**I affirm the resolution: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.**

**Definitions**

**According to the CDC, vaccines are considered medicine**

“Basics of Vaccines.” *Centers for Disease Control and Prevention*, Centers for Disease Control and Prevention, 14 Mar. 2012, www.cdc.gov/vaccines/vpd/vpd-vac-basics.html.

A vaccine stimulates your immune system to produce antibodies, exactly like it would if you were exposed to the disease. After getting vaccinated, you develop immunity to that disease, without having to get the disease first.

This is what makes vaccines such powerful medicine. Unlike most medicines, which treat or cure diseases, vaccines *prevent* them.

**Framework**

**I value morality.**

**Util is the only moral system available to policymakers.**

Robert E. Goodin 95 [professor of government at the University of Essex, and professor of philosophy and social and political theory at Australian National University], “Utilitarianism as a Public Philosophy”, Cambridge Studies in Philosophy and Public Policy, May 1995, BE

Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices - public and private alike - are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. Public officials, in contrast, are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices. But that is all. That is enough to allow public policy-makers to use the utilitarian calculus - if they want to use it at all - to choose general rules of conduct. Knowing aggregates and averages, they can proceed to calculate the utility payoffs from adopting each alternative possible general rule. But they cannot be sure what the payoff will be to any given individual or on any particular occasion. Their knowledge of gener- alities, aggregates and averages is just not sufficiently fine-grained for that.

**Thus, the standard is maximizing well-being.**

**Contention 1: Intellectual property protections restrict healthcare**

**Deaths caused by inadequate access to healthcare are preventable**

**Schreiber**, Melody. Margaret E. **Kruk 18** “What Kills 5 Million People A Year? It's Not Just Disease.” *NPR*, NPR, 5 Sept. 2018, www.npr.org/sections/goatsandsoda/2018/09/05/644928153/what-kills-5-million-people-a-year-its-not-just-disease#:~:text=The%20study%20estimates%20that%205,not%20having%20access%20to%20care. [Schreiber is a freelance journalist, Dr. Margaret E. Kruk is Professor of Health Systems at the Harvard T.H. Chan School of Public Health.  Dr. Kruk’s research generates evidence on how health systems can improve health for people living in low-income countries.]

In the global health world, giving people access to health care — even if they're just basic services — has long been a top priority.But what if that approach is wrong?A [new report](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(18)31668-4/fulltext) published in *The Lancet* on Wednesday finds that when it comes to health, quality — not quantity — seems to be more important.The study estimates that **5 million people die every year because of poor-quality health care in low- and middle-income countries.** That's significantly more than the **3.6 million** people in those countries who **die from not having access to care**.It's also five times more than annual deaths from HIV/AIDS (1 million) and three times more than diabetes (1.4 million) in the same countries — although, of course, poor health care for these conditions can also be fatal."For a very long time in global health, we have been really mandating and supporting and pushing access to care, without really thinking about what happens when people get to the clinic," says [Dr. Margaret Kruk](https://www.hsph.harvard.edu/margaret-kruk/), the co-commissioner of this study and a professor at the Harvard T. H. Chan School of Public Health.These findings come from *The Lancet* Global Health Commission on High Quality Health Systems, a two-year project on measuring and improving the quality of health systems around the world.The commission is made up of 30 experts — academics, policymakers, health advocates — in 18 countries. Their data comes from a range of surveys, including household surveys in 47 countries, a survey they conducted about quality of care and 81,000 assessments of care by researchers, funded by USAID, who observed health visits at clinics and hospitals in 18 countries.NPR spoke with Kruk about the study.This interview has been condensed and edited for clarity.**What was perhaps the biggest finding of the report?**There are **8.6 million deaths every year** in low- and middle-income countries — the majority of the world, 134 countries — that could have been saved with good-quality health systems. These **were deaths from treatable conditions because people didn't get good care**.Of that 8.6 million, we found that 5 million were people who got care but just got poor quality care. The remaining 3.6 million were because of a lack of access, which has been the traditional focus in global health.

**Healthcare is meant to be a basic human right, but it is withheld from those who cannot afford it, especially in low to middle income countries. As a result, millions of people die every year from treatable illnesses.**

**Pharma monopolies raise prices and reduce access**

**Delgado**, By: Andrés, et al. “Inequality Explained: The Trouble with Pharmaceutical Patents.” *Open Canada*, 22 Sept. 20**20**, opencanada.org/inequality-explained-trouble-pharmaceutical-patents/.

