### Framing

**We just have to win a high probability of our impact scenario and it should come first. There are no infinite extinction scenarios just the da.**

**Bostrom 11**

Nick Bostrom (Future of Humanity Institute & Professor at Oxford). “Infinite Ethics.” *Analysis and Metaphysics*, Vol. 10 (2011): pp. 9-59. http://www.nickbostrom.com/ethics/infinite.pdf

By discounting values that are spatiotemporally remote from the decision‐maker, one could prevent dangerous infinities from arising in certain cases. The cost of this option, however, is forbidding. To be effective, it would have to involve both temporal and spatial discounting. Temporal discounting, as an alleged feature of fundamental axiology, rather than as a merely practically convenient proxy, is often viewed with great suspicion. Spatial discounting has been seen as a patent absurdity. Thus, Derek Parfit:

Remoteness in time roughly correlates with a whole range of morally important facts. So does remoteness in space… But no one suggests that, because there are such correlations, we should adopt a Spatial Discount Rate. No one thinks that we would be morally justified if we cared less about the long‐range effects of our acts, at some rate n percent per yard. The Temporal Discount Rate is, I believe, as little justified.26

We don’t mean everything that could possibly contribute to these scenarios, just why the aff is going to lead to this catastrophic impact, judge should default if there is a credible impact scenario not just bc it is extinction – if both of us have a credible ! scenario for structural violence or extinction then they should vote for us – we are giving a very well researched reason that causes bioterror

Also always a risk of producing structural violence of some sort so if it applies to us then it applies to them.

Nixon – bioterrorism is not some immediate impact, it is the slow violence that they talk about. The process of dying from some engineered disease is long and painful. The fights of it all and the fears of it is slow violence that their cards talk about. The bio terror scenario specifically is credible bc their aff is about it – so we all agree on this bad issue and that there are health disparities and drug – we just think that the aff makes it radically worse than the squo, there is no huge new scenario

### 1NC – Innovation

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

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

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.**

**Marjanovic and Fejiao ‘20** Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

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.

#### Bioterrorism and future pandemics cause extinction.

Hamish De Bretton-Gordon, CBRN Expert @ British Army, 20 [Director @ DBG Defense, Consultant on CBRN and Biosecurity], “Biosecurity in the Wake of COVID-19: The Urgent Action Needed,” Combatting Terrorism Center Sentinel, November/December 2020, Volume 13, Issue 11, <https://ctc.usma.edu/biosecurity-in-the-wake-of-covid-19-the-urgent-action-needed/> C.VC

Policymakers around the world did not grasp just how large the impact of a bio threat could be. Beyond the enormous human and economic impact, the current pandemic has exposed the weakness, lack of preparedness, and poor responsiveness of healthcare systems of even highly developed countries like the United States and the United Kingdom. And the virus has inflicted carnage, even though SARS-CoV-2 (the virus that causes COVID-19) is not especially virulent. The world may be confronted with other viruses in the future whose combination of virulence (the harm a pathogen does to its host), transmissibility, and other characteristics pose much greater danger.

While overwhelming evidence points to SARS-CoV-2 spontaneously spreading to humans, the advances in synthetic biology and the growth in the number of Level 3 and 4 biocontainment facilities around the world storing deadly viruses1 mean there is also the very real possibility that in the future, bad actors will try to engineer or steal/obtain a highly transmissible and highly virulent virus and unleash it onto the world. Another risk is accidental releases from such biocontainment facilities.

COVID-19, a highly transmissible but not very virulent pathogen, has had a devastating global impact, a fact that will not have gone unnoticed by rogue states and terror organizations. Advances in synthetic biology have created tools that could be put to malevolent use. In the last two decades, scientists synthesized the poliovirus from its genetic sequence,2 recreated the 1918 Spanish flu virus,3 and succeeded in modifying the H5N1 avian flu virus so that it resulted (in a research laboratory) in airborne transmission among mammals.4 In the future, we should think of weaponized biology as no less of an existential threat to the planet than weaponized atomic science. It should also be noted that the fear and panic that even a medium-scale bioterror attack could create could have dangerous implications that may rival or even surpass the immediate loss of life.

