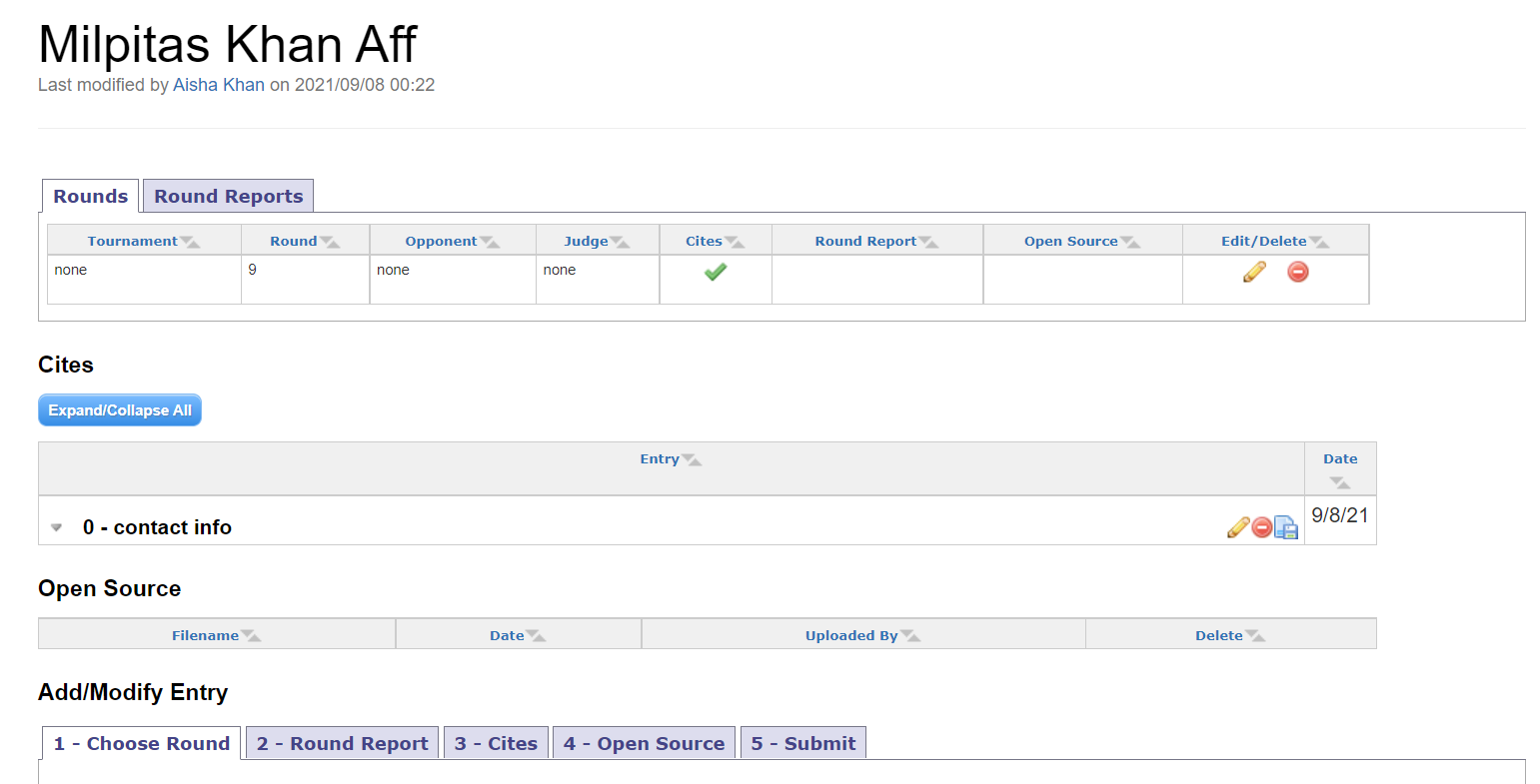
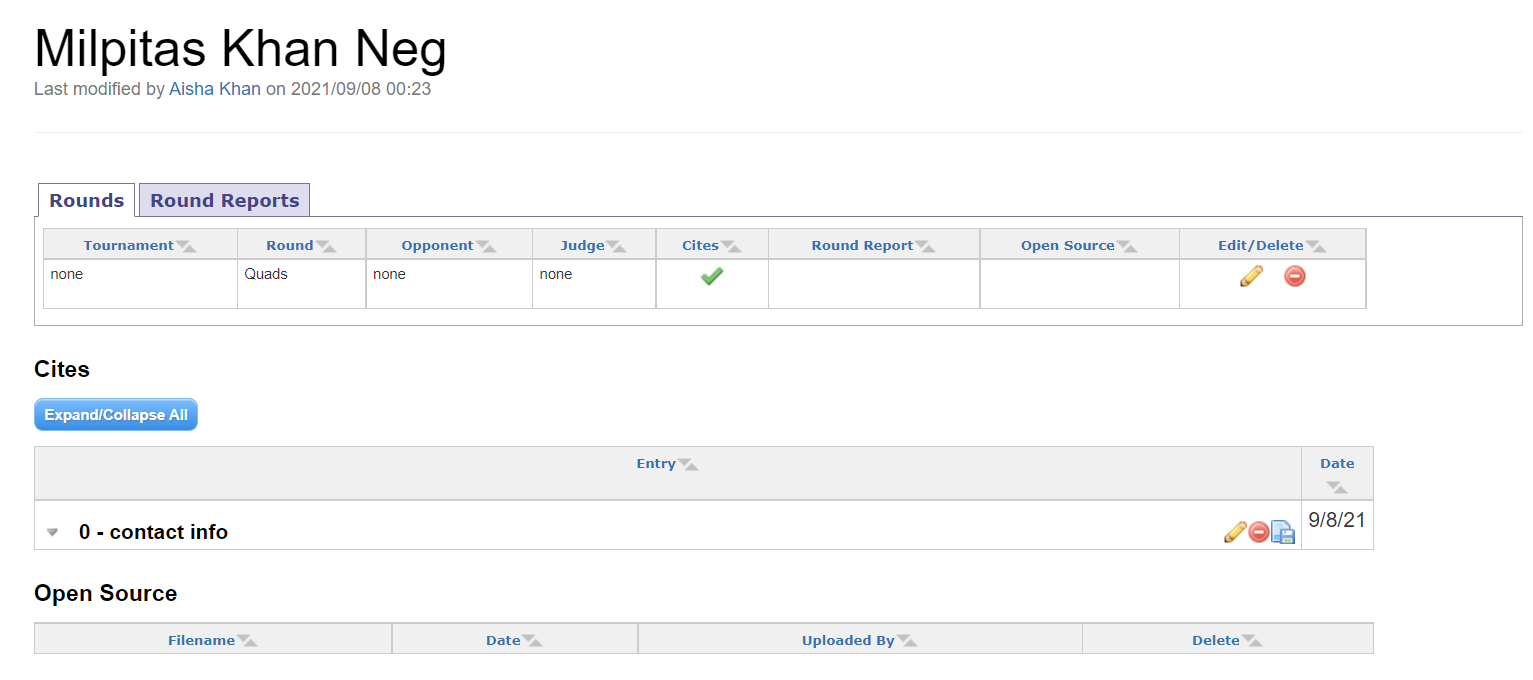
# 1nc

## 1

#### Interp: All debaters must disclose all broken positions on the NDCA LD wiki.  The disclosure must include tags, complete citations, including page numbers, and the full text from each piece of evidence. The disclosure must occur within 10 hours.

#### Violation: [insert here]





#### Standards

**Quality research: disclosure promotes quality research and in-depth engagement.**

**Nails 13.** Jacob Nails debated on the high school LD national circuit and now debates for Georgia State University, 10-10-2013, "A Defense of Disclosure (Including Third-Party Disclosure) by Jacob Nails," NSD Update, <http://nsdupdate.com/2013/10/10/a-defense-of-disclosure-including-third-party-disclosure-by-jacob-nails/> //RS

I fall squarely on the side of disclosure. I find that the largest advantage of widespread disclosure is the educational value it provides. First, disclosure streamlines research. Rather than every team and every lone wolf researching completely in the dark, the wiki provides a public body of knowledge that everyone can contribute to and build off of. Students can look through the different studies on the topic and choose the best ones on an informed basis without the prohibitively large burden of personally surveying all of the literature. The best arguments are identified and replicated, which is a natural result of an open marketplace of ideas. Quality of evidence increases across the board. In theory, the increased quality of information could trade off with quantity. If debaters could just look to the wiki for evidence, it might remove the competitive incentive to do one’s own research. Empirically, however, the opposite has been true. In fact, a second advantage of disclosure is that it motivates research. Debaters cannot expect to make it a whole topic with the same stock AC – that is, unless they are continually updating and frontlining it. Likewise, debaters with access to their opponents’ cases can do more targeted and specific research. Students can go to a new level of depth, researching not just the pros and cons of the topic but the specific authors, arguments, and advocacies employed by other debaters. The incentive to cut author-specific indicts is low if there’s little guarantee that the author will ever be cited in a round but high if one knows that specific schools are using that author in rounds. In this way, disclosure increases incentive to research by altering a student’s cost-benefit analysis so that the time spent researching is more valuable, i.e. more likely to produce useful evidence because it is more directed. In any case, if publicly accessible evidence jeopardized research, backfiles and briefs would have done LD in a long time ago.

#### Accessibility – Not all debaters have access to research libraries like Jstor or Lexis Nexis. Disclosing full text is uniquely key to maximize clash among small schools and controls the internal link to your solvency. Limits the activity to big schools and kills participation.

#### Clash – disclosing solves predictability and allows debaters to prep for arguments before tournaments. Means, 1NC and 1AR blocks will become better because debaters can more easily form a coherent strategy. Strategy outweighs because it allows for in-depth argumentation and coherent rebuttals. Key to fairness because without strategy, debaters couldn’t win. Key to education because it creates better argumentation.

#### Sending message fails – only a few mins before round – I was stuck in stasis not knowing what to prep – also o/w because skew was pre-round

#### + no doc or fulltext – supercharges the disclosure debate

#### Voters:

#### Education

#### Education is the only portable impact from debate – we care about what we learn rather than if we were fair.

#### Education is prerequisite- the critical thinking skills we generate are key to being creating fair rules.

#### Fairness

#### Constitutive to the judge to decide the better debater- only fairness is in your jurisdiction because it skews decision making

#### Fairness prerequisite – multiple warrants

#### If debate wasn’t fair, no one would participate; participation prerequisite to education being gained.

#### Control internal link– if someone is excluded from engaging they can’t get benefits of debate.

#### Drop the debater

#### DTA doesn’t make sense because you were abusive out of round.

#### Sets a precedent that debaters cant run unfair arguments because they will be scared to lose.

#### Competing interps

#### Reasonability causes a race to the bottom because debaters keep being barely reasonable, magnifying abuse.

#### Critical thinking –competing interps promotes in depth argumentation on theory which increases quality of clash.

#### No RVIs

#### RVIs center the debate on theory instead of substance because it’s the only place the round can be decided. Outweighs on time frame; we only get two months to talk about the topic and on research - where the majority of debate education occurs

#### RVIs discourage checking abuse because debaters will be afraid to lose on theory

#### Real world applicability- Winning theory is not a reason to vote them up- In the real world proving you are meeting a necessary rule will not give you reward.

