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Resolved: The member nations of the World Trade Organization ought to reduce intellectual property for medicines.

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Topic Analysis and Background

Coming off the throes of Nationals, it is fitting to start the new season with another public health topic: Resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines. For many debaters, old impacts about the danger of pandemics can be recycled for September. However, the Nationals topic did not deal explicitly with intellectual property rights, so defining that term is imperative. The Journal of Advanced Technology and Research defines *intellectual property rights* as "legal rights given to the inventor or creator to protect his invention or creation for a certain period of time" (Bhattacharya & Saha, 2011). Intellectual property protections (IPP) are set at 20 years to give the creator of the medication time to profit from its sales. The rationale for this is that medical development is costly, and allowing for guaranteed profit reduces the risk of quality medical research. Whether intellectual property protections are necessary for this, however, will be the crux of the debate.

Intellectual property protections have a rich history in the WTO, and understanding that background will be helpful in both rebuttal and cross-examination. The main agreement through the WTO is the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). TRIPS set a unified minimum standard of intellectual property protection that member nations were obligated to follow (Hoen et al., 2011). Before TRIPS, the patent systems between countries differed, and governments could opt to exempt certain products from patent protection (Crook, 2005). For many developing countries, exemptions were common, and TRIPS meant that many were offering patents on medications for the first time. TRIPS, therefore, represented a more substantial shift in legal policy for the developing world than the developed.

TRIPS, however, caused significant controversy in the developing world. The concern was that requiring intellectual property protections would reduce the ability of LDCs to offer life-saving treatments for their citizens. In 2001, to remedy this, WTO member nations issued the Doha Declaration. The Doha Declaration declared that "least-developed country members… were not obliged to implement patent law for pharmaceuticals until January 1, 2016" (Westerhaus & Castro, 2006). Historically, many developed countries did not require patents on medications until they had developed enough to manufacture branded medicines of their own. Thus, the Doha Declaration provided developing countries with a bit of leeway to ease their transition.

The extension of patent exemption, however, was not the only concern of least-developed countries. In the original TRIPS Agreement, the only exemption for violating intellectual property protections was the ability to manufacture generic drugs (copies of patented versions) in the face of a public health emergency. The issue, however, was that this rule only assisted countries that could manufacture generic drugs themselves; the majority of the Global South lacked supplies and equipment needed for production. In response, in 2003, the WTO member nations issued the Decision on Implementation of Paragraph 6 of the Doha Declaration. The decision included a litany of temporary waivers, the most important being a waiver to Article 31. Before the decision, Article 31 declared that countries could only manufacture generic medications for their citizens in light of a public health crisis. The decision, however, opened up their ability to export them to countries without manufacturing capabilities (Kerry & Lee, 2007). The exemptions, therefore, allowed countries that could not receive essential medicines a path to treatment.

Framework

Though intellectual property protections do not often focus on moral issues, several frameworks allow one to tap into philosophy. Human rights advocates point to several international covenants that establish a right to health. The Constitution of the WHO requires the right to the "enjoyment of the highest attainable standard of health" as a fundamental right, with health defined as a "state of complete physical, mental and social well-being" (Crook, 2005). Similarly, the International Covenant on Economic, Social, and Cultural Rights (ICESCR) guarantees "all individuals the right to the benefits of scientific progress, which could include access to break-through medications" (Crook, 2005). International law links best to an affirmative that focuses on the failure of patents to allow communities to access lifesaving medicines by focusing on a legal obligation to such treatment.

The second potential framework is Rawls/structural violence. The history of patents makes this argument clear, as patents have historically benefited the developed world. However, before the TRIPS agreement, patents only applied after a certain level of development had been achieved. Because the TRIPS Agreement subjugated countries regardless of development, there are concerns of distributional fairness. Similarly, this concern also arises because developing countries cannot subsidize medications to the extent of the developed world (Mah, 2019). Therefore, their citizens are left at the mercy of the high prices set by the pharmaceutical companies. Rawls specifically links best to an affirmative running arguments focused on both price and disparities between the Global North and South. Structural violence, however, can also be run on the negative. The argument here is that manufacturing disparities necessitate a donation program instead of a blanket waiver to IPP. Negatives would argue that this best solves access issues and thus the structural violence concerns forwarded in the Doha Declaration.

The final framework is sovereignty-based. Essentially the argument here is that the patent system is an extension of a country's sovereignty. The caveat of running this framework is that having responses to the argument that global health outweighs the ability of one country to profit off its patent is imperative. The other issue is that IPP protections through the WTO replaced the patent system where each country determined what drugs would receive protection, a purely sovereign decision instead of one mandated by the international community.

AFF Playbook and Arguments

The affirmatives for this topic will all surround the idea of access. The most relevant link here is that intellectual property protections result in exorbitant prices for medicine that erodes the ability of least developed countries to afford treatment. The journal, Nature, explains that the main reason for these high costs is that patent protection gives pharmaceutical companies a temporary monopoly on the medication, and as a result, the ability to charge whatever they want (Rajkumar, 2020). The International Journal of Health Services found that a "higher level of IPR is associated with low access to prescribed medicines" (Jung & Kwon, 2015). Concerningly, the journal found the same results even when controlling for GDP and level of development. Pharmaceutical companies frequently argue that broken health care systems in the Global South are the primary reason for access issues; however, the journal's conclusion suggests that advocates of the poverty, not patents argument are incorrect.

One of the most important case studies to highlight access disparities is HIV. When antiretroviral cocktails (ARVs) were first released, patents protected them. Due to patent protection, the cost of combination therapy was $10,000-$15,000 per patient per year (Forsythe, 2019). For many developing countries, this price denied the majority of their population from accessing treatment. These prohibitive costs resulted in developing countries looking to other manufacturers for medicine. In 2001, this new supply line opened up: Indian pharmaceutical company Cipla Ltd. Cipla began offering AIDS cocktails at less than $1 a day, enabling millions across the developing world to access medications (McNeil, 2001). The use of generic drugs also expanded patient outreach when the US began giving more money to global AIDS prevention. When the President's Emergency Plan for AIDS Relief (PEPFAR) switched to generic drugs, the number of patients on HIV treatment increased from 66,700 to 3,905,500 (El-Sadr et al., 2012). The HIV case study is beautifully articulated in the Netflix Documentary *Fire in the Blood*, and I strongly encourage watching that before competition. Understanding how generic drugs increase the treatment population is imperative.

The other prominent case study will be COVID-19. Like HIV, there is a significant disparity in vaccine access between the Global North and South: "By late June 2021, 46% of people in high-income countries had received at least one dose of the covid-19 vaccine compared with 20% in middle-income countries and only 0.9% in low-income countries" (Erfani et al., 2021). Infectious disease

experts explain that equitable vaccine access is necessary to stop the pandemic. As more individuals get infected, the virus reproduces more frequently. This reproduction raises the risk that the virus will mutate, and another variant will emerge. Advocates of patent waivers argue that waiving IPP can allow the Global South to produce vaccines and expand vaccine coverage. The WHO has recognized manufacturing capabilities in many developing countries and launched mRNA technology transfer hubs to allow for training and logistical support for vaccine production. South Africa was chosen as the first hub, and the removal of IPP could encourage more hubs to appear in the developing world (Erfani et al., 2021). A waiver, therefore, would allow for vaccine production now and a buildup of necessary infrastructure to fight future pandemics.

As HIV and COVID make clear, there are significant differences in medical access between the Global North and South. There are two unique strategic ways to leverage this argument that goes outside the generic access contentions. First, despite the existence of TRIPS flexibilities, those provisions have often been denied to developing countries. Article 31 of TRIPS allows countries to import generics during a public health emergency. During the AIDS epidemic, South Africa began importing generic ARVs, arguing that importation was legal under Article 31. However, instead of granting the waiver, the US put South Africa on a sanctions watchlist for infringing on intellectual property rights, declaring their mounting case count did not justify a public health emergency (Borger, 1999). However, when the US made a similar argument during the Anthrax Attacks, politicians pushed for the end of patents on the drug Cipro. Comparing the two pandemics, 4.7 million patients had contracted AIDS at the time, whereas only 13 individuals died from the Anthrax Attacks, making it clear that patent protection disproportionately serves the interests of MDCs (Singh, 2002). Second, patent protections give disproportionate attention to diseases that impact the developed world. The International Journal of Health Services reports that 90% of the world's health research is committed to diseases that impact 10% of the population" as pharmaceutical companies prioritize drugs that will sell (Jung & Kwon, 2015). This lack of focus means that even though diseases like malaria, dengue fever, and cholera will likely increase in frequency, money towards their treatment will remain next to non-existent.

Along with concerns of access, structural violence contentions will be run. The structural violence contentions are still related to medical access but allow for a more detailed equity debate. Price issues impact impoverished individuals,

and minority groups bear the brunt of this economic harm due to socioeconomic inequality. White Americans have 8.3 times the net worth of Black Americans, and more than half of uninsured Americans under 65 are from minority groups, which results in struggles more to afford prescription drug prices (Benavidez, 2018). There are two impacts to this. First, medical disparities lead to disparate health outcomes between white and black Americans. Second, ethnicity is a significant predictor in underusing medication (Benavidez, 2018). Medicine underuse leads to disease mutation and reduced efficacy of the drug. Therefore, disparate drug access also raises public health for the whole of society.

NEG Playbook and Arguments

The most common argument for the negative is that patents promote medical innovation. Pharmaceutical companies argue that patents are necessary to recoup the costs of research and development. Journals consistently find that the cost of bringing a new drug to market is between 1-2 billion dollars (Globerman et al., 2016). Waiving patent protection allows generics to enter the market, hurting pharmaceutical companies' profits. Researchers from Boston University found that "for all new molecular entities…, the average brand's unit share of molecule sales declined to 16% 12 months after generic entry, versus 44% in 1999–2000" (Cockburn & Long, 2015). Strategically, this allows negatives to argue that trying to remedy access cannot come at the expense of new drug production. Without the ability to increase innovation and develop new medicines, future pandemics could pose a significant threat.

Another common negative argument will likely be that reducing patents will decrease drug quality. I would not, however, recommend not running the argument that generic drugs are of poor quality. You will struggle to find any sophisticated medical journal that makes this argument and a litany of papers saying generics are bioequivalent to branded drugs. However, arguing that IPP is necessary to prevent counterfeit drug exportation has factual support. Several articles in TRIPS relate specifically to counterfeit medications. For example, Article 45 requires countries producing counterfeit medications to pay adequate damages, and Article 46 requires the disposal of counterfeit products (World Intellectual Property Organization, 2014). As member nations, 160 countries, except for some developing countries, have established legislation for enforcement agencies, the most famous being IMPACT and the UK-based Anti-Counterfeiting Group (World Intellectual Property Organization, 2014). Strategically, this argument allows the NEG to argue that access means nothing if the medications are faulty.

While the affirmative can argue that the FDA standards prevent counterfeit drugs from entering the US, the FDA's inspections are limited, especially at foreign firms. As late as 2010, the US Government Accountability Office found that 64% of foreign drug firms had never been inspected (Macauley, 2019). As late as 2019, the FDA still lacked data on 33% of foreign drug companies (Macauley, 2019). The lack of data, however, is not the only issue. Even when inspections happen, standards are different from domestic firms. For example, while domestic firms receive surprise inspections, foreign companies

generally receive up to 12 weeks' notice before the FDA inspector arrives, raising concerns that foreign companies would have the ability to cover up dangerous practices (Macauley, 2019). Negatives, therefore, can argue that the FDA standards alone are sub-par and negating is necessary.

One alternative negatives can run is that the existing TRIPS flexibilities solve for access to medicines. As discussed above, Article 31 of TRIPS allows countries to import or manufacture generic medications in the face of a public health emergency (Globerman et al., 2016). Researchers from the Global Health Unit in the Netherlands report that in the 176 instances between 2011 and 2016 where countries asked for a waiver, the TRIPS Flexibilities were invoked 86.4% of the time (Hoen et al., 2011). Additionally, the researchers found that 103 instances revolved around the procurement of ARVs (Hoen et al., 2011). This allows negatives to argue that the critical case studies of the US blocking the importation of ARVs to South Africa or Uganda are not the norm, and the TRIPS Flexibilities were useful at mitigating HIV spread. The TRIPS Flexibilities will also become relevant if India and South Africa are granted their waiver for COVID-19. Negatives can argue that a blanket reduction of IPP is not necessary. Instead, one can protect drug quality and allow for drug access in the status quo.

The other alternative is donations. The main argument is that countries will still need supplies and technology to produce the medication if one waives IPP. These barriers become more significant as the manufacturing process increases in complexity. This has led GAVI, the vaccine alliance, to advocate for vaccine donations through COVAX. The goal of COVAX is to have equitable vaccine distribution. Developed countries have committed significant doses to the program, and in June, the G7 countries had committed 1 billion vaccines (Ferguson, 2021). COVAX has had significant success in its early stages. Forty-two days after its first international delivery, COVAX had delivered doses to 100 different economies, 61 being in LDCs (Ferguson, 2021). COVAX, therefore, can solve the issue of unequal production capability, allowing for access without reducing IPP.

Overall, this will be a debate about the best way to ensure access to pharmaceuticals and our ability to deal with future pandemics. Like the Nationals topic, arguing that nothing should be done is a pretty bitter pill to swallow in the face of a global pandemic. Best of luck to all those competing!

Further Readings and Resources

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AFF Evidence

Access

Stronger IPP limits developing country access to medicine

Jung and Kwon 15 [Jung, Youn, Institute of Health and Environment, Seoul National University, Seoul, Republic of Korea and Soonman Kwon, School of Public Health, Seoul National University, Seoul, Republic of Korea, "The Effects of Intellectual Property Rights on Access to Medicines and Catastrophic Expenditure," International Journal of Health Services, vol. 45, no. 3, July 2015, pp. 507–29. DOI.org (Crossref), doi:10.1177/0020731415584560. Accessed: 8/15/2021]

Discussion This study investigated how the national level of IPR is associated with individuals' access to medicines and households' experience of catastrophic expenditure for medicines. **First, our results show that higher level of IPR is associated with low access to prescribed medicines. This adverse relationship between IPR and access to medicines is significant even after controlling for country income level and individuals' socioeconomic status and demographic characteristics**. Adding other variables, which reflect the characteristics of each country's healthcare system, in the model did not change the significant effect of IPR on access to medicines, although the magnitude of the effect slightly decreased. **These results imply that strengthened IPR for pharmaceuticals is functioning as a barrier to people's access to medicines. Even though each country's policy efforts, such as strengthening the infrastructure of healthcare provision and increasing the public expenditure for healthcare, have contributed to offsetting the negative impact of IPR on medicine utilization to some extent, the effect of IPR was still significant.** Our results also show that IPR exerts an influence on medicine utilization only in countries above a certain income level. We did not observe the significant effect of IPR on access to medicines in low-income countries where GDP per capita is below $1000, whereas it was negatively associated with access to medicines in middle-income countries. These results are more likely to be related with access to healthcare, which is the premise of utilizing the prescription drugs. This study only included the population for whom medicines were prescribed when they visited health care providers, excluding the population who could not see healthcare providers even though they were in need. Given that a greater number of people are suffering from poor access to healthcare in low-income countries than in middle-income ones, no association between IPR and access to 524 International Journal of Health Services 45(3) medicines in low-income countries is more likely to be explained by this kind of sample selection problem. Furthermore, a gap between rules and practice in the enforcement of IPR may contribute to the non-significant impact of IPR in low-income countries. As Shadlen and colleagues pointed out,41 low-income countries may have a large gap between rules and reality with regard to IPR, considering their limited resources for implementation and enforcement of IPR. The GP index that we used as an index of IPR in this study was developed by a text-based approach using the existing legal and institutional arrangements for patent systems, so it may not show us the full picture of actual protection level for IPR. Thus, we cannot exclude the possibility of this type of measurement error in low-income countries. We also found that those who live in rural areas have better access to medicines than those who live in urban areas. This may be related to sample selection process. Rural areas are likely to have inferior healthcare infrastructure, so rural residents have more difficulties in utilizing healthcare service. Because rural residents included in this study are those who visit healthcare providers despite this barrier, it is possible that they have more propensity to use healthcare, including prescribed medicines, than urban residents. This possibility is supported by the result that the coefficient of rural residence is bigger and significant in lowincome countries, but not in middle-income countries, because the difference in healthcare infrastructure between rural and urban areas would be bigger in low-income countries than in middle-income ones. Next, our results show that the effects of the national healthcare system on access to medicines are not the same across countries with different income levels. Although essential medicines lists and the number of doctors had positive significant relationships with access to medicines in low-income countries, only a public share of total health expenditure had a significant impact in middleincome countries. This suggests that the main types of access barrier that countries face are different according to their income level. Middle-income countries tend to suffer from nonaffordable price of medicines rather than availability problems, whereas low availability of essential medicines is a more serious issue for low-income countries. Last, our results show that IPR is not associated with households' catastrophic expenditure for medicines even though it is significantly associated with access to prescribed medicines. This is due to the possibility that many people cannot purchase medicines at all because of their poor purchasing capacity and the high price of medicines. As a result, they are likely to be excluded from the analysis. **Accordingly, the results of this study provide strong empirical evidence for the linkage between IPR and access to medicines in developing countries. As we hypothesized, strengthening IPR led to lower access to medicines in developing countries, and particularly lower access for the poorest of the**

poor. This result Jung and Kwon 525 supports previous theoretical debate that patent protection may result in welfare loss in developing countries.6,18,42

Affordability proves a major barrier to LDC drug access, and patents are significantly increasing drug costs

Oxfam 01 [Oxfam, "Patent injustice: How world trade rules threaten the health of poor people," Oxfam, Jan 2001, https://www.eldis.org/document/A29216, Accessed 8/15/2021]

