## One and Done CP (1:30)

#### Text: Member nations of the WTO should reform the patent system with a “one and done” approach

#### Reform is distinct from reduction and therefore competetive – we are not removing any rules, just clarifying

#### Solves price through evergreening

Silverman 18

Ed Silverman Nov. 7, 2018, 11-7-2018, "Some tactics AbbVie allegedly used to thwart biosimilar versions of Humira," STAT, <https://www.statnews.com/pharmalot/2018/11/07/abbvie-biosimilars-humira-patents/> // AW

in a perfect world, the system for conveying medications from their makers to patients should be designed to deliver the lowest-cost drugs. The system in the U.S. doesn’t even come close. Insurers should provide the lowest-cost and highest-quality drug benefit for each plan, public or private. But they don’t. Pharmacy benefit managers should use their volume buying power to obtain rebates that individuals could never obtain on their own and pass those rebates along to patients. But they don’t. Pharmacists, who know the prices of the drugs in their stock and who see patients’ cost-sharing amounts at the cash register, should be motivated to provide their customers with information on how to find the best deal so they can afford their medicines. But they aren’t. Doctors should make medication decisions that are in the best interests of their patients. But they often don’t. All of this occurs against the backdrop of a national conversation to lower drug costs and a policy to expedite and encourage vigorous competition in the pharmaceutical industry through the rapid entry of generic drugs as soon as patents expire. But even though the vast majority of prescriptions are filled with generic drugs, rising prices on existing brand-name drugs and sky-high prices for new drugs are swamping the savings from generics. Why isn’t the system working as it should? Some experts believe the U.S. can rein in drug process with [value-based pricing](https://www.statnews.com/pharmalot/2017/06/01/drug-prices-outcomes-health-plans/), which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for [dismantling pharmacy benefit managers](https://www.statnews.com/2018/08/23/pbms-rebates-drug-purchasing/). Still others want large groups like Medicare [to negotiate with drug companies](https://www.hsgac.senate.gov/imo/media/doc/REPORT-Manufactured%20Crisis-How%20Better%20Negotiation%20Could%20Save%20Billions%20for%20Medicare%20and%20America's%20Seniors.pdf) for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, [“Drugs, Money, and Secret Handshakes,”](https://www.cambridge.org/us/academic/subjects/law/us-law/drugs-money-and-secret-handshakes-unstoppable-growth-prescription-drug-prices?format=HB) the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. Drug companies have brought great innovations to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection over and over again. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug [Humira](https://www.statnews.com/pharmalot/2018/11/07/abbvie-biosimilars-humira-patents/) is protected by [more than 100 patents](https://www.wsj.com/articles/biosimilar-humira-goes-on-sale-in-europe-widening-gap-with-u-s-1539687603). Walls like that are insurmountable. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, [more than three-quarters](https://academic.oup.com/jlb/advance-article/doi/10.1093/jlb/lsy022/5232981) of the drugs associated with new patents were not new ones coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be obtained on minor tweaks such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit. I believe that one period of protection should be enough. We should make the legal changes necessary to prevent companies from building patent walls and piling up mountains of rights. This could be accomplished by a “one-and-done” approach for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but not all of the above and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through legislative changes to the FDA’s drug approval system, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing [patent obviousness](https://www.law.cornell.edu/wex/nonobviousness) doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

#### Striking a balance is K2 innovation – development won’t be financially viable without protections

Krattiger 13

(Anatole Krattiger; Global Challenges Division at WIPO, Adjunct Prof. School of Integrative Plant Science Plant Breeding and Genetics Section, works on strategic and intellectual property aspects related to ag-biotech and global health at the crossroads of development, government, science, businesses and philanthropy; (September 2013) Promoting access to medical innovation; WIPO Magazine; <https://www.wipo.int/wipo_magazine/en/2013/05/article_0002.html>; CKD)

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.

#### The only major study confirms – thickets decimates competition by resulting in functional monopolies

Arnold Ventures 20 9-24-2020 "'Evergreening' Stunts Competition, Costs Consumers and Taxpayers" <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> (Arnold Ventures is focused on evidence-based giving in a wide range of categories including: criminal justice, education, health care, and public finance)//Elmer