## 2

#### Counterplan – The member nations of the World Trade Organization ought to reduce patent protections for medicines.

#### Competitive – reduce, not eliminate – CP doesnt

#### Solves the aff – reduce insofar as to eliminate evergreening & harms of the aff but avoids the DA

## 3

### 1NC – Hegemony

#### America’s maintaining hegemony and countering China’s rise through “counter-punching” strategies, but sustained innovation and private sector investment are key – reject “US declining now” args – the US has historically punched over its weight whenever it’s challenged

Harr 8/3 [Scott, Army Special Forces Officer and Ph.D. Candidate at the Helms School of Government, Liberty University. He holds an undergraduate degree in Arabic Language Studies from West Point and a Master’s degree in Middle Eastern Affairs from Liberty University. A trained Arabic and Farsi speaker with over four years of cumulative deployment time in the Middle East, his work has been featured in The Diplomat, RealClearDefense, The Strategy Bridge, Modern War Institute, Military Review, The National Interest, and Joint Force Quarterly among other national security-focused venues, “By Avoiding Arms Races, America Can Counter China’s Rise”, 08-03-2021, https://nationalinterest.org/feature/avoiding-arms-races-america-can-counter-china%E2%80%99s-rise-191094]//pranav

Rather than falling into the power projection arms race “trap“ that China desires, U.S. competitive strategies addressing China should adopt a framework based on “counter-punching.” As its name suggests, the counterpunch incorporates both defensive (“counter”) and offensive (“punch”) elements. Additionally, it is an adaptive maneuver that requires disciplined understanding and controlled strength that, effectively employed, offers better alternatives towards protecting and preserving U.S. power in the face of challenges from China. The defensive element of an American counterpunch towards China involves adopting military restraint and a revamped examination of deterrence. Classic deterrence strategy involves presenting the credible threat of force to adversaries to create undesirable risks for would-be aggressors. The key to deterrence, as Kenneth Waltz famously argued, is determining how much deterrence is “enough” to dissuade aggressors. That is, deterrence does not necessarily require the presentation of power projection assets capable of completely destroying an adversary, but only enough assets to make the risks of aggressive behavior not worth the projected losses involved. Seen in this light, a strategy that diligently examines how much deterrence is “enough” potentially eliminates the impulse to sustain the ever-increasing stakes in costly arms races while, critically, offering a chance to reinvest excess “deterrence” resources into areas that will preserve and protect U.S. power. The national resources freed up by foregoing an arms race with China represent the potent offensive element of the counterpunch. These resources can be reinvested in other areas such as the private sector which, besides being the hallmark of American prosperity and thus the critical reason for protecting American power in the first place, has historically played a decisive role in the United States’ successful war efforts. Buoyed by a strong and vibrant private sector where the United States remains a desirable global hub for innovation and technology, the needed capabilities for war (or intense competition) can be adaptively produced and rapidly called forward to tip the competitive (or combative) scales towards victory when required. Of course, the “punch” loses its effectiveness without clearly articulated triggers for employment. If China seeks to induce the United States into an uncontrolled arms race, then the current U.S. obsession with China—which seems to interpret every Chinese action in any sphere as a threat requiring a U.S. response—must be viewed as very encouraging in Beijing. An effective U.S. counterpunch requires clearly defined red lines that regulate and set behavior expectations between great powers and indicate when a Chinese competitive action warrants a U.S. response. Detractors of the counterpunch framework will immediately note the call for military restraint and interpret it as a reactive recipe for military weakness at precisely a time requiring proactive military strength. But military restraint does not imply weakness any more than eating fewer calories implies malnutrition. It simply means making smarter decisions that play to U.S. strengths and away from Chinese strategy. It also entails properly viewing the risks inherent in competition with China. The counterpunch skeptic incorrectly perceives greater risks in short-term military restraint (traded for economic investment and fortification) than in long-term arms races (traded for potential economic collapse). The counterpunch skeptic also fails to appreciate the United States’ historic strengths in adopting this approach. In fact, America has demonstrated exceptional skill as an adaptive counter-puncher—reacting and adapting to adversity and setbacks to rise above them and create positive effects preserving U.S. power and ideas. U.S. institutions have counter-punched their way to success in the political (from the failed Articles of Confederation to the Constitution), social (from abhorrent slavery to civil rights), and military (from disastrous Pearl Harbor to WWII victory) arenas to produce the stable and prosperous nation that exists today. As John Mearsheimer points out, China has the population size and economic capacity (the “sinew of power”) to pose unique and unprecedented challenges to U.S. power. Additionally, wasteful military exploits—often employed as a means of competing with rivals—have contributed to bringing down world powers again and again throughout history. China understands this apparent axiom and has woven its truth into its competitive strategy to displace the United States as the world’s preeminent power in the twenty-first century. U.S. competitive strategy against China must, therefore, resist the powerful (but seemingly prudent) urge to continually increase the stakes projecting power against China. Rather, the United States needs to adopt a disciplined counterpunch framework focused on protecting and preserving (not projecting) power. This framework leverages the elements of a successful counterpunch: it demonstrates a superior understanding of adversary strategy (China’s desire to economically exhaust the United States with power projection), it leverages smart defensive elements (adopting only “enough” deterrence to influence China’s actions), and it fortifies conditions of economic strength to ensure offensive actions can be brought to bear when required in competition or conflict (re-investing resources into a globally-leading private sector). Employing a counterpunch framework asks Americans to trust its institutions—which is a difficult task in the face of a rising China. But the ask is not for blind trust. As a country with less than one-sixth of the world’s population, the United States as a superpower has been punching above its weight for decades and has historically counter-punched successfully to muster adaptive and superlative responses whenever challenged with adversity. America must follow these historical impulses to remain a superpower in the twenty-first century.

#### The 1AC’s reduction of IPP for [medicine] is America “handing over its crown jewels” to competing nations by disincentivizing record setting innovation that causes spillover to other fields and destroys American hegemony.

Iancu 8/11 [Andrei, American-Romanian engineer and intellectual property attorney, who served as the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office from 2017 to 2021, “Biden is trying to undermine America's world-leading IP protections”, https://m.washingtontimes.com/news/2021/aug/11/biden-is-trying-to-undermine-americas-world-leadin/]//pranav

In May of this year, the Biden administration announced its support for a proposal at the World Trade Organization that would allow other countries to seize American intellectual property on COVID-19 technologies, including vaccines. On cue, those countries promptly modified their ask. Whereas the original proposal called for the waiver to last a limited number of years, the new proposal makes the waiver effectively permanent. And why not? If America is willing to hand over its crown jewels, it might as well demand to keep them forever. As a former Director of the U.S. Patent and Trademark Office, I know that America’s world-leading IP protections laid the foundation for our economic success and technological prowess. And as an immigrant from a communist nation, I know all too well how disrespect for private property rights undermines innovation and saps economic vitality. Since the Founding Fathers, Americans have understood that private property extends well beyond land, buildings, factories, and machines. The real source of America’s power and promise are ideas. Walls, locks, or guards can protect physical property, but the implementation of ideas — new songs, artificial intelligence, or medicines — requires special protections and trust in the rule of law. That’s why the Founders included intellectual property rights in the Constitution — in the form of an “exclusive right” for authors and inventors — to “promote the progress of science and useful arts.” Indeed, this is the only time the word “right” appears in the Constitution (amendments aside). The Founders knew that only the rule of law, and our respect for it, can protect and enable the development of these ideas. Yet, President Biden undermined that respect by signaling his support for the appropriation of America’s intangible assets. In doing so, he jeopardized America’s uniquely successful intellectual property system. The history of our nation — indeed, much of the history of the world — since 1789 has been the revolution in knowledge led by American ingenuity in agriculture, industry, medicine, and information technology. Progress like this does not just happen. Indeed, it didn’t, for the millennia of the entire human history until our nation’s founding a couple of hundred years ago! It’s not a coincidence that the last two centuries of uninterrupted, IP-driven innovation — up to and including the miraculous creation in a record time of the Covid vaccines themselves — began when one nation finally committed itself to protect intangible assets as much as physical property. The reason is simple: knowledge is cumulative. Every new discovery becomes the basis for new research. The revolutionary mRNA technology behind Pfizer and Moderna’s vaccines is, in fact, an evolutionary iteration of previous — patented — breakthroughs over the last two decades. Sen. Bernie Sanders, among others, turns up his nose at all this science, history, and progress. Like President Biden, he supports waiving vaccine patents because, he says, “We need a people’s vaccine, not a profit vaccine.” Ignore for a moment that many companies have agreed to sell their vaccines at non-profit prices for the duration of the pandemic, or that the vaccines are completely free for all patients at pharmacies nationwide, or that the federal government pays $19.50 per Pfizer dose, about $15 per Moderna dose, and $10 for the Johnson & Johnson shot — less than the cost of a pizza for medicines that are saving millions of lives and restoring our economy. Instead, focus on the fact that intellectual property protections enabled the creation of “people’s vaccines” in the first place. The choice isn’t between cheap vaccines and even cheaper vaccines — it’s between shots that are protected by strong IP laws or no shots at all. The same goes for every industry. If President Biden doesn’t protect the IP behind new vaccines, investors and inventors will ask, what other technologies are next? Will similar takings be imposed on climate change technologies, for example? Food processing? Essential semiconductor technologies? Companies will scale back investments in medical devices, microchips, energy, and everything in between if they think the U.S. Government might waive IP protection after the fact so that others may copy their inventions with impunity. Of immediate concern is the need for more treatments for Covid-19, especially as the pandemic keeps raging with new variants. Knowing that their IP may be appropriated as soon as it is developed, private industry — especially start-ups and smaller businesses that depend heavily on outside capital — may not invest the resources necessary to develop these new technologies that are desperately needed right now. Here’s the reality: remove patents and other forms of intellectual property, and private-sector investment in innovation dries up. The government will then try to step in to fill the gap, inefficiently as always. Like the taking of factories to nationalize industry, this taking of intellectual property is effectively the nationalization of our innovation economy. The result will be the same as in every other socialist regime that nationalized its industries: the kind of poverty, corruption, and misery that my family escaped from decades ago. American innovation has cured diseases, enabled human flight, led to the development of computers, and made our nation the envy of the world. Waiving intellectual property rights could forfeit it all.

#### Only U.S. hegemony prevents global instability---alternatives can't maintain peace

Haass, 17 - President of the Council on Foreign Relations (Richard, "Who Will Fill America’s Shoes?," *Project Syndicate*, 6-24-2017, https://www.project-syndicate.org/commentary/global-leadership-successor-to-america-by-richard-n--haass-2017-06)

Still, a shift away from a US-dominated world of structured relationships and standing institutions and toward something else is under way. What this alternative will be, however, remains largely unknowable. What we do know is that there is no alternative great power willing and able to step in and assume what had been the US role.

China is a frequently mentioned candidate, but its leadership is focused mostly on consolidating domestic order and maintaining artificially high economic-growth rates to stave off popular unrest. China’s interest in regional and global institutions seems designed mostly to bolster its economy and geopolitical influence, rather than to help set rules and create broadly beneficial arrangements.

Likewise, Russia is a country with a narrowly-based economy led by a government focused on retaining power at home and re-establishing Russian influence in the Middle East and Europe. India is preoccupied with the challenge of economic development and is tied down by its problematic relationship with Pakistan. Japan is held back by its declining population, domestic political and economic constraints, and its neighbors’ suspicions.

Europe, for its part, is distracted by questions surrounding the relationship between member states and the European Union. As a result, the whole of the continent is less than the sum of its parts – none of which is large enough to succeed America on the world stage.

But the absence of a single successor to the US does not mean that what awaits is chaos. At least in principle, the world’s most powerful countries could come together to fill America’s shoes. In practice, though, this will not happen, as these countries lack the capabilities, experience, and, above all, a consensus on what needs doing and who needs to do it.

#### Goes nuclear---extinction

Thomas H. Henricksen 17, emeritus senior fellow at the Hoover Institution, 3/23/17, “Post-American World Order,” <http://www.hoover.org/research/post-american-world-order>

The tensions stoked by the assertive regimes in the Kremlin or Tiananmen Square could spark a political or military incident that might set off a chain reaction leading to a large-scale war. Historically, powerful rivalries nearly always lead to at least skirmishes, if not a full-blown war. The anomalous Cold War era spared the United States and Soviet Russia a direct conflict, largely from concerns that one would trigger a nuclear exchange destroying both states and much of the world. Such a repetition might reoccur in the unfolding three-cornered geopolitical world. It seems safe to acknowledge that an ascendant China and a resurgent Russia will persist in their geo-strategic ambitions.

What Is To Be Done?

The first marching order is to dodge any kind of perpetual war of the sort that George Orwell outlined in “1984,” which engulfed the three super states of Eastasia, Eurasia, and Oceania, and made possible the totalitarian Big Brother regime. A long-running Cold War-type confrontation would almost certainly take another form than the one that ran from 1945 until the downfall of the Soviet Union.

