# Biotech DA

### *IP strikes a needed balance between innovation and access.*

[WIPO]. "Promoting access to medical innovation." 05, 2013. https://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html Accessed on August 09, 2021. [No initials set.]

"The rationale of the intellectual property (IP) system in general, and the patent system in particular, is to make investment in innovation attractive and to offer a mechanism which ensures that the knowledge contained in patent applications is accessible to society. In this way, it seeks to balance competing private and public interests. Anyone applying for a patent is required to disclose the details of their technology so that the public is aware of, and can eventually use, the knowledge contained in patent documents. Patent information available through public databases, such as WIPO's PATENTSCOPE, offers useful insights about innovation trends and freedom-to-operate, and can help shape patenting and licensing strategies. Data indicate overall long-term growth in patenting of medical technologies (a sign of renewed investment in this area) and that an increasingly diverse range of public and private users (see Figures 2 and 3), including from emerging economies, are using the international patent system. While the patent system is designed to promote innovation by providing an incentive to invest in R&D, the impact of patents on access to medical technologies is complex and much debated. Just as the existence of a patent need not be a barrier to access, the absence of a patent right does not guarantee effective access. As noted in the WHO's Framework for Access to Medicines, access to medicines is rarely dependent on a single factor; it also includes rational selection and use of medicines, affordable prices, sustainable financing and reliable health and supply systems, among others. Striking an appropriate balance between encouraging medical innovation and enabling access to it has been a major preoccupation of policymakers, health activists and the private sector, since the 1990s when concerns about access came to the fore in relation to the treatment of HIV/AIDS in many African countries. The WTO's Doha Declaration on the TRIPs Agreement and Public Health of 2001, clarified a number of rules specific to IP and helped reassure the global community that IP should not prevent access to the medicines needed in developing countries. Medical technologies are usually very expensive to develop but relatively cheap to reproduce. Without the protection conferred by a patent it would not be financially viable for companies to continue investing in research, product development and regulatory approval. If competitors could "free ride" on the cost of developing a product and were able to immediately introduce their own versions, the inventor would not get the expected financial returns thereby weakening any incentive to develop new products."

### *That's crucial, as Pharmaceutical innovation and research spurs gene editing, biotechnology and other spin off applications*

Bradshaw 17 – Julia Bradshaw is a Business News Editor at The Telegraph. ("How gene editing is revolutionising the pharmaceuticals industry," The

Telegraph, http://www.telegraph.co.uk/business/2017/02/05/gene-editing-revolutionising-pharmaceuticals-industry/, February 5, 2017)
Fourteen years ago the first human genome was sequenced. It cost somewhere in the region of $2.7bn (£2.16bn). It was a collaborative effort across the globe that started in 1990 and took 13 years to complete. Fast forward to today, and companies are offering genome sequencing at a mere $1,000 a pop, taking hours or days, not years, and the price continues to fall. This revolution in human genomics has transformed the way we think about disease and our understanding of what causes it, paving the way for the development of treatments that are much more targeted at both the illness and the patient, such as cancer sufferers with a particular genetic mutation. It has also led to the rise of gene editing, a pioneering field in biotechnology whereby scientists can chop and change DNA at specific sites in an organism or cell using special molecular scissors. It's becoming increasingly crucial in the discovery, testing and manufacture of new drugs. Sequencing costs have fallen dramatically "Gene editing has been something of a revolution. It has transformed from something that is fantastically difficult to carry out into a day-to-day laboratory technology," says Dr Mike Mitchell, an analyst at Panmure Gordon. "It is now vital in both drug discovery and diagnostics and it's oncology and precision medicine that are driving this." The technique has taken off over the past decade. New editing tools to create genetically defined human cell lines have come to the fore, some open-access, others privately owned. The most popular is called Crispr and is accessible to all researchers. This has spurred a wave of activity in the biotech sector, with several companies now offering a suite of complex gene editing services that big pharmaceutical companies are more than happy to pay for. "We've had new companies with multi-billion dollar valuations coming to the market. I'm sure we will see many more active in this space, creating their own niches and applications and IP spurring further advances," says Dr Mitchell.