The affordability of medicines is only one of the problems facing poor countries. Inadequate and inequitable public spending on health infrastructure, weak planning, failure to prioritise preventative interventions, and ineffective service provision are also contributory factors. **But the price of basic medicines is a vital factor in determining public health. The price of medicines is a critical issue in rich countries as well as in poor. In Britain and the United States, the budget implications of escalating drugs prices are a matter of mounting political concern**. But it is the poorest countries, where budget resources are more limited, and where household poverty is most widespread, that face the gravest threat from rising drugs prices. **Most health spending in the poorest countries comes directly out of household budgets, rather than though national health budgets or pre-paid insurance schemes. For the poor, the cost of treating sickness is often prohibitive. In Zambia, where two-thirds of rural households live below the poverty line, it costs one such household US$9 to treat a single case of childhood pneumonia - an amount equivalent to half the family's monthly income. The high cost of treatment relative to income can result in poor households either delaying or not seeking treatment**. It can also lead to the diversion of expenditure from other vital areas such as food and education. The WTO and drugs: the rules are loaded against the poor **The WTO's Agreement on Trade Related Intellectual Property Rights (TRIPS) establishes minimum standards for intellectual property protection, including the right to exclusively market a patented product for at least 20 years.** Some Northern governments are using bilateral and regional trade agreements to negotiate even more stringent protection for patents under so-called 'TRIPS plus' agreements. WTO rules recognise the potential conflict between public-health interests and the private interest of patent holders. Under Article 31 of the Agreement, governments can issue compulsory licences to authorise production without the consent of patent holders, subject to adequate compensation. Another measure open to governments is that of parallel importing, whereby governments allow the importation of a patented product which is marketed elsewhere at prices lower than those in the domestic market. These safeguards should be strengthened. There is a need to clarify and broaden the criteria for introducing compulsory licences, and to diminish the burden of proof currently placed on governments seeking to establish public-health threats as grounds for compulsory licensing. In the event of a dispute, patent holders should be required to prove that there is no threat to public health from the strict application of their patent privileges. Even with less onerous conditions for compulsory licensing, countries with limited production capacity or small internal markets will find it impossible to obtain the required drug at an affordable price, unless there is a larger country which is producing it under a compulsory licence and which is willing and able to export it to them. The deeper problem lies in the unwarranted political influence of pharmaceutical corporations which leads to a subordination of trade policy to corporate goals, notably in the USA**. In the course of the past year, a large number of developing countries, which have failed to strengthen patent rules on terms dictated by PhRMA, have been threatened with trade sanctions: India has been placed on the hit list for trade sanctions for failing to include highly restrictive compulsory licensing conditions in national legislation, and for allowing generic companies to export copies of patented drugs. These exports are a major source of basic medicines for low-income developing countries.** The US has threatened trade sanctions against the Dominican Republic, including the withdrawal of trade preferences for textiles, for failing to comply with the demands of PhRMA members. Despite the small size of the local market, the country has been targeted by PhRMA, which claims that it represents a bad example that others will follow. **WTO disputes have been initiated against Argentina and Brazil. Both countries are accused of failing to incorporate highly restrictive conditions for the granting of compulsory licences into national legislation. In each case, the target has been national legislation authorising production of low-cost equivalents of patented drugs to meet**

public-health needs. Governments in Europe may have been less public in their threats, but they have silently colluded in supporting the coercive trade diplomacy practised by the United States. PhRMA's political influence comes at a price. **Between 1997 and 1999, PhRMA's members spent US$236m lobbying Congress and the executive branch of government.** Another US$14m was provided to political parties in 1999 alone. Approximately two-thirds of corporate investment in political lobbying in the USA is directed towards the Republican Party, raising concerns about corporate influence over the new Administration. Various polite formulations and legalistic arguments can be used to explain what is happening in the name of IP protection. But the truth is that corporate self-interest is being placed before people's lives. Patents and prices: the threat to public health **Most developing countries have in the past avoided stringent patent regimes on medicines in the interests of public health.** Highly sophisticated generic industries have emerged with a specialisation in the development of low-cost equivalents of expensive patented medicines for low-income populations. **Countries such as India, Thailand, Egypt, and Brazil have succeeded not just in reducing their dependence on imported medicines, but also in developing their capacity to export them. Across sub-Saharan Africa, most front-line medicines used in the treatment of infectious diseases are imported from generic-drugs suppliers**. These drugs are typically available at prices ranging between one-fifth and one-tenth of those for patented brand-name products. **Because generic-drugs industries are able to market products at a fraction of the costs associated with patented brands, they provide a lifeline to low-income households. The WTO agreement on intellectual property rights threatens to cut that lifeline. Price comparisons between Pakistan, which has traditionally provided strong product patent protection, and India, which has one of the world's strongest generic-drugs industries, are instructive. They show that prices for ciprofloxacin, a safe anti-infective medicine used in the treatment of illnesses such as resistant bloody diarrhoea in children, are up to eight times more costly in Pakistan.** Price increases resulting from the extension of exclusive marketing rights will have grave consequences for public health in developing countries. Infectious diseases that were once relatively easily curable with simple antibiotics are becoming increasingly drug-resistant. Old killers such as malaria, tuberculosis, bloody diarrhoea, and respiratory infections - a group of diseases that cost millions of lives each year - are proving increasingly difficult to treat. Improved access to effective and affordable medicines is essential if these threats are to be addressed. But the danger is that use of the next generation of drugs needed to protect public health will be restricted, either by new patent protection or by the extension of old patent rights.

The most important reason for high drug prices is monopolies that can be remedied with modifying patent structure and promoting generics

Rajkumar 20 [Vincent Rajkumar, S- The Division of Hematology, Mayo Clinic, "The High Cost of Prescription Drugs: Causes and Solutions," Blood Cancer Journal, vol. 10, no. 6, June 2020, pp. 1–5. www.nature.com, https://doi.org/10.1038/s41408-020-0338-x, Accessed: 8/14/2021].

The most important reason for the high cost of prescription drugs is the existence of monopoly4,5. For many new drugs, there are no other alternatives. In the case of cancer, even when there are multiple drugs to treat a specific malignancy, there is still no real competition based on price because most cancers are incurable, and each drug must be used in sequence for a given patient. Patients will need each effective drug at some point during the course of their disease. There is seldom a question of whether a new drug will be needed, but only when it will be needed. **Even some old drugs can remain as virtual monopolies. For example, in the United States, three companies, NovoNordisk, Sanofi-Aventis, and Eli Lilly control most of the market for insulin, contributing to high prices and lack of competition6. Ideally, monopolies will be temporary because eventually generic competition should emerge as patents expire. Unfortunately, in cancers and chronic life-threatening diseases, this often does not happen. By the time a drug runs out of patent life, it is already considered obsolete (planned obsolescence) and is no longer the standard of care4. A "new and improved version" with a fresh patent life and monopoly protection has already taken the stage.** In the case of biologic drugs, cumbersome manufacturing and biosimilar

approval processes are additional barriers that greatly limit the number of competitors that can enter the market. Clearly, all monopolies need to be regulated in order to protect citizens, and therefore most of the developed world uses some form of regulations to cap the launch prices of new prescription drugs. Unregulated monopolies pose major problems. **Unregulated monopoly over an essential product can lead to unaffordable prices that threaten the life of citizens. This is the case in the United States, where there are no regulations to control prescription drug prices and no enforceable mechanisms for value-based pricing.** Seriousness of the disease High prescription drug prices are sustained by the fact that treatments for serious disease are not luxury items, but are needed by vulnerable patients who seek to improve the quality of life or to prolong life. A high price is not a barrier. For serious diseases, patients and their families are willing to pay any price in order to save or prolong life. High cost of development Drug development is a long and expensive endeavor: it takes about 12 years for a drug to move from preclinical testing to final approval. It is estimated that it costs approximately $3 billion to develop a new drug, taking into account the high failure rate, wherein only 10–20% of drugs tested are successful and reach the market7. Although the high cost of drug development is a major issue that needs to be addressed, some experts consider these estimates to be vastly inflated8,9. Further, the costs of development are inversely proportional to the incremental benefit provided by the new drug, since it takes trials with a larger sample size, and a greater number of trials to secure regulatory approval. More importantly, we cannot ignore the fact that a considerable amount of public funding goes into the science behind most new drugs, and the public therefore does have a legitimate right in making sure that life-saving drugs are priced fairly. Lobbying power of pharmaceutical companies Individual pharmaceutical companies and their trade organization spent approximately $220 million in lobbying in the United States in 201810. Although nations recognize the major problems posed by high prescription drug prices, little has been accomplished in terms of regulatory or legislative reform because of the lobbying power of the pharmaceutical and healthcare industry. Solutions: global policy changes There are no easy solutions to the problem of high drug prices. The underlying reasons are complex; some are unique to the United States compared with the rest of the world (Table 1). Table 1 Reasons for the high cost of prescription drugs and possible solutions. Full size table Patent reform **One of the main ways to limit the problem posed by monopoly is to limit the duration of patent protection. Current patent protections are too long, and companies apply for multiple new patents on the same drug in order to prolong monopoly.** We need to reform the patent system to prevent overpatenting and patent abuse11. Stiff penalties are needed to prevent “pay-for-delay” schemes where generic competitors are paid money to delay market entry12. Patent life should be fixed, and not exceed 7–10 years from the date of first entry into the market (one-and-done approach)13. **These measures will greatly stimulate generic and biosimilar competition.** Faster approval of generics and biosimilars **The approval process for generics and biosimilars must be simplified**. A reciprocal regulatory approval process among Western European countries, the United States, Canada, and possibly other developed countries, can greatly reduce the redundancies14. In such a system, prescription drugs approved in one member country can automatically be granted regulatory approval in the others, greatly simplifying the regulatory process. This requires the type of trust, shared standards, and cooperation that we currently have with visa-free travel and trusted traveler programs6. For complex biologic products, such as insulin, it is impossible to make the identical product15. The term “biosimilars” is used (instead of “generics”) for products that are almost identical in composition, pharmacologic properties, and clinical effects. Biosimilar approval process is more cumbersome, and unlike generics requires clinical trials prior to approval. Further impediments to the adoption of biosimilars include reluctance on the part of providers to trust a biosimilar, incentives offered by the manufacturer of the original biologic, and lawsuits to prevent market entry. It is important to educate providers on the safety of biosimilars. A comprehensive strategy to facilitate the timely entry of cost-effective biosimilars can also help lower cost. In the United States, the FDA has approved 23 biosimilars. **Success is mixed due to payer arrangements, but when optimized, these can be very successful. For example, in the case of filgrastim, there is over 60% adoption of the biosimilar, with a cost discount of approximately 30–40%16.** Nonprofit generic companies **One way of lowering the cost of prescription drugs and to reduce drug shortages is nonprofit generic manufacturing. This can be set up and run by governments, or by nonprofit or philanthropic foundations. A recent example of such an endeavor is Civica Rx, a nonprofit generic company that has been set up in the United States.** Compulsory licensing Developed countries should be more willing to use compulsory licensing to lower the cost of specific prescription drugs when negotiations with drug manufacturers on reasonable pricing fail or encounter unacceptable delays. This process permitted under the Doha declaration of 2001, allows countries to override patent protection and issue a license to manufacture and distribute a given prescription drug at low cost in the interest of public health.

HIV

When ARVs were first released, they were $15,000 per patient per year, far too expensive for the developing world

Forsythe et al 19 [Steven S. Forsythe is deputy director for economics and costing at Avenir Health, in Glastonbury, Connecticut. William McGreevey is an associate professor of international health at Georgetown University, in Washington, D.C. Alan Whiteside is the CIGI Chair in Global Health Policy at the School of International Policy and Governance, Wilfrid Laurier University, in Waterloo, Ontario. Maunank Shah is an associate professor in the Division of Infectious Diseases, Johns Hopkins University, in Baltimore, Maryland. Joshua Cohen is an independent health care analyst in Boston, Massachusetts. Robert Hecht is president of Pharos Global Health, in Boston. Lori A. Bollinger is vice president of Avenir Health. Anthony Kinghorn health economist in the Perinatal HIV Research Unit, University of the Witwatersrand, in Soweto, South Africa, "Twenty Years Of Antiretroviral Therapy For People Living With HIV: Global Costs, Health Achievements, Economic Benefits," Health Affairs, vol. 38, no. 7, July 2019, pp. 1163–72, healthaffairs.org (Atypon), https://doi.org/10.1377/hlthaff.2018.05391, Accessed: 8/14/2021].

In 1987 the US Food and Drug Administration approved the use of azidothymidine (AZT), the first antiretroviral drug for treatment of HIV/AIDS. AZT monotherapy slowed viral replication and disease progression but added only months to life and had severe side effects. HIV rapidly developed resistance to this single drug.1 **In the period 1988–95, four additional reverse transcriptase inhibitors and the first protease inhibitors were approved by the Food and Drug Administration. Scientists recognized that a combination of antiretrovirals could greatly improve treatment outcomes**. In 1995 Merck and the National Institute of Allergy and Infectious Diseases began a trial of a three-drug combination. The success of this was announced at the 1996 International AIDS Conference and in the New England Journal of Medicine.2 **Antiretroviral therapy (ART) using three-drug combinations remained complex, with multiple tablets, complicated schedules, and the need for extensive monitoring**. Poor funding and infrastructure, and sometimes political opposition, challenged many countries that considered expanded provision of ART. **Treatment was expensive, at $10,000–$15,000 per patient per year.**

Rwanda had substantial time delays getting ARVs due to the barriers of TRIPS

D'Angelo et al 21 [Alexa B. D'Angelo, Department of Community Health and Social Sciences, CUNY Graduate School of Public Health and Health Policy Christian Grov, Department of Community Health and Social Sciences, CUNY Graduate School of Public Health and Health Policy Jeremiah Johnson, Treatment Action Group, New York, NY, USA& Nicholas Freudenberg, Department of Community Health and Social Sciences, CUNY Graduate School of Public Health and Health Policy, "Breaking Bad Patents: Learning from HIV/AIDS to Make COVID-19 Treatments Accessible," Global Public Health, May 2021. world, www.tandfonline.com, https://www.tandfonline.com/doi/full/10.1080/17441692.2021.1924223, Accessed: 8/14/2021].

In 2006, Rwanda utilised TRIPS flexibilities to begin the process of exporting a compulsory license to manufacture and import ARVs from Canada into Rwanda through the generic manufacturer Apotex (Kohler et al., 2010**). In this case, the Rwandan government was forced to comply not only with TRIPS articles, but also with Canadian patent law. The exchange was**

marred by constant delays, a result of bureaucratic complexities built into TRIPS and Canadian patent law (Kohler et al., 2010). **The first delay came from a missed formality wherein the Rwandan government did not complete a 'formal' request to begin the importation process. The second delay, a result of Canadian law, forced Apotex to negotiate with the patent holding companies for 30 days to come to a 'reasonable' royalty deal, before they were permitted to apply for a compulsory license from the World Trade Organization (Kohler et al., 2010). After failed negations with the patent holders, Apotex was cleared to pursue a compulsory license with the World Trade Organization. This entire process took thirteen months, followed by five months to manufacture the ARVs for importation (Kohler et al., 2010).** Further, Canadian law stipulated that the importation agreement was valid for two years, and could only be extended if the agreed upon number of pills were not imported during the two-year window. During the twoyear license period, seven million ARVs were imported into Rwanda (Chami & Wasswa-Kintu, 2011). Due to bureaucratic and legal hurdles, Apotex was unwilling to participate in compulsory licensing and importation following this experience (Chami & Wasswa-Kintu, 2011). Additionally, the Rwanda/Canada case revealed to other generic manufacturers how difficult the process was, discouraging other firms from participating in similar efforts (Kohler et al., 2010). **This case highlights some of the challenges that arise when additional patent laws are layered on top of the existing barriers inherent to TRIPS.**

Due to Patent Protections less than 1% of South African's were able to get ARVs

Crook 05 [Jamie Crook- director of litigation for the Center for Gender and Refugee Studies, "Balancing Intellectual Property Protection with the Human Right to Health," Berkeley Journal of International Law *23*(3). 2005. 524-550. https://lawcat.berkeley.edu/record/1119803?ln=en, Accessed: 8/14/2021].

In 2003, the Human Immunodeficiency Virus (HIV) newly infected an estimated five million people worldwide; three million died of complications related to Acquired Immunodeficiency Syndrome (AIDS). 2 Since its discovery in the 1980s, AIDS has killed twenty-two million people worldwide, leaving thirteen million AIDS orphans. 3 The Joint United Nations Programme on HIV/AIDS (UNAIDS) estimates that between thirty-four and forty-six million people around the world are living with the condition.4 **While sub-Saharan African states have suffered the worst epidemics to date, UNAIDS and the World Health Organization (WHO) predict new outbreaks in North Africa, India, China, states in Central Asia, and the Baltic states.**5 HLV/AIDS rates in Latin America are also rising.6 **Globally, costly anti-retroviral drugs that prolong the lives and improve the health of infected individuals do not reach the almost 90% of HIV/AIDS patients living in the poorest 10% of the world's countries. South Africa's experience with the AIDS crisis provides a representative example of the deadly combination of poverty and patent protection in the context of public health disasters. With less than 2% of the global population, South Africa is home to 30% of the world's HIV/AIDS-infected people and to 80% of those patients who cannot afford their own healthcare. 8 Though effective generic anti-retroviral drug therapies can sell for as little as $140 for one year's supply, patent protections prevent their sale in most developing countries.**9 According to a lawyer for South Africa's Aids Law Project, "[i]n South Africa, tens of thousands of people are dying every year because excessive prices are charged for life-saving anti-retroviral medicines." 10 The worst is probably yet to come for South Africa, where lack of access to effective medication will facilitate the rapid spread of AIDS-related deaths over the next five years.1 1 In 2003, UNAIDS and the WHO determined that the immediate implementation of a national anti-retroviral program in South Africa would "significantly cushion the country against the impact" of the AIDS crisis. 12 **Nevertheless, as of October 2003, no generic anti-retrovirals were available in South Africa, desrite the plentitude of successful generic versions produced in India and Brazil.' ,** HIV/AIDS patients in South Africa and throughout the global South would substantially benefit from the increased affordability of generic anti-retroviral drug therapies. **Yet in 2002, out of an estimated**

twenty-eight million people in sub-Saharan Africa living with HIV/AIDS, only 50,000 people, or less than 0.2%, had access to such treatment. 14 This limited access largely results from patent protections held by multinational pharmaceutical corporations that maintain inflated drug prices and severely restrict the generic manufacture of anti-retrovirals. 1 Drug-patent supporters argue that patents guarantee profit returns, which in turn enable continuing research and development. Public health advocates counter that the unfolding AIDS catastrophe requires a more immediate palliative than the distant hope of discovering a cure or treatment, neither of which would likely be any more accessible to infected populations than current patented drug therapies. Tensions between intellectual property protection and the health needs of their impoverished people plague the leaders of developing states, who fear endangering trade relations with wealthy states should they violate the patent rights enforced through various international agreements. 16 This paper will explore whether existing international law creates a right to health that includes a right to generic, or at least affordable, anti-retroviral treatment, enforceable against state and non-state actors seeking to maintain patent protection. It will further consider whether relaxing patent protection is a feasible means toward the ultimate goal of substantially increasing access to anti-retroviral treatment. AIDS is a global threat with unique impacts on many regions; this paper will focus Iprimarily on the impact of U.S. patent-protection policy in sub-Saharan Africa. 1 ' Part I presents the need for increased access to anti-retroviral treatment. Part II examines patent-related barriers to access. Part III summarizes sources of international law that suggest the existence of a right to health that would be enforceable against both domestic governments and third parties, such as other states and multinational corporations. Part IV turns to policy arguments that might encourage wealthier states to take proactive measures to increase access, even at the expense of patent protection. Part V suggests methods for easing patent restrictions that would be consistent with the goal of immediately increasing access to anti-retroviral drug therapy for the world's poorest and most vulnerable HIV/AIDS victims.