What prescriptions can be offered in the face of the escalating competition among the three global powers? First, by staying militarily and economically strong, the United States will have the resources to deter its peers’ hawkish behavior that might otherwise trigger a major conflict. Judging by the history of the Cold War, the coming strategic chess match with Russia and China will prove tense and demanding—since all the countries boast nuclear arms and long-range ballistic missiles. Next, the United States should widen and sustain willing coalitions of partners, something at which America excels, and at which China and Russia fail conspicuously.

There can be little room for error in fraught crises among nuclear-weaponized and hostile powers. Short- and long-term standoffs are likely, as they were during the Cold War. Thus, the playbook, in part, involves a waiting game in which each power looks to its rivals to suffer grievous internal problems which could entail a collapse, as happened to the Soviet Union.

## 4

### 1NC – Biotech

#### Biopharma R&D is surging, but it’s shaky because of productivity levels – now is not a time to let up

Adams 5/19 [Ben Adams, Ben Adams is a business, science and healthcare journalist, 5-19-2021, "Biopharma R&D 'surged' in 2020, but trial productivity levels a mixed bag: report," FierceBiotech, <https://www.fiercebiotech.com/biotech/biopharma-r-d-surged-2020-but-trial-productivity-levels-a-mixed-bag-report>] // WW LD

A major global pandemic was not enough to stop surging rates of biopharma research and development, but trial productivity still remains below the long-term average. That is according to a new report out by CRO analytics firm IQVIA, which found that funding for early- and late-stage R&D, as well as deals, jumped last year regardless of the pandemic, while aggregate R&D spend for the top 15 companies “reached a record high.” It also found that, overall, clinical trial activity recovered from midyear 2020 to levels above 2019–even without factoring in COVID-19 trials, which clearly didn’t exist the year before. Total trials reached 4,686, more than 300 extra than 2019 and an 8% rise, with 985 in phase 3, 1,880 in midstage testing and 1,821 in phase 1. But there is more complexity here: There was an increase in the clinical trial productivity index, i.e., the way IQVIA measures how these trials are doing, but in 2020 it found this was mostly due to an improvement in phase 3 trials, widening the gap with phase 1 trials, “which score significantly lower with this index.” When it comes to midstage tests, trials “have consistently been above the overall index” as success rates have been trending up and durations have been trending down, “even as complexity has been rising in phase 2 as rising numbers of endpoints and eligibility criteria are attributes of these trials.” Overall, however, productivity “remains below historic levels,” the report found, as success rates are below the long-term average. This is because the complexity of trials is generally increasing, as are study durations in many diseases, IQVIA’s authors note. Looking at the pipeline of pharma, IQVIA saw that growth in the late-stage pipeline continued in 2020, bringing total expansion to 43% since 2015, as cancer drugs reached record-high numbers. Growth in the early-stage pipeline, including next-generation biotherapeutics, paused in 2020, however. RELATED: The top 10 pharma R&D budgets in 2020 The dismal lack of diversity in clinical trials also continued: African Americans or races identified as Black account for 13.4% of the U.S. population, while the clinical trials used to approve new medicines had a median participation of only 3% in the past six years and “were under-representative 79% of the time from 2015 to 2020,” IQVIA said. Persons of Asian descent are also estimated to comprise 6.5% of the U.S. population, but again, only in 2015 was the median above this threshold, and 52% of trials in the past six years that were used by the FDA to approve medicines had under-representative participation. “The growth in research and development driven by new oncology drugs, new funding and strategic investments is a testament to the resilience and strength of the innovative, global biopharmaceutical industry,” said Murray Aitken, executive director of the IQVIA Institute for Human Data Science, in an accompanying release. “Faced with significant disruptions and the need to reprioritize research and development, the global life sciences industry has demonstrated its ability to meet and even exceed expectations for new and better lifesaving therapies and vaccines.”

#### Patents foster innovation

Grabowski et al 15 [Henry G. Grabowski, Joseph A. DiMasi, and Genia Long, February 2015, "The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation," https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047] // WW DL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term. Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6 As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market. Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents. New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment. Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms. Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13 University licensing trends have generated debate. For instance, there have been recent proposals to encourage the federal government to “march in” and require a university to license a patent or enforce reduced pricing or other terms. 14 The percentage of approved drugs with public-sector patents is relatively small. 15 Nevertheless, if the government exercised its march-in rights in this way, that action could have adverse effects on technology transfer activities and early-stage company investment, particularly if it were to disrupt existing expectations of grantees, licensees, and investors. 12 There have been four petitions to the NIH requesting it to exercise march-in rights on behalf of the federal government; none has been granted. 16

#### Biotech relies on innovation from pharma

Cooper 6 [Garth JS Cooper, independent medical scientist at the University of Auckland, “Fates Intertwined,” March 2006, <https://library.wur.nl/WebQuery/file/cogem/cogem_t4505194e_001.pdf>] //recut WW LD

Biotechnology and pharmaceuticals are inextricably intertwined. Although biotech companies often rely upon the resources of larger pharma companies, the converse is also true. Among other things, biotechs require funding, validation, and access to expertise and markets. Big pharma continues to need ideas and products, and places to outsource risk. The pharmaceutical industry faces uncertainties driven by falling innovation 1,2, its relevance to reducing the global burden of disease , and the equity of access to its products3. If biotechs are not embraced by pharma—they cannot be copied —then as competitors they will increasingly come to dominate the industrial nexus. The issues of both industries need to be addressed together. Apart, biotech and pharma will continue to struggle with the self-determining issues that they currently confront. Working together, the fabric of these industries will be transformed and the world of human therapeutics will flourish.

#### Biotech is key to solving food insecurity

Doyle 08 [Alister Doyle, Environment Correspondent, 6-3-2008, "Biotechnology seen as a key to solving food crisis," U.S., <https://www.reuters.com/article/us-food-summit-biotech/biotechnology-seen-as-a-key-to-solving-food-crisis-idUSL0356693120080603>] // WW LD

“Biotechnology is one of the most promising tools for improving the productivity of agriculture and increasing the incomes of the rural poor,” U.S. Agriculture Secretary Ed Schafer said. “We are convinced of the benefits it offers to developing countries and small farmers,” he told a U.S.-led briefing on the sidelines of the June 3-5 summit seeking ways to combat high food prices when climate change may aggravate shortages. Some green groups say genetically-engineered crops threaten biodiversity while many European consumers are wary of eating products dubbed by critics as “Frankenfoods”. Schafer said biotechnology, including genetically-modified organisms (GMOs), could help produce more food by raising yields and producing crops in developing nations that are resistant to disease and pests. “Genetic engineering offers long-term solutions to some of our major crop production problems,” said Philippine Agriculture Minister Arthur Yap. But he said that it was not a panacea for all of his country’s agricultural problems. ADVERTISEMENT Progress being made in the Philippines included research into rice and coconuts resistant to disease, he said. “We’re also working on virus-resistant papaya, papaya hybrids with a longer shelf life that should be ready for market in 2009,” he said. Climate change could aggravate production around the world with more droughts, floods, disruptions to monsoons and rising sea levels, says the U.N. Climate Panel. In Africa alone, 250 million people could face extra stress on water supplies by 2020. COTTON Burkina Faso Agriculture Minister Laurent Sedogo said the African country had worked with U.S. agriculture group Monsanto to battle pests that blighted the cotton crop. ADVERTISEMENT “We are about to plant 15,000 hectares” of a new crop that was resistant to pests, he said. That would also cut down on the use of pesticides that could damage the health of farmers. The World Bank and aid agencies estimate that soaring food prices could push as many as 100 million more people into hunger. About 850 million are already hungry. Bangladesh said that it was going ahead with efforts to make crops able to survive floods and more salinity in the soil. A cyclone last year “is a wake-up call for all of us”, said C.S. Karim, an adviser to Bangladesh’s agriculture ministry. “It shows the vulnerability of Bangladesh. “

#### Food wars go nuclear—multiple studies

FDI 12 (Future Directions International - a Research institute providing strategic analysis of Australia’s global interests; citing Lindsay Falvery - PhD in Agricultural Science and former Professor at the University of Melbourne’s Institute of Land and Environment, “Food and Water Insecurity: International Conflict Triggers & Potential Conflict Points,” 5/25/12, <http://www.futuredirections.org.au/publication/international-conflict-triggers-and-potential-conflict-points-resulting-from-food-and-water-insecurity/>) // recut WW DL

There is a growing appreciation that the conflicts in the next century will most likely be fought over a lack of resources. Yet, in a sense, this is not new. Researchers point to the French and Russian revolutions as conflicts induced by a lack of food. More recently, Germany’s World War Two efforts are said to have been inspired, at least in part, by its perceived need to gain access to more food. Yet the general sense among those that attended FDI’s recent workshops, was that the scale of the problem in the future could be significantly greater as a result of population pressures, changing weather, urbanisation, migration, loss of arable land and other farm inputs, and increased affluence in the developing world. In his book, Small Farmers Secure Food, Lindsay Falvey, a participant in FDI’s March 2012 workshop on the issue of food and conflict, clearly expresses the problem and why countries across the globe are starting to take note. . He writes (p.36), “…if people are hungry, especially in cities, the state is not stable – riots, violence, breakdown of law and order and migration result.” “Hunger feeds anarchy.” This view is also shared by Julian Cribb, who in his book, The Coming Famine, writes that if “large regions of the world run short of food, land or water in the decades that lie ahead, then wholesale, bloody wars are liable to follow.” He continues: “An increasingly credible scenario for World War 3 is not so much a confrontation of super powers and their allies, as a festering, self-perpetuating chain of resource conflicts.” He also says: “The wars of the 21st Century are less likely to be global conflicts with sharply defined sides and huge armies, than a scrappy mass of failed states, rebellions, civil strife, insurgencies, terrorism and genocides, sparked by bloody competition over dwindling resources.” As another workshop participant put it, people do not go to war to kill; they go to war over resources, either to protect or to gain the resources for themselves. Another observed that hunger results in passivity not conflict. Conflict is over resources, not because people are going hungry. A study by the International Peace Research Institute indicates that where food security is an issue, it is more likely to result in some form of conflict. Darfur, Rwanda, Eritrea and the Balkans experienced such wars. Governments, especially in developed countries, are increasingly aware of this phenomenon. The UK Ministry of Defence, the CIA, the US Center for Strategic and International Studies and the Oslo Peace Research Institute, all identify famine as a potential trigger for conflicts and possibly even nuclear war.

#### Food insecurity cause extinction

Cribb ‘10 [Julian, principal of JCA, fellow of the Australian Academy of Technological Sciences, “The Coming Famine: The¶ Global Food Crisis and What We Can Do to Avoid It”, pg 10] // recut WW LD/WWVL

The character of human conflict has also changed: since the early 1990S, more wars have been triggered by disputes over food, land, and water than over mere political or ethnic differences. This should not surprise US: people have fought over the means of survival for most of history. But in the abbreviated reports on the nightly media, and even in the rarefied realms of government policy, the focus is almost invariably on the players—the warring national, ethnic, or religious factions—rather than on the play, the deeper subplots building the tensions that ignite conflict. Caught up in these are groups of ordinary, desperate people fearful that there is no longer sufficient food, land, and water to feed their children—and believing that they must fight ‘the others” to secure them. At the same time, the number of refugees in the world doubled, many of them escaping from conflicts and famines precipitated by food and resource shortages. Governments in troubled regions tottered and fell. The coming famine is planetary because it involves both the immediate effects of hunger on directly affected populations in heavily populated regions of the world in the next forty years—and also the impacts of war, government failure, refugee crises, shortages, and food price spikes that will affect all human beings, no matter who they are or where they live. It is an emergency because unless it is solved, billions will experience great hardship, and not only in the poorer regions. Mike Murphy, one of the world’s most progressive dairy farmers, with operations in Ireland, New Zealand, and North and South America, succinctly summed it all up: “Global warming gets all the publicity but the real imminent threat to the human race is starvation on a massive scale. Taking a 10—30 year view, I believe that food shortages, famine and huge social unrest are probably the greatest threat the human race has ever faced. I believe future food shortages are a far bigger world threat than global warming.”2° The coming famine is also complex, because it is driven not by one or two, or even a half dozen, factors but rather by the confluence of many large and profoundly intractable causes that tend to amplify one another. This means that it cannot easily be remedied by “silver bullets” in the form of technology, subsidies, or single-country policy changes, because of the synergetic character of the things that power it.