In 2011, Elsa Dixler was diagnosed with multiple myeloma. That August, she was prescribed Revlimid, a drug that had come on the market six years earlier. By January 2012, she went into full remission, where she has remained since. So long as Revlimid retains its effectiveness, she will take it for the rest of her life. “I was able to go back to work, see my daughter receive her Ph.D, and have a pretty normal life,” said Dixler, a Brooklyn resident who is now 74. “So, on the one hand, I feel enormously grateful.” But Dixler’s normal life has come at a steep financial cost to her family and to taxpayers. Revlimid typically costs nearly $800 per capsule, and Dixler takes one capsule per day for 21 days, then seven days off, and then resumes her daily dose, requiring 273 capsules a year. Since retiring from The New York Times at the end of 2017, she has been on Medicare. Dixler entered the Part D coverage gap (known as the donut hole) “within minutes,” she said. She estimates that adding her deductible, her copayment of $12,000, and what her Part D insurance provider pays totals approximately $197,500 a year. Revlimid should have **been subject to competition** from generic drug makers starting in 2009, bringing down its cost by many orders of magnitude. But by obtaining **27 additional patents**, eight orphan drug exclusivities and 91 total additional protections from the U.S. Food and Drug Administration (FDA) since Revlimid’s introduction in 2005, its manufacturer, Celgene, has extended the drug’s **monopoly** **period** **by 18 years** — through March 8, 2028. “I cannot fathom the immorality of a business that relies on **squeezing people with cancer**,” Dixler said, noting her astonishment that Revlimid has obtained orphan drug protections when it treats a disease that is not rare and does not serve a very limited population. She also observed that Revlimid’s underlying drug is thalidomide, which has been around for decades. “They didn’t invent a new drug, rather, they found a new use for it,” she said. “The cost of Revlimid has imposed constraints on our retirement,” Dixler said, “but when I hear other people’s stories, I feel very lucky. A lot of people have been devastated financially.” Revlimid is a case study in a process known as “evergreening” — artificially sustaining a monopoly for years and even decades by manipulating intellectual property laws and regulations. Evergreening is most commonly used with blockbuster drugs generating the highest prices and profits. **Of the roughly 100 best-selling drugs, more than 70 percent have extended their protection** from competition at least once. More than half have extended the protection cliff multiple times. The true scope and cost of evergreening has been brought into sharper focus by a groundbreaking, publicly available, comprehensive database released Thursday by the Center for Innovation at the University of California Hastings College of Law and supported by Arnold Ventures. **The Evergreen Drug Patent Search is the first database to exhaustively track the patent protections filed by pharmaceutical companies**. Using data from 2005 to 2018 on brand-name drugs listed in the FDA’s Orange Book — a listing of relevant patents for brand name, small molecule drugs — it demonstrates the full extent of how evergreening has been used by Big Pharma to prolong patents and delay the entry of generic, lower-cost competition. “Competition is the backbone of the U.S. economy,” said Professor Robin Feldman, Director of the UC Hastings Center for Innovation, who spearheaded the database’s creation. “But it’s not what we’re seeing in the drug industry. “With evergreening, pharmaceutical companies repeatedly make slight, often trivial, modifications to drugs, dosage levels, delivery systems or other aspects to obtain new protections,” she said. “They pile these protections on over and over again — so often that 78 percent of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.” Competition is the backbone of the U.S. economy. But it’s not what we’re **seeing in the drug industry**. Professor Robin Feldman Director of the UC Hastings Center for Innovation In recent decades, evergreening has systematically undermined the Drug Price Competition and Patent Term Restoration Act of 1984, which created the generic drug industry. Commonly known as the Hatch-Waxman Act, it established a new patent and market exclusivity regime in which new drugs are protected from competition for a specified period of time sufficient to allow manufacturers to recoup their investments and earn a reasonable profit. When that protection expires, generic drug makers are incentivized to enter the market through a streamlined regulatory and judicial process. Drug prices typically drop by as much as 20 percent when the first generic enters the market**, and with more than one generic manufacturer, prices can plummet by 80 to 85 percent**. “Hatch-Waxman created an innovation/reward/competition cycle, but it’s been distorted into an innovation/reward/more reward cycle,” Feldman said. “To paraphrase something a former FDA commissioner once said, the greatest creativity in Big Pharma should come from the research and development departments, not from the legal and marketing departments.” Feldman led the development of the Evergreen Drug Patent Search in response to repeated requests from Congressional committees, members of Congress, state regulators and journalists for information about specific drugs and companies. “We want to make it so anyone can have the question about drug protections at their fingertips whenever they want,” Feldman said. “It’s designed to be easy and user-friendly, and to enhance public understanding about how competition may be limited rather than enhanced through the drug patent system.” The **database** was **created through** a painstaking process of **combing** through **160,000 data points** **to examine every instance where a pharmaceutical company added a new drug patent or exclusivity**. “Most of it was done by hand,” Feldman said, “with multiple people reviewing it at every stage. And along the way we repeatedly made conservative choices. **We erred on the side of underrepresenting the evergreen gain** to be sure we were as fair and reasonable as possible.” Among the 2,065 drugs covered in Evergreen Drug Patent Search, there are many examples of the evergreening strategy used by pharma to delay the entry of competition, especially generics, often for widely prescribed drugs, including those used to treat heartburn, chronic pain, and opioid addiction. Nexium Before Nexium, there was Prilosec, a popular drug to treat gastroesophageal reflux disease (GERD). But its patent exclusivity was due to expire in April 2001. In the late 1990s, with a precipitous drop in revenue looming, Prilosec’s manufacturer, AstraZeneca, decided to develop a replacement drug. Using “one-half of the Prilosec molecule — an isomer of it,” the result was Nexium, which received approval in February 2001. Essentially an evergreened version of Prilosec, Nexium’s exclusivity was then extended by more than 15 years, as AstraZeneca received 97 protections stemming from 16 patents. These included revised dosages, compounds, and formulations. Feldman said that tinkering changes such as Nexium’s do not involve the substantial research and development required for a new drug, nor do they constitute true innovations, yet for a decade and a half, patients and taxpayers were forced to pay far more than was warranted for GERD relief. In fact, in 2016 — one year after patent exclusivity expired — Nexium still topped all drugs in Medicare Part D spending, totaling $1.06 billion. Suboxone Use of this combination of buprenorphine and naloxone for treating opioid addiction has exploded in the wake of the opioid epidemic. Since its approval, Suboxone’s manufacturer, Reckitt Benckiser (now operating as Indivior), extended its protection cliff eight times, gaining nearly two extra decades of exclusivity through early 2030. The drug maker gained six patents for creating a film version of the drug — notably around the time protection was expiring for its tablet version. (The therapeutic benefits of the film and tablet are identical.) An earlier version of Suboxone also obtained an orphan drug designation, despite an opioid epidemic that has expanded Suboxone’s customer base to millions of potential customers. Suboxone generates more than $1 billion in annual revenue and ranks among the 40 top-selling drugs in the U.S. Truvada When Truvada, commonly referred to as PrEP, was approved in 2004, this HIV-prevention drug was a breakthrough. But 16 years later — and 14 years after its original exclusivity was to expire — it retains its monopoly status. Truvada’s manufacturer, Gilead, has received 15 patents and 120 protections since it came on the market, extending its exclusivity for more than 17 years, until July 3, 2024. In countries where generic Truvada is available, PrEP costs $100 or less per month, compared to $1,600 to $2,000 in the U.S. As a result, Truvada is unaffordable to many people **who need protection from HIV**. Barred from access, they are left vulnerable to infection. “We’re establishing a precedent that a pharmaceutical company can charge whatever it wants even as it allows an epidemic to continue, and the government refuses to intervene,” said James Krellenstein, co-founder of the group PrEP4All. “That should scare every American. If it’s HIV today, it will be another disease tomorrow.” EpiPen First approved in 1987, the EpiPen has saved the lives of countless numbers of people with deadly allergies. But it is protected from competition until 2025 — 38 years after its introduction — because its owner, Mylan, has filed five patents, four since 2010, all involving tweaks to the automatic injector. The actual medication used, epinephrine, has existed for more than a century — the innovation here is in the delivery device. Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from $94 when Mylan purchased the device to between $650 and $700 today. For many people, especially parents of children with severe reactions to common allergens like peanuts, EpiPen’s increasing price tag imposes an onerous financial burden. What Can Be Done As the Evergreen Drug Patent Search makes clear, the positive impact of Hatch-Waxman has been steadily and severely eroded by a regulatory system vulnerable to increasingly sophisticated forms of manipulation. “You might say that the patent and regulatory system has been weaponized,” Feldman said. “When billions of dollars are at stake, there’s a lot of money available to look for ways to exploit the legal system. And companies have become adept at this, as our work has found.” There are several key steps that Congress could take to restore the balance between innovation and competition that is the key to a successful prescription drug regulatory process. These may include: Imposing restrictions on the number of patents that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets. Limiting the patentability of so-called secondary patents — which don’t improve the safety or efficacy of a drug — through patent and exclusivity reform. Reforming the 180-day generic exclusivity, which can currently be abused to block other competitive therapies. “**The Evergreen Drug Patent Search provides the publicly available, evidence-based foundation that defines the extent of the problem**, and it can be used to develop policies that solve the problem of anti-competitive patent abuses,” said Kristi Martin, VP of Drug Pricing at Arnold Ventures. “Our incentives have gotten out of whack,” Martin said. “The luxury of monopoly protection should only be provided to innovations that provide meaningful benefits in saving lives, curing illnesses, or improving the quality of people’s lives. It should not be provided to those gaming the system. If we can change that, we can save consumers, employers, and taxpayers many billions of dollars while increasing the incentives for pharmaceutical companies to achieve breakthroughs."