### *Affirming is devastating, Poor IP protection wrecks the healthcare and biotech industries*

George Goodno, 7-19-2017, "Weak Patent Law Endangers Healthcare Innovation," BiotechNow, http://www.biotech-now.org/public-policy/patently-biotech/2017/07/weak-patent-law-endangers-healthcare-innovation, George Goodno is the Director of Communications at the Biotechnology Innovation Organization, graduated from Oklahoma State University. ZKMSU
Strong patents are the lifeblood of America's innovation economy including the biotechnology industry. They are critical in ensuring a steady stream of capital to biotechnology companies developing innovative medicines, alternative energy sources, and insect and drought resistant crops – capital that has now begun to flow to other countries with stronger patent protections like the European Union and China. In a recent review of global patent protections, the U.S. Chamber of Commerce reported that the United States dropped from its #1 position to #10, tying with Hungary and falling behind most EU nations, Japan, and Singapore. Read the full report here. It can take a decade or more of privately funded research and development before a biotech company can bring its product to market. Only one in ten candidate drugs that make it as far as clinical trials will actually get licensed. Despite the risks of biotech investment, the industry attracts billions of dollars in new investments each year based on the promise of its innovative and patented discoveries, which will only be translated into actual commercial products providing a return on investment after years, sometimes decades, of capital-intensive investment and research efforts. Without strong and predictable protections for validly patented innovations, investors will shy away from investing in biotech innovation, degrading the ability to provide solutions to the most pressing medical,

agricultural, industrial, and environmental challenges facing our nation and the world. A short-sighted approach to patent reform will undermine the promise of these initiatives. Biotechnology is one of the fields where the U.S. remains an undisputed world leader – both in terms of conceptualizing new products and bringing them to market. Our Congress should be working to preserve and nurture the sectors where the U.S. remains head and shoulders above the rest of the world, where continued advancements hold the greatest societal and economic promise. Make no mistake: the impact of weakening patent protection would be severe, and the aftershock could be devastating.

### *Biotech solves a laundry list of impacts*

ICAF, 2010 (Industrial College of the Armed Forces, National Defense University, Authors include many US military colonels and faculty of the National Defense University, "Biotechnology 2010", Spring 2010, http://es.ndu.edu/Portals/75/Documents/industry-study/reports/2010/icaf-is-report-biotechnology-2010.pdf)//JBS

Biotechnology has the potential to solve some of the most complex problems of the 21st century. As an industry, biotechnology is unparalleled in its potential to impact global health, food and water security, energy security, and the environment. This innovation-based industry is strategically significant because it impacts both national security and the sustained growth of the domestic economy. For the United States to maintain its current competitive advantage in the industry, it must focus on policy and investments which strengthen the industry's ability to rapidly innovate and to transform innovative ideas into products and services for the global market. The purpose of this report is to conduct a strategic level examination of the biotechnology industry – an industry vital to the nation's security and economic welfare. The study includes over fifty activities spanning lectures by leading biotechnology experts and field visits to important government and corporate organizations. The industry study program includes travel to key domestic and international biotechnology centers such as Boston, Chicago, San Francisco, Taiwan, Singapore, Malaysia, and Japan. The study methodology uses critical thinking to analyze the structure, conduct and performance of the biotechnology industry and market sectors. This includes using the five forces of competition (new entrants, supplier power, buyer power, substitutes and the degree of rivalry) to assess the capacity and capability of U.S. biotechnology firms to deliver globally competitive products and services. Additionally, the methodology evaluates the biotechnology industry's performance in meeting national security interest and promoting economic growth.