The Need to Rethink Likelihood

Given the fact that in late 2019 when, as far as is known, COVID-19 cases first started emerging in China, it had been more than a century since the previous catastrophic outbreak (the 1918-1919 “Spanish flu” pandemic),d it was unsurprising that many thought of such pandemics as a one-in-a-100-year event. Such assumptions should no longer hold. The encroachment of human settlements into areas that had previously been sanctuaries for wildlife5 and the popularity in some parts of the world of markets where people and wild animals are brought into proximity have made it more likely viruses will make the species leap to human beings.e And when they do, as the COVID-19 pandemic illustrated, the interconnectedness of a world in which millions of people fly each day6 means they can spread very rapidly.

There is also growing concern about engineered viruses. Not only have advances in synthetic biology (SynBio) created growing capacity for extremely dangerous viruses to be engineered in a laboratory, but the number of people with access to potentially dangerous ‘dual use’ technology has greatly expanded and continues to expand, making malevolent use of such technology ever more likely.

In the August 2020 issue of this publication, scientists at the U.S. Military Academy at West Point warned that:

The wide availability of the protocols, procedures, and techniques necessary to produce and modify living organisms combined with an exponential increase in the availability of genetic data is leading to a revolution in science affecting the threat landscape that can be rivaled only by the development of the atomic bomb. As the technology improves, the level of education and skills necessary to engineer biological agents decreases. Whereas only state actors historically had the resources to develop and employ biological weapons, SynBio is changing the threat paradigm.

The cost threshold of engineering viruses is also lowering, with the West Point scientists warning that synthetic biology has “placed the ability to recreate some of the deadliest infectious diseases known well within the grasp of the state-sponsored terrorist and the talented non-state actor.”7

As already noted, another source of vulnerability is that deadly viruses could be stolen from or escape from a research laboratory. There are now around 50 Biosafety Level 4f facilities around the world, where the deadliest pathogens are stored and worked on, and this figure is set to increase in the next few years.g This is a large increase over the last 30 years, creating bigger risk of a breach. Of equal, if not greater concern are the thousands of Biosafety Level 3 labs globally,8 which handle deadly pathogens like COVID-19.9

Given what has been outlined above, the risk of a future destructive biological attack or another devastating global pandemic should no longer be seen as low. From this point forward, there should no higher priority for the international community than biosecurity.

### 1NC - CP

#### International donors should allocate 30% of vertical disease funding towards infrastructure in developing nations.

#### Disease specific funding causes budget imbalances and inequity in treatment. Using that funding to improve primary health care is key to non-HIV diseases and pandemics.

De Maeseneer et al. ’20 (Jan De Maeseneer is the Head of the Department of Family Medicine and Primary Health Care of Ghent University. He is also the Director of the International Centre for Primary Health Care and Family Medicine; Jan De Maeseneer, Donald Li, Bjorg Palsdottir, November 2020, “Universal health coverage and primary health care: the 30 by 2030 campaign,” Bulletin of the World Health Organization, <https://www.researchgate.net/publication/345938887_Universal_health_coverage_and_primary_health_care_the_30_by_2030_campaign>)