## 5

### 1NC

#### Members of the WTO should

#### [a] increase patent examination

#### [b] allocate resources to the PTO

#### [c] amend the patent statute to require an application on a secondary invention

#### [d] improve examination of parents

#### [e] reduce the issue of patents that improperly extend exclusivity

Richards et al 20[ Kevin T. Richards, Coordinator is a Legislative Attorney Kevin J. Hickey is a Legislative Attorney Erin H. Ward is a Legislative Attorney Drug Pricing and Pharmaceutical Patenting

Practices https://fas.org/sgp/crs/misc/R46221.pdf 2/11/2020 Congressional Research Service ] // aaditg

\*pto is patent and trademark office

Increasing Examination Resources Several commentators have proposed that increasing patent examination resources could reduce the number of arguably weaker later-filed patents.319 These commentators contend that patent examiners “often do not have enough time or resources to investigate whether a patent application is truly inventive.” 320 In these commentators’ view, allocating more resources to the PTO would potentially prevent low-quality patents from issuing in the first place, thus preventing the need for accused infringers to spend time and resources defending against infringement

or attempting to invalidate such patents.321 Although one commentator notes that “most patents are not economically significant,” he also recognizes that the PTO “is not well positioned to identify which patents are important and which are worthless.” 322 Enhancing Patentability Standards Some proposals aim to reduce evergreening by making it more difficult for later-filed applications to meet the requirements for patentability. For example, one commentator has suggested raising the substantive patentability requirements for later-filed or secondary patents.323 Specifically, the commentator suggests amending the patent statute to require that an application for a patent on a secondary invention “demonstrate through clear and convincing evidence in the written description that such invention has increased efficacy as compared to the original.” 324 The proposal defines “increased efficacy” as “a proven improvement in the mechanism of action, as disclosed in the patent claims,” and “mechanism of action” as “the process by which a drug functions to produce a therapeutic effect, as disclosed in the patent claims.” 325 In the commentator’s view, this would reduce evergreening by requiring that the secondary patent actually improve the manner in which the pharmaceutical product operates, and thus incentivize pharmaceutical companies to create new drugs, “rather than creating minor changes that prolong the time they can profit off monopolies at the expense of patients.” 326 At least one other country has adopted a similar standard: Under Indian law a patent may not issue on “a new form of a known substance which does not result in enhancement of the known efficacy of that substance.” 327 Drug Pricing and Pharmaceutical Patenting Practices Congressional Research Service 34 Reducing the Impact of Later-Filed Patents The Terminating the Extension of Rights Misappropriated (TERM) Act of 2019328 is one example of a legislative proposal to curtail patent evergreening by reducing the impact of later-filed patents. If enacted, it would establish a presumption that, in patent challenges under HatchWaxman or BPCIA procedures,329 the patentee “disclaimed the patent term for each of the listed patents after the date on which the term of the first patent expires.” 330 In effect, this presumption would mean that later-expiring patents listed in the Orange Book (or provided during the BPCIA’s “patent dance”) would, as a default, be treated as expiring on the date when the earliestexpiring patent on the drug or biologic expires. However, the patentee would be able to overcome this presumption by affirmatively demonstrating with a preponderance of the evidence that the later-expiring patents on the drug or biologic claim “patentably distinct inventions.” 331 Because the law of double patenting already requires later-expiring patents to cover patentably distinct inventions to be valid,332 the TERM Act’s legal effect would be to place the burden of proving patent validity on the patentee for certain later-expiring pharmaceutical patents. Under current law, patents are presumed valid in a judicial proceeding unless the challenger proves patent invalidity by clear and convincing evidence.333 The TERM Act would also require the PTO to determine if changes to patent examination practice may be necessary. Specifically, the Act would require the PTO to review the agency’s patent examination procedures to determine whether the PTO is using the best practices to avoid the issuance of duplicative patents relating to the same drug or biologic.334 The bill would also require the PTO to determine the need for new practices or procedures to (1) improve examination of patents relating to the same drug or biological product and (2) reduce the issuance of patents that “improperly extend the term of exclusivity.” 335 Finally, the Act would require the PTO to submit a report to the House Committee on the Judiciary containing its findings and recommendations.336 The Reforming Evergreening and Manipulation that Extends Drug Years Act (REMEDY) Act,337 like the TERM Act, seeks to curb evergreening by reducing the benefit of later-filed patents. Under the REMEDY Act, a generic’s filing of a Paragraph (IV) certification in an ANDA would only trigger Hatch-Waxman’s thirty-month stay if the patent claims a “drug substance”—that is, the drug’s active ingredient. 338 The stay would not be available for a patent that claims only a “drug product or method of use for a drug,” unless the patent also claims the drug substance itself.339 In that case, the bill would allow FDA to approve the generic product immediately, without waiting for the litigation to determine the validity of the nondrug substance patents.340 This approach is aimed at allowing the generic to enter the market more quickly by limiting the grounds under which a brand can receive a thirty-month stay of FDA approval.341 The Act would also require that patents canceled by the PTO be removed from the Orange Book. 342 The bill would also clarify that challenging a patent that is later struck from the Orange Book would not affect the first-generic-filer 180-day exclusivity period.34

## 6

#### CP Text – The members nations of the World Trade Organization ought to invigorate the existing patent obviousness doctrine to minimize patent evergreening of medicines.

#### It competes – the CP explicitly defends all IP,

#### That solves innovation without ridding ourselves of every secondary patent that could lead to improvements.

1AC Feldman 19 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

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 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.

#### Secondary patents are good, solve many medication problems, and increase innovation which turns the Aff.

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $3.2 billion.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the confidence to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, in the global public’s long-term interests. Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### Their claim that no secondary patent innovation can ever be good is blatantly false.

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer

Why Protect Follow-On Innovation? The **attack on secondary** pharmaceutical **patents is based** in part **on** the **flawed premise** that **follow-on innovation is of marginal value** at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, **follow-on innovation** **can play** a **critical role in transforming** **an interesting drug candidate into a safe and effective treatment option** for patients. A good example can be seen in the case of **AZT** (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT **began** its life **as a** failed attempt at a **cancer drug**, and it was **only years later** that its potential **application in the fight against AIDS** was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include **Evista** (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), **Zyprexa** (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. **Pharmaceutical development** **is prolonged and unpredictable**, and frequently **a safe and effective drug** **occurs only as a result of** **follow-on innovation** occurring **long** **after the initial synthesis** and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be **just as critical to the development of drugs as a patent on the active ingredient itself**. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are **many examples** of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of **Lumigan** (used to treat glaucoma) had an unfortunate tendency to **cause** severe **hyperemia** (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a **new formulation** **which** largely **alleviated** the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

## 7

#### The counterfeit medicine market is attracting new suppliers, but new technologies are evolving to crack down on counterfeits – it’s prevalence is tentative

Hallie B Forcinio 21 [Hallie Forcinio is BioPharm International's packaging editor, editorhal@sbcglobal.net . PharmTech, 2-2-2021, "Countering Counterfeiters and Diverters," https://www.pharmtech.com/view/countering-counterfeiters-and-diverters]//anop

