment centers did not actually have Ebola. Many dangerous pathogens similarly require laboratory testing that is difficult to scale. Florida, for example, has not been able to expand testing for Zika, so pregnant women wait weeks to know if their babies might be affected. What's needed are point-of-care diagnostics that, like pregnancy tests, can be used by frontline responders or patients themselves to detect infection right away, where they live. These tests already exist for many diseases, and the technology behind them is well-established. However, the process for their validation is slow and messy. Point-of-care diagnostics for Ebola, for example, were available but never used because of such bottlenecks. Greater Global Coordination **We need stronger global coordination**. The responsibility for controlling pandemics is fragmented, spread across too many players with no unifying authority. In Guinea we forged a response out of an amalgam of over 30 organizations, each of which had its own priorities. In Ebola's aftermath, there have been calls for a mechanism for responding to pandemics similar to the advance planning and training that NATO has in place for its numerous members to respond to military threats in a quick, coordinated fashion. This is the right thinking, but we are far from seeing it happen. The errors that allowed Ebola to become a crisis replayed with Zika, and the WHO, which should anchor global action, continues to suffer from a lack of credibility. Stronger Local Health Systems International actors are essential but cannot parachute into countries and navigate local dynamics quickly enough to contain outbreaks. In Guinea it took months to establish the ground game needed to stop the pandemic, with Ebola continuing to spread in the meantime. We need to help developing countries establish health systems that can provide routine care and, when needed, coordinate with international responders to contain new outbreaks. Local health systems could be established for about half of the $3.6 billion ultimately spent on creating an Ebola response from scratch. Access to routine care is also essential for knowing when an outbreak is taking root and establishing trust. For months, Ebola spread before anyone knew it was happening, and then lingered because communities who had never had basic health care doubted the intentions of foreigners flooding into their villages. The turning point in the pandemic came when they began to trust what they were hearing about Ebola and understood what they needed to do to halt its spread: identify those exposed and safely bury the dead. With Ebola and Zika, we lacked these four things — vaccines, diagnostics, global coordination, and local health systems — which are still urgently needed. However, prevailing political headwinds in the United States, which has played a key role in combatting pandemics around the world, threaten to make things worse. The Trump administration is seeking drastic budget cuts in funding for foreign aid and scientific research. The U.S. State Department and U.S. Agency for International Development may lose over one-third of their budgets, including half of the funding the U.S. usually provides to the UN. The National Institutes of Health, which has been on the vanguard of vaccines and diagnostics research, may also face cuts. The Centers for Disease Control and Prevention, which has been at the forefront of responding to outbreaks, remains without a director, and, if the Affordable Care Act is repealed, would lose $891 million, 12% of its overall budget, provided to it for immunization programs, monitoring and responding to outbreaks, and other public health initiatives. Investing in our ability to prevent and contain pandemics through revitalized national and international institutions should be our shared goal. However, if U.S. agencies become less able to respond to pandemics, leading institutions from other nations, such as Institut Pasteur and the National Institute of Health and Medical Research in France, the Wellcome Trust and London School of Hygiene and Tropical Medicine in the UK, and nongovernmental organizations (NGOs have done instrumental research and response work in previous pandemics), would need to step in to fill the void. There is no border wall against disease. **Pandemics are an existential threat on par with climate change and nuclear conflict**. We are at a **critical crossroads**, where we must either take the steps needed to prepare for this threat or become even more vulnerable. **It is only a matter of time before we are hit by a deadlier, more contagious pandemic.** Will we be ready?

affirmative case

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strong IP is important for developing countries access to medicine

IP protections are key to pharmaceutical investment in developing countries.