How current polices can hurt the rich and poor alike. Though the idea of **a government enforced monopoly** may seem like a necessary incentive for drug manufactures, **it is not effective in** stimulating important pharmaceutical innovation, nor a sustainable means of **delivering medicines to poorer countries** in the long run.Pharmaceutical companies are part of an industry that enjoys the [largest profit margin compared to any other private industry](http://www.bbc.com/news/business-28212223), even surpassing oil and gas. The ratio of revenue spent on promotion and marketing – upwards of 25 percent – compared to the 1.3 percent devoted to [discovering new molecules](http://dx.doi.org/10.1136/bmj.e4348) is striking. **The pharmaceutical industry**, in both [domestic policies](http://www.fda.gov/Drugs/DevelopmentApprovalProcess/ucm079031.htm) and under potential [trade agreements like the TPP](https://ustr.gov/about-us/policy-offices/press-office/press-releases/2015/october/summary-trans-pacific-partnership), **is granted exclusive power over the market; companies** rationally **use this power to make as much profit as possible** before their exclusive rights expire. There are real and under-discussed consequences to this system. As Nobel laureate and economist Joseph Stiglitz [writes](http://bmj.com/cgi/content/full/333/7582/1279), “research needs money but the current [intellectual property] system results in limited funds being spent in the wrong way.” [Ten million people](http://apps.who.int/medicinedocs/pdf/s4962e/s4962e.pdf) die each year due to a lack of access to essential medicines, and nearly **three billion worldwide are at risk from diseases that lack market incentives for drug development.** The Commission on Health Research for Development found that [less than 10 percent of worldwide resources](http://www.cohred.org/downloads/open_archive/ComReports_0.pdf) devoted to health research were put towards health in low and middle income countries, where over 90 percent of all preventable deaths worldwide occurred. Although **high drug prices as a result of the intellectual property system** have [long been identified](http://www.who.int/phi/CEWG_Report_5_April_2012.pdf) primarily as a problem for developing countries, they **are becoming a growing concern even for industrialized nations.** Pharmaceutical **patents and exclusivity reduce access to lifesaving drugs, and allow technologies developed with public funding to be purchased and monetized by private entities in developed nations.** Taxpayer-sourced research funding from governmental organizations like the Canadian Institutes of Health Research or the National Institutes of Health is a [major component of the R&D landscape](http://www.ncbi.nlm.nih.gov/pubmed/16174691). Furthermore, [between one fourth and one third of new drugs](https://dx.doi.org/10.1038/nrd3251) originate on public university campuses, but are then bought out by the industry to be monetized. Though development costs are borne by the taxpayer, the benefits of the research are mostly enjoyed by private parties.

**Intellectual property protections make medicines unaffordable**

**Oxfam. 2015** “Intellectual Property and Access to Medicine.” *Policy & Practice*, policy-practice.oxfamamerica.org/work/trade/intellectual-property-and-access-to-medicine/. [oxfam is a charity for combating global poverty]

Today, **more than two billion people across the developing world lack access to affordable medicines,** including many patients in countries negotiating in the Trans-Pacific Partnership (TPP) free trade agreement. Two critical factors limit access to treatment: the high prices of new medicines, particularly those that are patent-protected, and the lack of medicines and vaccines to treat neglected diseases, a consequence of lack of R&D.Intellectual property (IP) has different forms; in the case of access to medicines, we are talking about patents. Patents are a public policy instrument aimed at stimulating innovation. By providing a monopoly through a patent—which gives inventors an economic advantage—governments seek to provide an incentive for R&D. At the same time, the public benefits from technological advancement.This trade-off underpins patent systems everywhere. Governments need to maintain an appropriate balance between incentivizing innovation, on the one hand, and, on the other, ensuring that new products are widely available. **High levels of IP protection in developing countries exacerbate,** rather than help solve, **the problem of access to affordable medicines**. Extensive **patent protection for new medicines delays the onset of generic competition**. And because generic competition is the only proven method of reducing medicine prices in a sustainable way, **such high levels of IP protection are extremely damaging to public health outcomes**.A word on background: The 1994 TRIPS Agreement represented the single greatest expansion of IP protection in history, but it also includes a range of public health safeguards and flexibilities, which were reinforced by the 2001 Doha Declaration on the TRIPS Agreement and Public Health.Yet US trade agreements over the past decade have sought to redefine and even undermine the Doha Declaration, as FTAs have included provisions that curb governments’ ability to use the health safeguards in TRIPS and have mandated higher levels of IP protection. These provisions block or delay the onset of generic competition, keeping medicine prices high. Higher treatment costs are devastating to poor people, and they undermine the sustainability of public health programs—particularly in low- and middle-income countries, where public finance for health care is limited and most patients pay for medicines out of pocket.The agreement reached between Congressional leadership and the Bush administration on May 10, 2007, broke this trend of imposing increasingly stricter IP protections in trade agreements by scaling back so-called TRIPS-plus rules in the FTAs with Peru, Panama, and Colombia. This agreement was very significant—not only did it confirm the importance of the Doha Declaration on the TRIPS Agreement and Public Health, but it also recognized that higher levels of IP protection can in fact run counter to public health interests and US trade and development goals. Under this agreement, which has become known as the May 10 Agreement, three key TRIPS-plus provisions that Oxfam believes have been most harmful in delaying generic competition were rolled back: namely, patent linkage and patent-term extensions were made voluntary, and important flexibilities were included in the data exclusivity (DE) provisions to speed up the introduction of generic medicines.**Patent linkage** prohibits a country’s drug regulatory authority from approving a medicine if there is any patent—even a frivolous one—in effect. It requires regulatory officials to police patents in addition to their core work of evaluating the safety and efficacy of medicines.**Patent extension provisions** allow companies to seek extensions of the 20-year patent term to compensate for administrative delays by patent offices and drug regulatory authorities. (Such delays are inevitable in developing countries, where these offices are chronically underfunded and are facing increasing numbers of patent applications.)[**Data exclusivity**](https://policy-practice.oxfamamerica.org/work/trade/data-exclusivity) creates a monopoly that is separate from patents by prohibiting a country’s drug regulatory authority from approving a generic medicine based on the clinical trial data provided by the originator company.Although the May 10 Agreement did not eliminate all TRIPS-plus rules, Oxfam considered it to be a step in the right direction—after a long time going the wrong way. It reflected a meaningful effort to ensure that US trade policy more appropriately balances IP protection with public health considerations in developing countries. Oxfam fully expected this new approach in US trade policy to continue.But the Office of the US Trade Representative (USTR) effectively abandoned the May 10 Agreement in TPP negotiations and added new provisions that would further constrain generic competition—for example, by expanding the scope of what can receive monopoly protection—and Oxfam’s concerns with the USTR TPP proposal relate not only to the IP chapter, but also to a proposed chapter on “transparency” in pharmaceutical reimbursement, which would hinder government efforts to control the cost of reimbursing medicines through public health care programs.The reality is that fragile gains in health in developing country TPP partners are at risk from the USTR proposal. For example, Peru is a low- to middle-income country with high levels of poverty and inequality and with a high burden of chronic and noncommunicable diseases that require medicines over the long term. Prices for patented medicines to treat cancer, for example, are unaffordable for households and have exhausted most of the government’s resources available to pay for treatments under the public health system.**A 2010 study by a Peruvian government entity** (the Director General of Medicines, Supply and Drugs, or DIGEMID) **revealed** this stark reality: **the monthly cost of one key patented medicine** needed to treat head and neck cancer **is equivalent to 880 times the daily minimum wage in Peru**, an amount that would take a worker more than two years to earn, without a single day off. The TPP would not only undermine the efforts of other countries to protect public health, but would also undermine US efforts to improve access to health care around the world. Thanks to the cost savings from use of generics, PEPFAR (the President’s Emergency Plan for AIDS Relief) has successfully initiated treatment for more than three million people worldwide, and saved $380 million in 2010 alone.In Vietnam, where more than half the population lives in poverty, 97 percent of antiretroviral medicines purchased under PEPFAR ($323 million in 2004–2009) are generics.