Indian company CIPLA sold HIV treatment for less than $1 a day

McNeil 01 [Donald G. McNeil, science and public health reporter at The New York Times "Indian Company Offers to Supply AIDS Drugs at Low Cost in Africa," The New York Times, 7 Feb. 2001. NYTimes.com, https://www.nytimes.com/2001/02/07/world/indian-company-offers-to-supply-aids-drugs-at-low-cost-in-africa.html, Accessed: 8/14/2021].

In a move that could force big drug multinationals to cut the prices of their AIDS drugs in poor countries, an Indian company offered today to supply triple-therapy drug "cocktails" for $350 a year per patient to a doctors' group working in Africa. The Indian company, Cipla Ltd. of Bombay, a major manufacturer of generic drugs, made the offer to Doctors Without Borders, which won the Nobel Peace Prize in 1999 for its work in war-torn and impoverished areas. In Africa the group sets up small pilot programs to develop models for broader approaches to combat AIDS, and would distribute the Cipla drugs free. As part of its program, Cipla **would also sell the drugs to larger government programs for $600 a year per patient, about $400 below the price offered by the companies that hold the patents**. "This is the way to break the stranglehold of the multinationals," said Dr. Yusuf K. Hamied, chairman of Cipla, who will meet with the doctors' group on Feb. 15 to discuss strategy. For two years, Doctors Without Borders has led an aggressive campaign to force multinationals to cut prices on life-saving drugs for the world's poorest patients. ADVERTISEMENT Continue reading the main story Other parties in the campaign are the Philadelphia and Paris chapters of the AIDS Coalition to Unleash Power, and the Consumer Project on Technology, a Washington group started by Ralph Nader. **The normal cost of the AIDS cocktail in the West is $10,000 to $15,000 a year**. Last May five multinationals, backed by the World Health Organization and other United Nations agencies, offered to sell their components to poor nations at sharply reduced prices. But Cipla and other makers of generic drugs in Brazil, Thailand and other countries have not been part of the talks with W.H.O., a situation that Cipla hopes to change with its aggressive entry onto the scene. The country-by-country negotiations about how the multinationals distribute the drugs have gone slowly, and so far only Uganda, Senegal and Rwanda have agreements. The companies refuse to release figures, but the cost of a typical cocktail in Senegal is $1,000 a year, according to Doctors Without Borders. Dr. Bernard Pecoul, director of the Access to Essential Medicines project for Doctors Without Borders, said the Cipla offer, which he learned of only today, "will let us start up our pilot projects on a larger scale." ADVERTISEMENT Continue reading the main story **The doctors' group has 40 AIDS projects around the world, about half in Africa, where the infection rate reaches as high as 36 percent.** Only five of these pilot programs are giving out antiretroviral cocktails. **With the Cipla offer, or matching ones from other companies, up to 20 could be distributing the drugs by the end of year.** Cipla is offering to sell the agency as many doses as it is wants at $350 a year. Dr. Hamied said that his company would lose money at that price, but that he would supply "10,000 doses or 20,000 or 30,000, however many they want." **The $600 price to governments is near**

Cipla's break-even point, he said, but costs could drop with greater production. If that happens, he would cut prices further. In India he sells the same cocktail for about $1,100 a year. But he denied that he was trying to grab market share in Africa. ''What do I want with market share?'' he asked. ''I don't have a monopoly, and the only way to make real money in drugs is with a monopoly. In this disaster, there is room for everybody.'' Wide distribution of the drugs in Africa is not without critics, given the attendant need for careful monitoring. Some experts argue that it would be better to spend the money on providing clean water, controlling malaria and increasing the use of condoms. But Doctors Without Borders says that the dangers and side effects of the drugs pale beside the immensity of the epidemic itself, and that Western testing standards are overcautious. The typical AIDS cocktail is a combination of any three of about nine protease inhibitors or reverse transcriptase inhibitors. The chemicals suppress the human immunodeficiency virus but, as with any chemical therapy, they are toxic and can damage the liver. In the West, doctors carefully monitor the levels of the drug in the blood, test for organ damage and check the levels of the virus in the bloodstream. If the virus mutates to resist the therapy, the combinations are changed. Careful monitoring may not be possible in many African settings. But with 25 million Africans infected with the AIDS virus, Doctors Without Borders and other agencies argue, imperfect treatment is better than none. ADVERTISEMENT Continue reading the main story Dr. Pecoul pointed out that large numbers of infected Africans live in urban areas where, ''with a quite simple clinic, you can deal with anti retrovirals.'' He is also ''not convinced'' that the batteries of tests routinely ordered for Western patients are really necessary. ''Some people suggest that H.I.V. testing and clinical followup can be enough,'' he added. The Cipla drug combination is two tablets of 40 milligrams of stavudine, two tablets of 150 milligrams of lamivudine and two tablets of 200 milligrams of nevirapine. In the United States and many other countries, the Bristol-Myers Squibb Company holds the patent on stavudine, also known as Zerit or d4T; Glaxo-Wellcome of Britain holds the patent on lamivudine, also known as Heptovir or 3TC, and Boerhinger Ingelheim G.m.b.H. of Germany holds the patent on nevirapine, or Viramune. Western drug companies have shown themselves determined to defend their patent rights to be sole distributors throughout the world, and Dr. John Wecker, head of Boerhinger Ingelheim's efforts to negotiate cheaper prices in Africa, said he did not yet know what his company would do if Cipla undercut its prices. ''We offer a standard quality from the original manufacturer and can meet any demand that exists out there that can be delivered with safe procedures,'' he said. He refused repeatedly to say at what price Boerhinger Ingelheim sells nevirapine to Senegal or Uganda, saying, ''Affordability is an issue, but not the major issue.'' Representatives from Glaxo-Wellcome and Bristol-Myers did not return phone calls, but the three companies can be expected to wage a hard fight against the distribution of generic versions of their drugs. ADVERTISEMENT Continue reading the main story Late last year, Glaxo-Wellcome threatened to sue Cipla when it tried to sell Duovir, its generic version of Glaxo's Combivir, a lamivudine/zidovudine combination, in Ghana. Cipla offered the drug for $1.74 a day; Glaxo had cut its price to $2, from $16. But even though the African regional patent authority said Glaxo's patents were not valid in Ghana, Cipla backed down and stopped selling Duovir. Asked what he would do if the three drug companies sued to stop him, Dr. Hamied said: ''We won't fight it. I don't look at it as a fight. There's room for everybody. This is a holocaust in Africa. It's like the earthquake in India right now -- everybody is helping out. I'm not looking to pick anybody's business; there's room for the multinationals at their price and room for us at our price, a partnership.''

Once PEPFAR switched to generic ARVs they were able to dramatically increase patient output

El-Sadr et al 12 [Wafaa M. El-Sadr, Columbia University, Mailman School of Public Health, Charles B. Holmes, MD, MPH, Office of US Global AIDS Coordinator, Washington, DC Peter Mugyenyi, MD, Joint Clinical Research Centre, Kampala, Uganda Harsha Thirumurthy, PhD, Department of Health Policy and Management, Gillings School of Global Public Health, University of North Carolina at Chapel Hill, Chapel Hill, NC.“Scale-up of HIV Treatment Through PEPFAR: A Historic Public Health Achievement,” Journal of Acquired Immune Deficiency Syndromes (1999), vol. 60, no. Suppl 3, Aug. 2012, pp. 96-104, PubMed Central, https://doi.org/10.1097/QAI.0b013e31825eb27b, Accessed: 8/14/2021].

Improved efficiency in selection and transportation of ARVs, the increasing use of generic drugs and fixed-dose combinations (FDCs), and the transition to preferred ARV regimens has lowered the cost of treatment substantially while improving the overall quality of HIV treatment in PEPFAR-supported focus countries. PEPFAR’s per-patient treatment costs, including drugs and service delivery, have declined to $335 per year, from nearly $1100 just 7 years ago.20 One key improvement adopted by the Supply Chain Management System (SCMS), established and funded by PEPFAR and supported by the USAID, was the transition from air transport to land- or sea-based shipment.21 It is estimated that using sea freight for major shipments saved up to 85% in transportation costs, and as of December 31, 2010, sea transport had saved PEPFAR $39.8 million in transportation costs.21 SCMS also established regional distribution centers in Ghana, Kenya, and South

Africa, increasing commodity availability and reducing the lead time needed for delivery. **PEPFAR has also increased its use of generic drugs and FDCs.7 In 2005, only 16% of PEPFAR-procured drugs were generic. This proportion increased to 97% in 2010, resulting in considerable savings compared with branded drugs** (Fig. 1). Between 2008 and 2011 PEPFAR increased purchases of 2- and 3-drug FDCs, as recommended by the WHO (Fig. 2). These regimens are less complex, easier to administer, and may improve patient adherence. Similarly, over the past 4 years since WHO HIV treatment guidelines recommended that countries phase out stavudine in favor of less toxic zidovudine- or tenofovir-based regimens, SCMS orders for stavudine have declined by more than 70%, whereas orders for zidovudine and tenofovir have increased 20-fold (Fig. 3). An external file that holds a picture, illustration, etc. Object name is nihms397419f1.jpg Open in a separate window FIGURE 1 Number of generic versus branded drugs procured (monthly packs, 2005–2010). PEP-FAR increased its use of generic drugs from 16% in 2005 to 97% in 2010. An external file that holds a picture, illustration, etc. Object name is nihms397419f2.jpg Open in a separate window FIGURE 2 Total SCMS orders for 2- and 3-drug ARVs. Between 2008 and 2011, PEPFAR increased its purchases of 2- and 3-drug FDCs, as recommended by WHO. An external file that holds a picture, illustration, etc. Object name is nihms397419f3.jpg Open in a separate window FIGURE 3 SCMS order quantity for zidovudine (AZT), stavudine (d4T), and tenofovir (TDF) in fiscal year (FY) 2008–2011. Since 2008, SCMS orders for stavudine have declined by more than 70%, whereas orders for zidovudine and tenofovir have increased 20-fold. Go to: ACHIEVEMENTS Scale-up of ART Access The number of individuals receiving ART is one metric by which PEPFAR's achievement can be summarized. **PEP-FAR support increased the number of individuals who initiated ART from 66,700 to 3,905,500** (63% women and girls) from 2004 to 2011 (Fig. 4). During the first phase of PEPFAR, there was a rapid increase in the number of patients receiving ART, doubling each year between 2004 and 2007. In addition, during 2008–2011, **PEPFAR increased the number of individuals receiving ART by more than 650,000 patients each year.** Importantly, while the growth of PMTCT programs has likely reduced the number of infants newly infected with HIV each year, HIV-infected children comprise about 9% of those supported on treatment by PEPFAR, up from 7% earlier in the response. The treatment program's rapid expansion is also reflected in the increase in the number of health facilities providing ART, growing from 300 sites in 2004 to more than 6400 in 2009 (last year this indicator was reported centrally). An external file that holds a picture, illustration, etc. Object name is nihms397419f4.jpg Open in a separate window FIGURE 4 Number of adults and children with HIV infection receiving ART with direct PEPFAR support in fiscal year 2004–2011. PEPFAR support increased the number of individuals who initiated ART from 66,700 to 3,905,500. Although the majority of treatment services are concentrated in 8 countries that collectively account for over half of the global HIV/AIDS epidemic, **PEPFAR has supported treatment programs in more than 30 countries around the world26 through contributions to health system's strengthening in the form of policy developments, logistics, protocol or guideline development, advocacy, laboratory support, training, information systems, and capacity building of national HIV/AIDS programs**. PEPFAR also has had a strong focus on ensuring quality of services and has used a variety of methods to monitor and ensure the quality of its programs,27 including sampled national survey studies28 and other methods, as described in more detail in an article in this journal issue.

COVID

By reducing IP, we can boost vaccine manufacturing in LDCs; allowing more suppliers in the market increases vaccine dose supply

Erfani et al 21 [Parsa Erfani, Fogerty Fellow at Harvard School of Public Health, Agnes Binagwaho, Vice Chancellor of the University of Global Health Equity, Mohamed Juldeh Jalloh, Vice President of the Republic of Sierra Leone. I hold a PHD in Political Science from the University of Bordeaux, France, Muhammad Yunus, Recipient of the 2006 Nobel Peace Prize, Paul Farmer, Kolokotrones University Professor and chair of the Department of Global Health and Social Medicine at Harvard Medical School, Vanessa Kerry, founder and CEO of Seed Global Health, "Intellectual Property Waiver for Covid-19 Vaccines Will Advance Global Health Equity," BMJ, vol. 374, Aug. 2021, p. n1837. www.bmj.com, https://doi.org/10.1136/bmj.n1837., Accessed: 8/12/2021].

By late June 2021, 46% of people in high income countries had received at least one dose of the covid-19 vaccine compared with 20% in middle income countries and only 0.9% in low income countries.1 This inequity has been driven by a global political economy that has permitted some countries to purchase more vaccine than they require while others have very limited supplies. **Canada, for example, with a gross domestic product (GDP) of $46 000 (£32 000; €39 000) per head has vaccines for 434% of its population, whereas Jordan, which has twice the incidence of covid-19 and a GDP of $4400 per head, has secured doses for only 6% of its people.**2 As covid-19 variants are already showing some ability to evade the current vaccines**, it is evident that without global vaccine equity and immunity, our efforts against covid-19 are in jeopardy. Equitable vaccine distribution to the world's highest risk populations requires a multipronged approach that includes vaccine development and approval; scaling manufacturing; streamlining shipment, storage, and distribution; and building vaccine confidence.** International collaborations have helped tackle several of these fundamentals. However, the global community remains deeply divided on how to overcome the scarcity of supply. **Pharmaceutical trade associations claim that supply is not a problem as manufacturers can supposedly provide 10 billion doses by the end of 2021.3 But as suppliers consistently fall short in achieving manufacturing targets**, production is clearly a bottleneck to global vaccination.**3 Indeed, at the current global vaccination rate, it will take years to achieve the needed level of global immunity.4 The barrier to adequate vaccine supply today is not lack of vaccine options, nor even theoretical production capacity; the problem is the intellectual property (IP) protection governing production and access to vaccines**—and ultimately, the political and moral will to waive these protections in a time of global crisis. Without such liberty, there will not be enough vaccine fast enough to prevent the spread of variants, the avoidable deaths, and the continued choking of low and middle income countries (LMICs) through poor health. Beyond donor based models of global vaccine equity **As covid-19 became a pandemic, global efforts emerged to help ensure vaccines would be delivered across the globe to the highest risk populations. One of the first was Covax, a risk sharing mechanism in which countries, tiered by means, contribute to collectively source and equitably distribute vaccines globally**. The effort, however laudable in intent, **has been undercut by vaccine scarcity and underfunding. Covax aims to vaccinate 20% of the population in 92 low and middle income countries by the end of 2021. At the end of April, however, it had shipped only one fifth of its projected estimates and lacked critical resources for distribution**.3 **LMICs are wary about participating in well worn dynamics of global health aid. Instead, they are mobilising to overcome the fundamental paucity of available vaccines by**

challenging established global IP rules. At issue is the 1995 Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement, which established minimum protection standards for IP—including patents, industrial designs, trade secrets, and copyright—that all 164 members of the World Trade Organization (WTO) must respect.5 Subsequent rulings (such as the Doha declaration) have strived to clarify safeguards on patents, including compulsory licensing, which allows governments to license patents to a third party without consent (table 1).6 Today, these rules provide strong IP protection for vaccine technologies and affect the quantity and location of vaccine production and availability. Table 1 Licensing of intellectual property View popupView inline **In October 2020, South Africa and India submitted a proposal to the WTO to temporarily waive certain provisions of the TRIPS agreement for covid-19 health products and technologies. The waiver would prevent companies that hold the IP for covid-19 vaccines from blocking vaccine production elsewhere on the grounds of IP and allow countries to produce covid-19 medical goods locally and import or export them expeditiously (table 1). Although the proposed IP waiver is supported by over 100 countries, WTO has not reached a consensus on the proposal because of opposition and filibustering by several high income countries, including the UK, Germany, and Japan.7** Waiver opponents argue that the limited capacity of LMICs to produce complex covid-19 vaccines safely is the true barrier to global production, not IP. They suggest that the TRIPS waiver would penalise drug companies, stifle biomedical innovation, and deter future investments in research and development—in sum, that it would reduce returns on investment and dismantle an IP system that provided the goods needed to end the pandemic. Others are concerned that an IP waiver would fuel supply chain bottlenecks for raw materials and undermine ongoing production. Moreover, policy makers argue that a waiver is unnecessary as company driven voluntary licensing—in which companies decide when and how to license their technologies—and existing TRIPS flexibilities (such as country determined compulsory licensing) should suffice in establishing production in LMICs (table 1). They suggest that waiving IP for covid-19 vaccines would provide no meaningful progress, but the data do not support this. What effect would a waiver have? **Contrary to detractors' concerns about the possible effect of a temporary TRIPS waiver, global health analyses suggest that it will be vital to equitable and effective action against covid-19. LMIC's manufacturing capabilities have been underestimated,** even though several LMICs have the scientific and manufacturing capacity to produce complex covid-19 vaccines. **India, Egypt, and Thailand are already manufacturing viral vector or mRNA-based covid-19 vaccines,8910 and vaccine production lines could be established within months in some other LMICs,11 offering substantial benefit in a pandemic that will last years.**11 **Companies in India and China have already developed complex pneumococcal and hepatitis B recombinant vaccines, challenging existing vaccine monopolies 12 The World Health Organization launched an mRNA technology transfer hub in April 2021 to provide the logistical, training, and know-how support needed for manufacturers in LMICs to repurpose or expand existing manufacturing capacity to produce covid-19 vaccines and to help navigate accessing IP rights for the technology.13 Twenty five respondents from LMICs expressed interest, and South Africa was selected as the first hub**, with plans to start producing the vaccine through the Biovac Institute in the coming months.14 **Removing IP barriers through the waiver will facilitate these efforts, more rapidly enable future hubs, engage a greater number of manufacturers, and ultimately yield more doses faster. Moreover, as the waiver facilitates vaccine production, demand for raw materials and active ingredients will increase. Coupled with pre-emptive planning to anticipate and expand raw material production, the waiver—which encompasses the IP of all covid-19 vaccine-related technology— can offer a path to overcome bottlenecks and expand production of necessary vaccine materials.**

The existing mechanisms in the Doha agreement doesn't do enough to increase COVID-19 vaccine access

Erfani et al 21 [Parsa Erfani, Fogerty Fellow at Harvard School of Public Health, Agnes Binagwaho, Vice Chancellor of the University of Global Health Equity, Mohamed Juldeh Jalloh,

Vice President of the Republic of Sierra Leone. I hold a PHD in Political Science from the University of Bordeaux, France, Muhammad Yunus, Recipient of the 2006 Nobel Peace Prize, Paul Farmer, Kolokotrones University Professor and chair of the Department of Global Health and Social Medicine at Harvard Medical School, Vanessa Kerry, founder and CEO of Seed Global Health, "Intellectual Property Waiver for Covid-19 Vaccines Will Advance Global Health Equity," BMJ, vol. 374, Aug. 2021, p. n1837. www.bmj.com, https://doi.org/10.1136/bmj.n1837., Accessed: 8/12/2021].