The never-ending battle against counterfeit pharmaceutical products has become fiercer with the pandemic. With product protection a constant concern, the market for anticounterfeiting technologies is strong, regulatory efforts are ongoing, and authentication and anticounterfeiting technologies are evolving. As a result, the anticounterfeiting packaging market is projected to grow at a 7.8% compound annual growth rate to $189.9 billion in 2026 (1). A major driver for this growth is the expanding use of e-commerce platforms, which make it easy to set up shop to sell fraudulent products and are largely unregulated. A study by Local Circles noted that approximately 20% of all products sold on e-commerce sites are counterfeit (1). Anticounterfeiting laws and regulations, such as the European Union’s Falsified Medicine Directive and the US’s Drug Supply Chain Security Act (DSCSA), safeguard prescription drugs available from pharmacies. “However, pharmaceutical manufacturers should be aware that these measures alone will not guarantee a product’s integrity and authenticity,” says Gene Dul, president of Schreiner MediPharm US. He says, “Only additional counterfeit-proof authenticity features can provide a comprehensive approach against fraud, misuse, and tampering.” Unfortunately, the coronavirus pandemic has increased the opportunities for counterfeiting. “In a survey issued by IDC in June 2020, 70% of companies agreed that their supply chain is ‘very vulnerable’ to suffering more problems if the COVID-19 crisis lasted more than a couple of months longer, and 75% of companies agreed that the COVID-19 pandemic has ‘greatly increased/will greatly increase’ problems with diversion, theft, and counterfeiting of critical products such as test kits, vaccines, and antivirals,” reports Aimee Genzler, vice-president, Corporate & Brand Communications at TraceLink, the study sponsor (2). In fact, in anticipation of a spike in counterfeiting, the US Immigration and Customs Enforcement Homeland Security Investigations (HSI) has launched Operation Stolen Promise 2, to halt the production, distribution, and sale of illicit COVID-19 treatments and vaccines. HSI reported that its agents have seized illicit proceeds and goods, made arrests, and shut down fraudulent websites (3), including the seizure of two domain names in December 2020 (4). The proliferation of counterfeit goods stems in part from the shift to e-commerce, which has been accelerated by stay-at-home orders and advisories and reduced access to physical retail pharmacies. “The emergence of on-line pharmacies poses a significant threat of escalation in counterfeit pharmaceuticals and underscores the urgent need for on-dose countermeasures,” reports Peter Wong, chief operating officer at TruTag Technologies, which recently entered a partnership with Colorcon to provide advanced security coatings for on-dose use. “Counterfeiters are opportunistic,” explains John Pitts, key account manager for Antares Vision, noting, “COVID-19 provided the ‘perfect storm’ for the counterfeiters: panic in consumers; product shortages from the brand name ethical providers; desire and, in many cases, requirement to purchase via e-commerce; and lack of and often conflicting information from the media and authorities.” Joe Farrell, life sciences expert at Loftware, concurs, “It seems clear that whenever there are high-value pharmaceutical products, there will be people trying to profit illegally. The fact that the COVID-19 vaccines need to be shipped in stringent cold storage containers with radio frequency identification (RFID) temperature sensors along with specialized transportation methods will make it more difficult for counterfeiters to enter the supply chain, but not impossible.” With COVID-19 vaccines now rolling out in limited quantities, demand will outstrip supply in the coming months. “This will create a ripe environment for unscrupulous parties to offer fake product,” says Wong, noting, “Distribution of the COVID-19 vaccine is designed to go to many more points of dispensing than for a normal pharmaceutical drug, as governments seek to deliver vaccinations broadly and as quickly as possible while maintaining demanding cold-chain requirements. These logistical requirements will create higher than normal transition points in the overall supply chain, which in turn create increase opportunities for diversion, adulteration, and fake product to reach the patient.” Counterfeiting countermeasures The pharmaceutical industry has been on the leading edge of anticounterfeiting and brand protection efforts for many years. “Anticounterfeit solutions are usually tailor-made according to the needs of the brand owner,” says Paavo Sillanpää, senior business manager, Pharma at UPM Raflatac. A diverse strategy considering threat scenario and product is needed. “Most pharma companies have a multi-layered approach,” notes Farrell. The most common physical solutions are tamper-evident labels and packaging materials, designs that prevent the placement of a counterfeit product into the original packaging, serialization, and overt and covert authentication methods such as holograms, invisible markers, and taggants. “Ideally, multi-level security concepts should be used that are individually tailored to a specific use case, combining analog and digital features, which can be verified by different stakeholders within the supply chain,” says Dul. There is heightened interest in tools and technologies that go beyond the package to protect patients, such as on-dose solutions. In addition, says Wong, “the industry is increasing its public awareness campaigns of the problem of fake and unsafe medicine in an effort to educate consumers about the dangers of unauthentic drug products.” As a result, Pitts predicts an increased focus on consumer engagement. He notes, “Enabling the end consumer and the dispenser to authenticate their products is powerful on so many levels. It makes counterfeiting more difficult, provides vital and real-time data to the consumer, and can offer the manufacturer feedback.” Labeling technologies Labeling plays an important role in the fight against counterfeit products. As the passport for moving products through the global supply chain, it contains any track-and-trace or authentication information. “In the label business, we have seen an increased interest in various tamper-evident (TE) solutions and holograms,” reports Sillanpää. One new product from UPM Raflatac combines heat resistance, advanced adhesion, and conformability. Designed primarily for the European market where cartoned blister packaging is common, the heat-resistant TE label won’t shrink in heat tunnels used to produce multipacks. UPM Raflatac has also introduced sustainable TE labeling. It’s produced from Forest Film, which Sillanpää says is “the world’s first wood-based plastic labeling material.” Benefits include performance equivalent to traditional plastic film label materials and the ability to help pharmaceutical brands achieve sustainability goals. Demand for more sustainable products extends to RFID and near-field communication (NFC) tags. Eco-friendly RFID and NFC tags from Identiv feature paper-based transponder inlays that reduce polyethylene terephthalate content, resulting in a repulpable substrate (5). RFID technology is integral to the Cap-Lock plus RFID cap adapter and label combination from Schreiner MediPharm. The label-integrated RFID inlay provides digital proof of integrity and first-opening evidence for syringes as well as product authentication. Dul explains, “The adapter is placed on top of the syringe’s primary closure and interlinked with it to equalize the diameter differences of the syringe body and closure. The label wraps around the syringe body and cap adapter and—once opened—provides irreversible tamper evidence due to an integrated perforation.” Printing and tagging technologies Magnetic ink is another potential anticounterfeiting tool. Technology from Inspectron relies on a proprietary reader, track-and-trace software, and magnetic ink, long used on checks to facilitate automated sorting. The magnetic ink is used to print a barcode, which is detectable even if it’s not visible to the eye. That means the code, which may be serialized, can be hidden on the inside of a carton or under a label and still be read. The current reader works from a distance of up to 2 mm, but units with longer read ranges are under development. “However, longer read ranges require bigger codes,” notes Nathalie Muller, head of Innovation at Inspectron. Although the first commercial application of the technology inkjets the codes on paper to enable identification of diverted product, Muller says, the permanent magnetic codes could be printed on plastic or glass containers and potentially support tasks like vial tracking. Also under development is a hybrid one- and two-dimensional barcode that would hold more data. On-dose technology enables authentication at the product level. Edible microparticles coupled with the Smart Medicine solution from TruTag Technologies confirms product authenticity and can help boost patient adherence and outcomes. A new Pharma Mobile App allows patients to scan each dose with their smartphone, authenticate it, and record that it was taken. If desired, the record of the dose can be shared with healthcare providers. The system also can link to other product information. In April 2020, FDA accepted molecular tagging technology from Applied DNA Sciences into its Emerging Technology Program (6). The company says that its technology is a multilayered platform that gives both the dose and the packaging an immutable identity for authentication. On Nov. 30, 2020, AlpVision launched its Alpvision COVID-19 Initiative to protect COVID-19-related therapeutics and vaccines against counterfeiting. Under the program, AlpVision provides pharmaceutical companies and their suppliers with the tools to deploy its Cryptoglyph digital security feature on their packaging. Invisible to the human eye, the Cryptoglyph feature can be authenticated via smartphone. Adopting the technology does not change the production process or involve additional consumables. In addition, the smartphone applications connect to AlpVision’s Brand Monitoring System, a centralized server platform that enables real-time monitoring of product authentication activities. AlpVision plans to provide this service for free until the World Health Organization declares the pandemic has ended (7). Software tools Physical technologies are common anticounterfeiting tools, but counterfeit and diversion prevention also relies on software. Farrell reports, “At Loftware, we are being asked for help in getting the correct information onto the label. It’s important to have an enterprise labeling solution that integrates with a company’s sources of data to make sure the correct approved information is automatically applied to the labels. This includes languages, barcodes, regulatory symbology, and regional product information. You also need a labeling solution that can aid with approving, managing, and promoting electronic information for use [data] to help speed the process for a faster time to market for these critical products.” Although not specifically an anticounterfeiting product, Loftware Spectrum software integrates with serialization solutions and ensures labeling is consistent, accurate, and contains the right serialized data and barcodes. “The use of global templates in an enterprise solution also helps our life sciences customers to globally standardize on the look of their supply chain labels to help identify counterfeited products,” he explains. The scalable Track My Way platform from Antares Vision offers single-unit, batch, and custom traceability; provides direct consumer engagement; and can extend from raw materials tracking to end-of-life package disposal/recycling. Geolocation functionality can track the harvesting of the raw materials, packaging locations, the movement of products through the supply chain, and the point-of-sale location. In April 2020, TraceLink released an anticounterfeiting tool called Smart Distribution Tracking. By integrating the Internet of Things with product serialization, Smart Distribution Tracking provides full track-and-trace visibility for the secure delivery of vaccines, test kits, and high-value products. Another software tool, the Summit Authentication Platform from Microtrace Solutions, is a customized system consisting of a self-authenticating, encrypted barcode; a Spectral Taggant; and a handheld detector plus a smartphone mobile app. “Our Spectral Taggant is a chemistry formulated into an ink that, when printed, is a highly secure ‘signature’ or ‘fingerprint,’” explains Brian Brogger, president at Microtrace Solutions. This signature can be authenticated instantly via the handheld spectrometer or smartphone without an Internet connection. For vaccines and therapeutics, the barcode and Spectral Taggant can be applied to security labels. The mobile app is then able to verify that the barcode was genuinely issued and the Spectral Taggant verifies that the barcode has not been copied. The system also can provide real-time reporting and analysis. The latest release of the Systech Brand Protection Suite from Systech International, the software solutions division of Markem-Imaje, delivers a fully integrated solution to combat counterfeiters, identifies product diversion, meets regulatory compliance, and provides analytics. The centerpiece of the suite, the company’s non-additive e-Fingerprint technology, turns any existing barcode into a unique, digital identifier to provide end-to-end visibility and actionable information as a product moves through the supply chain. New functions include the ability to push unique responses and content to users and smartphone authentication of e-Fingerprinted products. Responses can be tailored to the user, location, time, and safety of the product, and include photos or other information. A new analytics platform, Systech Insight, offers a series of Information on Demand dashboards and an analytics data pool (8).

#### **IP protection prevents and quickly stops spread counterfeit medicines – multiple warrants**

FIFARMA 21, [FIFARMA is the Latin American Federation of the Pharmaceutical Industry created in 1962. We represent 16 research-based biopharmaceutical companies and 11 local associations dedicated to discovering and developing innovative, quality and safe health products and services that improve the lives of patients in Latin America and the Caribbean and advocate for patient-centric, sustainable health systems characterized by high regulatory standards and ethical principles. (Apr 22, 2021), "This is how we fight counterfeit medicines with Intellectual Property," https://fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/]//anop

In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate. On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines. In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP. Also, IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines. Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products. This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection. On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem. Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

#### Pharmaceutical counterfeiting is increasingly used to support terrorism – used for funding and mediums of attacks

née Lybecker 18, Kristina M.L. Acri [Kristina M. L. Acri née Lybecker is an Associate Professor of Economics in the Department of Economics and Business at Colorado College in Colorado Springs, CO. (February 2018), "Pharmaceutical Counterfeiting: Endangering Public Health, Society and the Economy" Fraser Institute, https://www.fraserinstitute.org/sites/default/files/pharmaceutical-counterfeiting-endangering-public-health-society-and-the-economy.pdf]//anop

Pharmaceutical counterfeiting is linked to numerous forms of organized crime: drug trafficking, money laundering, and terrorism (Lybecker, 2016; Pfizer, 2007; Redpath, 2012; Criminal Intelligence Service Canada, 2006; UNODC, 2017). As reported by Redpath (2012: 7), “not only have groups such as the Russian mafia, Colombian drug cartels, Chinese triads and Mexican drug gangs all become heavily involved in producing and trafficking counterfeit drugs over the past decade, but mounting evidence also points to the direct involvement of Hezbollah and al Qaeda.” *Given the profitability of the endeavor, it is not surprising that pharmaceutical counterfeiting is increasingly a source of funding for terrorist groups* (Lybecker, 2016; Pfizer, 2007; Redpath, 2012). Moreover, by their very nature, organized criminal operations are well suited to the intricacies of pharmaceutical counterfeiting. “Criminal organisations have the advantage of huge resources, international networks and skilled labour. They can move with a speed that often confounds the authorities. Counterfeit versions of the antiviral drug Tamiflu were available on fake internet pharmacy sites, like the one posing as the ‘Canadian Pharmacy,’ within weeks of the [World Health Organization] declaration of H1N1 as a pandemic” (Redpath 2012: 8). While anecdotal evidence of the link is quite plentiful, the clandestine nature of the business as well as the secrecy maintained by law enforcement make it virtually impossible to either completely understand or measure the extent of the trade. A 2014 INTERPOL study provides perspective on pharmaceutical crime and organized criminal groups. INTERPOL’s Medical Product Counterfeiting and Pharmaceutical Crime Sub-Directorate has prepared an analysis of available data, dating from 2008 to 2014, to establish the extent of organized criminal groups (OCGs) activity in the realm of pharmaceutical crime (INTERPOL, 2014).5 According to the report, a recent Europol threat assessment concludes that there are “a wide variety of actors, operating within the pharmaceutical crime arena, encompassing both OCGs and individual criminals, both of which are involved at any point in the supply chain.” The report points to the involvement of both traditionally structured hierarchical crime groups in addition to highly organized, yet generally informal, networks of illicit online pharmacies and finally, small groups of three to ten members. The INTERPOL study, as well as those from other agencies, provides some perspective on the involvement of organized criminal groups in Canada. Numerous investigations in the US, Canada, and Sweden have linked the Hell’s Angels to the production and distribution of counterfeit medicines, in particular ED medications and steroids (INTERPOL, 2014). • Fake oxycontin pills containing fentanyl were responsible for more than 50 deaths in Alberta in 2015. The counterfeit pills are also responsible for three deaths in Saskatchewan (Partnership for Safe Medicines, 2015b). • In November 2013, Canadian authorities began an organized crime investigation named “Project Forseti,” targeting the Hells Angels and the Fallen Saints (Customs Today Report, 2015). In January of 2015, police in Saskatchewan and Alberta, Canada seized guns and drugs, including significant amounts of counterfeit oxycontin. A United Nations Interregional Crime and Justice Research Institute (UNICRI) study suggests that criminal networks use routes and methods to transport counterfeit medicines that are similar to those used to traffic in drugs, firearms, and people (UNICRI, 2012). Evidence suggests that organized criminal gangs involved in the production of synthetic drugs are able to easily access the materials and expertise needed to also produce counterfeit medicines. In both Europe and Southeast Asia, authorities cite evidence of “criminal manufacturers of amphetamine-type substances [that] have been involved in the production and distribution of counterfeit medicines” (INTERPOL, 2014).