The World Health Organization (WHO) considers primary health care a cornerstone of universal health coverage (UHC) and describes it as an approach to health and well-being centred on the needs and circumstances of individuals, families and communities. Primary health care should address physical, mental and social health and well-being, and is about providing whole-person care for health needs throughout life, not just treating a set of specific diseases.1 We argue that implementing primary health care should focus on broadbased participatory action, including integrated and comprehensive personcentred care, community development and social determinants of health. The 30 by 2030 campaign To prevent most diseases and treat people in a holistic way, community-based primary health-care systems need to be strengthened. Therefore, organizations such as the World Organization of Family Doctors, European Forum for Primary Care, African Forum for Primary Care, Primary Health Care and Family Medicine, as well as The Network: Towards Unity for Health and Training for Health Equity Network are launching the 30 by 2030 campaign in November 2020. These organizations call for international donors to assign 30% of their vertical top-down, disease oriented budgets to strengthening integrated horizontal community-based primary health-care systems by 2030. The campaign seeks to put into practice Resolution WHA62.12, which urges Member States “to encourage the development, integration and implementation of vertical programmes, including disease-specific programmes, in the context of integrated primary health care.”2 This integration should also allow primary health-care services to become more responsive to the health needs of populations. The campaign has two components: (i) information, analysis and awareness on the impact of vertical programmes on health systems; (ii) encouraging the use of 30% of vertical donor investment to strengthen primary health-care services through coordination, increased human resources and improved infrastructure. The first component The average public expenditure in the WHO Africa Region on non-primary health care (hospitals and specialist care, mostly used by population groups with high incomes) is up to three times higher than the spending on primary health care and prevention.3 Only one third of total spending on primary health care comes from governments, and the lower the country’s income, the lower the share. The predominant source of financing for primary health-care services are private and external funds, including out-of-pocket expenses.3 Most of these funds are channelled through categorical programmes – that is, programmes that focus on the health problems of specific population subgroups or conditions – with little funding going through integrated primary health-care services, which address health conditions in a holistic manner. In the strategy to achieve UHC, WHO has put forward the target of adding 1% of gross domestic product (GDP) to the budget of primary health care. In low-income countries, adding 1% of GDP to current primary healthcare expenditures would increase annual spending in this sector, per capita, from 26 United States dollars (US$) to US$ 33.4 Such an increase could help, but new strategies should be explored to further strengthen primary health care. In 2006, the United States President’s Emergency Plan for AIDS Relief (PEPFAR) provided Zambia with a budget of US$ 150 million targeted for human immunodeficiency virus (HIV), whereas the entire budget of the health ministry was only US$ 136 million. This is an example of unbalanced distribution of health funding, and it continues to occur across sub-Saharan Africa.5 In many countries in the African continent, people living with HIV receive free care, food and educational grants for their children, whereas those with other diseases receive poor care and still have to pay out-of-pocket, leading to inequity by disease. Worldwide, the primary care facilities that address all diseases across the life-cycle, including common illnesses such as diarrhoea, malnutrition and respiratory tract infections, are largely underfunded. In addition, salaries of health-care providers working for donor-funded vertical programmes are often more than double those of equally trained government workers in the fragile public health sector, creating an internal brain drain. Interviews with 796 alumni from a medical school in Uganda found an influence of the PEPFAR projects on career choices of health professionals, with almost half working for an HIV-related nongovernmental organization and only over one third for government. We recommend that donor funds earmarked for HIV be channelled to primary health-care budgets through the 30 by 2030 mechanism, to attract health workers into other disease areas and broaden health-care capacity.6

## Adv 1

### Plan already done

#### WTO already did the AFF – Doha Declaration nullifies medical patents for developing countries struggling with pricing

**World Trade Organization 17** (World Trade Organization – you should know who this is, “WTO IP rules amended to ease poor countries’ access to affordable medicines”, <https://www.wto.org/english/news_e/news17_e/trip_23jan17_e.htm>, 23 January 2017, EmmieeM)

**An amendment to** the agreement on **intellectual property entered** into force today (23 January) **securing for developing countries a legal pathway to access affordable medicines under WTO rules**.

The amendment to the WTO Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement marks the first time since the organization opened its doors in 1995 that WTO accords have been amended.

The WTO Secretariat has received in recent days notifications from five members that they have ratified the protocol amending the WTO TRIPS Agreement. These notifications — from Burkina Faso, Nigeria, Liechtenstein, the United Arab Emirates and Viet Nam — brought to two-thirds the number of WTO members which have now ratified the amendment. The two-thirds threshold was needed to formally bring the amendment into the TRIPS Agreement.

Members took the decision to amend the TRIPS Agreement **specifically to adapt** the **rules** of the global trading system **to the public health needs of people in poor countries**. This action follows repeated calls from the multilateral system for acceptance of the amendment, most recently by the United Nations General Assembly High-Level Meeting on Ending AIDS in June 2016.

“This is an **extremely important amendment**. It **gives legal certainty that generic medicines can be exported at reasonable prices to satisfy the needs of countries with** no pharmaceutical production capacity, or those with **limited capacity**. By doing so, **it helps the most vulnerable** access the drugs that meet their needs, helping to deal with diseases such as HIV/AIDS, tuberculosis or malaria, as well as other epidemics. I am delighted that WTO members have now followed through on their commitment and brought this important measure into force,” said WTO Director-General Roberto Azevêdo. In video statements available here, some of the key players share their thoughts on the TRIPS amendment.