Although a "special" compulsory licence system was agreed in the Doha declaration to allow for expeditious exportation and importation (formalised as the article 31bis amendment to TRIPS in 2017), the provision is limited by cumbersome logistical procedures and has been rarely used.16 Governments may also be hesitant to pursue compulsory licences as high income countries have previously bullied them for doing so. Since India first used compulsory licensing for sorafenib tosylate in 2012 (reducing the cancer drug's price by 97%), the US has consistently pressured the country not to use further compulsory licences.17 During this pandemic, Gilead sued the Russian government for issuing a compulsory licence for remdesivir.18 Furthermore, **while compulsory licences are primarily for patents, covid-19 vaccines often have other types of IP, including trade secrets, that are integral for production.19 The emergency TRIPS waiver removes all IP as a barrier to starting production (not just patents)** and negates the prolonged time, inconsistency, frequent failure, and political pressure that accompany voluntary licensing and compulsory licensing efforts. It also provides an expeditious path for new suppliers to import and export vaccines to countries in need without bureaucratic limitations.

The most promising COVID-19 vaccines were made with government/public money, and reducing IPP for them hasn't reduced innovation

Garrett 21 [Laurie- columnist at Foreign Policy, a former senior fellow for global health at the Council on Foreign Relations May 7 2021, "Stopping Drug Patents Has Stopped Pandemics Before," Foreign Policy, https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/. Accessed 3 Aug. 2021].

Of the multiple COVID-19 vaccines currently in use, the most promising—the mRNA and adenovirus vector products—all arose from government-funded research, mostly based in academic research centers. AstraZeneca's vaccine, for example, grew out of the United Kingdom's government-back research and development at Oxford University. The Moderna and Pfizer mRNA vaccines grew out of years of National Institutes of Health-funded research in the United States and with predecessor Ebola vaccines in the Democratic Republic of the Congo, Guinea, Sierra Leone, and Liberia. China's vaccine built on years of military immunization work. And thanks to Operation Warp Speed, many companies involved in the vaccine chain of production have benefited with a total of $18 billion of U.S. government subsidies. The speed and scale of COVID-19 vaccine production in the United States is largely thanks to the country's taxpayers. This week, Pfizer reported earning $3.5 billion in profits during the first quarter of this year from its COVID-19 vaccine. Moderna earned the first profits the fledgling company has ever seen—$1.73 billion—and projects nearly $20 billion in earnings this year. Despite setbacks, both the AstraZeneca and Johnson & Johnson adenovirus vector vaccines are making handy profits, projected to each garner multiple billions of dollars this year. Even Sinopharm from China and Gamaleya from Russia expect to reap ample profits in 2021, both in cash and diplomacy, as they sell vaccines directly to key governments. The Novavax company, which makes a not-yet-approved protein vaccine, expects massive earnings in late 2021. **Despite the threat of patent-voiding, all of these companies—as well as a long list of would-be vaccine makers further back in the research and development pipeline—have continued to innovate, trying to find formulations that can battle variant strains of the virus;**

be stored at room temperature; and get administered via skin patches, orally, or in a nasal mist. The creativity at these companies continues—and there's no reason to think it will stop anytime soon. It remains to be seen how many countries with big pharmaceutical industries will follow the Biden administration's lead in liberalizing patent protections for COVID-19-related vaccines and drugs. The WTO operates by consensus from member states, so the United States can't unilaterally alter the global landscape. But Ngozi Okonjo-Iweala, the new WTO director-general, is already raising the heat. A former Nigerian minister of finance, ex-World Bank official, and the first African and woman to hold the coveted World Trade Organization position, Okonjo-Iweala made it clear from her first day in office that a TRIPS-waiver for COVID-19-related products was her top priority. But even if one assumes the European Union, U.K. Prime Minister Boris Johnson, Japanese Prime Minister Yoshihide Suga, and Swiss President Guy Parmelin will adopt Biden's example, waiving patent protections on their COVID-19 products, the next challenges will be far more difficult. Adar Poonawalla, CEO of India's Serum Institute, the world's largest vaccine manufacturer, has complained that his company's production facilities are already overwhelmed filling orders for generic AstraZeneca and other COVID-19 vaccines—orders places by countries other than India. The Modi government, Poonawalla said, placed a paltry order for just 15 million doses of a generic version of AstraZeneca's vaccine in January, supplemented by an April order for 110 million doses—a drop in the bucket for a nation of more than 1.3 billion people needing a two-dose vaccine. (Poonawalla's statements riled Modi supporters, and Poonawalla fled the country this week, staying "indefinitely" in London.)

Global South

Despite the flexibilities in TRIPS, when LDCs tried to use them, they were met with opposition or weren't able to use them

D'Angelo et al 21 [Alexa B. D'Angelo, Department of Community Health and Social Sciences, CUNY Graduate School of Public Health and Health Policy Christian Grov, Department of Community Health and Social Sciences, CUNY Graduate School of Public Health and Health Policy Jeremiah Johnson, Treatment Action Group, New York, NY, USA& Nicholas Freudenberg, Department of Community Health and Social Sciences, CUNY Graduate School of Public Health and Health Policy "Breaking Bad Patents: Learning from HIV/AIDS to Make COVID-19 Treatments Accessible," Global Public Health, May 2021, world, www.tandfonline.com, https://www.tandfonline.com/doi/full/10.1080/17441692.2021.1924223, Accessed: 8/16/2021].

Early attempts by LMICs to utilise TRIPS flexibilities, by codifying compulsory licensing and parallel importation into state law, faced aggressive retaliatory threats from patent holding countries, often a result of pressure from pharmaceutical companies and trade associations (Subhan, 2006). Such cases made it clear that further protections for LMICs were needed. In 2001, a convention was held in Doha, Qatar, in response to the demand for greater enforcements of TRIPS flexibilities (Correa, 2002). The Doha Ministerial Declaration did not fundamentally rewrite TRIPS flexibilities, but rather provided further protection for countries utilising TRIPS flexibilities, and achieved this goal by outlining the language around compulsory licensing in the interest of public health (Correa, 2002). Following Doha, TRIPS was amended to allow for some countries to export compulsory licenses for the manufacture and import of needed drugs, a change that responded to implementation challenges due to the limited manufacturing capacity of some member nations (WTO, 2017). **Despite promising increases in use, implementation of TRIPS flexibilities has produced mixed results, with some countries experiencing success in making essential medicines more available, while others have not been able to use compulsory licensing and importation to improve access (t Hoen et al., 2018).**

Few countries have been able to utilize public health emergencies waiver

Westerhaus and Castro 06 [Michael Wasterhaus, Center for Global Health and Social Responsibility, Global-Local Course Director and Arachu Castro, Ph.D., M.P.H., is Samuel Z. Stone Chair of Public Health in Latin America and Director of the Collaborative Group for Health Equity in Latin America at Tulane School of Public Health and Tropical Medicine, "How Do Intellectual Property Law and International Trade Agreements Affect Access to Antiretroviral Therapy?" PLOS Medicine, vol. 3, no. 8, Aug. 2006, p. e332. PLoS Journals, https://doi.org/10.1371/journal.pmed.0030332, Accessed: 8/16/2021].

Have WTO Rules Improved Access to ART? For all the wrangling over the specific provisions of the TRIPS agreement and the self-proclaimed interest by multinational pharmaceutical companies and the US government in promoting global health, **we argue that little has changed to suggest that WTO rules improve global public health. In fact, compulsory licenses, the primary mechanism offered for public health protection by the TRIPS agreement and the Doha Declaration, have rarely been used [12].** The exact procedures for issuing a compulsory license for ARV production remain unclear and largely untested. **Significant international pressure also exists against declaring compulsory licenses—as seen when Brazil recently threatened to issue compulsory licenses for efavirenz, lopinavir/ritonavir, and tenofovir [13,14]. For these reasons in part, only four countries—Malaysia, Indonesia, Zambia, and Mozambique—have thus far issued compulsory licenses for ARV production, all of them in 2004 [15]. No country has yet**

made use of the provisions instilled in the temporary waiver, even though many low- and middle-income countries face public health emergencies. Southern Africa, for example, is currently witnessing a decimation of its population by AIDS, while malaria kills at least 1 million people, predominantly children, per year. So why aren't these countries using the waiver provisions? Some might suggest the old mantra that low- and middle-income governments are too corrupt and power-seeking to actually care about the health of their populations. But if this were true, how could we explain the health successes of countries such as Brazil, Cuba, and Thailand? An alternative explanation, as suggested by the African Group, is that WTO rules are far too cumbersome and impractical for poor countries to navigate. Viewed in this light, the humanitarian motives pled by pharmaceutical companies and economically powerful governments can be seen as empty lip service, functioning only to counter growing calls for social justice in global health.

There's been a historical double standard between rich and poor countries with IPP. TRIPA pushing IPP provisions too early serves to disenfranchise the Global South

Ghidini 11 [Gustavo Ghidini University of Milano, and Luiss Guido Carli University, Rome, Italy. "On the impact of TRIPS on 'least developed countries': a tale of double standards?" *Queen Mary Journal of Intellectual Property, Vol. 1* No. 1, April 2011, pp. 73-79. https://www.elgaronline.com/view/journals/qmjip/1-1/qmjip.2011.01.04.xml, Accessed: 8/16/2021].

As is well known, the TRIPs Agreement (Article 65) has obliged developing countries to apply its provisions within a short period (very short from a historical perspective: five years from the signing of the WTO Agreement) that is furthermore fixed and equal for all - save for a limited (from a historical perspective) delay of a further five years (Article 66) in favour of the least developed countries - this term being further extended in 2001 in Doha to 2016 as concerns the rules on pharmaceutical product patents. (However, the Council for TRIPs may, upon duly justified request by a leastdeveloped country member, accord further extensions.) Let us dwell for a while on the geopolitical significance of this unification of models and time limits for compliance - particularly as regards the latter. In my view, 2 it reflects a double standard in the framing of the rule: since, by putting a short and fixed term to developing countries to toe the line with Western IP law standards, today's industrialized countries 'have done unto others' what they themselves refused be 'done unto them' in the initial stages of their own industrial development. It is an undeniable fact, indeed, that contemporary established powers themselves determined, based on their own stage of development, how and when to apply strong models for the protection of intellectual property. For example, at the beginning of the nineteenth century the German states were considered by France as havens for plagiarists. And Germany introduced legislation against unfair competition between the end of the nineteenth and the beginning of the twentieth centuries, when it recognized that it could afford the 'luxury of fairness'. 3 May I also recall that before its rapid industrial reconstruction after World War II, Japan was famous for its eagerness to copy almost anything new produced in Western countries. As for the US, current aggressive champion of the need for world-wide stringent protection of intellectual property, Professor Jane Ginsburg4 reminds us that, as concerns copyright, they grew and flourished, till the end of the nineteenth century, as a 'pirate nation', i.e. free riding on the works of English and Irish authors (Dickens' exasperated protests have remained famous). This continued till the end of the nineteenth century, when the American publishing industry produced 'enough' successful own authors to 'sell' even on the international market (just think of Beecher Stowe, Twain, Hawthorne, Melville, James, Thoreau, Emerson, Whitman, Alcott, Fuller, etc.), 5 thereby eventually accepting the principle of reciprocal international copyright protection. But please note: even under those circumstances, the Chace Act 1891, which acknowledged foreign authors' and publishers' copyright, and which remained in force for decades, granted such protection on condition that foreign texts were printed in the US, banning the import of editions published abroad. 6 (The less said about Italy the better. Suffice it to say that while the industries of my country's northern regions clamour for protection against counterfeit goods, a huge amount of such goods is produced and/or distributed by 'entrepreneurs' rooted in southern regions). In the final analysis,

those 'one-sized' deadlines, willy-nilly accepted by developing countries for applying Western models of IP protection, objectively risk 'sticking' the same countries to the disadvantaged economic situation mentioned above: precisely because the value of high-tech products that, in international exchanges, flows from the protection of IPRs mostly relates to the production of 'the others'. 'No, the contrary is true!', outright supporters of the present system proclaim. Quick legal unification tends to speed up recourse to R&D by developing countries, they say. **These optimists argue that a healthy lash of the whip does help 'backward' countries to escape their long dependence on the primary sector, as well as the clutches of technological stagnation. It is a serious objection,** certainly convincing when it refers to the 'innovation divide' that still characterizes the relations between countries which have, however, attained a reasonable level of development - take, e.g., the technological gap existing in several sectors between Northern European and Mediterranean European industrial systems. But as regards relations between developed and developing countries in the strict sense, **that objection draws little comfort from experience; and in any case the historical reality contradicts its underlying assumption.** Indeed, not only has the prophecy of the healthy whiplash come true for a limited number of developing countries whose levels of industrial investment have enabled them to marshal sufficient resources to give birth to technically complex productions, but, even more significantly, as hinted, is a distinct factual observation: **the countries in question have reached or are on the verge of reaching that capacity also thanks to a previous refusal - and not a previous acceptance! - of strong IPR models.** In short, these emerging technologically proficient developing countries7 have extensively done what today's many industrialized countries did in the 1800s and part of the 1900s when they effectively ignored or got around an effective enforcement of IPRs until their own industries were no longer in their infancy. By contrast, these same countries started effectively to respect and enforce IPRs as they, in turn, became producers of advanced technologies (often acquired through imitation) and it became in their own interests to adopt a policy of safeguarding intangible assets in domestic and above all international trade. Cosi fan tutte in the initial stages of industrial development.

Medical research disproportionately goes to diseases that impact the developed world

Jung and Kwon 15 [Jung, Youn, Institute of Health and Environment, Seoul National University, Seoul, Republic of Korea and Soonman Kwon, School of Public Health, Seoul National University, Seoul, Republic of Korea, "The Effects of Intellectual Property Rights on Access to Medicines and Catastrophic Expenditure," International Journal of Health Services, vol. 45, no. 3, July 2015, pp. 507–29. DOI.org (Crossref), doi:10.1177/0020731415584560. Accessed: 8/15/2021].

In addition to these increases in medicine prices, disparities in pharmaceutical research and development are expected to grow because the current system for IPR does not provide an incentive for pharmaceutical companies to invest in developing medicines for the treatment of neglected diseases in poor countries.9–12 Me´decins Sans Frontie`res estimates **that 90% of the world's health research and development expenditure is devoted to conditions that affect just 10% of the world's population, with priority conditional upon ability to pay**.13 Global inequities in access to medicines are also obvious. **Nearly one-third of the world's population is estimated to lack regular access to essential medicines that they need, a figure that rises to one in two in the most impoverished parts of Africa and Asia. In 2006, just 20% of the world's population in high-income countries was responsible for about 80% of global pharmaceutical sales, whereas the poorest 80% of the population in developing countries accounted for only 20% of global pharmaceutical expenditures.14** This reality raises serious doubts about whether strengthening IPR for pharmaceuticals contributes to public health, specifically access to medicines. However, the relationship between intellectual property protection and access to medicines has been discussed primarily around AIDS treatment or low-income countries, most of which were based on estimated impact of extending patent protections.15–18 Few empirical studies have examined this issue. Jung and Kwon 509 This study aims to examine the effect of stronger IPR on public health, especially on medicine use in low- and middle-income countries, based on empirical data. **In developing countries, pharmaceutical expenditure accounts for a relatively large portion of total health care costs. In addition, medicines are mainly paid out-**

of-pocket because health insurance and public financing for pharmaceuticals are limited in developing countries.19 Consequently, high medicine prices triggered by strengthening IPR may make people forego treatment or go into extreme economic hardship. This study will provide empirical evidence on the linkage between IPR and medicine use in developing countries. Here, we hypothesize that a higher level of protection for IPR on medicines would lower access to medicines and increase the occurrence of households' catastrophic expenditure for purchasing medicines.