#### Terrorism escalates to nuclear war

Ayson 10 (Robert Ayson. Robert Ayson is Professor of Strategic Studies at Victoria University of Wellington, New Zealand, where he works closely with the Centre for Strategic Studies. “After a Terrorist Nuclear Attack: Envisaging Catalytic Effects”. 6-21-2010. Studies in Conflict and Terrorism. <https://www.tandfonline.com/doi/abs/10.1080/1057610X.2010.483756?journalCode=uter20>) **//TruLe**

But these two nuclear worlds—a non-state actor nuclear attack and a catastrophic interstate nuclear exchange—are not necessarily separable. It is just possible that some sort of terrorist attack, and especially an act of nuclear terrorism, could precipitate a chain of events leading to a massive exchange of nuclear weapons between two or more of the states that possess them. In this context, today’s and tomorrow’s terrorist groups might assume the place allotted during the early Cold War years to new state possessors of small nuclear arsenals who were seen as raising the risks of a catalytic nuclear war between the superpowers started by third parties. These risks were considered in the late 1950s and early 1960s as concerns grew about nuclear proliferation, the so-called n+1 problem. It may require a considerable amount of imagination to depict an especially plausible situation where an act of nuclear terrorism could lead to such a massive inter-state nuclear war. For example, in the event of a terrorist nuclear attack on the United States, it might well be wondered just how Russia and/or China could plausibly be brought into the picture, not least because they seem unlikely to be fingered as the most obvious state sponsors or encouragers of terrorist groups. They would seem far too responsible to be involved in supporting that sort of terrorist behavior that could just as easily threaten them as well. Some possibilities, however remote, do suggest themselves. For example, how might the United States react if it was thought or discovered that the fissile material used in the act of nuclear terrorism had come from Russian stocks,40 and if for some reason Moscow denied any responsibility for nuclear laxity? The correct attribution of that nuclear material to a particular country might not be a case of science fiction given the observation by Michael May et al. that while the debris resulting from a nuclear explosion would be “spread over a wide area in tiny fragments, its radioactivity makes it detectable, identifiable and collectable, and a wealth of information can be obtained from its analysis: the efficiency of the explosion, the materials used and, most important … some indication of where the nuclear material came from.”41 Alternatively, if the act of nuclear terrorism came as a complete surprise, and American officials refused to believe that a terrorist group was fully responsible (or responsible at all) suspicion would shift immediately to state possessors. Ruling out Western ally countries like the United Kingdom and France, and probably Israel and India as well, authorities in Washington would be left with a very short list consisting of North Korea, perhaps Iran if its program continues, and possibly Pakistan. But at what stage would Russia and China be definitely ruled out in this high stakes game of nuclear Cluedo? In particular, if the act of nuclear terrorism occurred against a backdrop of existing tension in Washington’s relations with Russia and/or China, and at a time when threats had already been traded between these major powers, would officials and political leaders not be tempted to assume the worst? Of course, the chances of this occurring would only seem to increase if the United States was already involved in some sort of limited armed conflict with Russia and/or China, or if they were confronting each other from a distance in a proxy war, as unlikely as these developments may seem at the present time. The reverse might well apply too: should a nuclear terrorist attack occur in Russia or China during a period of heightened tension or even limited conflict with the United States, could Moscow and Beijing resist the pressures that might rise domestically to consider the United States as a possible perpetrator or encourager of the attack? Washington’s early response to a terrorist nuclear attack on its own soil might also raise the possibility of an unwanted (and nuclear aided) confrontation with Russia and/or China. For example, in the noise and confusion during the immediate aftermath of the terrorist nuclear attack, the U.S. president might be expected to place the country’s armed forces, including its nuclear arsenal, on a higher stage of alert. In such a tense environment, when careful planning runs up against the friction of reality, it is just possible that Moscow and/or China might mistakenly read this as a sign of U.S. intentions to use force (and possibly nuclear force) against them. In that situation, the temptations to preempt such actions might grow, although it must be admitted that any preemption would probably still meet with a devastating response. As part of its initial response to the act of nuclear terrorism (as discussed earlier) Washington might decide to order a significant conventional (or nuclear) retaliatory or disarming attack against the leadership of the terrorist group and/or states seen to support that group. Depending on the identity and especially the location of these targets, Russia and/or China might interpret such action as being far too close for their comfort, and potentially as an infringement on their spheres of influence and even on their sovereignty. One far-fetched but perhaps not impossible scenario might stem from a judgment in Washington that some of the main aiders and abetters of the terrorist action resided somewhere such as Chechnya, perhaps in connection with what Allison claims is the “Chechen insurgents’ … long-standing interest in all things nuclear.”42 American pressure on that part of the world would almost certainly raise alarms in Moscow that might require a degree of advanced consultation from Washington that the latter found itself unable or unwilling to provide. There is also the question of how other nuclear-armed states respond to the act of nuclear terrorism on another member of that special club. It could reasonably be expected that following a nuclear terrorist attack on the United States, bothRussia and China would extend immediate sympathy and support to Washington and would work alongside the United States in the Security Council. But there is just a chance, albeit a slim one, where the support of Russia and/or China is less automatic in some cases than in others. For example, what would happen if the United States wished to discuss its right to retaliate against groups based in their territory? If, for some reason, Washington found the responses of Russia and China deeply underwhelming, (neither “for us or against us”) might it also suspect that they secretly were in cahoots with the group, increasing (again perhaps ever so slightly) the chances of a major exchange. If the terrorist group had some connections to groups in Russia and China, or existed in areas of the world over which Russia and China held sway, and if Washington felt that Moscow or Beijing were placing a curiously modest level of pressure on them, what conclusions might it then draw about their culpability.

## Case

### Case wooo

#### The aff doesn’t solve – access to medicine is not a one-way street and there are multiple other factors that they just can’t resolve

Motari 21, Marion Motari, [Jean-Baptiste Nikiema](javascript:;), [Ossy M. J. Kasilo](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Ossy_M__J_-Kasilo), [Stanislav Kniazkov](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Stanislav-Kniazkov), [Andre Loua](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Andre-Loua), [Aissatou Sougou](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Aissatou-Sougou), [Prosper Tumusiime](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Prosper-Tumusiime) are Adjunct Faculty, Daystar University School of Law, Nairobi, Kenya, “The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement”, <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y>, accessed apark 6/27/21

Although this paper focuses on the role of intellectual property rights on access to medicines, it is recognized that limited access to medicines in countries of the World Health Organization (WHO) African Region[Footnote3](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#Fn3) is a multidimensional problem. It is affected by other factors such as lack of public financing for health care and over-reliance on out of pocket expenditure[[7](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR7)], fragile logistics, storage challenges and high transport and distribution costs [[2](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR2)] and inadequate or inappropriate medicines regulatory frameworks [[8](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR8)]. These factors are further exacerbated by insufficient scientific, technological and local manufacturing capabilities in the Region [[9](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR9)].

### Presumption

#### Vote neg on presumption, the squo solves all of their impacts – it provides less developed countries with access to patent protected drugs

#### and sets precedent for future pandemics

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The **World Trade Organisation** has agreed to **extend** a **waiver** that **allows poor countries to copy patented medicines**. The waiver, which was due to expire in January 2016, has now been **extended to 2033.** The **countries that** will **benefit** from the waiver **are the 48 poorest nations, classified by** the **U**nited **N**ations **as “Least Developed Countries”** or LDCs, and include many African and some Asian countries. About half of the 900m population across these countries live on less than US$1.25 a day. All other countries, including developing countries such as India and China, are still bound by the WTO’s agreement on trade-related intellectual property rights (or TRIPS) with respect to drug patents. The **waiver is critical for the least developed countries**. Compared with richer countries, they have a **much higher disease burden**, especially infectious diseases such as HIV and malaria. In **2011, about 9.7m people in these countries were living with HIV**. **Many** of the **drugs that treat these diseases are still under patent protection**. Drug patents last for 20 years and allow drugs companies time to recoup their investment into research and development and turn a profit. Once the patent protection period ends, other drugs companies can then copy the drug and sell it as a generic medicine. These **generics are much cheaper than branded drugs.**

Countries such as Uganda, Cambodia and Rwanda have already taken advantage of the WTO’s temporary waiver and begun to develop their own pharmaceutical industry. This has been helped by investments from drug companies in the developing world. For example, Uganda-based Cipla Quality Chemicals was originally a joint-venture between Cipla, a large Indian generics manufacturer, and the Ugandan government. It is the only company in Africa that makes triple-combination antiretroviral drugs. Developing and strengthening manufacturing capacities in LDCs is important as these countries are often unable to import cheap copies of patent protected drugs from countries like India. India has many large generics firms within its borders and, although it ratified TRIPS in 1995, it only brought its patent laws in line with the treaty in 2005. It too now has to respect international drug patents. So the extension of the **waiver** is important, but it is **only temporary**, which doesn’t please everybody. **L**east **d**eveloped **c**ountrie**s** **and some NGOs** would have **preferred** an **indefinite extension** or at least an extension until a country is no longer classified as a least developed country, rather than the set date of 2033. This position is supported by the European Union, but not by the US. It costs pharmaceuticals companies about US$2.6 billioin to develop a new drug. If these companies were not allowed to protect their investment with patents, it is doubtful that any new drugs would be developed. So patents are an important incentive. But **patent protection doesn’t work for poor countries**. Intellectual property **(IP) rights**, like patents, **aren’t an effective incentive in countries which have not reached an adequate level of economic development because they have no intellectual property to protect**. IP rights might be effective over the long term, but only after a local and relatively strong pharmaceutical industry is developed. The exemption could be dropped once countries that have benefited from it have developed enough, and the industry reaches a self-sustaining size. Although building a home grown pharmaceuticals industry is not a requirement of the WTO waiver, **a strong local industry would give poor countries direct access to much needed cheap medicines.** The WTO’s transitional waiver makes sense. By temporarily allowing LDCs to ignore patents on drugs, it gives them time to develop their own pharmaceuticals industries. And we are already **seeing evidence of this happening**. According to the UN agencies, UNDP and UNAids, the proportion of people with HIV who are not receiving antiretrovirals reduced from 90% in 2006 to 63% in 2013 thanks to the availability of drugs made by LDCs. Despite some criticisms, the WTO’s decision to extend the waiver should be praised. It seems fair and reasonable, and it doesn’t excessively jeopardise companies that make branded (non-generic) drugs. They don’t seem to lose much from missed royalties. Overall, the poorest countries account for less than 2% of the world’s gross domestic product and about 1% of global trade in goods. Not a big business opportunity for big pharma.

#### **Current COVID-19 patent waivers will solve the pandemics advantage**

Pti 21 [6-10-2021, "India, South Africa’s patent waiver proposal in WTO achieved tremendous mileage, progression: Commerce Secretary," Hindu, https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece]

The proposal of India and South Africa on providing temporary patent waiver at the World Trade Organisation (WTO) to deal with the COVID-19 pandemic has achieved tremendous mileage and progression as the WTO member countries have agreed to commence text-based negotiations on it, a top government official said on June 10. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council of the World Trade Organization (WTO) on June 9 agreed with consensus to start text-based negotiations on a proposal submitted by India and South Africa seeking patent waivers to deal with the COVID-19 crisis. Commerce Secretary Anup Wadhawan said that the text-based negotiations is the way forward and it means that the members have broadly and in-principle accepted the objective behind the waiver proposal. “India and South Africa’s proposal has achieved tremendous mileage and tremendous progression at a very fast pace,” he told reporters. “There is a deadline that by July-end, the members are expected to come to an agreed text. So it is a very positive development,” he added. How the objective will be given effect and to what extent and for how much duration, all that would happen though text-based negotiations, the Secretary noted. In October 2020, India and South Africa had submitted the first proposal suggesting a waiver for all WTO members on the implementation of certain provisions of the TRIPS Agreement in relation to the prevention, containment or treatment of COVID-19. In May this year, a revised proposal was submitted by 62 co-sponsors, including India, South Africa, and Indonesia. The agreement on TRIPS came into effect in January 1995. It is a multilateral agreement on intellectual property (IP) rights such as copyright, industrial designs, patents and protection of undisclosed information or trade secrets. According to the revised proposal of 62 co-sponsors, the waiver should be in force for at least three years from the date of the decision on the matter. The co-sponsors have stated that the duration has to be practical for manufacturing to be feasible and viable. The revised text has also proposed waiver for health products and technologies as the prevention, treatment or containment of COVID-19 which involves a range of things and “intellectual property issues may arise with respect to the products and technologies, their materials or components, as well as their methods and means of manufacture.”