#### Only innovation now solves AMR super-bugs -- timeframe’s key.

Sobti 19 [Dr. Navjot Kaur Sobti is an internal medicine resident physician at Dartmouth-Hitchcock-Medical Center/Dartmouth School of Medicine and a member of the ABC News Medical Unit. May 1, 2019. “Amid superbug crisis, scientists urge innovation”. <https://abcnews.go.com/Health/amidst-superbug-crisis-scientists-urge-innovation/story?id=62763415>] Dhruv

[The United Nations](https://abcnews.go.com/Politics/amal-clooney-angelina-jolie-speak-us-weighed-vetoing/story?id=62574726) has called antimicrobial resistance a “global crisis.” With the [rise in superbugs](https://abcnews.go.com/Health/superbug-fungus-global-health-threat-600-us-infected/story?id=62297532) across the globe, common infections are becoming harder to treat, and lifesaving procedures riskier to perform. Drug-resistant infections result in about 700,000 deaths per year, with at least 230,000 of those deaths due to multidrug resistant tuberculosis, [according to a groundbreaking report from the World Health Organization (WHO).](https://www.who.int/antimicrobial-resistance/interagency-coordination-group/IACG_final_report_EN.pdf?ua=1) Given that antibiotic resistance is present in every country, antimicrobial resistance (AMR) now represents a global health crisis, according to the UN, which has urged immediate, coordinated and global action to prevent a potentially devastating health and financial crisis. With the rising rates of AMR -- including antivirals, antibiotics, and antifungals -- estimates from the WHO show that AMR may cause 10 million deaths every year by 2050, send 24 million people into extreme poverty by 2030, and lead to a financial crisis as severe as the on the U.S. experienced in 2008. Antimicrobial resistance develops when germs like bacteria and fungi are able to “defeat the drugs designed to kill them,” according to the Centers for Disease Control and Prevention. Through a biologic “survival of the fittest,” germs that are not killed by antimicrobials and continue to grow. WHO explains that “poor infection control, inadequate sanitary conditions and inappropriate food handling encourage the spread” of AMR, which can lead to “superbugs.” Those superbugs require powerful and oftentimes more expensive antimicrobials to treat. Examples of superbugs are far and wide, and can range from drug-resistant bacteria like Pseudomonas aeruginosa and Staphylococcus aureus to fungi like Candida. These bugs can cause illnesses that range from pneumonia to urinary tract and sexually transmitted infections. According to the WHO, AMR has caused complications for nearly 500,000 people with tuberculosis, and a number of people with HIV and malaria. The people at the [highest risk for AMR](https://www.who.int/news-room/detail/27-02-2017-who-publishes-list-of-bacteria-for-which-new-antibiotics-are-urgently-needed) are those with chronic diseases, people living in nursing homes, hospitalized in the ICU or undergoing life-saving treatments such as organ transplantation and cancer therapy. These people often develop infections, which can become antimicrobial-resistant, rendering them difficult, if not impossible, to treat. [(MORE: Melissa Rivers talks about her father's suicide with Dr. Jennifer Ashton)](https://abcnews.go.com/Health/melissa-rivers-talks-fathers-suicide-dr-jennifer-ashton/story?id=62733179&cid=clicksource_26_null_headlines_hed) The CDC notes that “antibiotic resistance has the potential to affect people at any stage of life,” including the “healthcare, veterinary, and agriculture industries, making it one of the world’s most urgent public health problems." AMR can cause prolonged hospital stays, billions of dollars in healthcare costs, disability, and potentially, death. “The most important thing is to understand and embrace the interconnectedness of all of this,” said Dr. Robert Redfield, director of the CDC, in a recent interview with ABC News’ Dr. Jennifer Ashton. It’s not just our countries that are connected.” Research has shown that superbugs like Candida auris “came from multiple places, at the same time. It wasn’t just one organism that [evolved]” in a single location, Redfield added. Given longstanding concerns about antimicrobial misuse leading to AMR, physicians have embraced a medical approach called antibiotic stewardship. This encourages physicians to carefully evaluate which antibiotic is most appropriate for their patient, and discontinue it once it is no longer medically needed. WHO has also highlighted that the inappropriate use of antimicrobials in agriculture -- such as on farms and in animals -- may be an underappreciated cause of AMR. Noting these trends, the WHO has urged for “coordinated action...to minimize the emergence and spread of antimicrobial resistance.” It urges all countries to make national action plans, with a focus on the development of new antimicrobial medications, vaccines, and careful antimicrobial use. Redfield emphasized the importance of vaccination during the global superbug crisis, stating that “the only way we have to eliminate an infection is vaccination.” He added that investing in innovation is key to solving the crisis. While WHO continues to advocate for superbug awareness, they warn that AMR has reversed “a century of progress in health.” The WHO added that “the challenges of antimicrobial resistance” are “not insurmountable,” and that coordinated action will “help to save millions of lives, preserve antimicrobials for generations to come and secure the future from drug-resistant diseases.”

## Threat CP (15)

#### Plan text: The member nations of the WTO ought to threaten [to remove IP protections for medicine]

#### Threat of waiver is distinct from action and avoids any disads therefore competitive

**Zarocostas quoting Appleton 5/22**

~John, Geneva-based independent international correspondent and broadcaster; Arthur, adjunct professor at Johns Hopkins University, May 22, 2021, The Lancet, Vol 397, [https://doi.org/10.1016/S0140-6736(21)01151-X//lhs-ap~~](https://doi.org/10.1016/S0140-6736(21)01151-X/lhs-ap~~)

“Even if a waiver is approved, there may still be bottlenecks related to production capacity, distribution, and the production of raw materials and equipment used to manufacture package and transport vaccines”, said Appleton. “Of course, just the threat of a waiver may help drive down the cost of vaccines, therapeutics, and diagnostic tools, and result in increased access in the developing world. The threat may also lead to voluntary licensing agreements on terms favourable to developing countries.”