**People are dying due to IP protection**

***Byanyima 16.***

*Written by Winnie Byanyima, Undersecretary-General of the United Nations; Executive Director. “People Are Dying Because They Can't Access Life-Saving Drugs. That Has to Change.” World Economic Forum, 23 Sept. 2016,* [*www.weforum.org/agenda/2016/09/people-are-dying-access-to-drugs-this-has-to-change/*](http://www.weforum.org/agenda/2016/09/people-are-dying-access-to-drugs-this-has-to-change/)*.*

**I am** still **haunted by** the memory of **my Ugandan[s] friends dying from HIV** years ago **because high prices kept the medicines they needed out of reach.** This was – finally – a serious chance to rethink the global research and development (R&D) system to ensure all people have access to affordable medicines.

Access to medicines has been the subject of intense debate for many years but this panel was different. It recognised that the **i**ntellectual **p**roperty **rules promoted by** the **pharma**ceutical industry **are at odds with the human right to health – a position which placed it in conflict with the powerful pharma**ceutical **lobby from the outset. It also recognised that access to medicines is** not just a problem for poor countries or neglected diseases – but **a global problem** affecting people in rich and poor countries alike.

**The high price of medicines is crippling healthcare systems and denying people access to the treatments they** so **desperately need. In the UK, the** [**National Institute for Health and Care Excellence**](https://www.nice.org.uk/news/press-and-media/nice-kadcyla-price-still-too-high) **recommended that the National Health Service does not pay for** Kadcyla, **a new medicine for breast cancer, because of its cost. The medicine costs £102,405 – almost four times the UK’s 2014 per capita income**. In France, it was calculated that providing medicines to treat all people with Hepatitis C – which can cost over $100,000 per patient - would exceed the annual budget of the public hospitals in Paris.

**While IPPs line the pockets of big pharma execs, high drug prices reduce access to lifesaving treatments.**

**Demodernization, as a result of health inequality, risks nuclear war**

**Global health inequality drives demodernization**

Katherine **Hirschfeld 19,** Associate Professor in the University of Oklahoma&#39;s Department of Anthropology, “Microbial insurgency: Theorizing global health in the Anthropocene,” October 23 rd , 2019, <https://journals.sagepub.com/doi/full/10.1177/2053019619882781>

**There is no public health in these spaces** because there is no public sector—conflict zones remain within the mapped boundaries of mapped political space, but **[They are] beyond the reach of** government **health agencies**. As a result, **these regions are vulnerable to rapid “demodernization,**” including demodernization of health and mortality patterns that may ultimately shift the world’s health patterns **back to an “age of pestilence and famine.”**

**Demodernization spurs ethnic nationalism and cascading state failure**

Yakov **Rabkin 18**, professor emeritus of history at the Université de Montréal, “Undoing Years of Progress,” in “DEMODERNIZATION A Future in the Past,” downloaded via b-ok at https://b- ok.cc/book/3706747/c28b08.