# Microbial Resistance DA

### *IPR harmonization undermines the ability to market counterfeit drugs.*

**Ferrill**, Spring **2007** (Elizabeth – Law Clerk to the Honorable Liam O'Grady, Magistrate Judge, U.S. District Court for the Eastern District of Virginia, Clearing the Swamp for Intellectual Property Harmonization: Understanding and Appreciating the Barriers to Full TRIPS Compliance for Industrializing and Non-Industrializing Countries, University of Baltimore Intellectual Property Law Journal, p. Lexis-Nexis)

In 1994, the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) was created. n2 TRIPS requires all 150 members n3 of the World Trade Organization (WTO) to provide minimal standards of protection for intellectual property (IP). n4 **TRIPS** is part of the larger WTO framework that **promotes trade liberalization**. n5 Through a series of [*138] agreements designed to lower trade tariffs and eliminate other barriers to trade, the WTO strives to improve standards of living of all members, expand production of and trade in goods and services, and sustain development, especially in developing countries worldwide. n6 Most economists view trade liberalization as a means to wealth maximization. n7 If each country produces what it is best at producing, then output of efficiently produced products is higher worldwide. n8 Hence, countries that are the

most efficient producer of a certain good would produce that good and trade with other countries for those goods it produces more efficiently, all without the cost of trade barriers. n9 Yet, countries are reluctant to unilaterally lower their trade barriers. n10 To avoid this problem, the WTO established rules for reciprocal [*139] lowering of trade barriers. n11 In the realm of intellectual property, **harmonization**, defined as the standardization of intellectual property laws, **is analogous to trade liberalization.** If every country were to respect and protect the intellectual property rights of all other countries, inventors and creators would have the maximum incentive to create, mutually benefiting the world. More than a decade after its ratification, there remains tension and widespread noncompliance with **TRIPS**, as many countries **continue to** not **enforce foreign IP rights**, despite the potential benefits of harmonization. **Counterfeiting**, n12 which could be **mitigated by such enforcement, costs the world economy about $ 600 billion annually** and includes a multitude of products, such **as pharmaceuticals**, DVDs, software, toys, spare parts for cars and aircraft, and apparel. n13 This prompts the question of why complying with TRIPS and curbing counterfeiting and pirating has been so difficult over the past decade. There are a number of possible explanations.

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

**Kelesidis '15 (**Theodoros Kelesidis – MD @ the University of Athens Medical School, Fellowship @ the UCLA School of Medicine, Specializes in Infectious Diseases. Mathew E. Falagas – MD @ the University of Athens Medical School, MSc in Epidemiology @ Harvard, Adjunct Assistant Professor of Medicine at Tufts University School of Medicine, Boston, Massachusetts, President, Board of Directors, Alfa Institute of Biomedical Sciences (AIBS), Athens, Greece, and Director, Infectious Diseases Clinic of Henry Dunant Hospital. "Substandard/Counterfeit Antimicrobial Drugs," 18 March 2015, https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4402958/)

Consequences for the Community **Counterfeit** and/or substandard antimicrobial **medicines** may **promote antimicrobial resistance**. **Emergence of antimicrobial resistance as a result of low-quality antimicrobials has been reported** with antimicrobials that are often used in combination therapy, such as antimalarials (45, 45, 123, 217,–220) and antituberculosis agents (1, 121, 221). The use of substandard products **may lead to underdosing of antibiotics**, **which can increase antimicrobial resistance** (2, 4, 8, 24, 222, 223). **As a result**, in some developing countries **multidrug-resistant bacteria may emerge**, and the development of travel may further promote **the spread of drug-resistant bacteria worldwide** (15, 17, 51). Furthermore, therapeutic failure **prolongs the period of contagiousness and increases the prevalence of infections** from multidrug-resistant pathogens in the community. With regard to malaria, WHO has recommended that if 10% of patients fail treatment, the malaria treatment guidelines should change (224). However, the contribution of substandard/counterfeit medicines to treatment failure for malaria needs to taken into account and addressed in future research studies. Low-quality antimicrobials **may significantly decrease confidence** in the efficacy of certain antibiotics. **Poor-quality antimicrobials may lead physicians to lose confidence** in specific antibiotics and thus to use broad-spectrum antibiotics as the drugs of choice for infections (215, 225). According to the WHO, this may lead to loss of efficacy of relatively inexpensive drugs and will promote the use of more expensive antibiotics that patients in developing countries are not able to afford. The **public confidence in health care systems and in governments may**

**decline significantly**. If **patients** with infectious diseases do not take antimicrobials due to lack of trust in their efficacy, **they remain infectious and pose risks for global public health.**