## Proteomic tech CP (30)

#### CP text: Technology providers, research institutions and governmental CBRNE services should invest in proteomic technology to use against bioterrorism

Armengaud 8-1

Jean Armengaud,( CEA, INRAE, Département Médicaments et Technologies Pour la Santé (DMTS), SPI, Université Paris-Saclay, Bagnols-sur-Cèze, France), 8-1-2020, "The proteomics contribution to the counter-bioterrorism toolbox in the post-COVID-19 era," Taylor &amp; Francis, [https://www.tandfonline.com/doi/full/10.1080/14789450.2020.1822745 //](https://www.tandfonline.com/doi/full/10.1080/14789450.2020.1822745%20//) AW

A better knowledge of how bacterial pathogens and viruses – our age-old enemies – propagate is key to counteracting possible CBRNE threats. Next-generation proteomics methods can contribute to many aspects of basic research and development with potential for applications in diagnosis, prognosis, counter-measures, and therapies, together with genomics and other omics technologies. Thus, proteomics could play a determinant role in quick on-site diagnosis of disease, but only if manufacturers of high-resolution tandem mass spectrometers miniaturize their instruments and decrease costs. Such approaches could lead to the development of instruments similar to those used to detect explosives in airports, providing precise answers in minutes. Evidently, **other technologies should be improved and benchmarked in parallel to continuously improve the counter-bioterrorism toolbox.** The Covid-19 pandemic has, naturally, attracted huge attention to coronavirus-related research, and proteomics has proved to be quite successful in this field, demonstrating its capacity to rapidly gather new knowledge on a novel emerging pathogen [[25](https://www.tandfonline.com/doi/full/10.1080/14789450.2020.1822745)]. However, the enormous impact demonstrated for this type of novel threat should make us aware of the need for preventive actions. Studies of other pathogens, especially those relevant to the CBRNE field and newly emerging lethal pathogens, should not be discontinued, but rather reinforced. Finally, international collaborations between researchers, technology providers, first responders, and governmental CBRNE services is needed more than ever to tackle the increasing CBRNE risks. Figure 1. Spread of SARS-CoV-2 worldwide over the first half of 2020. The figure was created with the nextstrain interface (<https://nextstrain.org/>) using GISAID genomic epidemiology data on SARS-CoV-2 (<https://www.gisaid.org/>). Panel A shows how SARS-CoV-2 lineages, established from the ~75 000 sequences available, spread across continents. The radius scales with the number of genome sequences from each continent and the color of sectors and continent connections reflects distinct SARS-CoV-2 lineages. Panel B shows the different SARS-CoV-2 lineages and the time-scale for their emergence Figure 2. Strategies for proteomics-based detection of pathogens. Schematic representation of whole-cell MALDI-TOF, targeted proteomics, and tandem mass spectrometry proteotyping by shotgun proteomics 6. Expert opinion Biological agents, or live pathogens, could represent unconventional weapons. **Luckily, CBRNE counter-terrorism experts can rely on an extended toolbox of next-generation technologies to detect them and minimize their impact.** However, the Black Swan Theory, which considers an extremely improbable event which would have a disproportionately large impact, may apply to biological threats. This scenario is possible because some living organisms have an amazing capacity for amplification, and propensity to spread, while also having drastic effects. The etiological agent responsible for the COVID-19 pandemic, SARS-CoV-2 virus, has shown how pernicious and damaging sarbecoviruses can be. In the post-COVID-19 era, we must re-assess biological risks without compromise, taking into account the three grey swan coronavirus known outbreaks and the most recent societal changes. Proteomics has important roles to play in improving and accelerating detection of pathogens and their potential resistance to current treatments, determining their source as quickly as possible, stratifying patients to improve therapeutic interventions, investigating new drug or vaccine therapies, characterizing pathogen reservoirs, and improving predictive epidemiological models. It thus constitutes an essential element in the counter-terrorism toolbox to deal with biological threats as developed here.

## Pharma DA (2)

**. UQ: Pharma profits are up from COVID vaccines, patent waivers threaten this**

**Buchholz 5-17-21**

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales took a nosedive on the news of Biden’s reversal. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the short term, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 vaccines in the long term. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

**B. Link: Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing—prefer statistical analysis of multiple studies**

**Ezell and Cory 19**

[Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

IPRs Strengthen Innovation Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46 IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that R&D to GDP ratios are positively related to the strength of patent rights, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

**C. IL: Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao 20**

[Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

## Trademark CP (45)

The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines with the exception of trademark

#### Trademark is the single effective preventative measure against counterfeit medicine, solvency is reverse causal

Konski 08

Antoinette Konski, 2008, “Ip Strategies to combat distribution of counterfeit drugs”, Foley and Lardner LLP, [https://www.foley.com/-/media/files/insights/publications/2008/04/ip-strategies-to-combat-distribution-of-counterfei/files/ip-strategies-to-combat-distribution-of-counterfei/fileattachment/combatcounterfeitdrugs\_a-konski.pdf //](https://www.foley.com/-/media/files/insights/publications/2008/04/ip-strategies-to-combat-distribution-of-counterfei/files/ip-strategies-to-combat-distribution-of-counterfei/fileattachment/combatcounterfeitdrugs_a-konski.pdf%20//) AW