West Asia represents a convincing example of the application of the principle of selective modernization. Israel, the country most closely allied to the United States, was free to modernize its economy and develop sophisticated weapons, including nuclear arms and long-range missiles. In contrast, the most modernized secular states of Iraq and Libya were subjected to direct military operations. Syria, another pole of secularism in the region, was first subverted by means of externally fomented armed conflict and, as noted earlier, subjected to direct military intervention. All these countries suffered substantial damage to their modern infrastructure, which caused qualified professionals to emigrate. **Divisions along ethnic** and religious **lines**, **destruction of homes, collapse of social services, mass exodus of** medical **doctors** and other professionals, and **rapid increase in unemployment** reduced populations that were relatively modern, educated, and secular to a more precarious and primitive state **embody**ing **demodernization**. Maintaining religious and ethnic diversity is an important aspect of modernity currently under siege. One wonders if the Ottoman order, which ensured autonomy (albeit not formal equality) to the many confessional groups under its aegis, was more modern than its successor states destabilized by Western interventions. Former Ottoman territories that would become Yugoslavia, Egypt, Tunisia, Syria, Iraq, and Libya have suffered from tribal and religious conflict, undermining the basic security of the citizens and the very survival of some of those states. Ethnic nationalism, tribalism, religious militancy (or militancy under the banner of religion), and various (economic, social, etc.) kinds of exclusion are gaining legitimacy, where once relatively stable multicultural and multiethnic societies used to exist. The effectiveness of external factors of demodernization largely depends on the history of the countries experiencing such pressure. In order to slow down Iran’s modernization, economic sanctions (limitations on importing certain products, on transferring funds, etc.) proved to be effective and forced Iran to abandon modernization of its arsenal in spite of it being encircled by dozens of U.S. military bases. However, they were less effective with respect to Russia, a veteran nuclear power. Nor were sanctions effective against North Korea, which succeeded in producing nuclear weapons and ballistic missiles in spite of severe economic difficulties. Russia and North Korea share a history of mass destruction at the hands of Western forces leading to millions of casualties. This memory may have made their respective populations more resilient and united in the face of foreign threats. Demodernization Gathers Momentum Events in the post-Soviet space constitute an accelerated variant of trends observed in other industrialized countries. The reforms in Russia, the Ukraine, and a few other post-Soviet republics in the 1990s contained many of the same elements, but, in contradistinction to Western democracies, were implemented with lightning speed. These societies experienced historically the most massive and rapid transfer of wealth from the public domain into a few private hands. They led to radical income polarization and an instant formation of a stratum of wealthy businessmen who have since come to be known as “the oligarchs.” This is why it is so instructive to understand the drastic changes that occurred in the former Soviet Union since its dismantlement at the end of 1991. Triumphant capitalism of the turn of the twentieth century appears to have eliminated other forms of social and economic organization: The citizen has been transformed into a consumer while politics has lost its role as a viable domain for individual expression. This depolitization may be more pronounced in Russia, Kazakhstan, and Belarus, but it also characterizes mature liberal democracies. **The range of political alternatives is** often **perceived as** so **narrow** as to prevent personal engagement on the part of citizens. Falling rates of election turnout support this perception. Procedurally, democracy may have triumphed in the Ukraine or Iraq, but this hardly bestowed lasting political legitimacy since winners were impotent or reluctant to arrest the demodernization affecting their countries. This partly explains why the territorial integrity of these countries remains fragile. American policies of invasive democratization have largely failed. 3 Democratization by force tends to produce demodernization rather than viable democracy. **The effects** of current political and economic trends **have** **led** some critics **to** characterize the dominant political system as **“financial totalitarianism”** (Зиновьев 2012). The same word “totalitarianism” can be found in the title of a recent book on petroleum companies (Deneault 2018). These attempts at **total control** have been facilitated by the culture industry, **heavily concentrated in the hands of giant transnational corporations** and long portrayed as exercising totalitarian domination over the masses. Political scientists have consistently shown that in the United States “economic elites and organized groups representing business interests have substantial independent impacts on U.S. government policy, while average citizens have little or no independent influence” (Gilens and Page 2014). This brings to mind Marx’s observation that governments become “the capitalists’ trade union,” their protectors and enablers. Advocates of privatization are usually financial strategists allied with oligopolies in the mining, oil, and gas sectors—those that derive benefit from the extraction of rents. They transformed the financial crisis beginning in 2008 into a public debt crisis, which permitted massive privatization of public enterprises and public services, a reduction of taxes on real estate and financial transactions, as well as deregulation of the economy in areas such as price formation, labor laws, and terms of 62 File Title credit. While in the former USSR, the demodernization of the early 1990s was massive and abrupt, the process has been slower in countries of Western Europe and North America. **Inequality, a sure sign of demodernization, keeps increasing**. In 2017, 82 percent of the wealth generated went to the richest 1 percent while 3.7 billion people who make the poorest part of the world population saw no increase in their income (Oxfam 2018). Economic equality is usually ensured by the availability of public services—**pensions and social security, public health**, and other elements of infrastructure that used to provide essential services at subsidized prices or free of charge (Oxfam 2014). When these **are undermined, demodernization sets in**. It was a true revolution to undo the social achievements of the postwar period. Some trace the impetus of this revolution to an informal memo written by a lawyer later appointed to the Supreme Court by Richard Nixon (The Powell Memo 1971). Whatever the origin, it was this revolution that produced demodernization. The extent, shape, and speed of demodernization may vary but its main features presented in this chapter remain largely the same. The chapters that follow will explore this phenomenon in a wide gamut of contexts and periods.

**Inequality-driven nationalism exacerbates the conditions for nuclear conflict.**

Frederick **Solt 11**, Associate Professor, Political Science, University of Iowa. “Diversionary Nationalism: Economic Inequality and the Formation of National Pride.” The Journal of Politics 73(3): 821-30. Emory Libraries.