### *Disease pandemics threaten extinction.*

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

We fear it is **only a matter of time before** we face a **deadlier and more contagious pathogen**, yet the threat of a deadly pandemic remains dangerously overlooked. **Pandemics now occur with greater frequency, due to** factors such as **climate change, urbanization, and international travel**. Other factors, such as a weak World Health Organization and potentially massive cuts to funding for U.S. scientific research and foreign aid, including funding for the United Nations, stand to deepen our vulnerability. **We also face the specter of novel and mutated pathogens that could spread and kill faster than diseases we have seen before.** With the advent of genome-editing technologies, bioterrorists could artificially engineer **new plagues**, a threat that Ashton Carter, the former U.S. secretary of defense, thinks could **rival nuclear weapons in deadliness**. The two of us have advised the president of Guinea on stopping Ebola. In addition, we have worked on ways to contain the spread of Zika and have informally advised U.S. and international organizations on the matter. Our experiences tell us that the world is unprepared for these threats. We urgently need to change this trajectory. We can start by learning four lessons from the gaps exposed by the Ebola and Zika pandemics. Faster Vaccine Development The most effective way to stop pandemics is with vaccines. However, with Ebola there was no vaccine, and only now, years later, has one proven effective. This has been the case with Zika, too. Though there has been rapid progress in developing and getting a vaccine to market, it is not fast enough, and Zika has already spread worldwide. Many other diseases do not have vaccines, and developing them takes too long when a pandemic is already under way. We need faster pipelines, such as the one that the Coalition for Epidemic Preparedness Innovations is trying to create, to preemptively develop vaccines for diseases predicted to cause outbreaks in the near future. Point-of-Care Diagnostics Even with such efforts, vaccines will not be ready for many diseases and would not even be an option for novel or artificially engineered pathogens. With no vaccine for Ebola, our next best strategy was to identify who was infected as quickly as possible and isolate them before they infected others. Because Ebola's symptoms were identical to common illnesses like malaria, diagnosis required laboratory testing that could not be easily scaled. As a result, many patients were only tested after several days of being contagious and infecting others. Some were never tested at all, and about 40% of patients in Ebola treatment centers did not actually have Ebola. Many dangerous pathogens similarly require laboratory testing that is difficult to scale. Florida, for example, has not been able to expand testing for Zika, so pregnant women wait weeks to know if their babies might be affected. What's needed are point-of-care diagnostics that, like pregnancy tests, can be used by frontline responders or patients themselves to detect infection right away, where they live. These tests already exist for many diseases, and the technology behind them is well-established. However, the process for their validation is slow and messy. Point-of-care diagnostics for Ebola, for example, were available but never used because of such bottlenecks. Greater Global Coordination **We need stronger global coordination**. The responsibility for controlling pandemics is fragmented, spread across too many players with no unifying authority. In Guinea we forged a response out of an amalgam of over 30 organizations, each of which had its own priorities. In Ebola's aftermath, there have been calls for a mechanism for responding to pandemics similar to the advance planning and training that NATO has in place for its numerous members to respond to military threats in a quick, coordinated fashion. This is the right thinking, but we are far from seeing it happen. The errors that allowed Ebola to become a crisis replayed with Zika, and the WHO, which should anchor global action, continues to suffer from a lack of credibility. Stronger Local Health Systems International actors are essential but cannot parachute into countries and navigate local dynamics quickly enough to contain outbreaks. In Guinea it took months to establish