Race

Patents leave minority communities more at risk of price gouging

ACRE 20 [Action Center on Race and the Economy, August 2020, "Poi$on: How Big Pharma's Racist Price Gouging Kills Black and Brown Folks," Action Center on Race and the Economy, https://acrecampaigns.org/wp-content/uploads/2020/08/new-poison-final.pdf]/ Accessed: 8/9/2021].

As this report goes to press, Gilead's decision to charge over $3,000 for remdesivir, a COVID-19 drug that was jointly developed by Gilead and federal research agencies, is reigniting debate about drug pricing in the United States.ii At the same time, COVID-19 itself has brought structural racism in the U.S. health care system to the foreground as Black and Brown communities bear vastly disproportionate levels of COVID-19 infections and death. Systemic race-based exclusion, discrimination, and violence in employment, housing, policing, and health care have created greater risk for COVID-19 exposure, infection, complications, and death in Black and Brown communities.iii **Under the U.S. model of monopoly drug patents, Black and Brown people have also been exposed to more concentrated risk of price gouging by pharmaceutical companies.** This report confronts the **complicity of price gouging by pharmaceutical companies in racial and ethnic health inequities** by bringing together two sets of research: data analysis showing that Black and Latinx patients are forced to ration medications at higher rates than white patients and historical analysis of the monopoly patent model, which gives private, for-profit pharmaceutical companies power over drug pricing. **Price gouging excludes Black and Brown communities from access to medications for the chronic diseases that put patients at higher risk of death** from COVID-19. Drug-pricing debates often focus on what prices pharmaceutical companies should charge rather than whether pharmaceutical companies should have the power to set prices for medicine. The public interest in government-regulated pharmaceutical pricing is undeniable: $33 billion in government-funded drug research makes most new drug discoveries possible; **price gouging adds significant costs to public programs, like Medicare and Medicaid; and medication rationing due to high cost leads to avoidable complications and premature death, defeating the fundamental public health goals of prevention and health equity.** The decision to rely on a monopoly patent model that cedes pricing power completely to pharmaceutical companies has always been motivated by neoliberal ideology. Medical innovation, the stated rationale for monopoly patents and inflated prices, is stymied by the maze of intellectual property protections that protect private pricing power. The profits that ostensibly incentivize research and development for breakthrough medicines actually flow directly to Wall Street in the form of stock buybacks and dividend payments. A steady stream of political contributions and payments to researchers and medical providers props up the narrative of private profits as "the price of progress." This rationale dismisses the damage, disproportionately afflicting Black and Brown communities, that results from price gouging essential medications. Our Preexisting Condition: Race COVID-19 has shined a light on long-standing health inequities that harm Black and Latinx communities. The higher prevalence and mortality rates of Black and Latinx COVID-19 patients mirror the heightened incidence of diabetes, hypertension, heart disease, and other illnesses that put Black and Brown people at greater risk for COVID-19 complications and death. At the root of the United States' social and economic system is the plunder of wealth and health from Black and Indigenous people and other people of color to enrich wealthy white individuals and institutions. The much-discussed economic and health disparities experienced by these communities are the result of this targeted racial discrimination. Yet the disproportionate effect of prescription drug price gouging on Black and Latinx communities is rarely mentioned, even as the competition for COVID-19 vaccines and cures puts pharmaceutical companies at the center of attention. **Across insurance status, age, and disease type, Black and Latinx patients report higher rates of medication rationing—forgoing or delaying filling a prescription, skipping doses, and reducing doses below the prescribed amount due to cost.**iv Even before the current pandemic, medication rationing due to inflated prices was contributing to unconscionable levels of preventable disease and death in Black and Latinx communities. This should be a forewarning of the likely barriers to access to COVID-19 vaccines and medicine and of the empty promises of pharmaceutical companies to mitigate the harm of their own practices. **Consider diabetes and hypertension, two conditions that appear to be strongly associated with COVID-19 mortality and that disproportionately afflict Black and Latinx people. Black people are twice as likely as whites to have hypertension**, are more likely to experience the onset of hypertension at younger ages,v and are more likely to experience severe complicationsvi Latinx hypertension patients are less likely than white people to have their blood pressure controlled, and Mexican Americans are more likely to die from hypertensionvii Black and Latinx people are both more likely than whites to have diabetes and more likely to die from diabetes Latinx patients have higher rates of diabetes-related kidney

failure and vision lossviii Black people with diabetes have higher rates of kidney failure and amputationsix **A strong body of evidence shows that high levels of stress due to racial and ethnic discrimination, including that involving police encounters, are associated with elevated blood pressure and high levels of inflammation (which is a characteristic of diabetes, hypertension, and COVID-19) in Black and Latinx people**. The heightened vigilance and 8 anticipatory stress that characterize Black and Latinx people's attempts to cope with persistent but unpredictable threats of racism in their daily lives trigger stress responses that over time can cause or worsen cardiovascular and cardiometabolic disease.x **Racism contributes to the development of hypertension and diabetes, and price gouging blocks Black and Latinx patients from accessing treatment.** Diabetes and hypertension are manageable chronic diseases for which the standard of care includes prescription medications to control symptoms and avoid complications. In surveys of medication use, Black hypertension patients report more medication rationing due to cost than do white patients.xi **Analysis of pharmacy claims and patient registry data confirms that Black and Latinx patients experience more barriers to either filling or routinely refilling prescriptions for diabetes and hypertension medications**.xii Price gouging that restricts access to medications literally costs Black and Brown people their lives and limbs. Whereas taking the proper doses of anti-hypertensive medications has been shown to reduce cardiovascular mortality,xiii medication rationing is "a leading cause of inadequate hypertension management leading to cardiovascular disease, stroke, and chronic kidney disease."xiv Restricted access to affordable hypertension medication is one reason that overall decreases in cardiovascular disease mortality in the U.S. have not been equally seen by Black, Latinx, and white people.xv Diabetes medications are among the most expensive among all chronic disease medications, and insulin users in particular are most likely to report medication rationing.xvi Black and Latinx diabetics are more likely than whites to use insulinxvii and more likely to report that they skip or reduce doses of diabetic medications due to cost.xviii Underusing necessary diabetes medications is a major cause of poor glycemic control, which is, in turn, a cause of vascular disease that can (though, with proper and timely treatment, usually should not) lead to amputations, kidney failure, and blindness.xix A ProPublica investigative report on racism in U.S. diabetes care documents a systemwide disinvestment in diabetes-related vascular disease prevention that drives the "epidemic of amputations" in Black communities. The same racist policies and practices also increase the risks of other diabetes-related vascular complications, such as kidney disease, retinopathy, and blindness, all of which disproportionately afflict Black and Latinx patients.xx This pattern of treatment amounts to systemic neglect of and inhumanity for the health of these patients. 9 But the academic literature on racial disparities generally discusses "race" rather than racism and avoids the topic of price gouging by pharmaceutical companies altogether. Too often, researchers shift responsibility for medication access onto Black and Latinx patients.xxi The language of medication "nonadherence" and "underuse" conveys this assumption of individual failings and echoes the Trump administration's victim blaming that attributes susceptibility to COVID-19 to the unhealthy "culture" of immigrant Latinx meat plant workers and the individual behavior of Black people.xxii Yet, mainstream research does recognize the high stakes of medication rationing. **One study acknowledged that racial inequities in health outcomes are due at least in part to "persistent problems in getting necessary medications** that eventually lead to the most debilitating effects of unmanaged chronic illness."xxiii **Researchers tend to identify at the root of these persistent problems some version of the "financial wherewithal to pay for prescription medications."**xxiv This explanation obscures the fundamental factor of wealth extraction from Black and Brown communities. Most notably, the history of residential segregation and racial and ethnic discrimination in employment, wages, and access to basic goods and services in the U.S. drives a racial wealth gap that gives white households greater "financial wherewithal."xxv Structural barriers to Black and Brown wealth attainment and intergenerational progress expose Black and Brown households to greater economic insecurity, which makes them more vulnerable to the price-gouging tactics of pharmaceutical companies.xxvi As a mechanism to maximize profit and enrich pharmaceutical company investors at the expense of Black and Brown health and wealth, drug price gouging is itself another instance of the same process of wealth extraction. The profits accumulated from price gouging further enrich wealthy investors, feeding the cycle of wealth extraction and exploitation. The History and Politics of the Pharmaceutical Patent Monopoly Model Along with attention to racial and ethnic health inequities, the COVID-19 pandemic has directed public awareness to the complexity of the health care supply chain. The complexity of the pharmaceutical industry, from research and manufacturing to regulatory approval and insurance negotiations, has been used to muddy the waters of debate over medication access for decades. What appears plainly as price gouging— triple-digit-percentage increases in lifesaving drugs that have existed for years or astronomical markups from the cost of drug production—are explained away as one piece of a complex process that leads to innovative medicine that would otherwise be undiscovered and unavailable to treat sick people around the globe. The unstated assumption behind the "myth of the price of progress"xxvii is that the current pharmaceutical pricing regime arose naturally, as the best possible solution to produce 10 the best possible medicines to meet the most pressing health care needs. Demands for changes to the status quo to make drugs affordable are greeted with patronizing explanations of how such well-meaning policies would inevitably result in the opposite: higher prices for more people and fewer medical breakthroughs for everyone. Such demands "represent an easy but wrongheaded way to avoid the messy work of constructing a system to incentivize medical breakthroughs and make them widely available in the context of 21st century economic realities," according to one such

admonishment.xxviii The actual political history of the U.S. pharmaceutical industry and its complicity in racial health inequities is obscured in the heroic tales of market-driven discovery and in the scolding dished out to its critics. So, too, is the racism embedded in "21st century economic realities" hidden in plain sight. The pricing power of private pharmaceutical companies was deliberately created by free-market ideologues, not to incentivize medical breakthroughs but to empower private corporations as a counterforce to public-sector regulations and consumer protections.xxix Apologists for unchecked corporate power repeat the myth of the price of progress more loudly as the evidence accumulates that the "innovation" that high drug prices are purportedly paying for amounts mostly to stock buybacks, executive compensation, and a flood of expensive new drugs with no demonstrated efficacy over established standards of care.xxx The Origins of Patent Monopolies in the Pharmaceutical Industry The history of patent monopolies in the pharmaceutical industry is a history of the gradual ceding of public control of public goods—drugs developed by government-funded research—to private companies. Drug patents granted to private entities were rare before 1968, when the Institutional Patent Agreement gave universities the right to own patents on federally funded drug discoveries.xxxi Those universities were then free to sell the licenses to manufacture new drugs to the highest bidder.xxxii The New Deal agencies that originally boosted U.S. medical research and vaccine development had required private contractors to assign intellectual property rights from publicly funded research back to the government.xxxiii Since 1968, freemarket ideologues have cast aside New Deal–era concerns about the corruption of medical research by "undue concentration of economic power in the hands of few large corporations"xxxiv and doubled down on the maximization of private profit from public research by 11 Expanding private patent rights for drugs developed with federal funds to all private contractors in the Bayh-Dole Act of 1980;xxxv Extending licenses and granting tax breaks for "rare diseases" in the 1983 Orphan Drug Act, under which remdesivir, Gilead's treatment candidate for COVID-19 (perhaps the least rare disease ever), briefly qualified for seven-year market exclusivity and federal grants and tax credits to reimburse clinical testing costs;xxxvi Extending drug patents from 17 to 20 years in the 1995 Uruguay Round Agreements Act;xxxvii Prohibiting Medicare from negotiating lower drug prices in the Medicare Modernization Act of 2003;xxxviii and Facilitating direct-to-consumer drug marketing in the Food and Drug Administration (FDA) Modernization Act of 1997.xxxix This is not a history of abandoning a just system for an unjust one, however. There is no golden age of truly equitable U.S. drug policy, and the development of pharmaceutical drugs is marked by racist and gendered exploitation. In the 1940s and '50s, when U.S. government officials were strongly insisting on "public control over patents"xl on vaccines and other medicines, Black and Brown people were excluded from "the public" by laws restricting every aspect of their lives and by the racial violence that enforced segregation and exclusion. The government's commitment to publicly funded and controlled medical research included medical experiments on Black and Brown bodies, like the deliberate withholding of medication in the U.S. Public Health Service–funded Tuskegee syphilis experiments on Black men from 1932 to 1972 and the deliberate, sometimes fatal, infection of healthy Guatemalan men, women, and children in experiments from 1946 to 1953.xli While some in the federal government fretted over the misuse of patented medical breakthroughs, a private surgeon was surreptitiously removing cancer cells from the body of Henrietta Lacks, without informing Lacks or her family.xlii The cells have been used for decades thereafter to develop profit-making drugs to treat cancer and other diseases.xliii This history must be the interpretive lens for understanding victimblaming statements attributing medication rationing and poor health in Black and Brown communities to "noncompliance" with medical experts and mistrust of medical authority. It must also guide a forwardthinking, explicitly antiracist solution to pharmaceutical price gouging that recognizes the racism in the New Deal–era public drug development system. 12 Maximizing Profit Extraction: Abuses of the Patent System Economic historian Edward Nik-Khah sums up the ideological roots of the monopoly patent model by noting, "Pharma was the perfect test case for a neoliberal project that celebrates markets, but is fine with large concentrations of power and monopoly."xliv Patents grant a temporary monopoly, but corporate power, once concentrated, rarely accepts such limits. The decision to transfer public knowledge to private profit-making corporations also transferred power. Pharmaceutical companies have used that power to extend patent monopolies far beyond the 20 years originally granted, all while maintaining the $33 billion in annual governmentfunded drug research that makes new discoveries possible.xlv Every drug approved in the U.S. between 2010 and 2016 was based on National Institutes of Health– funded research.xlvi The patent system privatizes the return from this public investment, and pharmaceutical companies further abuse patent law to perpetuate their monopoly power and continue profit-maximizing price gouging. **The Initiative for Medicines, Access, and Knowledge (I-MAK) submitted public comments to the Federal Trade Commission in 2018 warning that "people worldwide—including in the United States—are not receiving the lifesaving treatment they need due to skyrocketing prices based on the abuse of the patent system."**xlvii I-MAK outlines the abusive practices that the pharmaceutical industry uses to "secure the market on entire diseases and artificially inflate the price of treatment."xlviii **By obtaining multiple patents, pharmaceutical companies delay or block generic competition for decades, keeping cheaper medications off the market without improving treatment in any way**. I-MAK found that the 12 best-selling drugs in the U.S. have an average of 135 patent applications and 71 approved patents per drug. A member of I-MAK, Tahir Amin, pointed out that the decline of pharmaceutical industry investment in new antibiotics to treat drug-resistant infections, an urgent global health crisis, coincides with pharmaceutical companies' strategic decision to "spend more time finding ways to keep existing drug franchises profitable."xlix We could say the same about the indifference to preventing diabetesrelated amputations and avoidable deaths from chronic disease in Black and Brown communities in the United States. In a familiar trend, the financialized pharmaceutical sector directs more of its profits toward enriching shareholders and building "a tangle of IP protections"l to block access to the discoveries

it already owns than to productive uses, like research and development, or reducing the inflated prices that put lifesaving medication out of reach of Black and Brown patients. 13

Higher drug prices are harder to afford for minority groups and result in medicine underuse

Benavidez and Frankt 18 [Gilbert Benavidez is a policy analyst for the Partnered Evidence-based Policy Resource Center (PEPReC), Austin Frakt, PhD, is a health economist and director of the Partnered Evidence-based Policy Resource Center at the Boston, August 21 2018, "Racial Disparities, Prescription Medications, and Promoting Equity,"Public Health Post, https://www.publichealthpost.org/viewpoints/racial-disparities-prescription-medications-equity/]/ Accessed: 8/9/2021].

The United States has the highest drug prices in the world and it's not even close. For millions in the country, the cost of prescription drugs is an ever-growing barrier to proper disease treatment. This is most often the case for minority groups, who have long experienced disproportionally adverse health access and outcomes. But high drug prices alone do not explain the inequity we see. Though cost is a major factor, Colon, et al. found that disparities are not simply a function of socioeconomic status—the story is more complicated. Minorities Face Many Barriers to Prescription Medicines Costs **White Americans are, on average, much wealthier than Black and Hispanic Americans. The median net worth of White households in 2016 was 9.7 times higher than African-American households and 8.3 times higher than Hispanic households**. Wealth disparities result in negative health consequences. **Among insured adults with diabetes, Tseng, et al, found race and ethnicity to be a significant predictor of medication underuse—patients underusing their medication in order to prolong supply—due to cost.** (Medication underuse is a somewhat common cost saving strategy, per the CDC.) The authors attribute this to lower incomes and higher out-of-pocket drug costs. Although study participants all had health insurance, disparities persisted. Lack of Insurance **Affording medications is even harder for those without coverage**. Though the Affordable Care Act (ACA) reduced the number of uninsured Americans, over 28 million remain without insurance. **More than half (55%) of uninsured Americans under the age of 65 are people of color.** For those with no insurance, paying retail prices for medications is often financially impossible. Implicit Racial Bias in Prescribing Practice Race can have an implicit effect on the prescribing practices of providers. For example, one study showed that White children treated at pediatric emergency departments inappropriately received antibiotics for respiratory infections more often than Black or Hispanic children, indicating that prescribing patterns can vary depending on the race of the patient. Terrell, et al., found that in their sample, ethnic and racial minorities were prescribed analgesics at a lower rate compared to White patients when discharged from the emergency department. Practical Policy Pursuits Here are four policy options for addressing racial disparities in access to prescription medication: Continue to Expand Medicaid One in five people of color have access to prescription drugs through Medicaid. Virginia recently expanded Medicaid (becoming the thirty-third state to do so). Medicaid expansion is on the November 2018 ballot in Utah and Idaho (Atkeson and Jones write more about the Idaho intiative here) while supporters in Nebraska are collecting signatures to get it on the ballot. A Maine state court has ruled that Governor LePage must submit the paperwork to expand. Promote the ACA and an Essential Benefits Package The ACA has played a key role in increasing health insurance among low-income people of color. Prescription drugs are one of ten essential health benefits the ACA requires insurers to cover. Interventions to increase coverage are needed, particularly in regard to medications. Research shows that promoting coverage gains through increased advertising is effective. Reduce Implicit Bias in Prescribing Parity in prescribing practices is possible. New research shows that reducing stigmatizing language in electronic health records can reduce implicit bias in physicians-in-training, influencing their attitudes about both patients and prescribing behavior.