One of the oldest theories of nationalism is that **states instill the nationalist myth** in their citizens **to divert** their **attention from great economic inequality** and so forestall pervasive unrest. Because the very concept of **nationalism obscures** the extent of **inequality** and is a potent tool for delegitimizing calls for redistribution, it is a perfect diversion, and states should be expected to engage in more nationalist mythmaking when inequality increases. The evidence presented by this study supports this theory: across the countries and over time, where economic inequality is greater, nationalist sentiments are substantially more widespread. This result adds considerably to our understanding of nationalism. To date, many scholars have focused on the international environment as the principal source of threats that prompt states to generate nationalism; the importance of the domestic threat posed by economic inequality has been largely overlooked. However, at least in recent years, domestic **inequality is a far more important stimulus for the generation of nationalist sentiments than the international context.** Given that **nuclear weapons**—either their own or their allies’—rather than the mass army now **serve as the primary defense** of many countries against being overrun by their enemies, perhaps this is not surprising: nationalism-inspired mass mobilization is simply no longer as necessary for protection as it once was (see Mearsheimer 1990, 21; Posen 1993, 122–24). Another important implication of the analyses presented above is that growing economic inequality may increase ethnic conflict. States may foment national pride to stem discontent with increasing inequality, but this pride can also lead to more hostility towards immigrants and minorities. Though pride in the nation is distinct from chauvinism and outgroup hostility, it is nevertheless closely related to these phenomena, and recent experimental research has shown that members of majority groups who express high levels of national pride can be nudged into intolerant and xenophobic responses quite easily (Li and Brewer 2004). This finding suggests that, by leading to the creation of more national pride, higher levels of inequality produce environments favorable to those who would inflame ethnic animosities. Another and perhaps even more worrisome implication regards the likelihood of war. **Nationalism is frequently** suggested as **a cause of war,** and more national pride has been found to result in a much greater demand for national security even at the expense of civil liberties (Davis and Silver 2004, 36–37) as well as preferences for “a more militaristic foreign affairs posture and a more interventionist role in world politics” (Conover and Feldman 1987, 3). To the extent that these preferences influence policymaking, the **growth in** economic **inequality** over the last quarter century **should** be expected to **lead to** more aggressive foreign policies and more **international conflict.** If economic inequality prompts states **to** generate diversionary nationalism as the results presented above suggest, then rising inequality could **make for a more dangerous world**. The results of this 63 File Title work also contribute to our still limited knowledge of the relationship between economic inequality and democratic politics. In particular, it helps explain the fact that, contrary to median-voter models of redistribution (e.g., Meltzer and Richard 1981), democracies with higher levels of inequality do not consistently respond with more redistribution (e.g., Bénabou 1996). Rather than allowing redistribution to be decided through the democratic process suggested by such models, this work suggests that states often respond to higher levels of inequality with more nationalism. Nationalism then works to divert attention from inequality, so many citizens neither realize the extent of inequality nor demand redistributive policies. By prompting states to promote nationalism, greater economic inequality removes the issue of redistribution from debate and therefore narrows the scope of democratic politics.

**Without access to healthcare, regions are vulnerable to demodernization. Inequality will be rampant as public services and infrastructure are undermined, a sure consequence of demodernization. Inequality is frequently the cause of strife with nuclear weapons as the primary defense.**

**In the status quo, IPPs raise prices, restricting access to healthcare, meaning that millions of people will continue to die every year from treatable conditions.**

**Contention 2 - Innovation**

**failing clinical trials, drug prices, econ recovery and more are swamping invest now**

Langley 4/21 [(Kare, reporter for The Wall Street Journal in New York, where she primarily covers the U.S. stock market), “Biotech Stocks Fall Out of Favor After Disappointing Trial Results, Big Rally “, WSJ, 4/21/2021, https://www.wsj.com/amp/articles/biotech-stocks-fall-out-of-favor-after-disappointing-trial-results-big-rally-11619016330]