Ezell and Cory 19 [(Stephen, vice president, global innovation policy, at the Information Technology and Innovation Foundation, B.S. from the School of Foreign Service at Georgetown University, and Nigel, associate director covering trade policy at the Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies, MA in public policy from Georgetown University) "The Way Forward for Intellectual Property Internationally," Information Technology and Innovation Foundation, 4/25/2019] TDI

Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that **IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment**.34 Research has revealed that a country's level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, **foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries**.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that **weak IP rights reduce pharmaceutical investment**.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank's International Finance Corporation found that, with variations by sector, country, and technology, **at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights**; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations' levels of economic development.41

Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that **weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries**.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the "global South" (e.g., developing countries) may be associated with FDI increases in the "global North" (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that **developing countries can entice technology transfer**

IPR is not the cause of medicine inequality-- Multiple alternative causes exist

Haugen 2021 [Hans Morten, Professor of International Diakonia at the VID Specialized University, Oslo, Norway, The Journal of World Intellectual Property, "Does TRIPS (Agreement on Trade-Related Aspects of Intellectual Property Rights) prevent COVID-19 vaccines as a global public good?" March 18, https://onlinelibrary.wiley.com/doi/10.1111/jwip.12187

This article analyzes the context for the allegation that IP is among the crucial factors in promoting health innovation globally, and not preventing the universal and equitable access to vaccines, even if supply of medicines is held by developed countries to be "difficult" (WTO

Secretariat, 2020a). Biotechnology actors expressed criticism of the UN High-level Panel on Access to Medicines (2016), arguing that **IP tends to be overemphasized in debates over access** to medicines, **ignoring** the wider context of **what impedes such access** (International Council of Biotech Associations [ICBA], 2016; Biotechnology Innovation Organization [BIO], 2016). Hence, **developed countries** and biotech associations **concur in identifying weak funding** of health care **and lack of manufacturing capacity as constituting the** core of the **problem of access** (WTO Secretariat, 2020a; see also U.S. Department of State, 2016), **as well as regulatory inefficiencies, trade policies and inadequate** health **insurance** (ICBA, 2016).

C2---

Bioterror is not a problem

Bioterror is comparatively ineffective, expensive, and inefficient and wouldn't cause widespread death– empirically proven

Stratfor 07

Stratfor, private intelligence agency, analyzes geopolitical trends, 12/21/07 ("Bioterrorism: Sudden Death Overtime?," http://www2.stratfor.com/analysis/bioterrorism_sudden_death_overtime)