NEG Evidence

Innovation

Costs of new drugs can range from 1-2 billion dollars, hence justifying current or extended IPP protections to cover the costs of R&D

Globerman 16 [Steven Globerman- Resident Scholar and Addington Chair in Measurement, Professor Emeritus, Western Washington University, "Intellectual Property Rights and the Promotion of Biologics, Medical Devices and Trade in Pharmaceuticals," Fraser Institute, October 14 2016, https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-and-promotion-of-biologics-medical-devices-and-trade-in-pharmaceuticals-post.pdf, Accessed: 8/6/2021].

The 148 countries that are signatories to the Patent Cooperation Treaty (PCT) that was negotiated as the Paris Convention of 1978 allows any resident or national of another signatory country to file a single international application. This has the effect of a national patent application (and certain regional patent applications) in some or all PCT contracting states, including Canada, which became a signatory in 1990. The PCT is administered by the World Intellectual Property Organization, and while the PCT provides a benefit to originators in the form of expedited patent rights recognition, there is no corresponding coordination on regulatory approval. Patent approval processes are similar in most countries that are members of the Organization for Economic Cooperation and Development (OECD)—a group of relatively developed and mature markets that are important consumer markets for pharmaceutical manufacturers. The authorities in these countries will confer a patent for a drug if it meets three criteria: originality (or novelty), meaning that the drug is truly something new; non-obvious (a US term; for the EU the standards it is called an "innovative step"), meaning that there is something inventive in the idea fraserinstitute.org Intellectual Property Rights for Pharmaceuticals and the Global Trade Agenda / 53 or creation or process that is proposed to be patented; and utility, meaning that there is a specified use or purpose to the invention that could have a commercial value, making the certification of ownership significant to the person applying for the patent. Patent examiners may require details of the process or formulation of a drug or specifics concerning the design and functioning of a medical device. This information is provided on a confidential basis by the applicant for a patent, but this information becomes public eventually, either when the patent right is granted or after a period specified by a national statute. Individuals can apply for a patent for a new drug or device, or a new use for an existing drug or device, on the basis of initial evidence of potential utility, such as a study published in a medical journal or a report from a lab. This standard is lower than what is required to convince regulators that a drug is safe to be sold to the public, even when limited by prescription issued by a qualified medical professional. Regulators typically require evidence from clinical trials using humans (rather than animals or another substitute). **The disparity is important and deliberate in order to encourage an innovator who thinks a drug might work to secure the rights to the innovation prior to undertaking the investment of time and resources to conduct trials. Clinical trials can be expensive to conduct. The US regulator, the Food and Drug Administration (FDA), requires a three-stage clinical trial protocol for most pharmaceuticals. One recent estimate placed the cost of clinical trials through all three stages at US$1.3 billion per drug** (Roy, 2012). **Another study found it cost an average of US$2.558 billion to win regulatory approval for a single drug (Tufts Center for the Study of Drug Development, 2014). The second, larger estimate reflects the time-cost of delays of up to ten years in the regulatory approval process**. Both these figures are for approval in the US market only; regulators in other countries may accept the same clinical trial data used to win US approval, but in some cases will require additional testing before approving a drug for use in their respective markets. Delays in regulatory approval for a drug that has been successfully patented mean that the pharmaceutical company that originated a drug cannot sell it and begin recouping its costs as quickly as it could with shorter delays. **As a result, pharmaceutical originators have called on governments to provide "patent term restoration," an extension of intellectual property rights (IPR) for the full term (typically 20 years of exclusivity, although this varies by country) effective from the date of regulatory approval.** The asynchronous nature of patent rights and regulatory approval can affect originators in another way. **A drug that has secured regulatory approval is the exclusive property of the patent holder for the duration of the patent, giving the patent holder the exclusive right to produce and market that specific drug in that specific market. When the patent term expires, other firms can produce copies of the drug and market them where regulators have approved the drug for use.** Although patent and regulatory approvals processes are parallel,

regulatory approval does not expire (although it can be rescinded or altered if new medical evidence warrants, in which case the approval affects the originator and the copier of the drug alike). **Copies of patented medicines are called generic drugs in the case of chemical pharmaceuticals**. A new class of drugs made from genetic material called biologics can also be copied, and the resulting medications are referred to as biosimilars. Biosimilar copies of biologic drugs are just beginning to enter the market and are being treated by US courts like generic drugs (Grant, 2015). **Although the costs of research and development of a new drug are high, as are the added costs of securing patent rights and regulatory approval, the period of patent exclusivity can allow a firm to recoup its initial investments by pricing the drug accordingly**. However, there are obstacles confronting firms seeking to set prices at a level sufficient to recapture their initial investment. **The structure of the market for pharmaceuticals is one challenge. In many markets, there are a limited number of customers for a particular medication. First, there may be a limited number of potential patients for whom a drug is appropriate. Second, government health programs, large hospital and health care systems, and private insurers that must approve the purchase of a medication, are often able to exert downward pressure on drug prices** (in effect, to act as an oligopsony (i.e., a market in which only a small number of buyers exist for a product). **Third, in cases where governments are the exclusive health care provider, drug prices may be regulated with upper limits on unit prices that suppliers may charge. Competition also limits the pricing power of a pharmaceutical originator once its period of patent-secured monopoly has ended.** In the most direct case, **once a generic or biosimilar alternative is available in the market, the opportunity to recoup the costs of drug development and approvals is constrained**. Firms that produce copies of the original drug or medical device do not have to incur the research, development, patent or regulatory approval costs associated with the introduction of a new product, and so are able to price copies at a far lower level. Some insurers and government programs require medical professionals—and even patients— to choose a generic or biosimilar drug if it is available. **To forestall the entry of competitors into a market, pharmaceutical originators have in some cases sought a second patent for a drug on the basis of a new use (utility) for which they have an existing patent. The practice of second patenting is known pejoratively as "evergreening"** because it can allow an originator to have a second period of exclusivity for the new application, expanding the potential population of users and extending the period during which the originator can engage in monopoly pricing to recoup development costs.

Generics hurt branded products and after generics are introduced patent holders lose significant products

Cockburn and Long 15 [Iain Cockburn, Professor of Management at Boston University, Graduate School of Management, Genia Long, Senior advisor, Analysis Group, Inc. "The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals," Expert Opinion on Therapeutic Patents, vol. 25, no. 7, July 2015, pp. 739–42, Taylor and Francis+NEJM, https://doi.org/10.1517/13543776.2015.1040762, Accessed: 8/7/2021].

Due to distinctive economic characteristics, patents and regulatory exclusivity have long been considered essential to prescription drug development. These characteristics include the costly, lengthy, and risky nature of innovative research and development (R&D) and the much lower investment required for generic drugs. Because of this disparity, without patent protection and regulatory exclusivity, particularly in the USA, innovators would be unlikely to make the substantial investments required to bring new drugs to market. Whereas drug development is global, patent law and regulation are country-specific. In the USA, regulatory exclusivity operates in parallel with patents, defining when generics or biosimilars may not submit abbreviated applications and/or enter the market. **Generic imitation may require several million dollars, whereas the cost to bring a single FDA-approved drug to**

market (including the cost of failed attempts) has been estimated at $1.4 billion in out-of-pocket costs and $2.6 billion including the cost of capital [1,2]. New drug R&D requires more than a decade, including pre-clinical testing, clinical trials, and US regulatory approval [1,2]. **In comparison, clinical testing is not required for generics; manufacturers need only demonstrate bioequivalence to an already-approved drug**. Risk is also high; the vast majority of candidates are eliminated, most before clinical testing**. For those that begin clinical testing, the probability of proceeding to approval averages only 12% [2,3]. Therefore, R&D must be funded by a few successful, on-market medicines [**4]. Generally, in the USA, once patent protection and any 180-day generic exclusivity end, multiple generics launch, and generic share increases rapidly. **For all new molecular entities experiencing first generic entry in 2011–12, the average brand's unit share of molecule sales declined to 16% 12 months after generic entry, versus 44% in 1999–00 [5]. In 2013, generics represented 86% of all US prescriptions [6].** In addition to distinctive R&D and market competition economic characteristics, biopharmaceuticals are also distinguished from other industries by a large gap between the statutory patent term (20 years from the effective patent filing date) and the effective patent term (years remaining at launch), even after any patent term restoration and additional regulatory exclusivity (e.g., for pediatric studies). **The average time between brand launch and first generic sale for drugs experiencing initial generic entry in 2011–12 was 12.6 years for drugs with sales greater than $100 million (in 2008 dollars) in the year prior to generic entry, and 12.9 years overall** [5]. In contrast, assuming < 3 years for the US Patent and Trademark Office to examine and approve a patent application (overall average of 29 months for FY2013), the remaining duration (assuming 20 years from the effective patent filing date) would be > 17 years in other industries [7]. Finally, patents serve other particularly important economic functions in biopharmaceuticals, developing robust markets for technology and 'signaling' to potential investors the quality of pre-market assets [8]. Since the 1980s, a number of scientific, economic, and legal developments have created the modern-day US biopharmaceutical sector [9]. In addition to scientific discoveries creating new areas of life sciences research, patent law developments made obtaining and enforcing patents for genes and recombinant entities possible, the Bayh-Dole Act encouraged university licensing of government-sponsored research, and a venture capital industry emerged, supporting early phase companies. **Between 1980 and 2012, life sciences venture investments totaled $108 billion in 4,600 start-ups (19% of all US venture investment then) [10]. Potential start-up investors weigh patents heavily, including expected effective patent terms of molecules in development, and patent strength for proprietary technology.**

Recent data shows that for 61% of medications patents are very important for pharma companies

Cockburn and Long 15 [Iain Cockburn, Professor of Management at Boston University, Graduate School of Management, Genia Long, Senior advisor, Analysis Group, Inc. "The Importance of Patents to Innovation: Updated Cross-Industry Comparisons with Biopharmaceuticals." Expert Opinion on Therapeutic Patents, vol. 25, no. 7, July 2015, pp. 739–42. Taylor and Francis+NEJM, https://doi.org/10.1517/13543776.2015.1040762, Accessed: 8/7/2021].

3. Recent government and licensing executive surveys **Recent US government and licensing executive surveys confirm these results. In the three annual Business R&D and Innovation Surveys (BRDIS) conducted by the US Census Bureau for the National Science Foundation (2008–10), companies most likely to report that utility (including composition of matter) patents were 'very' or 'somewhat important' were in pharmaceuticals and medicine**s; semiconductor machinery; and electromedical, electrotherapeutic, and irradiation apparatus (North American Industry Classification System four-digit level) [15]. **Sixty-one percent of "R&D-active pharmaceuticals and medicines" companies reported utility patents being 'very' or 'somewhat important.'** In comparison, utility patents were rated as 'very' or 'somewhat important' by < 4% and 'not important' by 96% of all respondents (2010 results). In addition, between 2004 and 2009, the LES Foundation conducted an annual online survey of US and Canada members of the Licensing Executive Society [16]. The most recent

(collected in 2008, referring to 2007) gathered data from ~ 600 licensing professionals in small (fewer than 500 employees) and large (> 500 employees) 'technology creator' and 'technology user' organizations. The 2007–08 LES survey also found differential patent importance: Eighty-nine percent of respondents in the healthcare (including biotechnology, pharmaceuticals and medical) industry characterized patents as 'extremely important' in 'creating a competitive advantage for your organization' (Figure 1). In comparison, 79% of energy and chemicals respondents (energy, chemicals, petrochemicals, polymers, and allied industries), 73% of electronics and software respondents, and 47% of other respondents (financial markets, food and beverage, transportation and mechanics, and other industries) reported patents were 'extremely important.' The gap between the importance of patents and other forms of intellectual property (IP) protection (know-how, trade secrets, trademarks, and copyrights) was greatest in healthcare (including biotechnology, pharmaceuticals and medical devices) (Table 1). Table 1. 'Extremely important' ratings by type of IP protection. CSVDisplay Table Figure 1. Importance of patents – healthcare respondents. Includes biotechnology, pharmaceuticals, and medical. Blank responses excluded from calculations. Display full size 4. Conclusion **Since the 1980s, US-focused researchers have found patents to be relatively more important to R&D than other forms of IP protection (trademarks, copyrights, confidential trade secrets, confidential or non-confidential know-how) and strategic complementary assets (such as lead time, sales and service, and manufacturing advantages) in biopharmaceuticals than in other industries.** The most recent data from US government and annual US and Canada licensing professional surveys are consistent with these findings

Generics

Indian generic drug company, Ranbaxy, has been cited for quality issues with the FDA since 2002. These issues culminated into the largest generic drug settlement suit in history

Agarwal et al 18 [Vinti Agarwal, BBC Media Action, Omprakash Gupta, University of Houston Downtown, USA, Keren Priyadarshini, Truven Healthcare, Shubham Agrawal, Credit Suizze, August 2018, "A Failure of Regulatory Diligence: A Case Study of Ranbaxy Laboratories Ltd," AIMS International, http://www.aims-international.org/aims15/15ACD/PDF/A228-Final.pdf, Accessed: 8/9/2021].

2. The Brush with the Food and Drug Administration, USA **Since 2002, Ranbaxy has seemed to actively court the wrath of FDA regarding its compliances with the United States Current Good Manufacturing Practices (CGMP).** The degree of seriousness intensified from the year 2006 with 4 of its manufacturing facilities declared as being under a consent decree by 2014. **A first letter of warning was issued to Ranbaxy Laboratories in 2002 regarding the safety and effectiveness in relation to Guafenesin LA Tablets 600 mg. The second warning issued in 2006 was in relation to the pharmaceutical manufacturing facility in Paonta Sahib detailing significant deviations from U.S. Current Good Manufacturing Practice (CGMP) Regulations in the manufacture of drug products as per FDA 483 form**. **The deviations among others referred to failure in retaining [redacted] analytical raw data, undocumented stability sample test intervals, the unclear purpose of "standby samples, the FDA lab results for Isotretinoin capsules, and the inadequate staffing and resources in the stability laboratory. The 3rd warning letter detailing significant violations from the Current Good Manufacturing Practice (CGMP) regulations for finished pharmaceuticals was issued in 2009** with regard to its pharmaceutical manufacturing facility, Ohm Laboratories, Inc., located at New York, USA. **The inspection revealed drug product(s) to be adulterated in that the methods used in; or the facilities or controls used for, their manufacture, processing, packing, or holding did not conform to or were not operated or administered in conformity with CGMP regulations. It also charged the company with manufacturing and distributing a prescription drug without approved application. In, 2008 the FDA issued two warning letters and an import alert for generic drugs produced by Ranbaxy's Dewas and Paonta Sahib plants in India which covered 30 generic drugs produced by Ranbaxy for deviations from U.S. Current Good Manufacturing Practice (cGMP). The deviations identified included:-** The facility's beta-lactam containment program (**measures taken to control cross-contamination**), appeared inadequate to prevent the potential for cross-contamination of pharmaceuticals; **Inadequate batch production and control records; Inadequate failure investigations to address any manufacturing control or product rejection to determine the root cause and prevent recurrence); Inadequate aseptic (sterile) processing operations; The lack of assurance that responsible individuals were present to determine whether the firm was taking necessary steps under cGMP; Inaccurate written records of the cleaning and use of major equipment;** Incomplete batch production and control records **In 2009, the FDA halted review of drug applications from the Paonta Sahib plant due to evidence of falsified data and invoked the Application Integrity Policy(AIP). It announced that the facility falsified data and test results in approved and pending drug applications** and that it had submitted stability information in numerous approved and pending applications that contain untrue statements of material fact. This led the Department of Justice, on behalf of the U.S. Food and Drug Administration, to file a consent decree of permanent injunction against

Ranbaxy Laboratories, Ltd., an Indian corporation and its subsidiary Ranbaxy Inc., headquartered in Princeton, N.J. The consent decree required that Ranbaxy comply with detailed data integrity provisions before FDA would resume reviewing drug applications containing data or other information from the Paonta Sahib, Batamandi, and Dewas facilities. Specifically, Ranbaxy was required to:- 1. Hire a third-party expert to conduct a thorough internal review at the facilities and audit applications containing data from the affected facilities; 2. Implement procedures and controls sufficient to ensure data integrity in the company's drug applications; and Fifteenth AIMS International Conference on Management 129 3. Withdraw any applications found to contain untrue statements of material fact and/or a pattern or practice of data irregularities that could affect approval of the application. In addition, the consent decree prevented Ranbaxy from manufacturing drugs for introduction to the U.S. market and for the President's Emergency Plan for AIDS Relief (PEPFAR) Program at the Paonta Sahib, Batamandi, Dewas, and Gloversville facilities until drugs can be manufactured at such facilities in compliance with U.S. manufacturing quality standards. **In 2013, Ranbaxy USA Inc., a subsidiary of Ranbaxy Laboratories Limited, pleaded guilty to three felony FDCA counts, and four felony counts of knowingly making material false statements to the FDA regarding generic drugs made at two of Ranbaxy's manufacturing facilities in India. It agreed to pay a criminal fine and forfeiture totaling $150 million and to settle civil claims under the False Claims Act and related State laws for $350 million. This happened to be USA's largest financial penalty paid by a generic pharmaceutical company for FDCA violations** Specifically, Ranbaxy USA admitted to introducing certain batches of adulterated drugs that included Sotret (branded generic form of isotretinoin, a drug used to treat severe recalcitrant nodular acne), Gabapent in (used to treat epilepsy and nerve pain), and Ciprofloxacin (broad-spectrum antibiotic) **The FDA also followed up the above order with an import alert under which U.S. officials could detain at the U.S. border drug products manufactured at Ranbaxy Laboratories**, Ltd.'s facility in Mohali, India. It's Mohali plant was prohibited from manufacturing FDA regulated drugs until the firm's methods, facilities, and controls used to manufacture drugs at the Mohali facility are established, operated, and administered in compliance with CGMP. In 2014, the FDA prohibited the Toansa facility of Ranbaxy to manufacture and distribute active pharmaceutical ingredients (APIs) for FDA-regulated drug products. Among others the FDA's form 483 listed numerous violations from CGMP which included flies in the sample storage room, inadequate control over sample and non-adherence of procedures in sample analysis. **The report especially came strongly on the deliberate falsification of data by Ranbaxy through methods of retesting suspect API results until acceptable results were obtained, or in failing that not reporting suspect results**. **Some other lapses that were discovered during inspection included- samples not being analysed according to established laboratory test method procedures, non-reporting of numerous test results, lack of written procedures and documentation of test results, inadequate controls over computerized systems, backdating testing records and log books, and non-control of laboratory samples to prevent mixing of samples. There were also inadequacies in laboratory facilities, maintenance of manufacturing equipment, and calibration of analytical instruments.**

Intellectual Property Protections Play a Crucial Role in Protecting Against Counterfeit Medicine

Ancevska-Netkovska et al 20[Katerina Ancevska-Netkovska, 2 Institute of Applied Chemistry, Faculty of Pharmacy, University "Ss. Cyril and Methodius" Mother Teresa , Katerina Brezovska, 2 Institute of Applied Chemistry and Pharmaceutical Analysis, Faculty of Pharmacy, University "Ss. Cyril and Methodius" Mother Teresa, , Nikola Geskovski, 3 Institute of Pharmaceutical Technology, Faculty of Pharmacy, University "Ss. Cyril and Methodius" Mother Teresa, , Jasmina Tonik-Ribarska, Institute of Applied Chemistry and Pharmaceutical Analysis, Faculty of Pharmacy, University "Ss. Cyril and Methodius" Mother Teresa , Biljana Petrovska-Jakimovska, 3 Institute of Pharmaceutical Technology, Faculty of Pharmacy, University "Ss. Cyril and Methodius" Mother Teresa, , Blagoj Achevski, Institute of Applied Chemistry and Pharmaceutical Analysis, Faculty of Pharmacy, University "Ss. Cyril and Methodius" Mother Teresa , Katerina Goracinova, Institute of Pharmaceutical Technology, Faculty of Pharmacy,

University “Ss. Cyril and Methodius” Mother Teresa, 2020, “The role of intellectual property rights and package safety features in the prevention of counterfeit medicines,” Arh. farm. 2020; 70: 332 – 343, https://scindeks-clanci.ceon.rs/data/pdf/0004-1963/2020/0004-19632006332A.pdf, Accessed: 8/8/2021].