Shares of Sarepta Therapeutics Inc., Amicus Therapeutics Inc. and Frequency Therapeutics Inc. are among the recent losers for biotech investors, having lost more than half their value so far this year. “It’s felt like a kitchen sink in terms of the number of factors weighing on biotech sentiment in the near term,” said Andy Acker, who manages the Janus Henderson Global Life Sciences Fund. Among those are **disappointing clinical trials, concern about the possibility of renewed focus on drug prices** in Washington **and the recent rotation into economically sensitive stocks.** Biotech shares enjoyed a powerful rally last year. The Nasdaq biotech gauge soared 26% in 2020 on excitement about the potential for Covid-19 treatments and vaccines as well as a broader rally in shares of companies that can perform when the economy is struggling. The S&P 500, meanwhile, gained 16% last year, and the Nasdaq Composite surged 44%. Rapid gains or losses in share prices following clinical-trial results or regulatory decisions are a feature of **biotech investing,** but a smattering of **negative news has damped enthusiasm** in recent months. Shares of Sarepta Therapeutics plunged 51% on Jan. 8 after mixed results from a study of a drug targeting a form of muscular dystrophy. The shares are now down 58% for the year. Amicus Therapeutics shares dropped 33% on Feb. 12 after trial results for its treatment of a rare disorder called Pompe disease disappointed investors. And shares of Frequency Therapeutics plunged 78% on March 23 after the company found its lead drug aimed at treating sensorineural hearing loss didn’t lead to any hearing benefit when given in a four-dose schedule. Those stocks are down 57% and 72%, respectively, this year. Also weighing on sentiment**: The F**ederal **T**rade **C**ommission **has indicated it is preparing to take a harder line on drug-company mergers, which are a source of potential value for investors** in small biotech shops. The commission in March said it would reconsider its approach to scrutinizing deals that could harm competition. “Biotech can be driven by mergers,’ said Jeremie Capron, director of research at ROBO Global, a research and investment-advisory firm. “A change at the FTC, it reduces the probability of a favorable outcome in terms of an acquisition.” Analysts will also be keeping an eye on any efforts in Washington to reduce drug prices. Some **investors are betting against companies in the industry.** Biotech stocks accounted for five of the 10 most-shorted stocks on U.S. exchanges at the end of March, according to S&P Global Market Intelligence. Short interest in Esperion Therapeutics Inc.stood at 34% of shares outstanding as of March 31, followed by Clovis Oncology Inc. at 31% and Inovio Pharmaceuticals Inc. at 26%, an S&P analysis showed. As Covid-19 vaccines reach more people and the economy picks up, investors have favored shares of banks, energy producers and other companies that tend to do well in a strong economy. They have been less interested in stocks that hold out the prospect of innovation-driven growth in fields like technology and biotech. Expectations of a strong recovery have also been seen in the bond market, where falling prices lifted the yield on the benchmark 10-year U.S. Treasury note to 1.566% on Wednesday from 0.913% at the end of last year. As yields climb, borrowing costs for businesses also rise. That often lands hard on biotech companies, where hefty bills for research and development can arrive long before revenue.

**IP stifles innovation with unnecessary expenses and IP violations.**

**University of Notre Dame 19**

 [(University of Notre Dame, One of America’s leading undergraduate teaching institutions, Notre Dame also has been at the forefront in research and scholarship.) “Intellectual Property Rights: The Good, The Bad, and China” University of Notre Dame, Law and Entrepreneurship, 2/25/19. <http://sites.nd.edu/entrepreneurlaw/2019/02/25/intellectual-property-rights-the-good-the-bad-and-china/>] **¶**

Safeguarding a company’s intellectual property (IP) can be crucial to developing and maintaining a successful business. In a New York Times Magazine article “Z-Burger Case Shows Value of Trademark Protection,” Payam Tabibian, the original owner and creator of the successful Z-Burger fast-food chain, was able to protect his creation precisely because he had registered his trademarks at the outset of creating his business. IP rights not only help preserve an entrepreneur’s business, however, they are also crucial for encouraging innovation, protecting small businesses, and helping to establish brand trust and awareness. Additionally, IP rights can assist in securing secondary revenue streams and can also be used as leverage if an entrepreneur is in possession of a valuable patent they want to use as collateral when financing their startup. Although the United States has relatively strong IP rights, the legal landscape may not protect all IP equally. As Forbes article In Today’s Market, Do Patents Even Matter? points out, a patent does not protect your IP rights from being infringed upon; it simply provides the patent holder a means of legal recourse in the event they are infringed. Even if an entrepreneur decides to sue, most litigation lasts between three to five years and costs millions. Novice entrepreneurs and small startups are not financially equipped to fight in the IP battles that routinely occur between heavy-hitters such as Apple and Samsung. Another issue is larger firms using the **IP laws to register patents and then never actually use them, consequently stifling innovation.To make matters worse, around 97% of all patents never even recoup the costs of filing, making them an unnecessary expense in many circumstances.** Regardless of the argument whether IP rights are essential for new businesses and entrepreneurs, the facts illustrate that they nevertheless play a vital role in America’s economy. An article in The Economist, America Can’t Control the Global Flow of Ideas, underscores how the desire among businesses for strong IP laws is high because so much is at stake, with American businesses deriving 80% of their market value from intangible assets and own half of the world’s IP. These same businesses rely on selling their products across borders where IP protection is not nearly as a secure, specifically in China. The White House itself published a report accusing China of IP violations, which included accusations of “outright theft and forced transfer of IP to joint-venture partners in China.” As cited in a Forbes article, Feeding the Fire of Genius: Intellectual Property And America’s High-Tech Future, the United States Trade Representative stated that “Chinese theft of American IP currently costs between $225 billion and $600 billion annually.” With China being listed as “the world’s principal IP infringer,” startups and large firms alike are advocating for the Trump administration to tighten its grip over China’s unfair trade practices regarding IP. Whether the current administration will be able to successfully curtail such trade violations is still up for debate, with entrepreneurs **waiting on the sidelines hoping that the legal system will prevail in protecting their IP rights.**

**IP is worse for innovation— it favors developed countries and prevents innovation through imitation or innovation in places outside the wealthy nations,**

**Chao and Mody 15** [(Tiffany E, Department of Surgery, Massachusetts General Hospital, Boston, Massachusetts, USA) (Gita N, Program in Global Surgery and Social Change, Harvard Medical School, Boston, Massachusetts, USA) “The impact of intellectual property regulation on global medical technology innovation,” BMJ Journals, 3/5/15. <https://innovations.bmj.com/content/1/2/49>] ¶