the ground game needed to stop the pandemic, with Ebola continuing to spread in the meantime. We need to help developing countries establish health systems that can provide routine care and, when needed, coordinate with international responders to contain new outbreaks. Local health systems could be established for about half of the $3.6 billion ultimately spent on creating an Ebola response from scratch. Access to routine care is also essential for knowing when an outbreak is taking root and establishing trust. For months, Ebola spread before anyone knew it was happening, and then lingered because communities who had never had basic health care doubted the intentions of foreigners flooding into their villages. The turning point in the pandemic came when they began to trust what they were hearing about Ebola and understood what they needed to do to halt its spread: identify those exposed and safely bury the dead. With Ebola and Zika, we lacked these four things — vaccines, diagnostics, global coordination, and local health systems — which are still urgently needed. However, prevailing political headwinds in the United States, which has played a key role in combatting pandemics around the world, threaten to make things worse. The Trump administration is seeking drastic budget cuts in funding for foreign aid and scientific research. The U.S. State Department and U.S. Agency for International Development may lose over one-third of their budgets, including half of the funding the U.S. usually provides to the UN. The National Institutes of Health, which has been on the vanguard of vaccines and diagnostics research, may also face cuts. The Centers for Disease Control and Prevention, which has been at the forefront of responding to outbreaks, remains without a director, and, if the Affordable Care Act is repealed, would lose $891 million, 12% of its overall budget, provided to it for immunization programs, monitoring and responding to outbreaks, and other public health initiatives. Investing in our ability to prevent and contain pandemics through revitalized national and international institutions should be our shared goal. However, if U.S. agencies become less able to respond to pandemics, leading institutions from other nations, such as Institut Pasteur and the National Institute of Health and Medical Research in France, the Wellcome Trust and London School of Hygiene and Tropical Medicine in the UK, and nongovernmental organizations (NGOs have done instrumental research and response work in previous pandemics), would need to step in to fill the void. There is no border wall against disease. **Pandemics are an existential threat on par with climate change and nuclear conflict**. We are at a **critical crossroads**, where we must either take the steps needed to prepare for this threat or become even more vulnerable. **It is only a matter of time before we are hit by a deadlier, more contagious pandemic.** Will we be ready?

# On Case

Access and china rise

### *1-- Lack of IP protection makes medical innovation prohibitively risky and expensive*

**Grabowski et al 15** [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) "The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation," Health Affairs, 2/2015] TDI

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry.[5] The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs.[6] Only approximately one in eight drug candidates survive clinical testing.[6]

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns).[7,8] Once a new drug's patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high

likelihood of commercial success. **Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market**.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians' choices for patient treatment.

Patents play an essential role in the economic "ecosystem" of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. [11] The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

## *2- IP protections are key to pharmaceutical investment in developing countries.*

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

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

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

## *3- IPR is not the cause of medicine inequality. Multiple alternative causes exist*

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

This article analyzes the context for the allegation that IP is among the crucial factors in promoting health innovation globally, and not preventing the universal and equitable access to vaccines, even if supply of medicines is held by developed countries to be "difficult" (WTO Secretariat, 2020a). Biotechnology actors expressed criticism of the UN High-level Panel on Access to Medicines (2016), arguing that **IP tends to be overemphasized in debates over access** to medicines, **ignoring** the wider context of **what impedes such access** (International Council of Biotech Associations [ICBA], 2016; Biotechnology Innovation Organization [BIO], 2016). Hence, **developed countries** and biotech associations **concur in identifying weak funding** of health care **and lack of manufacturing capacity as constituting the** core of the **problem of access** (WTO Secretariat, 2020a; see also U.S. Department of State, 2016), **as well as regulatory inefficiencies, trade policies and inadequate** health **insurance** (ICBA, 2016).

## *4-- Generic drugs send their worst quality drugs to LDCs where risk of inspection is the lowest – this is a form of medical colonialism—further link into the second DA*

**Eban 19** [Katherine Eban, an investigative journalist and the author of the New York Times bestseller Bottle of Lies: The Inside Story of the Generic Drug Boom, May 17 2019, "How Some Generic Drugs Could Do More Harm Than Good," Time Magazine, https://time.com/5590602/generic-drugs-quality-risk/ ]/Triumph Debate