A number of international government initiatives have been established to combat the growing problem of counterfeits. The World Health Organization (WHO) and the U.S. Food and Drug Administration have specific programs to make it more difficult to manufacture and distribute counterfeit pharmaceuticals.7 Criminal actions by governmental entities also help impede counterfeiting and can provide a powerful deterrent. For example, on August 31, 2007, Johnson & Johnson, Inc. announced that a Shanghi Court fined and sentenced Su Zhiyong, Chinese business man, to 3 ½ years in prison for selling approximately 1 million counterfeit OneTouch™ test trips. The counterfeit strips were found in 35 U.S. States, Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia and Turkey.8 Such governmental efforts reduce the public health threat of counterfeit drugs but will not provide economic redress to those whose products are being copied. Enforcement of privately held intellectual property rights can however, address economic harm while at the same time, remove the copies from the market. Proactive procurement of intellectual property is the first step toward seeking private redress for economic harm. Patents, trademarks and copyrights, collectively referred to as intellectual property (IP), vary in scope, duration, geographical reach, as well as the investment of time and money required to obtain and enforce.9 It is useful at the outset for businesses to assess which form of IP protection is appropriate for a product and anticipate how illicit copying of their products and/or packaging may occur. Important considerations in this initial assessment include the type of product, the nature of the likely copying, the geographical scope of intended distribution and the duration of the exclusivity period needed to protect against copiers.10 Patents A patent allows the patentee to exclude third parties from making, using, importing, selling, or offering for sale patented products or methods of manufacture or use for a finite period of time, typically no more than 20 years from the date of initial patent filing. Patent protection must be obtained on a country-by-country basis. It is used to prevent others, for that geographical area and without the consent of the patent holder, from manufacturing and/or selling exact and close copies of the patented technology. Pharmaceutical patents are usually considered the first line of defense in protecting intellectual capital because patents can prevent others from manufacturing, using, selling and/or importing products that have the same or equivalent active ingredient or formulation. However, as compared to other intellectual property, patent rights are expensive to enforce and a final, enforceable judgment may only be obtained years after a lawsuit is filed. Patent holders must prove in civil litigation that the alleged copier is making or selling a product that is described in the patent. This requires a detailed review of the patent document and correspondence between the patent applicant and the patent office. Frequently, technical experts are retained to opine on technical terminology and the meaning of phrases or terms during this phase of the lawsuit. Only after this initial review is the alleged infringing technology compared to the property right defined during the initial phase of the proceeding. Thus, the patent can only prevent others from manufacturing, using, selling or importing products that are exact or close copies of the patented technology. Rarely, however, are counterfeit medicines close copies of the original. For example, counterfeit medicines often do not contain the same, or perhaps the same amount of the genuine, patented formulation. Therefore, a patent will not prevent the making or selling of a look-alike counterfeit drug that does not contain the same or similar active compound or formulation. In addition, a patent is granted to an “innovator” and therefore manufacturers of generic drugs, frequently manufactured after drugs have gone off-patent, cannot use patents to prevent distribution of counterfeited generics. 9 Under appropriate circumstances, misappropriation of trade secrets can provide economic redress. For a general discussion of trade secret protection, and its comparison to other forms of intellectual property, see Medd and Konski, Workplace Programs to Protect Trade Secrets, Nature Biotechnology (2003) Vol. 21:201-203. 10 Id. ©2008 Foley & Lardner LLP 4 Copyrights Copyrights prevent others from copying and claiming authorship of original works. Copyright protection is granted to original works of authorship that have been fixed in a tangible form of expression. Works of authorship include literary, musical, dramatic, pictorial, graphic, sculptural, cinematic, and architectural works. Titles, names, and short phrases are generally not copyrightable. Ownership of a copyright is secured from the time of creation and the work need not ever be published. Similar to patent protection, copyright protection is available on a countryby-country basis and requires a registration process to enforce the right against third parties. In terms of the use of copyrights to secure protection from counterfeiters, copyrights on package inserts may be useful but is of limited effectiveness in preventing the counterfeit from reaching the public or providing redress for economic harm. Trademarks Because trademarks seek to prevent exactly what counterfeiters seek to obtain, i.e. the economic benefit and investment in product integrity of the manufacturer, a strong trademark is the most valuable type of intellectual property that can be used to combat counterfeiting. Similar to patents, trademarks are enforceable on a country-by-country basis, and therefore trademark protection must be obtained in each country where the product is made or distributed.11 However, in contrast to patents, trademarks are not limited to a finite period of time but can extend as long as the trademark is used in commerce in connection with the product. Trademarks are used to identify the source of goods or services. Words, names, numbers, symbols, devices, designs, sounds, and colors that function as brands to distinguish the source of goods and their packaging may be registered as trademarks. The colors of pills as well as their shape may be trademarked. In contrast to patents, a trademark cannot be obtained on the process of making the product or medicine and does not protect the innovation of the underlying product. However, trademarks are available to generic manufacturers who identify their products with a unique logo or other identifying mark or property. Misappropriated trademarks mislead consumers by copying the unique name, logo, product packaging, shape and/or color used by the manufacturer on the genuine product or packaging, thus confusing consumers as to the actual source, and quality, of the product. Therefore, all unique aspects of the product and packaging should be considered as worthy of trademark protection and the company’s trademark should be applied as frequently as possible, e.g., on the pill itself, on both inner and outer packaging, etc. All modifications of the label, such as the product logo or other unique identifying descriptive marks should be protected in the language of the country where the product is to be sold. 11 Unlike patents, some countries recognize a trademark right without a formal application and review process, although other procedural requirements typically must be met in such cases as demonstrating proof of sale of the product within the relevant jurisdiction. ©2008 Foley & Lardner LLP 5 As compared to patents, obtaining and enforcing trademark rights are typically less costly, and a final enforceable judgment is usually obtained faster than in a patent infringement action. Indeed, evaluation of whether a trademark is likely to be infringed can be limited to a visual inspection rather than a complicated analysis of the patented technology. Most significantly, however, in many countries trademark owners can have the counterfeit goods and accompanying documents, and even sometimes manufacturing equipment immediately seized at the outset of the lawsuit. Such powerful preliminary remedies are generally not available in patent lawsuits and can lead to swift resolution of the action. Conclusion The rise of counterfeit medicines is a threat to public health and the economic investment made by innovators and generic manufacturers in the pharmaceutical industry. All manufactures of medicines can limit their economic harm by proactively assessing their product and available intellectual property options and anticipating counterfeit designs and products. After this initial assessment, appropriate intellectual property protection can be pursued in the relevant markets and countries. Although patents and to a lesser extent copyrights can be useful in combating counterfeiting and addressing economic harm, a strong trademark is the strongest intellectual property tool for combating counterfeiting.

## Case (2)

#### Mass production doesn’t solve – we need innovation to deal with NEW threats because the impact card talks about specifically NEW threats. Production is good for stuff we know exists like anthrax, but anthrax isn’t threatening extinction, but the new ones are, which is where the solvency defecit is

#### The evidence is from 4 years ago and it’s likely we’ve passed the brink since it was “any day now” in 2017 and bioweapons are already too powerful and with covid, it seems like the scenario is too powerful for the link to solve

#### We are over the worst of COVID – the mcpherson card is extremely exaggerated and proven by the fact that nothing has happened

#### Not to mention it is totally wrong that industrial activity is good for the environment – biggest users of fossil fuels and biggest polluters