Technology innovation has the potential to expand equitable healthcare to underserved populations in global health. At the same time, device **patents and their legislation can be barriers to innovation for developing countries.** For example, the WHO has developed a ‘Compendium of innovative health technologies for low-resource settings’.1 Most of these technologies are inexpensive to develop, inexpensive to manufacture and relatively easy to use. Nevertheless, the WHO clearly states that inclusion in their Compendium does not necessarily mean “the use of the technologies is…in accordance with the national laws and regulations of any country, including…patent laws.” Of course, it would be a challenge to innovate in the absence of legislation on trademark laws and trade secrets. Since the profitability of devices depends on leveraging existing pathways for device development, manufacturing and distribution, intellectual property (IP) protection is a major aspect of commercialisation of technologies. Certainly investors in new start-ups look for IP protection as a high priority. Regulation of IP, therefore, is necessary to stimulate invention and new technologies. However, for technologies in low-resource settings, IP protection has historically been sparse. The World Intellectual Property Organisation reports that in 2012, high-income countries shared 64.5% of the world's total number of patents, while lower-middle-income countries held only 2.9%, with low-income countries owning only 0.4%.2 **This disparity clearly demonstrates limited IP support for frugal innovation emerging from developing countries.** Ironically, inventors in low-resource settings are presented with an abundance of important clinical needs and fewer established infrastructure constraints, so that there is a vast untapped potential for innovations to originate in these settings and move to the more developed world (known as reverse innovation).3 Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.i High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.4 This means that international **IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.**5 As a result of these issues, the most prevalent strategy among global health technologies has often been to **develop without regard for IP protection.** A major advantage of this approach is that it **can allow for open-source innovation,** permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation. Nevertheless, there do exist some opportunities for frugal approaches to IP. Simplified legislation or pro bono opportunities for counsel allow an effective system of justice for inventors to take full advantage of legislation to promote innovation.6 Grants and other forms of non-dilutive funding enable inventors to develop global health technologies without being overly concerned about licensing or investment opportunities. Some potential legislative changes also could be made, such as creation of public–private partnerships that could facilitate government-funded research to be protected and disseminated at affordable cost in such countries.7 Other existing exemptions in international agreements could be implemented, including research exemptions for experimental uses of IP or government imposed non-exclusive or compulsory licensing.8 While there remains potential for more imaginative IP legislation in developing countries, original technologies continue to be developed in these settings. On the international stage, forums such as the WHO Global Forum on Medical Devices highlight emerging technologies that “impact the continuum of care ranging from screening to diagnosis, treatment and rehabilitation under the Universal Health Coverage Strategy.”9 These platforms demonstrate that despite the hurdles faced by developing economies in capturing the benefits of IP laws, global health technologies can be and will continue to be developed outside of these limitations.

**TRIPS decreases innovation especially for developing countries and creates monopolies Andrioti ‘18**

**Andrioti, Athina, et al. *The Right to Health and Pharmaceutical Companies in Developing Countries: Access to Medicines*. , 2018.**

‌The initial argument in favor of the adoption of the TRIPS Agreement and the provision of pharmaceutical patent protection was the avoidance of free riders and thus the promotion of innovation. However, doubt can be cast as to whether meaningful innovation is actually promoted through patents. Although patent protection may indeed incentivize R&D of - at least some - medicines through protecting innovators’ rights, there are some methods used by the pharmaceutical industry within the current patent system that give rise to certain concerns regarding the extent to which current R&D priorities and innovation are meaningful from a right-to-health perspective. To that extent it is argued that **‘Patents are increasingly used as strategict assets to influence the conditions of competition rather than as a defensive means to protect research and development outcomes’**.86 Firstly**, pharmaceutical companies are driven by their for-profit nature and seek to benefit as much as possible from the monopoly that is provided by the TRIPS** Agreement. They delay the generic competition through ‘evergreening’ of patents that ‘refers to the practice of obtaining new patents on a patented medicine by making minor changes to it’ before the patent period of the initial medicine expires.87 This leads to what Donald Light and Joel Lexchin refer to as ‘the real innovation crisis’ which ‘stems from current incentives that reward companies for developing large numbers of new drugs with few clinical advantages over existing ones’.88 A study by Robin Feldman published in 2018 supports this argument, showing that **‘78% of the drugs associated with new patents in the FDA’s records were not new to the market, but existing drugs’,** a percentage which is estimated to increase to 80% in the following years.89 Another issue that is related to the concern over whether the existing incentives for innovation are compatible with the right to health, is connected to the ‘neglected diseases’ and the amount of R&D efforts directed towards markets where the purchasing power is limited, namely developing countries. Lee C Moerman and A.L van der Laan define ‘neglected diseases’ as ‘a group of diseases that attract little or no research and development, and in some cases, a cessation of manufacture of drugs or vaccine’ and they categorize such diseases into two groups: diseases for which ‘effective treatment is not available’ at all and ‘diseases which have treatments but for reasons of access and affordability are not available’ in developing countries.90 According to the WHO Commission Report on Intellectual Property Rights, Innovation and Public Health, **‘Poverty affects purchasing power, and the inability of poor people to pay reduces effective demand, which in turn affects the degree of interest of for-profit companies**.’91 Thus, it is very likely that the **monopolies provided by the TRIPS** Agreement **will drive R&D towards diseases that are more likely to generate profit rather than towards diseases which are prevalent in developing countries**, where people have the highest needs for such R&D. On this basis it seems then that ‘The argument that intellectual property rights are a tortured solution to providing a social good, but alas necessary, does not work for those poor who may die because of the TRIPS regime.