For the 16 years that Dr. Brian Westerberg, a Canadian surgeon, worked volunteer missions at the Mulago National Referral Hospital in Kampala, Uganda, scarcity was the norm. The patients usually exceeded the 1,500 allotted beds. Running water was once cut off when the debt-ridden hospital was unable to pay its bills. On some of his early trips, Westerberg even brought over drugs from Canada in order to treat patients. But **as low-cost generics made in India and China became widely available through Uganda's government and international aid agencies in the early 2000s, it seemed at first like the supply issue had been solved. Then on February 7, 2013, Westerberg examined a feverish 13-year-old boy who had fluid oozing from an ear infection. He suspected bacterial meningitis, though he couldn't confirm his diagnosis because the CT scanner had broken down. The boy was given intravenous ceftriaxone, a broad-spectrum antibiotic that Westerberg believed would cure him. But after four days of treatment, the ear had only gotten worse**. As Westerberg prepared to operate, the boy had a seizure. With the CT scanner working again, Westerberg ordered an urgent scan, which revealed small abscesses in the boy's skull, likely caused by the infection. When a hospital neurosurgeon looked at the images and confidently declared that surgery was unnecessary and the swelling and abscesses would abate with effective antibiotic treatment, Westerberg was confused. They had already treated the boy with intravenous ceftriaxone, which hadn't worked. His confusion deepened when his colleague suggested that they switch the boy to a more expensive version of the drug. Why swap one ceftriaxone for another? Most people assume that a drug is a drug — that Lipitor, for example, or a generic version, is the same anywhere in the world, so long as it's made by a reputable drug company that has been inspected and approved by regulators. That, at least, is the logic that has driven the global generic-drug revolution: that drug companies in countries like India and China can make low-cost, high-quality drugs for markets around the world. These companies have been hailed as public-health heroes and global equalizers, by making the same cures available to the wealthy and impoverished. PAID PARTNER CONTENT 6 Prepaid Funeral Plan Myths: Learn More BY DIGNITY MEMORIAL **But many of the generic drug companies that Americans and Africans alike depend on, which I spent a decade investigating, hold a dark secret: they routinely adjust their manufacturing standards depending on the country buying their drugs, a practice that could endanger not just those who take the lower-quality medicine but the population at large. These companies send their highest-quality drugs to markets with the most vigilant regulators, such as the U.S. and the European Union. They send their worst drugs — made with lower-quality ingredients and less scrupulous testing — to countries with the weakest review. The U.S. drug supply is not immune to quality crises — over the last ten months, dozens of versions of the generic blood pressure drugs valsartan, losartan and irbesartan have been subject to sweeping recalls. The active ingredients in some, manufactured in China, contained a probable carcinogen once used in the production of liquid rocket fuel. But the patients who suffer most are those in so-called "R.O.W. markets" — the generic-drug industry's shorthand for "Rest of World." In swaths of Africa, Southeast Asia and other areas with developing**