#### And, the industrial centers like China and the US are alr out of quarantine, meaning no more halted production

#### Aff doesn’t attack all of the root causes of disease spread – means they don’t solve for covid nor bioterror

Brant & Burns 7-29-21 [Jennifer Brant, CEO and Founder of Innovation Insights, and Thaddeus Burns, Head of Life Science Government & Public Affairs at Merck and served in senior positions at the US Department of Commerce and the White House Office of the US Trade Representative, served as a member of the National Academy of Sciences Committee charged with preparing a report on the science and technology capabilities of the U.S. Department of State. “Trade restrictions are delaying the COVID response. The WTO must act.” July 29, 2021. <https://www.weforum.org/agenda/2021/07/wto-members-must-launch-new-work-to-reinforce-the-covid-response-in-november/>] AL

The COVID-19 pandemic hit at a time when bio-manufacturing was undergoing a process of democratization. Technological progress had enabled growing capacity in many countries including Brazil, Indonesia, South Africa, Tunisia, Argentina, and Egypt. By 2020, the business model for bio-manufacturing had fundamentally changed and it was becoming the norm for companies to distribute research, development and manufacturing across geographies and work with partners. As recently as 15 years ago, building a facility to produce biologics such as monoclonal antibodies or vaccines could require an investment of as much as €500m, and it would take up to 3 years to bring that facility online. New manufacturing technologies have made it cheaper and easier to build new facilities and to scale up existing ones. Today, an investment of €20m can get a bio-manufacturing plant up and running. Such changes are part of the reason the global community was able to launch production of new COVID-19 vaccines so quickly. The urgency of COVID-19 accelerated further innovations in bio-manufacturing equipment and processes, and compressed production time in a way that will have positive impacts in the future. But the pandemic also revealed major weaknesses in global value chains. It was difficult for manufacturers to keep up with the sudden surge for demand for raw materials and equipment, as many new research and development and manufacturing partnerships rapidly took off. To extend capacity, new employees, intensive training and collaboration, and more infrastructure were needed. The global community was faced with the reality that facilities cannot be built everywhere in an instant, and that there are bottlenecks in the supply chain. Government action in some cases made things worse. Some countries enacted export restrictions on COVID-related products, which made it extremely difficult to run a global supply chain. Another difficult issue has been the tariffs applied on biologics and the products needed for their manufacture. Eighteen months into the pandemic, biologics manufacturers are still trying to cope with a range of challenges. There is still surging demand for equipment and raw materials. In some cases, they have expanded manufacturing capacity to produce more equipment such as filters and bioreactors. This continues to require time and significant investments.

#### The TRIPS agreement and cheap vaccines in the squo solve the aff--independently, lack of manufacturing power and licensing transparency deck solvency.

Mercurio 21 (Bryan Mercurio [Simon F.S. Li Professor of Law at The Chinese University of Hong Kong], WTO WAIVER FROM INTELLECTUAL PROPERTY PROTECTION FOR COVID19 VACCINES AND TREATMENTS: A CRITICAL REVIEW, Virginia Journal of International Law, <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820>, 2/12/2021) hwof

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26 Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level. Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31 While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs. Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices. Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

#### Trade causes proliferation—results in the spread of dual-use technology – they link in the second contention

Kassenova 1/25/12 (Togzhan Kassenove- associate in the Nuclear Policy Program at the Carnegie Endowment and a Stanton Nuclear Security Fellow. She specializes in weapons of mass destruction nonproliferation issues, with a regional focus on Central Asia and Southeast Asia; nuclear security; strategic trade management; and civilian nuclear energy programs, January 25, “Preventing WMD Proliferation Myths and Realities of Strategic Trade Controls”, <http://carnegieendowment.org/files/wmd_proliferation_Togzhan_Jan_25_2012.pdf>)

WMD-relevant technology and materials are all around us. Semiconductors, for instance, are indispensable in the advanced electronics we use every day (including computers), but they can also be utilized in a variety of military equipment, such as satellites, infrared imaging products, and transistors. Freezedrying technology used to make instant coffee or instant noodles can also be used in biological-warfare research. Encryption technology has many civilian applications—for instance, in train-signaling systems—but malicious actors can also use it to communicate without being detected by law enforcement agencies. Similarly, satellite technology may have civilian applications, weather monitoring for example, or military ones, such as missile guidance. The broad applications for dual-use goods and technology in everyday life result in constant flows of proliferation-sensitive items across borders. And this poses a real danger. Gradual acquisition of components and technology from various sources that can enable a nonstate or state actor to build a WMD program is a more likely proliferation threat than an actor acquiring an already-built weapon from an external source. The best illustration of how real this threat is in the nuclear realm is the story of the A. Q. Khan network. Pakistani scientist A. Q. Khan and his associates successfully exploited gaps in controls of nuclear exports in Pakistan and beyond during the 1980s and 1990s. The network assisted Iran, North Korea, and Libya in acquiring a whole range of nuclear weapons–relevant items. 1 According to a recent report by nonproliferation expert Joshua Pollack, India, surprisingly, was the fourth customer of the Khan network, procuring uraniumenrichment technology. 2 Unfortunately for the proliferation outlook, progress in high-tech industries, especially in the fields of electronics and biotechnology, as well as the expansion of nuclear power and the globalization of trade, further exacerbate the challenge of firewalling international trade from WMD proliferation.

#### Nuclear war results

**Kroenig 15** (Matthew, Associate Professor and International Relations Field Chair in the Department of Government and School of Foreign Service at Georgetown University, 2015. “The History of Proliferation Optimism: Does It Have a Future?” *Journal of Strategic Studies*, Volume 38, Issue 1-2, 2015)