**Decline of medical innovation risks extinction**

**Sachs** 8/17/**14**—Professor of Sustainable Development, Health Policy and Management @ Columbia University [Jeffrey D. Sachs (Director of the Earth Institute @ Columbia University and Special adviser to the United Nations Secretary-General on the Millennium Development Goals) “Important lessons from Ebola outbreak,” Business World Online, August 17, 2014, http://tinyurl.com/kjgvyro]

Ebola is the latest of many recent epidemics, also including AIDS, SARS, H1N1 flu, H7N9 flu, and others. AIDS is the deadliest of these killers, claiming nearly 36 million lives since 1981. Of course, even **larger and more sudden epidemics are possible, such as the 1918 influenza** during World War I, **which claimed 50-100 million lives** (far more than the war itself). And, though the 2003 SARS outbreak was contained, causing fewer than 1,000 deaths, the disease was on the verge of deeply disrupting several East Asian economies including China’s.There are four crucial facts to understand about Ebola and the other epidemics. First, most emerging infectious diseases are zoonoses, meaning that they start in animal populations, sometimes with a genetic mutation that enables the jump to humans. Ebola may have been transmitted from bats; HIV/AIDS emerged from chimpanzees; SARS most likely came from civets traded in animal markets in southern China; and influenza strains such as H1N1 and H7N9 arose from genetic re-combinations of viruses among wild and farm animals. **New zoonotic diseases are inevitable** as humanity pushes into new ecosystems (such as formerly remote forest regions); the food industry creates more conditions for genetic recombination; and climate change scrambles natural habitats and species interactions.Second, **once a new infectious disease appears, its spread** through airlines, ships, megacities, and trade in animal products **is likely to be extremely rapid**. These epidemic diseases are new markers of globalization, revealing through their chain of death how vulnerable the world has become from the pervasive movement of people and goods.Third, **the poor are the first to suffer and the worst affected**. The rural poor live closest to the infected animals that first transmit the disease. They often hunt and eat bushmeat, leaving them vulnerable to infection. Poor, often illiterate, individuals are generally unaware of how infectious diseases -- especially unfamiliar diseases -- are transmitted, making them much more likely to become infected and to infect others. Moreover, **given poor nutrition and lack of access to basic health services, their weakened immune systems are easily overcome by infections** that better nourished and treated individuals can survive. And “de-medicalized” conditions -- with few if any professional health workers to ensure an appropriate public-health response to an epidemic (such as isolation of infected individuals, tracing of contacts, surveillance, and so forth) -- make initial outbreaks more severe.Finally, **the required** medical responses, including diagnostic tools and effective **medications** and vaccines, inevitably lag behind the emerging diseases. In any event, such tools **must be continually replenished. This requires cutting-edge biotechnology, immunology, and** ultimately **bioengineering to create large-scale industrial responses** (such as millions of doses of vaccines or medicines in the case of large epidemics).

The AIDS crisis, for example, called forth tens of billions of dollars for research and development -- and similarly substantial commitments by the pharmaceutical industry -- to produce lifesaving antiretroviral drugs at global scale. Yet each breakthrough inevitably leads to the pathogen’s mutation, rendering previous treatments less effective. **There is no ultimate victory, only a constant arms race between humanity and disease-causing agents.**

**Solvency**

**Drug prices are drastically lower after patent expiration, Schans ‘11**

“The Impact of Patent Expiry on Drug Prices: Insights from the Dutch Market.” *Journal of Market Access & Health Policy*, 2021, www.tandfonline.com/doi/full/10.1080/20016689.2020.1849984. Accessed 25 Aug. 2021.

‌This is the first study to investigate the impact of patent expiration on the drug prices for the Dutch market using two national databases including 250 drugs of which the patent expired. Four years after initial generic entry the median price ratio of these drugs was 0.59. However, the price decrease varied widely. Ranging from 0.08 to 0.81, depending on the revenue prior to patent expiration and the year of patent expiration. Additionally, it was shown that drug prices also decreased by 2.3% annually on average during the period of market exclusivity. The combination of the annual decrease during the market exclusive period with the impact of patent expiration indicates that **drug prices 48 months after patent expiration are 74% lower compared to initial market entry on average**. The results of **this** study **can** be used to **predict** the price developments and budget impact of **newly registered drugs** in the Netherlands, as well as those that are bound to face patent expiry **and generic entry** in the near future. This study can also be used to complement the Horizon scan, an initiative in the Netherlands to track all the innovative drugs that will come to the market as well as drugs that will have their patent expired in the near future [[8](https://www.tandfonline.com/doi/full/10.1080/20016689.2020.1849984)]. In particular, the outcomes of this study can be applied to estimate the cost-effectiveness of innovative drugs for pricing and reimbursement purposes. The data presented in this study enable the modelling of dynamic prices over the lifetime of a drug instead of the static price that is currently used in HTA and decision-making processes. Implementing price changes and possible generic substitution after patent expiry will retrieve a more reliable estimate of the cost-effectiveness of that drug in practice. **This is especially the case for** chronic diseases, as **drugs for chronic diseases [as they] are used during the patients’ entire life.**