**markets, some generic drug companies have made a cold calculation: they can sell their cheapest drugs where they will be least likely to get caught. In Africa, for instance, pharmaceuticals used to come from more developed countries, through donations and small purchases. So when Indian drug reps offering cheap generics started arriving, the initial feeling was positive**. But Africa soon became an avenue "to send anything at all," said Kwabena Ofori-Kwakye, associate professor in the pharmaceutics department at the Kwame Nkrumah University of Science and Technology in Kumasi, Ghana. **The poor quality has affected every type of medication, and the adverse impact on health has been "astronomical,"** he told me. Multiple doctors I spoke to throughout the continent said they have adjusted their medical treatment in response, sometimes tripling recommended doses to produce a therapeutic effect. Dr. Gordon Donnir, former head of the psychiatry department at the Komfo Anokye teaching hospital in Kumasi, treats middle-class Ghanaians in his private practice and says **that almost all the drugs his patients take are substandard, leading him to increase his patients' doses significantly. While his European colleagues typically prescribe 2.5 milligrams of haloperidol (a generic form of Haldol) several times a day to treat psychosis, he'll prescribe 10 milligrams, also several times a day, because he knows the 2.5 milligrams "won't do anything."** Donnir once gave ten times the typical dose of generic Diazepam, an anti-anxiety drug, to a 15-year-old boy, an amount that should have knocked him out. The patient was "still smiling," Donnir said. Many hospitals also keep a stash of what they call "fancy" drugs — either brand-name drugs or higher-quality generics — to treat patients who should have recovered after a round of treatment but didn't. Confronted with the ailing boy at the Mulago hospital, Westerberg's colleagues swapped in the more expensive version of ceftriaxone and added more drugs to the treatment plan. But it was too late. In the second week of his treatment, the boy was declared brain dead. Westerberg's Ugandan colleagues were not surprised. Their patients frequently died when treated with drugs that should have saved them. And there were not enough "fancy" drugs to go around, making every day an exercise in pharmaceutical triage. It was also hard to keep track of which generics were safe and which were not to be trusted, said one doctor in Western Uganda: "It's anesthesia today, ceftriaxone tomorrow, amoxicillin the next day." Westerberg, shaken by his newfound knowledge, flew back to Canada and teamed up with a Canadian respiratory therapist, Jason Nickerson, who'd had similar experiences with bad medicine in Ghana. They decided to test the chemical properties of the generic ceftriaxone that had been implicated in the Ugandan boy's death. Another of Westerberg's colleagues brought him a vial from the Mulago hospital pharmacy. The drug had been made by a manufacturer in northern China, which also exported to the U.S. and other developed markets. But when they tested the ceftriaxone at Nickerson's lab, it contained less than half the active drug ingredient stated on the label. At such low concentration, the drug was basically useless, Nickerson said. He and Westerberg published a case report in the CDC's Morbidity and Mortality Weekly Report. Although they couldn't say with certainty that the boy had died due to substandard ceftriaxone, their report offered compelling evidence that he had. Some companies claim that, while their drugs are all high-quality, there may be some variance in how they are produced because regulations differ from market to market. But Patrick H. Lukulay, former vice president of global health impact programs for USP (formerly U.S. Pharmacopeia), one of the world's top pharmaceutical standard-setting organizations, calls that argument "totally garbage." For any given drug, he says, "There's only one standard, and that standard was set by the originator," meaning the brand-name company that developed the product. It's not just those in developing markets who should be alarmed. **Often, substandard drugs do not contain enough active ingredient to effectively cure sick patients. But they do contain enough to kill off the weakest microbes while leaving the strongest intact. These surviving microbes go on to reproduce, creating a new generation of pathogens capable of resisting even fully potent, properly made medicine. In 2011, during an outbreak of drug-resistant malaria on the Thailand-Cambodia border, USP's chief of party in Indonesia Christopher Raymond strongly suspected substandard drugs as a culprit**. Treating patients with drugs that contain a little bit of active ingredient, as he put it, is like "putting out fire with gasoline." **USP is so concerned about this issue that in 2017 it launched a center called the Quality Institute, which funds research into the link between drug quality and resistance**. In late 2018, Boston University biomedical engineering professor Muhammad Zaman studied a commonly used antibiotic called rifampicin that, if not manufactured properly, yields a chemical substance called rifampicin quinone when it degrades. When Zaman subjected bacteria to this substance, it developed mutations that helped it resist rifampicin and other similar drugs. Zaman concluded from his work that substandard drugs are an "independent pillar" in the global menace of drug resistance. **The low cost of generic drugs makes them essential to global public health. But if those bargain drugs are of low quality, they do more harm than good**. For years, politicians, regulators and aid workers have focused on ensuring access to these drugs. Going forward, they must place equal value on quality, through an exacting program of unannounced inspections, routine testing of drugs already on the market and strict legal enforcement against companies manufacturing subpar medicine. One model is the airline industry, which through international laws and treaties, has established clear global standards for aviation safety. **Without something similar for safe and effective drugs, the twin forces of subpar medicine and growing drug resistance will be so destructive that developed countries won't be able to ignore them. As Elizabeth Pisani, an epidemiologist who has studied drug quality in Indonesia, put it, "The fact is, pathogens know no borders."**

***5-- Generics don't solve; they are wildly more expensive in LDCs due to the effects of colonial capitalism that fractures drug markets in the global south***

**Glassman 19** [Amanda Glassman Executive Vice President of CGD, CEO of CGD Europe, and Senior Fellow, JUNE 17, 2019, "New Study Finds Some Poor Countries Paying 20 to 30 Times More for Basic Medicines Than Others," Center for Global Development, https://www.cgdev.org/article/new-study-finds-some-poor-countries-paying-20-30-times-more-basic-medicines-others ]/Triumph Debate