In this season of large college bowl games and the National Football League playoffs in the United States, and large nonsporting events such as the New Year's Eve celebration in New York's Times Square — not to mention the upcoming Olympic Games in Beijing — a discussion of bioterrorism and the threat it poses might be of interest. First, it must be recognized that during the past several decades of the modern terrorist era, biological weapons have been used very infrequently — and there are some very good reasons for this. Contrary to their portrayal in movies and television shows, biological agents are difficult to manufacture and deploy effectively in the real world. In spite of the fear such substances engender, even in cases in which they have been somewhat effective they have proven to be less effective and more costly than more conventional attacks using firearms and explosives. In fact, nobody even noticed what was perhaps the largest malevolent deployment of biological agents in history, in which thousands of gallons of liquid anthrax and botulinum toxin were released during several attacks in a major metropolitan area over a three-year period. This use of biological agents was perpetrated by the Japanese apocalyptic cult Aum Shinrikyo. An examination of the group's chemical and biological weapons (CBW) program provides some important insight into biological weapons, their costs — and their limitations. In the late 1980s, Aum's team of trained scientists spent millions of dollars to develop a series of state-of-the-art biological weapons research and production laboratories. The group experimented with botulinum toxin, anthrax, cholera and Q fever and even tried to acquire the Ebola virus. The group hoped to produce enough biological agent to trigger a global Armageddon. Between April of 1990 and August of 1993, Aum conducted seven large-scale attacks involving the use of thousands of gallons of biological agents — four with anthrax and three with botulinum toxin. The group's first attempts at unleashing mega-death on the world involved the use of botulinum toxin. In April of 1990, Aum used a fleet of three trucks equipped with aerosol sprayers to release liquid botulinum toxin on targets that included the Imperial Palace, the Diet and the U.S. Embassy in Tokyo, two U.S. naval bases and the airport in Narita. In spite of the massive quantities of agent released, there were no mass casualties and, in fact, nobody outside of the cult was even aware the attacks had taken place. When the botulinum operations failed to produce results, Aum's scientists went back to the drawing board and retooled their biological weapons facilities to produce anthrax. By mid-1993, they were ready to launch attacks involving anthrax, and between June and August of 1993 the group sprayed thousands of gallons of aerosolized liquid anthrax in Tokyo. This time Aum not only employed its fleet of sprayer trucks, but also use sprayers mounted on the roof of their headquarters to disperse a cloud of aerosolized anthrax over the city. Again, the attacks produced no results and were not even noticed. It was only after the group's successful 1995 subway attacks using sarin nerve agent that a Japanese government investigation discovered that the 1990 and 1993 biological attacks had occurred. Aum Shinrikyo's team of highly trained scientists worked under ideal conditions in a first-world country with a virtually unlimited budget. The team worked in large, modern facilities to produce substantial quantities of biological weapons. Despite the millions of dollars the group spent on its bioweapons program, it still faced problems in creating virulent biological agents, and it also found it difficult to dispense those agents effectively. Even when the group switched to employing a nerve agent, it only succeeded in killing a handful of people. A comparison between the Aum Shinrikyo Tokyo subway attack and the jihadist attack against the Madrid trains in 2004 shows that chemical/biological attacks are more expensive to produce and yield fewer results than attacks using conventional explosives. In the March 1995 Tokyo subway attack — Aum's most successful — the group placed 11 sarin-filled plastic bags on five different subway trains and killed 12 people. In the 2004 Madrid attack, jihadists detonated 10 improvised explosive devices (IEDs) and killed 191 people. Aum's CBW program cost millions and took years of research and effort; the Madrid bombings only cost a few thousand dollars, and the IEDs were assembled in a few days. The most deadly biological terrorism attack to date was the case involving a series of letters containing anthrax in the weeks following the Sept. 11 attacks — a case the FBI calls Amerithrax. While the Amerithrax letters did cause panic and result in companies all across

the country temporarily shutting down if a panicked employee spotted a bit of drywall dust or powdered sugar from doughnuts eaten by someone on the last shift, in practical terms, the attacks were very ineffective. The Amerithrax letters resulted in five deaths; another 22 victims were infected but recovered after receiving medical treatment. The letters did not succeed in infecting senior officials at the media companies targeted by the first wave of letters, or Sens. Tom Daschle and Patrick Leahy, who were targeted by a second wave of letters. By way of comparison, John Mohammed, the so-called "D.C. Sniper," was able to cause mass panic and kill twice as many people (10) by simply purchasing and using one assault rifle. This required far less time, effort and expense than producing the anthrax spores used in the Amerithrax case. It is this cost-benefit ratio that, from a militant's perspective, makes firearms and explosives more attractive weapons for an attack. This then is the primary reason that more attacks using biological weapons have not been executed: The cost is higher than the benefit. Certainly, history has shown that militant organizations and homegrown militants are interested in large sporting events as venues for terror; one needs to look no further than the 1972 Munich Massacre, the 1980 Olympic Park bombing or even the 2005 incident in which University of Oklahoma student Joel Hinrichs died after a TATP-filled backpack he was wearing exploded outside a football game at Oklahoma Memorial Stadium, to see this. Because of this, vigilance is needed. However, militants planning such attacks will be far more likely to use firearms or IEDs in their attacks than they will biological agents. Unfortunately, in the real world guns and suicide bombs are far more common — and more deadly — than air horns filled with creepy bioterror.

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Any affirmative solvency would be short term as affirming will prevent the discovery of future medicines the world will need.

Bacchus 20, James Bacchus (is a 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. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland), "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," CATO Institute, December 16, 2020, https://www.cato.org/free trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines

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 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 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 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.