#### **Vote neg on presumption – the aff can’t solve any of their impacts**

Garde et al 5-6 [Damian Garde , Helen Branswell , and Matthew Herper May 6, 2021, 5-6-2021, "Waiver of patent rights on Covid vaccines may be mostly symbolic, for now," STAT, <https://www.statnews.com/2021/05/06/waiver-of-patent-rights-on-covid-19-vaccines-in-near-term-may-be-more-symbolic-than-substantive/>] // WW LD

The U.S.’s stunning endorsement of a proposal to waive Covid-19 vaccine patents has won plaudits for President Biden and roiled the global pharmaceutical industry. But, at least in the short term, it’s likely to be more of a symbolic milestone than a turning point in the pandemic. For months, proponents of the proposal have argued that the need to waive intellectual property protections was urgent given the growth of Covid cases in low- and middle-income countries, which have been largely left without the huge shipments of vaccine already purchased by wealthy countries. But patents alone don’t magically produce vaccines. Experts suggested the earliest the world could expect to see additional capacity flowing from the waiver — if it’s approved at the World Trade Organization — would be in 2022. Prashant Yadav, a supply chain expert and senior fellow at the Center for Global Development, said the biggest barrier to increasing the global vaccine supply is a lack of raw materials and facilities that manufacture the billions of doses the world needs. Temporarily suspending some intellectual property, as the U.S. proposes to do, would have little effect on those problems, he said. “My take is: By itself, it will not get us much benefit in increased manufacturing capacity, Yadav said. “But as part of a larger package, it can.” That larger package would include wealthy nations like the U.S. mounting an Operation Warp Speed-style effort to invest in manufacturing in low-income countries, he said, using their vast financial resources to actually produce vaccine doses rather than solely targeting patents. Lawrence Gostin, director of the O’Neill Institute for National and Global Health Law at Georgetown Law, said the waiver is necessary but hardly sufficient. It will likely take months of international infighting before the proposal would take effect, he said, months during which would-be manufacturers would not have the right to start producing vaccines. “We’re not talking about any immediate help for India or Latin America or other countries going through an enormous spread of the virus,” Gostin said. “While they’re going to be negotiating the text, the virus will be mutating.” Even James Love, director of the nonprofit Knowledge Ecology International and a longtime advocate of intellectual property reform, acknowledges a patent waiver would be a valuable first step, not a panacea. The fairly narrow proposal would mostly allow countries to issue compulsory licenses, essentially allowing third-party manufacturers to make and sell other companies’ patented products, while also helping free up some information about how that manufacturing is done. But that, at least, could provide a financial incentive for those third parties to invest in vaccine production. “In our experience, when the legal barriers disappear and there’s a market, capacity increases faster than you would think,” he said. In October, Moderna vowed not to enforce its Covid-19-related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines. “There are currently no generic vaccines primarily because there are hundreds of process steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, but the transfer of skills is not that simple,” said Norman Baylor, who formerly headed the Food and Drug Administration’s Office of Vaccines Research and Review, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — using messenger RNA technology — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instance, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in-demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry-wide … looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly all of the people who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing.” As Michelle McMurry-Heath, CEO of the trade group BIO, put it in a statement, “handing needy countries a recipe book without the ingredients, safeguards, and sizable workforce needed will not help people waiting for the vaccine.” Conversely, the drug industry claims that waiving patents, even temporarily, risks irreparable damage to the system of incentives that made the rapid development of Covid-19 vaccines possible. Stephen Ubl, CEO of the powerful lobbying group PhRMA, said in a statement that the idea “flies in the face of President Biden’s stated policy of building up American infrastructure and creating jobs by handing over American innovations to countries looking to undermine our leadership in biomedical discovery.” Umer Raffat, an equities analyst who tracks pharmaceuticals at Evercore ISI, thinks the risks to the drug industry might be overstated. It’s highly doubtful a patent waiver would set a precedent beyond vaccines, Raffat wrote in a note to investors, and the scarcity of raw materials combined with complexity of modern pharmaceutical manufacturing makes it unlikely that any third party could meaningfully compete with a multinational drug company. But the decision could nonetheless be a sea change for the way governments think about intellectual property — a hole in the IP dam that unleashes a tidal wave. Love, of Knowledge Ecology, said that the decision shifts the discussion around pandemic vaccines from countries believing there is nothing that can be done to a new position: “What do we need to do?” Said Love: “If you really think this is a big emergency, ‘what do we need to do’ should be the question, not just saying we can’t do anything.” That could, in turn, have long-term impacts on how countries view pharmaceutical intellectual property — and how much protection drug makers are provided on their own patents.

#### member nations ALREADY can – vote neg on presumption

**Bacchus**, James. “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines.” *Cato.org*, 16 Dec. 20**20**,www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#balancing-ip-rights-access-medicines-not-new-wto.

This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease.Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”[6](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref6) It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions. As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”[7](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref7) But, **in public health emergencies**, it may be impossible to obtain a license. In such cases, “**compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders**.[8](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref8)After years of debate, WTO members clarified in the Doha Ministerial Declaration in November 2001 that **each WTO member “has the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted.”**[9](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref9) In August 2003, WTO members followed up on the 2001 declaration by adopting a waiver that allows poorer countries that do not have the capacity to make pharmaceutical products—and thus cannot benefit from compulsory licensing—to import cheaper generic drugs from countries where those drugs are protected by patent.[10](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref10) In such a case, both the importing and exporting countries are excused from what would otherwise be their obligations under the TRIPS Agreement. This waiver was transformed into an amendment in the WTO IP rules in 2017.[11](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref11)Compulsory licensing of medicines is not popular with private drug manufacturers because it is a derogation from the customary workings of market‐​based capitalism. However, as these actions by WTO members in 2001, 2003, and 2017 illustrate, compulsory licensing is not a derogation from the balance struck by the members of the WTO between protecting IP rights and ensuring access to essential medicines. Rather, it is a crucial part of that balance. The balance struck in the WTO treaty includes the option of compulsory licensing during health emergencies.

### Counterfeit and climate stuff

#### Counterfeit drugs lead to drug resistant diseases turns the aff

**Jahnke, 19** (Art Jahnke, Art Jahnke began his career at the Real Paper, a Boston area alternative weekly. He has worked as a writer and editor at Boston Magazine, web editorial director at CXO Media, and executive editor in Marketing & Communications at Boston University, where his work was honored with many awards., 1-14-2019, accessed on 8-17-2021, Boston University, "How Substandard and Counterfeit Drugs Drive Drug-Resistant Infections", https://www.bu.edu/articles/2019/how-bad-drugs-turn-treatable-diseases-deadly/)

Muhammad Zaman learned at an early age that one did not shop for medicine at the convenient neighborhood pharmacy. In Pakistan, where he grew up, the safer thing to do was walk the extra mile to a pharmacy whose drugs were known to be high quality. Four decades later as a Boston University professor of biomedical engineering and materials science and engineering, Zaman was reminded of the dangers of low-quality drugs in his native country when he learned that more than 200 people in the city of Lahore died after being treated with an adulterated version of a hypertension drug. That event, in 2012, altered the course of Zaman’s research. Now, he focuses on the global problem of “substandard drugs,” poorly made medicines containing ingredients that are either ineffective or toxic. His most recent discovery has startling implications for our understanding of drug resistance: a low-quality version of rifampin, a broad spectrum antibiotic typically used as the first line of defense to treat tuberculosis, can greatly contribute to the development of drug-resistant infections. The findings, published in Antimicrobial Agents and Chemotherapy, are particularly pressing because drug-resistant TB is an increasing problem worldwide. Of the 10 million new cases of tuberculosis in 2016, about 600,000 were rifampin resistant, requiring second-line treatments which come with increased toxicity. “There had not been a definitive study showing that lack of [antibiotic] quality leads to resistance,” says Zaman, who is also a Howard Hughes Medical Institute Professor of Biomedical Engineering and International Health. “Now we are sure that it does, and it does with TB, a global problem that has become stubbornly hard to resolve.” “We had always thought of this a scientific issue, but now it is also an ethical issue.”Muhammad Zaman Zaman says substandard drugs, as well as drugs that are deliberate counterfeits, are all too common in developing nations. A recent survey by the World Health Organization found that in low- and middle-income countries, one in ten medicines is substandard or falsified. One contributing factor could be that government enforcement of safe manufacturing practices is feeble or nonexistent. In Pakistan, for example, a country of nearly 200 million people, only a handful of federal inspectors monitor the quality of drug manufacturing. Across sub-Saharan Africa, things are no better. A recent World Health Organization (WHO) study written in part by Paul Newton, an adjunct professor at BU School of Public Health, found that substandard antimalarials killed more than 120,000 children under the age of five in 2013. Another WHO study, conducted in 2008, found that 64 percent of antimalarial drugs tested in Nigeria were substandard. When the same study looked at antimalarials in Cameroon, Ethiopia, Ghana, Kenya, Nigeria, and Tanzania, it found that 28 percent of 267 samples were substandard. Zaman says it’s impossible to know how many deaths globally are caused by substandard drugs because people don’t usually die immediately. They could die, as the Lahore victims did, from a toxic reaction, or they could die from the disease that the drug was supposed to cure. Or, says Zaman, he and other scientists have long speculated that they could die for a third reason: adulterated medicines could encourage the development of drug resistance, rendering the disease incurable with standard treatments. Although that possibility had been considered for years, Zaman and Zohar Weinstein teamed up to finally put the hunch to the test. In the lab, Zaman and Weinstein, a postdoctoral researcher in biomolecular pharmacology who’s nearly finished with her medical degree as well, conducted several tests with rifampin to learn if a degraded form of the TB drug could build drug resistance in bacteria. They first ran a series of in vitro tests pitting rifampin against E. coli, sometimes referred to as the workhorse bacteria of laboratories because its rapid doubling time makes it ideal for such studies. The researchers exposed the bacteria to gradually increasing doses of rifampin, which suppresses RNA transcription in bacteria, leading to cell death. They then ran the same tests with rifampin quinone, the most commonly found form of degraded rifampin. Within a week, they observed that the bacteria became significantly more resistant to the drug. Next, the researchers repeated the experiment, swapping out E. coli for a strain of tuberculosis called M. smegmatis, selected because it has a conveniently short doubling time of two hours, while the more common strain of tuberculosis has a doubling time of about one day. After two weeks, the M. smegmatis also began to show signs of resistance. “We found that over five days, E. coli exposed to [rifampin quinone] became up to 64 times more resistant to rifampin,” says Weinstein. “And over 22 days, M. smegmatis became up to 100 [times] more resistant to rifampin.” “You could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to resistance.”Muhammad Zaman Zaman and Weinstein had expected such responses, but they didn’t expect to find such a powerful resistance. In fact, once the bacteria gained resistance, no amount of standard rifampin would kill them. The researchers also looked for another indicator of rifampin resistance: a genetic mutation in a gene called rpoB. What they discovered was alarming. “We found that the majority of bacteria exposed to [rifampin quinone] also had mutations in this gene, even though they had never been exposed to the standard drug,” says Weinstein. In other words, the degraded drug wasn’t just failing to cure the disease, it was cultivating cross-resistance to the high-quality, standard product. In that sense, says Zaman, bad drugs can become doubly dangerous. “That [observation] was very revealing,” says Zaman. “It changed the equation, because we had always thought of this a scientific issue, but now it is also an ethical issue. We usually think of the spread of resistant TB in two ways. We say you got it because you were exposed to resistant TB, maybe you were living with someone with resistant TB. The second way is you got it because you were supposed to take drugs and you didn’t adhere to the program. But what this study reveals is that you could be a good patient and still acquire drug-resistant bacteria, because the drugs you were taking were leading you to [treatment] resistance.” “While it is well established that subtherapeutic doses of medicines play a role in antimicrobial resistance, this is, as far as I know, the first demonstration of how substandard medicines directly drive the emergence of resistance genes in pathogens,” says Michael Levy, vice president of USP’s Quality Institute, which researches the influence of substandard drugs on health outcomes. USP is a nonprofit organization that sets drug quality standards that are legally recognized in the US and are also used in more than 140 other countries. Zaman’s next steps will be threefold. First, he plans to test the quality of drugs that are available in the community hospitals of several low-income countries, looking specifically for the presence of rifampin quinone, the degraded form of rifampin. Second, he plans to work with researchers at the National Emerging Infectious Diseases Laboratories (NEIDL) on a mouse model to study the resistance mechanism in vivo. Third, he says he hopes to expand his work to investigate adulterated forms of other commonly used, high-impact antibiotics. Meanwhile, patients around the world are still being prescribed substandard antibiotics every day. “The patient may be doing everything he or she is supposed to do and still become resistant [to treatment],” Zaman says. This work was supported by National Institute of General Medical Sciences and USP.