The fast growth of counterfeiting medicines in the last two decades has created one of the biggest problems facing the pharmaceutical industry on the global level. This problem addressed from the pharmaceutical industry aspect is mainly seen as a problem of a trade competition by unauthorized use of the intellectual property of the pharmaceutical industry, resulting in loss of income, product withdrawal, loss of brand value, etc. (1). Also, **the global rise in online pharmacies, have widened the market for falsified drugs, which is a serious threat to public health and safety as falsified medicinal products bypass the common distribution routes and easily reach the public** (2). Therefore, this problem is much more significant if being addressed as a public health risk, because of the severe consequences that may cause to the patient's health starting from lower therapeutic potential to serious side effects that can result in death. Hence, this problem should be considered primarily from a public health perspective, but also as an intellectual property concern. Taking into account that counterfeiting of medicines is an organized crime, violating both the laws for the medicines and medical devices and regulations for the protection of the intellectual property rights of the pharmaceutical industry, the approaches for solving this issue should be based on an integrated and multilateral methodology. They should be supported by cooperation between the authorities involved, such as public health authorities and medicines agencies, as well as customs and police authorities at a national, regional, and international level, assisted by the pharmaceutical industry (3–7). **The first step that must be taken for the prevention of counterfeit medicines is the establishment, implementation, and enforcement of legislation and regulatory infrastructure concerning: Legislation in the field of healthcare and pharmacy Legislation in the field of protection of intellectual property rights; Legislation in the field of trading – customs legislation, the legislation of transportation and storage; Legislation in the field of fight against organized crime – discovery and sanction of the falsified medicines;** In July 2011, the European Union (EU) strengthened patient and consumer protection by the introduction of new directive 2011/62/EU also known as EU Falsified Medicines Directive (EU FMD) (8) aimed to prevent counterfeit medicines from entering the supply chain and reaching the patient. The directive introduced harmonized safety and strengthened control measures throughout the whole of Europe by applying standards which include the introduction of safety features of the packaging of medicines, strengthened requirements for active substances and medicine distribution as well as regulation of internet sale of drugs (9). The Commission Delegated Regulation 2016/161 defines the requirements for the identification and confirmation system of the authenticity 334 of the medicines in the distribution chain using package safety features (Unique Identifier and Anti tampering device). According to this Regulation, the identity and authenticity of medicinal products are guaranteed by an end-to-end verification of all medicinal products bearing the safety features (10). To minimize the online-based falsified medicine frauds, the abovementioned Regulation and Directive also introduced a common logo for the websites of legal online pharmacies and approved merchants allowing the patients and consumers to easily identify authorized online pharmacies with approved and authenticated medicines. **The national laws regulate the protection of intellectual property rights, and additionally, the Trade-related Aspects of Intellectual property rights (TRIPS) Agreement is applicable on an international level. Pharmaceutical manufacturers have a crucial role in the prevention and early detection of counterfeited medicines, by the establishment of a strategy for the protection of their intellectual property rights and by providing transparency and traceability with an application of new technologies for identification and confirmation of the authenticity of the products in all stages of the distribution chain.** Intellectual property rights in the prevention of counterfeit medicines Intellectual property rights (IPRs) play a vital role in the modern economy, being a robust tool, for the protection of the investments, time, money, and effort of the intellectual property inventor, granting him an exclusive right for using his invention for a specific period. **IPRs are defined as mechanisms for the protection of ideas, patents, and innovations, taking into consideration the protection of trademarks, industrial design, or copyrights in every link of the supply chain, and are an essential tool in the fight against counterfeit medicines (11).** But, in consideration of the role of the intellectual property rights in the prevention of counterfeit medicines, the restricted period of validity of IPRs, and the exclusivity of the innovator's idea, the patent or the innovation must be taken into account. Additionally, the patent provides exclusive rights with a chance for industrial applicability of the innovation or achieving society value (12). The main issue of patent protection is the obligatory publication of technical information that can be useful for counterfeiters. The patent

rights have invaluable importance, for the brand protection of pharmaceutical products as well as the protection of their trademarks. Pharmaceutical product brands are designed for the promotion and recognition of pharmaceutical companies, and also for gaining loyalty and trust by the customers. Branded products also dictate the market price when compared to non-protected, non-branded, and generic medicines, giving the benefit to the pharmaceutical industry from the investment in protection and conduction of suitable strategy for protection of 335 intellectual property. Patients are aware of paying a higher price for branded medicine, with gained trust in comparison to a medicine that has not been recognized as a brand (13). Building up a brand involves time and investment for every manufacturer, which in combination with a good marketing campaign, results in a dominant role in the market and enormous profit. Consumer opinion for the brand can change through time, in a positive or negative connotation. Unwanted events can cause damage to the image, and the value of the brand, so-called "brand erosion". Brand erosion phenomenon can be subtle and gradual or catastrophic and unexpected. Information about the counterfeited product, mentioning the name of the original brand and holder of corporate rights, may gradually project a negative image in the customer perspective, causing damage in the future marketing of the branded product. In these cases, the patients may search for alternative medicine from another manufacturer. Recovery of the market share loss and renewal of the image of the brand, requires additional marketing costs, causing profit loss. Furthermore, the downfall of the brand can reduce the confidence of the public in the pharmaceutical company, affecting the marketing of other products of the manufacturer. The price that pharmaceutical companies pay, as a result of the counterfeit medicines, is high. The effects of this phenomenon on the pharmaceutical industry include reduction of employment, reduction in the investments in research and development, and at the same time investment of a lot of money in marketing to rebuild the clients' trust. **Before being released for use and market, branded medicines manufactured by the pharmaceutical companies go through many regulatory filters to ensure that the products are safe, efficient, and of suitable quality**. Additionally, the pharmaceutical industry has to invest in building the trust of doctors, pharmacists, and the public and convince them that they are prescribing the best medicine for a patient's needs. By using the Internet, patients have easier access to information about the medicines and an option to participate in the selection of suitable medication for their needs. But the available information usually does not include the authenticity check of the medicine (14). **If the quality and safety of medicines are questionable for the public then the trust in the whole medical system will be lost, harming the pharmaceutical industry as well, as financial loss.**

In 2010, 64% of foreign generic drug plants had never been inspected; in 2019 the FDA still lacked data on 33%

United States Government Accountability Office (GAO) 19 [GAO, December 10 2019, "DRUG SAFETY Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections," GAO, https://www.gao.gov/assets/gao-20-262t.pdf, Accessed: 8/10/2021].

Since 2010, FDA has taken steps to improve the accuracy and completeness of its catalog of foreign drug establishments. These steps are intended to address what FDA acknowledged as a challenge as early as 1988, following an internal evaluation that recommended that the agency develop a comprehensive catalog of all foreign establishments shipping drugs to the United States that could be used to improve longrange inspection planning and scheduling.37 We also highlighted this challenge in our previous reports.38 **Most recently, in 2010, we found that a majority (64 percent) of foreign establishments in FDA's catalog may never have been inspected by the agency**. Since then, FDA officials said that the agency has taken steps to improve the accuracy and completeness of its catalog by • Requiring establishments to use a unique, numeric identifier. FDASIA required establishments to provide a unique facility identifier during their annual registration with FDA, and FDA elected to require establishments to use the Dun and Bradstreet Data Universal Numbering System (D-U-N-S®) number.39 Using this number allows FDA to automatically validate data from every registration submission against the Dun and Bradstreet database to ensure the accuracy of the information. Any mismatch may result in rejection of a registration submission. The D-U-N-S® number also allows FDA to determine whether a firm has gone out of business or relocated. FDA officials said that it has also helped FDA improve the interoperability of the agency's data systems that collect or use registered facility information, as well as the interoperability of other agencies' systems. **• Adding two foreign inventory coordinators in 2013 tasked with incorporating foreign registrations and annual updates into FDA's master inventory. Additionally, these coordinators are responsible for updating FDA's inspection data to reflect accurate inventory updates.** • Establishing a data governance board to define standards, best practices, and policies for inventory data management. According to FDA officials, the governance board, which was created in May 2015, meets biweekly to examine the databases responsible for storing 37Office of Regulatory Affairs, Program Evaluation Branch, **"An Evaluation of FDA's Foreign Inspection Program," Rockville, Md., March 1988. This internal evaluation found that FDA did not maintain a catalog (previously referred**

to by FDA as an inventory) of all foreign drug establishments that were subject to FDA regulation. 38See GAO/HEHS-98-21; GAO-08-970; and GAO-10-961. 39Pub. L. No. 112-144, § 702(b), 126 Stat. 1065 (codified at 21 U.S.C. § 360(i). FDA Has Improved Information on Its Catalog of Foreign Drug Establishments, but Lacks Inspection History on OneThird of Them Page 21 GAO-17-143 FDA's Foreign Offices and Drug Inspections information about drug establishments. Officials said the board has developed guidance for merging data processes and is working toward defining data metrics to determine whether they have improved on their reporting. The board has also defined data standards for storing key attributes of establishments, such as companies' names, and continues to examine best practices for sharing establishment data across FDA. As a result of these steps, FDA has reduced its catalog of establishments that may never have had a surveillance inspection. **Currently, FDA lacks information on the inspection history of 33 percent of the foreign establishments in its catalog**, compared to the 64 percent for which it lacked inspection history in 2010. According to FDA officials, the establishments that are subject to inspections are continuously changing. For example, they said that some of the establishments without an inspection history may be newly registered with the agency, thus accounting for their lack of an inspection history; others could be establishments that are not subject to inspection, such as those that may have gone out of business or that have never shipped products to the United States. Although this may be the case for some—or even many— of these establishments**, the fact remains that FDA does not know whether or for how long these establishments have or may have supplied drugs to the U.S. market, and has little other information about them.** While the agency has made progress in reducing this knowledge gap, it is important to note that **the overall number of foreign establishments with no surveillance inspection history (about 1,000 of the approximately 3,000) remains large.40 (See app. II for information on the numbers and locations of the establishments for which FDA lacks an inspection history.)** To address this persistent concern, the agency plans to inspect all establishments in its catalog with no prior surveillance inspection history over the next 3 years (approximately one-third each year), beginning in fiscal year 2017. FDA will consider these establishments' risk scores as determined by the agency's risk-based site selection model to prioritize them for inspection, starting with those establishments having the highest risk scores. **Some recent FDA inspections have uncovered significant issues at foreign drug manufacturing establishments, including raw material storage rooms that had never been cleaned and the presence of 40The majority of these establishments are in China, India, and South Korea.** Page 22 GAO-17-143 FDA's Foreign Offices and Drug Inspections pests in a controlled processing area, underscoring the importance for FDA to fill this knowledge gap.

Foreign drug firms generally get 12 weeks in advance of FDA inspections, raising questions about the equivalence in foreign production to domestic standards

United States Government Accountability Office (GAO) 19 [GAO, December 10 2019, "DRUG SAFETY Preliminary Findings Indicate Persistent Challenges with FDA Foreign Inspections," GAO, https://www.gao.gov/assets/gao-20-262t.pdf, Accessed: 8/10/2021].

Our preliminary analysis indicates that FDA continues to face unique challenges when inspecting foreign drug establishments—as compared to domestic establishments—that raise questions about the equivalence of these inspections. Specifically, based on our interviews with drug investigators in the **dedicated foreign drug cadre and FDA's foreign offices in China and India, we identified four challenge areas related to conducting foreign inspections**, which are described below. Of the four challenge areas identified, **three areas—preannouncing inspections, language barriers, and lack of flexibility—were also raised in our 2008 report.34** Preannouncing Inspections. **As we reported in 2008, the amount of notice FDA generally gives to foreign drug establishments in advance of an inspection is different than for domestic establishments.35 Domestic drug establishment inspections are almost always unannounced, whereas foreign establishments generally receive advance notice of an FDA inspection. According to FDA officials, FDA is not required to preannounce foreign inspections**. However, they said the agency generally does so to avoid wasting agency resources, obtain the establishment's assistance to make travel arrangements, and ensure the safety of investigators when traveling in country. **FDA does conduct some unannounced foreign inspections, particularly if the investigators**

conducting the inspection are based in FDA's foreign offices. However, FDA officials told us that FDA does not have data on the frequency with which foreign drug inspections are unannounced, nor the extent to which the amount of notice provided to foreign establishments varies. According to FDA officials, this is because FDA does not have a data field in its database to systematically track this information.36 **However, the officials estimated that the agency generally gives 12 weeks of notice to establishments that investigators are coming when investigators are traveling from the United States. While investigators in FDA's China and India offices do conduct unannounced or short-notice inspections, these staff do not perform most of the inspections in these countries**. (See table 3). **Our preliminary work indicates that preannouncing foreign inspections can create challenges and raises questions about the equivalence to domestic inspections**. **Of the 18 investigators we interviewed, 14 said that there are downsides to preannouncing foreign inspections, particularly that providing advance notice gives foreign establishments the opportunity to fix problems before the investigator arrives. For example, when an inspection is preannounced, it gives establishments time to clean up their facility and update or generate new operating procedures.** However, establishments are expected to be in a constant state of compliance and always ready for an FDA inspection, and several investigators told us seeing the true day-to-day operating environment for an establishment is more likely during an unannounced inspection. Page 23 GAO-20-262T

TRIPS Flexibilities

Article 27 and Article 31 Exemptions of TRIPS

Globerman 16 [Steven Globerman- Resident Scholar and Addington Chair in Measurement, Professor Emeritus, Western Washington University. "Intellectual Property Rights and the Promotion of Biologics, Medical Devices and Trade in Pharmaceuticals." Fraser Institute. October 14 2016. https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-and-promotion-of-biologics-medical-devices-and-trade-in-pharmaceuticals-post.pdf], Accessed: 8/15/2021].

Generic and biosimilar producers can challenge these patents in court, and they can also petition regulators to deny or delay the approval of a drug for a second use to limit the advantage of pharmaceutical originators. In doing so, generic and biosimilar firms have sought allies in government, civil society, medical professionals, private insurers, and the general public on the basis that monopoly pricing by originators effectively denies access to medication to patients with limited means. The moral resonance of this claim has been particularly profound in emerging markets, but in developed countries where governments bear the costs of public health care provision, the pecuniary interest in lowering pharmaceutical prices as quickly as possible has resounded powerfully as well. **Under the World Trade Organization Trade Related Intellectual Property (TRIPS) agreement, two articles are particularly important for the pharmaceutical sector: Article 27 and Article 31. TRIPS Article 27 defines what may be patented, citing the standard criteria of originality, inventive step, and capacity for industrial application, but it provides for two important exceptions. Article 27 section 2 states: Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.** (World Trade Organization, 1986) **Protection of public order could lead to the denial of a patent for a drug to treat HIV–AIDS by a government (such as, for a time, South Africa's) bearing a prejudice against the infected**. Exemptions on the basis of "morality" are not defined, and this exemption could be used to deny patents to abortifacient drugs, treatments for erectile dysfunction, or birth control drugs in some countries. Similarly, the protection of human, animal, or plant life, and the avoidance of "prejudice to the environment" are undefined and provide broad latitude to governments to deny a patent to particular pharmaceuticals. **Article 27 section 3 erodes the protection for intellectual property for pharmaceutical firms even further, providing for Members may also exclude from patentability: (a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals; (b) plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes**. However, Members shall provide for the protection of plant varieties either by patents or by an effective sui generis system or by any combination thereof. The provisions of this subparagraph shall be reviewed four years after the date of entry into force of the WTO Agreement. (World Trade Organization, 1986) Hormonal therapies, biologics, and drugs based on modified genetic material (GMOs) could all be excluded from intellectual property protections under these broad provisions. For pharmaceutical originators, TRIPS Article 27 alone has the potential to vitiate the additional protections promised by TRIPS. **TRIPS Article 31 confirms the right of governments to issue "compulsory licenses" to generic manufacturers to produce copies of a patent medicine in the case of a public health emergency. The WTO has oversight over this clause, and a government can be challenged on its claim of an emergency by another WTO member government.** Apart from emergency conditions, the TRIPs agreement binds signatory states to enforce private intellectual property rights with regard to pharmaceuticals (Boulet, 2000).