The spread of nuclear weapons poses at least six severe threats to international peace and security including: nuclear war, nuclear terrorism, global and regional instability, constrained US freedom of action, weakened alliances, and further nuclear proliferation. Each of these threats has received extensive treatment elsewhere and this review is not intended to replicate or even necessarily to improve upon these previous efforts. Rather the goals of this section are more modest: to usefully bring together and recap the many reasons why we should be pessimistic about the likely consequences of nuclear proliferation. Many of these threats will be illuminated with a discussion of a case of much contemporary concern: Iran’s advanced nuclear program. Nuclear War The greatest threat posed by the spread of nuclear weapons is nuclear war. The more states in possession of nuclear weapons, the greater the probability that somewhere, someday, there will be a catastrophic nuclear war. To date, nuclear weapons have only been used in warfare once. In 1945, the United States used nuclear weapons on Hiroshima and Nagasaki, bringing World War II to a close. Many analysts point to the 65-plus-year tradition of nuclear non-use as evidence that nuclear weapons are unusable, but it would be naïve to think that nuclear weapons will never be used again simply because they have not been used for some time. After all, analysts in the 1990s argued that worldwide economic downturns like the Great Depression were a thing of the past, only to be surprised by the dot-com bubble bursting later in the decade and the Great Recession of the late 2000s.48 This author, for one, would be surprised if nuclear weapons are not used again sometime in his lifetime. Before reaching a state of MAD, new nuclear states go through a transition period in which they lack a secure-second strike capability. In this context, one or both states might believe that it has an incentive to use nuclear weapons first. For example, if Iran acquires nuclear weapons, neither Iran, nor its nuclear-armed rival, Israel, will have a secure, second-strike capability. Even though it is believed to have a large arsenal, given its small size and lack of strategic depth, Israel might not be confident that it could absorb a nuclear strike and respond with a devastating counterstrike. Similarly, Iran might eventually be able to build a large and survivable nuclear arsenal, but, when it first crosses the nuclear threshold, Tehran will have a small and vulnerable nuclear force. In these pre-MAD situations, there are at least three ways that nuclear war could occur. First, the state with the nuclear advantage might believe it has a splendid first strike capability. In a crisis, Israel might, therefore, decide to launch a preventive nuclear strike to disarm Iran’s nuclear capabilities. Indeed, this incentive might be further increased by Israel’s aggressive strategic culture that emphasizes preemptive action. Second, the state with a small and vulnerable nuclear arsenal, in this case Iran, might feel use them or lose them pressures. That is, in a crisis, Iran might decide to strike first rather than risk having its entire nuclear arsenal destroyed. Third, as Thomas Schelling has argued, nuclear war could result due to the reciprocal fear of surprise attack.49 If there are advantages to striking first, one state might start a nuclear war in the belief that war is inevitable and that it would be better to go first than to go second. Fortunately, there is no historic evidence of this dynamic occurring in a nuclear context, but it is still possible. In an Israeli–Iranian crisis, for example, Israel and Iran might both prefer to avoid a nuclear war, but decide to strike first rather than suffer a devastating first attack from an opponent. Even in a world of MAD, however, when both sides have secure, second-strike capabilities, there is still a risk of nuclear war. Rational deterrence theory assumes nuclear-armed states are governed by rational leaders who would not intentionally launch a suicidal nuclear war. This assumption appears to have applied to past and current nuclear powers, but there is no guarantee that it will continue to hold in the future. Iran’s theocratic government, despite its inflammatory rhetoric, has followed a fairly pragmatic foreign policy since 1979, but it contains leaders who hold millenarian religious worldviews and could one day ascend to power. We cannot rule out the possibility that, as nuclear weapons continue to spread, some leader somewhere will choose to launch a nuclear war, knowing full well that it could result in self-destruction. One does not need to resort to irrationality, however, to imagine nuclear war under MAD. Nuclear weapons may deter leaders from intentionally launching full-scale wars, but they do not mean the end of international politics. As was discussed above, nuclear-armed states still have conflicts of interest and leaders still seek to coerce nuclear-armed adversaries. Leaders might, therefore, choose to launch a limited nuclear war.50 This strategy might be especially attractive to states in a position of conventional inferiority that might have an incentive to escalate a crisis quickly to the nuclear level. During the Cold War, the United States planned to use nuclear weapons first to stop a Soviet invasion of Western Europe given NATO’s conventional inferiority.51 As Russia’s conventional power has deteriorated since the end of the Cold War, Moscow has come to rely more heavily on nuclear weapons in its military doctrine. Indeed, Russian strategy calls for the use of nuclear weapons early in a conflict (something that most Western strategists would consider to be escalatory) as a way to de-escalate a crisis. Similarly, Pakistan’s military plans for nuclear use in the event of an invasion from conventionally stronger India. And finally, Chinese generals openly talk about the possibility of nuclear use against a US superpower in a possible East Asia contingency. Second, as was also discussed above, leaders can make a ‘threat that leaves something to chance’.52 They can initiate a nuclear crisis. By playing these risky games of nuclear brinkmanship, states can increase the risk of nuclear war in an attempt to force a less resolved adversary to back down. Historical crises have not resulted in nuclear war, but many of them, including the 1962 Cuban Missile Crisis, have come close. And scholars have documented historical incidents when accidents nearly led to war.53 When we think about future nuclear crisis dyads, such as Iran and Israel, with fewer sources of stability than existed during the Cold War, we can see that there is a real risk that a future crisis could result in a devastating nuclear exchange. Nuclear Terrorism The spread of nuclear weapons also increases the risk of nuclear terrorism.54 While September 11th was one of the greatest tragedies in American history, it would have been much worse had Osama Bin Laden possessed nuclear weapons. Bin Laden declared it a ‘religious duty’ for Al- Qa’eda to acquire nuclear weapons and radical clerics have issued fatwas declaring it permissible to use nuclear weapons in Jihad against the West.55 Unlike states, which can be more easily deterred, there is little doubt that if terrorists acquired nuclear weapons, they would use them.56 Indeed, in recent years, many US politicians and security analysts have argued that nuclear terrorism poses the greatest threat to US national security.57 Analysts have pointed out the tremendous hurdles that terrorists would have to overcome in order to acquire nuclear weapons.58 Nevertheless, as nuclear weapons spread, the possibility that they will eventually fall into terrorist hands increases. States could intentionally transfer nuclear weapons, or the fissile material required to build them, to terrorist groups. There are good reasons why a state might be reluctant to transfer nuclear weapons to terrorists, but, as nuclear weapons spread, the probability that a leader might someday purposely arm a terrorist group increases. Some fear, for example, that Iran, with its close ties to Hamas and Hizballah, might be at a heightened risk of transferring nuclear weapons to terrorists. Moreover, even if no state would ever intentionally transfer nuclear capabilities to terrorists, a new nuclear state, with underdeveloped security procedures, might be vulnerable to theft, allowing terrorist groups or corrupt or ideologically-motivated insiders to transfer dangerous material to terrorists. There is evidence, for example, that representatives from Pakistan’s atomic energy establishment met with Al-Qa’eda members to discuss a possible nuclear deal.59 Finally, a nuclear-armed state could collapse, resulting in a breakdown of law and order and a loose nukes problem. US officials are currently very concerned about what would happen to Pakistan’s nuclear weapons if the government were to fall. As nuclear weapons spread, this problem is only further amplified. Iran is a country with a history of revolutions and a government with a tenuous hold on power. The regime change that Washington has long dreamed about in Tehran could actually become a nightmare if a nuclear-armed Iran suffered a breakdown in authority, forcing us to worry about the fate of Iran’s nuclear arsenal. Regional Instability The spread of nuclear weapons also emboldens nuclear powers, contributing to regional instability. States that lack nuclear weapons need to fear direct military attack from other states, but states with nuclear weapons can be confident that they can deter an intentional military attack, giving them an incentive to be more aggressive in the conduct of their foreign policy. In this way, nuclear weapons provide a shield under which states can feel free to engage in lower-level aggression. Indeed, international relations theories about the ‘stability-instability paradox’ maintain that stability at the nuclear level contributes to conventional instability.60 Historically, we have seen that the spread of nuclear weapons has emboldened their possessors and contributed to regional instability. Recent scholarly analyses have demonstrated that, after controlling for other relevant factors, nuclear-weapon states are more likely to engage in conflict than nonnuclear-weapon states and that this aggressiveness is more pronounced in new nuclear states that have less experience with nuclear diplomacy.61 Similarly, research on internal decision-making in Pakistan reveals that Pakistani foreign policymakers may have been emboldened by the acquisition of nuclear weapons, which encouraged them to initiate militarized disputes against India.62 Currently, Iran restrains its foreign policy because it fears major military retaliation from the United States or Israel, but with nuclear weapons it could feel free to push harder. A nuclear-armed Iran would likely step up support to terrorist and proxy groups and engage in more aggressive coercive diplomacy. With a nuclear-armed Iran increasingly throwing its weight around in the region, we could witness an even more crisis prone Middle East. And in a poly-nuclear Middle East with Israel, Iran, and, in the future, possibly other states, armed with nuclear weapons, any one of those crises could result in a catastrophic nuclear exchange.