WASHINGTON – Basic, everyday drugs can cost up to 20 to 30 times more in some poor countries than others, according to a new study released today by the Center for Global Development. The study examined billions of dollars of health spending on common, life-saving medicines in developing countries, mostly in Africa and Asia. To date, it is one of the largest-ever studies on global health procurement. "Developing countries are often paying far more for everyday drugs than they should be. Why do some poor countries pay 20 to 30 times as much as others for common medicines to relieve pain or treat hypertension? In large part, because of flawed drug buying practices and broken generic medicines markets," said Amanda Glassman, one of the authors of the study and the executive vice president at the Center for Global Development. "A robust market for generic drugs is a core part of an affordable health system. But in way too many countries, generic drug markets are broken and patients are paying the price," said Kalipso Chalkidou, the director of global health policy at the Center for Global Development and an author of the study. "You need enough competition to keep prices low and quality assurance that consumers trust, or essential medicines are going to be much more expensive than they should be." The study had three main findings: In developing countries, prices for basic generic medicines can vary widely and far exceed wealthy-country prices. Some purchasers in low- and middle-income countries pay as much as 20 to 30 times more for basic generic medicines like omeprazole, used to treat heartburn, or acetaminophen (also known as paracetamol), a common pain reliever. Low- and middle-income countries purchase more expensive branded generic drugs rather than unbranded quality-assured generics. In the US, most drugs are either on-patent medicines or unbranded generics, but in many developing countries more expensive brand-name generics are widely used, because people are concerned about unsafe or counterfeit drugs. In the poorest countries, unbranded generics are only 5 percent of the pharmaceutical market by volume—in comparison to the US where unbranded quality-assured generics are 85 percent of the market by volume. There is little competition in the supply of essential medicines in low- and middle-income countries. The largest seller of products like contraceptives, cancer medicines, and antiparasitics can account for upwards of 85 percent of all sales in some countries. "We're talking about access to common medications for pain or high blood pressure, not the latest cutting-edge cancer drugs," Glassman said. "It's not as exciting to talk about procurement as new health technologies or biotech breakthroughs," she continued. "But drug purchasing is incredibly important, and if it's done badly you end up with the poorest countries in the world paying some of the highest drug prices."

Climate change

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

Bacchus 20, James Bacchus (is a member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland), "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," CATO Institute, December 16, 2020, https://www.cato.org/free trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to "foster innovation," they make no mention of IP rights.19 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, "A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights."20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that "intellectual property rights are private rights" and that rules and disciplines are necessary for "the provision of effective and appropriate means for the enforcement of trade-related intellectual property rights."21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

## *2-Companies will just obtain a patent in a different sector—means no solvency*

**Thomas 15** [John R; Visiting Scholar, CRS; "Tailoring the Patent System for Specific Industries, Congressional Research Service," CRS; 2015; https://crsreports.congress.gov/product/pdf/R/R43264/7] Justin

In view of the concerns noted above, commentators have gone so far to say that "it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive."75 To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.76 Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.77 As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes. However, others have questioned the wisdom and practicality of such line-drawing.78 The following concerns, among others, have been identified:

· Over its long history, the U.S. patent system has **flexibly adapted to new technologies such as biotechnology and computer software**. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.79

· Defining a specific industry or category of technologies may prove to be a contested proposition.

80 · Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.

81 · Even if an industry or technology remains relatively stable, the **innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.**

82 · Distinct patent rights among industries or technologies may lead to **strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.**

83 ·The legislative effort to enact sector-specific patent laws may provide an opportunity for **politically savvy firms to exert more lobbying and political power**, at the possible expense of less sophisticated firms.

**3- there are many different causes of climate change—including burning fossil fuels, deforestation, livestock farming, fertilizers with nitrous oxide emissions, fluorinated gasses, electricity production, permafrost, volcanic eruptions, fossil fuel drilling, ecetera—this means aff has low solvency since they only target one component**