Unanimously adopted by WTO members in 2005, the protocol amending the TRIPS Agreement **makes permanent a mechanism to ease poorer WTO members’ access to affordable generic medicines produced in other countries**. The amendment **empowers** importing **developing and least-developed countries facing public health problems and lacking** the **capacity to produce drugs** generically to seek such medicines from third country producers under "compulsory licensing" arrangements. Normally, most medicines produced under compulsory licences can only be provided to the domestic market in the country where they are produced. This amendment allows exporting countries to grant compulsory licences to generic suppliers exclusively for the purpose of manufacturing and exporting needed medicines to countries lacking production capacity.

“As important as trade policy is, health and well-being must take precedence,” said Amina Mohamed, Kenya’s Foreign Minister who chaired the WTO General Council at the time when the amendment was approved in December 2005. “WTO members recognise this and have proven how seriously they take health issues by ratifying and putting into force an amendment to WTO rules which will facilitate access to essential medicines in low income countries.”

The amendment provides **a secure and sustained legal basis for** both potential exporters and importers to adopt legislation and establish the means needed to allow **countries** with limited or no production capacity **to import affordable generics from countries where pharmaceuticals are patented**. More and more WTO members are taking practical steps to implement the system in their laws. The bulk of global medicine exports is covered by laws enabling exports under this system, opening up new options for potential beneficiaries to access a wider range of potential suppliers and enabling new, innovative procurement strategies.

#### Kellner does not talk about the aff – cannabis patents are not the same as medicine and proves nothing about the aff solving. Means no il to global south !

#### AT staral: This invalidates the IPRs of western pharmaceutical companies and *terminates* their ‘*ethical right’* to Indigenous knowledge.

**Breske 4** [Ashleigh, visiting assistant professor of international studies in the global politics and societies (GPS) department @ Hollins University. She earned her Ph.D. in planning, governance, and globalization at Virginia Tech, her M.A.L.S. in social sciences with a focus on Roman history from Hollins University, and her B.S. in biology with a concentration in classical studies and chemistry. Her current research explores how institutions and cultural values mediate changes in repatriation policy for indigenous cultural property, “Biocolonialism: Examining Biopiracy, Inequality, and Power”, Spectra, 6(2), pp.58–73. DOI: http://doi.org/10.21061/spectra.v6i2.a.6]//pranav

Looking at the production of pharmaceuticals, **we can see the importance of Intellectual Property Rights (IPRs) in the debate over the accessibility of indigenous knowledge to outside corporations and investors**. IPRs impact many different fields: healthcare, biodiversity, technology, human and cultural rights, research and development, and agricultural innovations; but, the international system that established international intellectual property rights was hastily organized and linked to trade agreements. xli Shiva claims **IPR laws, under the development of TRIPS and the World Trade Organization (WTO), “have unleashed an epidemic of the piracy of nature’s creativity and millennia of indigenous innovation**.” xlii Transnational corporations are taking advantage of slight “innovations” on traditional knowledge to maintain many of their IPRs. xliii **Together, IPRs and TRIPS, work to suppress indigenous peoples’ ability to control their traditional way of life**. The regulatory system includes domestic laws of developed areas of the world, like the United States, Japan, and Europe, and broader international intellectual property rights agreements. **These agreements resemble doctrines promoting colonialism since they are legal documents fostering the idea of ownership by the dominant colonizers.** Xliv Attempts have been made to establish a declaration that would negate corporate intellectual property rights if public health issues were brought forward by struggling nations’ governments. xlv **But this does not address the issue of restoring indigenous intellectual property rights. Large pharmaceutical corporations in the United States and the European Union have used their vast corporate wealth to prevent the nullification of their IPRs. The inability to invalidate their IPRs means that pharmaceutical companies have ensured rigidity in the trade agreements and prevented generics from being manufactured. This has also ensured their continued legal right to Indigenous knowledge, if not an ethical right**. xlvi Patents are an apparatus of power with universal political and social consequences. Patent policies are developed in western countries but affect poorer, marginalized areas of the world. Unfortunately, there is no international governing body through which all patents are channeled, and they are granted according to individual national domestic laws. These patents are generally established in western countries like Canada, the European Union, and the United States. For all intents and purposes, pharmaceutical companies have more legal rights than people due to trade liberalization.

## Adv 2 -

#### Turn - Patents are key to adequate regulation and testing of drugs -- AFF leads to rampant counterfeiting and unsafe medication, which threatens public health, kills most vulnerable patients, and causes narcotic/human trafficking to surge. Especially true now due to public desperation over COVID, rise in e-commerce, and expansion of substandard medicine manufacturers targeting critical life-saving drugs