#### No econ impact

Walt 20 — (Stephen M. Walt, Robert and Renée Belfer professor of international relations at Harvard University., “Will a Global Depression Trigger Another World War?“, Foreign Policy, 5-13-20, Available Online at https://foreignpolicy.com/2020/05/13/coronavirus-pandemic-depression-economy-world-war/, accessed 11-5-2020, HKR-AR)

One familiar argument is the so-called diversionary (or “scapegoat”) theory of war. It suggests that leaders who are worried about their popularity at home will try to divert attention from their failures by provoking a crisis with a foreign power and maybe even using force against it. Drawing on this logic, some Americans now worry that President Donald Trump will decide to attack a country like Iran or Venezuela in the run-up to the presidential election and especially if he thinks he’s likely to lose.

This outcome strikes me as unlikely, even if one ignores the logical and empirical flaws in the theory itself. War is always a gamble, and should things go badly—even a little bit—it would hammer the last nail in the coffin of Trump’s declining fortunes. Moreover, none of the countries Trump might consider going after pose an imminent threat to U.S. security, and even his staunchest supporters may wonder why he is wasting time and money going after Iran or Venezuela at a moment when thousands of Americans are dying preventable deaths at home. Even a successful military action won’t put Americans back to work, create the sort of testing-and-tracing regime that competent governments around the world have been able to implement already, or hasten the development of a vaccine. The same logic is likely to guide the decisions of other world leaders too.

Another familiar folk theory is “military Keynesianism.” War generates a lot of economic demand, and it can sometimes lift depressed economies out of the doldrums and back toward prosperity and full employment. The obvious case in point here is World War II, which did help the U.S economy finally escape the quicksand of the Great Depression. Those who are convinced that great powers go to war primarily to keep Big Business (or the arms industry) happy are naturally drawn to this sort of argument, and they might worry that governments looking at bleak economic forecasts will try to restart their economies through some sort of military adventure.

I doubt it. It takes a really big war to generate a significant stimulus, and it is hard to imagine any country launching a large-scale war—with all its attendant risks—at a moment when debt levels are already soaring. More importantly, there are lots of easier and more direct ways to stimulate the economy—infrastructure spending, unemployment insurance, even “helicopter payments”—and launching a war has to be one of the least efficient methods available. The threat of war usually spooks investors too, which any politician with their eye on the stock market would be loath to do.

Economic downturns can encourage war in some special circumstances, especially when a war would enable a country facing severe hardships to capture something of immediate and significant value. Saddam Hussein’s decision to seize Kuwait in 1990 fits this model perfectly: The Iraqi economy was in terrible shape after its long war with Iran; unemployment was threatening Saddam’s domestic position; Kuwait’s vast oil riches were a considerable prize; and seizing the lightly armed emirate was exceedingly easy to do. Iraq also owed Kuwait a lot of money, and a hostile takeover by Baghdad would wipe those debts off the books overnight. In this case, Iraq’s parlous economic condition clearly made war more likely.

Yet I cannot think of any country in similar circumstances today. Now is hardly the time for Russia to try to grab more of Ukraine—if it even wanted to—or for China to make a play for Taiwan, because the costs of doing so would clearly outweigh the economic benefits. Even conquering an oil-rich country—the sort of greedy acquisitiveness that Trump occasionally hints at—doesn’t look attractive when there’s a vast glut on the market. I might be worried if some weak and defenseless country somehow came to possess the entire global stock of a successful coronavirus vaccine, but that scenario is not even remotely possible.

If one takes a longer-term perspective, however, a sustained economic depression could make war more likely by strengthening fascist or xenophobic political movements, fueling protectionism and hypernationalism, and making it more difficult for countries to reach mutually acceptable bargains with each other. The history of the 1930s shows where such trends can lead, although the economic effects of the Depression are hardly the only reason world politics took such a deadly turn in the 1930s. Nationalism, xenophobia, and authoritarian rule were making a comeback well before COVID-19 struck, but the economic misery now occurring in every corner of the world could intensify these trends and leave us in a more war-prone condition when fear of the virus has diminished.

On balance, however, I do not think that even the extraordinary economic conditions we are witnessing today are going to have much impact on the likelihood of war. Why? First of all, if depressions were a powerful cause of war, there would be a lot more of the latter. To take one example, the United States has suffered 40 or more recessions since the country was founded, yet it has fought perhaps 20 interstate wars, most of them unrelated to the state of the economy. To paraphrase the economist Paul Samuelson’s famous quip about the stock market, if recessions were a powerful cause of war, they would have predicted “nine out of the last five (or fewer).”

Second, states do not start wars unless they believe they will win a quick and relatively cheap victory. As John Mearsheimer showed in his classic book Conventional Deterrence, national leaders avoid war when they are convinced it will be long, bloody, costly, and uncertain. To choose war, political leaders have to convince themselves they can either win a quick, cheap, and decisive victory or achieve some limited objective at low cost. Europe went to war in 1914 with each side believing it would win a rapid and easy victory, and Nazi Germany developed the strategy of blitzkrieg in order to subdue its foes as quickly and cheaply as possible. Iraq attacked Iran in 1980 because Saddam believed the Islamic Republic was in disarray and would be easy to defeat, and George W. Bush invaded Iraq in 2003 convinced the war would be short, successful, and pay for itself.