Between 2011 and 2016, the TRIPS flexibilities were utilized; 103 instances used them from AIDS

't Hoen, et al 18 [Ellen FM 't Hoen, Global Health Unit, Department of Health Sciences, University Medical Centre Groningen, University of Groningen, Jacquelyn Veraldi, Faculty of Law, University of Groningen, Groningen, the Netherlands, Brigit Toebes, Department of International Law, University of Groningen, Groningen, the Netherlands, and Hans V Hogerzei, Global Health Unit, Department of Health Sciences, University Medical Centre Groningen, University of Groningen, PO Box 30.001, Groningen, 9700 RB, the Netherlands, "Medicine Procurement and the Use of Flexibilities in the Agreement on Trade-Related Aspects of Intellectual Property Rights, 2001–2016." Bulletin of the World Health Organization, vol. 96, no. 3, Mar. 2018, pp. 185–93. PubMed Central, https://doi.org/10.2471/BLT.17.199364, Accessed: 8/15/2021].

Go to: Use of TRIPS flexibility **We collected information on 176 instances of the possible use of TRIPS flexibilities by 89 countries between 2011 and 2016 that were associated with government actions to ensure access to patented medicines (Table 1). Of these, 144 (81.8%) made use of TRIPS flexibility measures:** of which 100 involved compulsory or public noncommercial use licences, 40 invoked the least-developed countries pharmaceutical transition measure, 1 involved parallel importation and 3 involved research exceptions. **Of the 100 instances of compulsory licensing, 81 were implemented, but 19 were not because: (i) the patent holder offered a price reduction or donation (6 instances**); (ii) the patent holder agreed to a voluntary licence allowing the purchase of a generic medicine (5 instances); (iii) no relevant patent existed that warranted the pursuit of the measure (1 instance); (iv) the application was rejected on legal or procedural grounds (5 instances); (v) the applicant withdrew the application (1 instance); and (vi) the application has been pending since 2005 with no response (1 instance). **The least-developed countries pharmaceutical transition measure was invoked in 40 instances by a total of 28 countries.** However, 2 of the 28 countries were developing countries that invoked the measure erroneously, 3 were observer countries and 1 was not a WTO Member. The 3 research exceptions involved generic medicines used in clinical studies. In the remaining 32 instances, governments used measures not related to patents (Table 1). In 26 of the 32, countries informed the supplier that there was no relevant patent in their territory. However, this was only the case in 4 of the 26. The other 6 instances involved import authorizations for products that did not refer to the patent status of the products: 4 concerned the importation of a product for which patents existed in the territory and 2 concerned countries that were not WTO Members. **Overall, TRIPS flexibilities were implemented in 152 of the 176 instances identified (86.4%). The 176 instances covered products for treating 14 different diseases**. Table 2 summarizes how often TRIPS flexibilities were used for different diseases according to the country's WTO classification. **Of the 140 instances in which either compulsory licences, public noncommercial use licences or the least-developed countries pharmaceutical transition measure was used, 103 (73.6%) concerned human immunodeficiency virus (HIV) infection and acquired immune deficiency syndrome (AIDS) or related diseases. For 25% (10/40) of instances in which the least-developed countries pharmaceutical transition measure was used, the flexibility was invoked for all medicines. A TRIPS flexibility was used for cancer medications in 6.8% (12/176)**. Fig. 1 shows the variation in the number of instances of TRIPS flexibility use over time: use of compulsory licences, public noncommercial use licences and the least-developed countries pharmaceutical transition measure peaked between 2004 and 2008. **Our study found that countries made extensive use of TRIPS flexibilities between 2001 and 2016. This was previously unreported. The most frequently used measures were compulsory licensing, public noncommercial use licensing and the least-developed countries pharmaceutical transition measure, which together accounted for 79.5% (140/176) of instances**. To date, the most comprehensive, published database lists 34 potential compulsory licences in 26 countries.9 **We also documented 26 instances in**

which generic medicines were procured after a declaration that there was no relevant patent in the territory. Strictly, this is not a TRIPS flexibility. However, generic medicines were procured despite patents actually being registered in 22 of the 26 instances. All concerned HIV medications, which points to a more flexible attitude towards the protection of intellectual property in the context of the global response to the HIV epidemic. **In the majority of instances we identified, the application of a TRIPS flexibility was driven by the procurement of medicines for the treatment of HIV/AIDS and related diseases.** In 1997, the World Health Organization (WHO) published the first guide for Member States on how to comply with TRIPS while limiting the negative effect of patent protection on medicine availability.17 The political momentum of WHO's "3 by 5" initiative for HIV treatment combined with HIV treatment campaigns and new funding from governments, the Global Fund to Fight AIDS, Tuberculosis and Malaria and the United States' President's Emergency Plan for AIDS Relief enabled countries to scale up the procurement of antiretroviral medicines. In addition, new global funding mechanisms incorporated procurement guidelines that encouraged countries to purchase low-priced medicines. The Global Fund, for example, urged its recipients "to attain and to use the lowest price of products through competitive purchasing from qualified manufacturers." The Global Fund also specifically encouraged "recipients in countries that are WTO Members to use the provisions of the TRIPS Agreement and interpreted in the Doha Declaration, including the flexibilities therein, to ensure the lowest possible price for products of assured quality."18 Furthermore, World Bank guidelines on the procurement of HIV medicines provided governments with practical advice on how to use various TRIPS flexibilities.19

Donations

COVAX delivered vaccines to more than 100 economies 42 days after first international delivery

WTO 21 [WTO, "COVAX reaches over 100 economies, 42 days after first international delivery." WTO. April 8 2021. https://www.unicefusa.org/stories/covax-mission-forges-ahead-vaccinate-world-against-covid-19/38636, Accessed: 8/7/2021].

The COVAX Facility has now delivered life-saving vaccines to over 100 economies since making its first international delivery to Ghana on 24 February 2021. So far, more than 38 million doses of vaccines from manufacturers AstraZeneca, Pfizer-BioNTech and Serum Institute of India (SII) have now been delivered, including 61 economies eligible for vaccines through the Gavi COVAX Advance Market Commitment. COVAX aims to supply vaccines to all participating economies that have requested vaccines, in the first half of 2021, despite some delays in planned deliveries for March and April. More than one hundred economies have received life-saving COVID-19 vaccines from COVAX, the global mechanism for equitable access to COVID-19 vaccines. The milestone comes 42 days after the first COVAX doses were shipped and delivered internationally, to Ghana on 24 February 2021. **COVAX has now delivered more than 38 million doses across six continents, supplied by three manufacturers, AstraZeneca, Pfizer-BioNTech and the Serum Institute of India (SII). Of the over 100 economies reached, 61 are among the 92 lower-income economies receiving vaccines funded through the Gavi COVAX Advance Market Commitment (AMC).** Despite reduced supply availability in March and April – the result of vaccine manufacturers scaling and optimizing their production processes in the early phase of the rollout, as well as increased demand for COVID-19 vaccines in India – COVAX expects to deliver doses to all participating economies that have requested vaccines in the first half of the year. "In under four months since the very first mass vaccination outside a clinical setting anywhere in the world, it is tremendously gratifying that the roll-out of COVAX doses has already reached one hundred countries," said Dr Seth Berkley, CEO of Gavi, the Vaccine Alliance. "COVAX may be on track to deliver to all participating economies in the first half of the year yet we still face a daunting challenge as we seek to end the acute stage of the pandemic: we will only be safe when everybody is safe and our efforts to rapidly accelerate the volume of doses depend on the continued support of governments and vaccine manufacturers. As we continue with the largest and most rapid global vaccine rollout in history, this is no time for complacency." **"COVAX has given the world the best way to ensure the fastest, most equitable rollout of safe and effective vaccines to all at-risk people in every country on the planet," said Dr Tedros Adhanom Ghebreyesus, WHO Director-General.** "If we are going to realize this great opportunity, countries, producers and the international system must come together to prioritize vaccine supply through COVAX. Our collective future, literally, depends on it." "This is a significant milestone in the fight against COVID-19. Faced with the rapid spread of COVID-19 variants, global access to vaccines is fundamentally important to reduce the prevalence of the disease, slow down viral mutation, and hasten the end of the pandemic," said Dr Richard Hatchett, CEO of the Coalition for Epidemic Preparedness Innovations (CEPI). **"The extraordinary scientific achievements of the last year must now be matched by an unprecedented effort to protect the most vulnerable, so the global community must remain firmly focused on reducing the equity gap in COVID-19 vaccine distribution."** "In just a month and a half, the ambition of granting countries access to COVID vaccines is becoming a reality, thanks to the outstanding work of our partners in the COVAX Facility," said Henrietta Fore, UNICEF Executive Director. "However, this is no time to celebrate; it is time to accelerate. With variants emerging all over the world, we need to speed up global rollout. To do this, we need governments, along with other partners, to take necessary steps to increase supply, including by simplifying barriers to intellectual property rights, eliminating direct and indirect measures that restrict exports of COVID-19 vaccines, and donating excess vaccine doses as quickly as possible." According to its latest supply forecast, COVAX expects to deliver at least 2 billion doses of vaccines in 2021. In order to reach this goal, the COVAX Facility will continue to diversify its portfolio further, and will announce new agreements with vaccine manufacturers in due course. Furthermore, in March it was announced that the United States government will host the launch event for the 2021 Gavi COVAX AMC Invest Opportunity to catalyze further commitment and support for accelerated access to vaccines for AMC-supported economies. An additional US$ 2 billion is required in 2021 to finance and secure up to a total of 1.8 billion donor-funded doses of vaccines**. COVAX is also working to secure additional sourcing of vaccines in the form of dose-sharing from higher income countries.**

G7 countries committed 1 billion vaccine doses through UNICEF's expansion of COVAX

Ferguson 21 [Sarah Ferguson- senior editor at UNICEF. June 14 2021. "COVAX Mission Forges Ahead: Vaccinate the World Against COVID-19." UNICEF USA, https://www.unicefusa.org/stories/covax-mission-forges-ahead-vaccinate-world-against-covid-19/38636, Accessed: 8/7/2021].

As countries with high vaccination rates begin to see a steady decline in COVID-19 transmission rates, poorer nations are lagging far behind. The vast majority of people in developing countries — including frontline health care workers — still have not received their first shot. "Globally, we are still in a perilous situation," warned World Health Organization Director-General Tedros Adhanom Ghebreyesus. "Yes, vaccines are reducing severe disease and death in countries that are fortunate enough to have them in sufficient quantities, and early results suggest that vaccines might also drive down transmission. But the shocking global disparity in access to vaccines remains one of the biggest risks to ending the pandemic." UN0469997.jpg.700w.jpg A health worker administers a COVID-19 vaccine dose supplied by the COVAX Facilty in Guinea-Bissau on May 25, 2021. A health care worker administers a dose of COVID-19 vaccine supplied by the COVAX Facility in Guinea-Bissau on May 25, 2021. Guinea-Bissau is one of the world's poorest and most fragile countries. © UNICEF/UN0469995/ Now's the time to close the dangerous gap in vaccine coverage between rich and poor countries In a May 31, 2021 Washington Post op/ed, Ghebreyesus joined the leaders of the International Monetary Fund, the World Bank Group and the World Trade Organization calling for a "stepped-up coordinated strategy, backed by new financing, to vaccinate the world." **The new proposal builds on the ongoing work of COVAX, the multi-agency global mechanism for equitable access to COVID-19 vaccines, a pillar of the Access to COVID-19 Tools Accelerator initiative (ACT-A). UNICEF is a key partner in COVAX and ACT-A, leading on procurement and providing on-the-ground support to prepare for and facilitate vaccine rollouts around the world. COVAX has proven it works. Designed and implemented in the midst of an unprecedented public health crisis, it has delivered almost 93 million doses to 134 countries and economies around the world since February —** from remote islands to conflict settings — managing the largest and most complex rollout of vaccines in history. **More than 35 countries received their first COVID-19 vaccine doses thanks to COVAX.** UN0451880.jpg.700w.jpg On April 26, 2021, health workers at Hanoi Medical University flash the V for vaccinated sign after receiving their COVID-19 doses supplied through the COVAX Facility. Health workers at Hanoi Medical University in Vietnam flash the "V for vaccinated" sign after receiving their COVID-19 vaccine doses through the COVAX Facility on April 26, 2021. © UNICEF/UN0451880/Le Vu No one is safe until everyone is safe **The proposed $50 billion investment will help end the pandemic faster in the developing world, preventing the spread of deadly variants,** saving lives and accelerating economic recovery, generating an estimated $9 trillion in additional global output. WHO's aim to vaccinate approximately 30 percent of the eligible population by the end of 2021 through COVAX could rise to 40 percent with the new investment, and at least 60 percent by the first half of 2022. There is no time to lose. "We have issued repeated warnings of the risks of letting down our guard and leaving low- and middle-income countries without equitable access to vaccines, diagnostics and therapeutics," said UNICEF Executive Director Henrietta Fore. "We are concerned that the deadly spike in India is a precursor to what will happen if those warnings remain unheeded. While the situation in India is tragic, it is not unique. Cases are exploding and health systems are struggling in countries near – like Nepal, Sri Lanka and Maldives – and far, like Argentina and Brazil. The cost for children and families will be incalculable." You can't vaccinate your way out of a surge One of the consequences of India's crushing second wave is a severe reduction in vaccines available to COVAX. Soaring domestic demand for vaccines in India, a global hub for vaccine production, meant that 140 million doses intended for distribution to low- and lower-middle-income countries by COVAX through the end of May were not available. Another 50 million doses slated for June delivery are likely to be unavailable as well. To meet that urgent need, COVAX is continuing to diversify its portfolio and channels for accessing vaccines. Advance negotiations with other vaccine manufacturers are underway. **On June 2, UNICEF signed a longterm agreement with Moderna for up to 34 million doses of the vaccine for around 92 countries and territories through COVAX in 2021.** The traumatic effects of the second wave in Southeast Asia and its impact on both health care systems and global vaccine supplies underscore the need to vaccinate before a surge hits. By the time a country's case rate escalates, the same health care workers needed to administer vaccines and conduct testing and contact tracing are already working around the clock caring for those who are severely ill. Meanwhile, as the coronavirus continues to circumnavigate the globe, the threat of dangerous variants looms. These variants may require booster shots, further straining the world's vaccine supply. The simplification of Intellectual Property Rights (IPR) through voluntary and proactive licensing by IPR holders will help pave the way for

product developers and manufacturers to collaborate and innovate, increasing the scale and geographic diversity of manufacturing capacity. UN0459773.jpg.700w.jpg Nurse Jeanne received her COVID-19 vaccine, supplied through the COVAX initiative, in Goma, Democratic Republic of the Congo. Nurse Jeanne received her COVID-19 vaccine, supplied through the COVAX initiative, in Goma, Democratic Republic of the Congo. The May 22 eruption of Mount Nyiragongo and subsequent earthquakes have displaced as many as 400,000 people — including 280,000 children — in and around Goma. © UNICEF/UN0459773/Wenga **To meet urgent demand, wealthy nations must step up and donate all available vaccine doses to developing countries** To prevent future deadly surges, wealthy nations must donate available vaccine doses to developing countries now. **UNICEF analysis shows that G7 countries will soon have enough doses to donate 20 percent of their vaccines between June and August — more than 150 million doses — without significant delay to current plans to vaccinate their adult populations. On June 3, the United States announced plans to share 80 million COVID-19 vaccine doses — 13 percent of total U.S. vaccine production — by the end of June; three-quarters of the initial 25 million doses will be donated through COVAX, prioritizing Latin America and the Caribbean, South and Southeast Asia and Africa.** In the lead-up to June's G7 Summit, **UNICEF mobilized a global #DonateDosesNOW advocacy and communications campaign.** On June 13, the G7 Group affirmed its support for all pillars of ACT-A and the COVAX Facility and announced pledges of at least 870 million additional COVID-19 vaccine doses, with the aim to deliver at least half by the end of 2021. **This brings the full commitment by the G7 to 1 billion doses.** G7 leaders have committed to donating 1 billion COVID-19 vaccine doses “We welcome the commitment this week by leaders of G7 nations to accelerate the rollout of safe, effective, accessible and affordable vaccines for the poorest countries, with a goal toward ending the pandemic in 2022," said UNICEF Executive Director Henrietta Fore. "Equitable access to COVID-19 vaccines represents the clearest pathway out of this pandemic for all of us — children included, and commitments announced by G7 members last week are an important step in this direction. “UNICEF is particularly pleased that some of the dose donations will be made available immediately to supplement ongoing shortfalls. However, time is still of the critical essence." UN0430550.jpg.700w.jpg On March 11, 2021, UNICEF staff oversee the delivery of Nepal's first shipment of syringes and vaccine safety boxes through the COVAX Facility at Tribhuvan International Airport in Kathmandu. UNICEF staff oversee the delivery of Nepal's first consignment of syringes and vaccine safety boxes through the COVAX Facility at Tribhuvan International Airport in Kathmandu on March 11, 2021. © UNICEF/UN0430550 UNICEF is preparing countries so they can introduce and scale up the rollout of COVID-19 vaccines Until vaccines are available for use, UNICEF is preparing countries so that they can introduce and then scale up the rollout of COVID-19 vaccines. As seen in the experience of high-income countries, this is a complex operation that requires resources, expertise and robust planning, including: pre-positioning syringes, cold chain equipment to keep vaccines at the proper temperature and protective gear including masks and gowns for vaccinators ensuring countries have plans to deliver the vaccines to people that are outside the scope of traditional immunization programs in low-income and lower-middle-income countries putting in place communication and community engagement plans to build trust in vaccines “We have reached a grim milestone in this pandemic: There are already more dead from COVID-19 in 2021 than in all of last year," said Fore. "Without urgent action, this devastation will continue." At this historic moment, with so much at stake, UNICEF is leveraging decades of immunization expertise to help end the pandemic.