#### Only IPRs can check back against counterfeit production – key to solving crisis.

FIFARMA 4/28. “This Is How We Fight Counterfeit Medicines with Intellectual Property.” FIFARMA, 28 Apr. 2021, fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/.

This is how we fight counterfeit medicines with Intellectual Property There is a threat to health security that is present in every country in the world: counterfeit medicines. These may appear as a promise to cure any disease, but they contain excessive, insufficient or no doses of the active ingredient that treats the disease. Counterfeit medicines also include stolen drugs, drugs that have been stored in poor conditions or are expired, so they may be ineffective or may be contaminated. In the end, the only goal of counterfeit medicines is to make money, regardless of the consequences they may have on people’s health. In fact, according to the World Health Organization (WHO), this business represents more than $30 billion dollars in low- and middle-income countries. Recently, EFPIA did a podcast where it deepens the relationship between the decrease in the distribution of counterfeit medicine and Intellectual Property. You can find it in the following link: [Fighting the fakes – what’s industry’s role?](https://shows.acast.com/19-conversations/episodes/fighting-the-fakes-whats-industrys-role) Why does this relationship occur? Counterfeit medicines are more present where there is less strict regulatory control, where there is a lack of basic medicines, where there are unregulated supply chains, where medicines are priced very differently in the market, where intellectual property is not protected, and where no attention is paid to quality assurance. Therefore, this is a transversal issue to different sectors outside the health industry. It is necessary for different actors to be part of the solution. Decision-makers can create campaigns to inform people about the existence of these medicines. They must go hand in hand with regulatory agencies, as they are the ones that control the entry of medicines into countries. Likewise, the pharmaceutical industry must take action, since they are the ones who research and manufacture products. Thus, the international Fight The Fakes campaign, supported by FIFARMA, aims at raising awareness regarding the dangers of counterfeit medicines. Each actor must play a role, however, without partnerships and collaboration between different parties, it is difficult to fight the problem. Moreover, there are other tools that contribute to the elimination of these threats to public health, such as Intellectual Property (IP). The role of IP In addition to functioning as a tool to maintain constant innovation in the industry, IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate. On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines. In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access. Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP. Also, IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime. Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines. Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products. This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection. On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand. The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem. Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

#### Big pharma is one of the greatest contributers to climate change.

Belkhir 7/28, Lotfi. “Big Pharma Emits More Greenhouse Gases than the Automotive Industry.” The Conversation, 28 Apr. 2021, theconversation.com/big-pharma-emits-more-greenhouse-gases-than-the-automotive-industry-115285.

Rarely does mention of the pharmaceutical industry conjure up images of smoke stacks, pollution and environmental damage. Yet our recent study found [the global pharmaceutical industry is not only a significant contributor to global warming](https://doi.org/10.1016/j.jclepro.2018.11.204), but it is also dirtier than the global automotive production sector. It was a surprise to find how little attention researchers have paid to the industry’s greenhouse gas emissions. Only two other studies had some relevance: one looked at the [environmental impact of the U.S. health-care system](https://www.doi.org/10.1001/jama.2009.1610) and the other at the [pollution (mostly water) discharged by drug manufacturers](https://doi.org/10.1098/rstb.2013.0571). Our study was the first to assess the carbon footprint of the pharma sector. More polluting More than 200 companies represent the global pharmaceutical market, yet only 25 consistently reported their direct and indirect greenhouse gas emissions in the past five years. Of those, only 15 reported their emissions since 2012. One immediate and striking result is that the pharmaceutical sector is far from green. We assessed the sector’s emissions for each one million dollars of revenue in 2015. Larger businesses will always generate more emissions than smaller ones; in order to do a fair comparison, we evaluated emissions intensity. We found it was 48.55 tonnes of CO2e (carbon dioxide equivalent) per million dollars. That’s about 55 per cent greater than the automotive sector at 31.4 tonnes of CO2e/$M for that same year. We restricted our analysis to the direct emissions generated by the companies’ operations and to the indirect emissions generated by the electricity purchased by these companies from their respective utilities companies. The total global emissions of the pharma sector amounts to about 52 megatonnes of CO2e in 2015, more than the 46.4 megatonnes of CO2e generated by the automotive sector in the same year. The value of the pharma market, however, is smaller than the automotive market. By our calculations, the pharma market is 28 per cent smaller yet 13 per cent more polluting than the automotive sector. Extreme variability We also found emissions intensity varied greatly within the pharmaceutical sector. For example, the emissions intensity of Eli Lilly (77.3 tonnes of CO2e/$M) was 5.5 times greater than Roche (14 tonnes CO2e/$M) in 2015, and Procter & Gamble’s CO2 emissions were five times greater than Johnson & Johnson even though the two companies generated the same level of revenues and sell similar lines of products. We found outliers too. The German company Bayer AG reported emissions of 9.7 megatonnes of CO2e and revenues of US$51.4 billion, yielding an emission intensity of 189 tonnes CO2e/$M. This intensity level is more than four times greater than the overall pharmaceutical sector. In trying to explain this incredibly large deviation, we found that Bayer’s revenues derive from pharmaceutical products, medical equipment and agricultural commodities. While Bayer reports its financial revenues separately for each division, it lumps together the emissions from all the divisions. The company also reports and tracks its emission intensity in terms of tonnes of CO2e produced for each tonne of manufactured goods, whether fertilizer or Aspirin, for example. This level of opacity makes it not only impossible to assess the true environmental performance of these kind of companies. It also raises questions about the sincerity of these companies’ strategies and actions in reducing their contribution to climate change. Climate compliance We also estimated how much the pharmaceutical sector would have to reduce its emissions to comply with the [reduction targets in the Paris Agreement](https://unfccc.int/sites/default/files/english_paris_agreement.pdf). We found that by 2025, the overall pharma sector would need to reduce its emissions intensity by about 59 per cent from 2015 levels. While this is clearly a far cry from their current levels, it is interesting to note that some of the 15 largest companies are already operating at that level, namely Amgen Inc., Johnson & Johnson and Roche Holding AG. If those performance levels are achievable by some, why can’t they be achieved by all?

#### More drug production leads to more greenhouse gasses and environmental damage. Also leads to more dumping of medicines.

**Randall, 19** (Ian Randall, 5-29-2019, accessed on 8-17-2021, Daily Mail, "Big Pharma companies create 13% more carbon emissions making medicine than CAR MAKERS", https://www.dailymail.co.uk/sciencetech/article-7081851/Big-Pharma-companies-create-13-carbon-emissions-making-medicine-CAR-MAKERS.html)

Pharmaceutical companies put out 13 per cent more carbon emissions making medicines than car manufacturers - despite having a market that is 28% smaller. Researchers analysed existing public data on the carbon emissions of around 200 pharma companies worldwide. They also did a more focused analysis on emission reports from 15 leading drug manufacturers in the industry, including Bayer AG, Johnson & Johnson and Pfizer. Emissions levels were highly variable, they found, even accounting for the differences between larger and smaller companies. Drug manufacturers emit greenhouse gases directly into the atmosphere from their factories as a result of their production processes, and indirectly through power use. Despite this, financial performance does not mean firms have to pollute, with the three most successful firms also the least polluting. Pharmaceutical companies put out 13 per cent more carbon emissions than car manufacturers despite having a market that is 28 per cent smaller (stock image) Emission reduction measures have traditionally been focused on industrial sectors such as energy production, car manufacturing and mining. However, studies are beginning to highlight that the carbon footprint of the healthcare industry — and particularly the pharmaceutical sector — is also a big problem. In 2007, for example, researchers found that the US Healthcare sector accounted for eight per cent of the nation's total greenhouse emissions. Drug manufacturers directly emit greenhouse gases into the atmosphere from their factories as a result of their production processes. In addition, these companies produce emissions indirectly through the carbon dioxide emitted in the production of the electrical power which they use in their manufacturing systems. Drug companies can also cause other forms of pollution, such as the accidental leak of medicines into the environment. Environmental engineers Lotfi Belkhir and Ahmed Elmeligi of McMaster University in Ontario, Canada, set out to analyse the carbon emissions put out by big pharma. Alongside considering existing data on emissions by the around 200 pharmaceutical firms worldwide, researchers focused in their analysis on the 15 firms that have consistently reported both their direct and indirect greenhouse gas emissions since 2012. Indirect emissions are those that come not as a result each company's operations, but from the emissions resulting from their share of the electricity produced by power companies. As larger businesses will inherently generate more emissions than their smaller counterparts, the researchers assessed each firm's emission intensity per million dollars of revenue. 'One immediate and striking result is that the pharmaceutical sector is far from green,' Professor Belkhir wrote in The Conversation. The researchers found that the global pharmaceutical sector puts out around 48.6 tonnes of carbon dioxide equivalent per million dollars in 2015. Emission reduction measures have traditionally been focused on industrial sectors such as energy production, car manufacturing and mining. However, studies are beginning to highlight that the carbon footprint of the healthcare industry — and particularly the pharmaceutical sector — is also a big problem. In 2007, for example, researchers found that the US Healthcare sector accounted for eight per cent of the nation's total greenhouse emissions. Drug manufacturers directly emit greenhouse gases into the atmosphere from their factories as a result of their production processes. In addition, these companies produce emissions indirectly through the carbon dioxide emitted in the production of the electrical power which they use in their manufacturing systems. Drug companies can also cause other forms of pollution, such as the accidental leak of medicines into the environment. Professor Belkhir reports that this is '55 per cent greater than the automotive sector, at 31.4 tonnes of carbon dioxide equivalent per million dollars for that same year.' 'Rarely does mention of the pharmaceutical industry conjure up images of smoke stacks, pollution and environmental damage,' Professor Belkhir said. 'Yet our recent study found the global pharmaceutical industry is not only a significant contributor to global warming, but it is also dirtier than the global automotive production sector,' he added. The total global emissions from the pharmaceutical sector about to around 52 megatonnes of carbon dioxide equivalent in 2015, compared to the 46.4 megatonnes put out by the car manufacturing industry in the same year. This, the researchers note, is despite drug manufacturing being a smaller market that the automotive industry. 'By our calculations, the pharma market is 28 percent smaller yet 13 percent more polluting than the automotive sector,' Professor Belkhir said. Emission levels vary wildly across the pharmaceutical sector, researchers found. For example, Eli Lilly and Company (pictured, stock image) had an emission intensity in 2015 that was 5.5 times greater than their fellow firm Roche Holding AG Alongside considering existing data on emissions by the around 200 pharmaceutical firms worldwide, researchers focused in their analysis on the intensity of emissions by the 15 firms that have consistently reported both their direct and indirect greenhouse outputs since 2012 Emission levels also vary wildly within the pharmaceutical sector, researchers found. For example, Eli Lilly and Company's emission intensity was 5.5 times greater than Roche Holding AG in 2015, at 77.3 tonnes of carbon dioxide equivalent per million dollars, compared with 14 tonnes. Similarly, experts found that Procter & Gamble's carbon dioxide emissions were around five times greater than those of competitor Johnson & Johnson, despite the two firms selling similar products and generating the same level of revenue. Professor Belkhir and Mr Elmeligi also encountered challenges in accurately assessing the emissions from some companies, such as Bayer AG. They were surprised to find that the German firm had reported emitting 9.7 mega-tonnes of carbon dioxide equivalent in 2015, while receiving a revenue of $51.4 billion (£40.7 billion) during the same period. This would yield an emission intensity of 189 tonnes of carbon dioxide equivalent per million dollars — a level four times larger than the pharmaceutical sector as a whole. Researchers found that the reason for this extreme outlier stemmed from how Bayer lumps together its emission data from across its pharmaceutical, medical equipment and agricultural product divisions, despite declaring revenue individually. 'This level of opacity makes it impossible to assess the true environmental performance of these kind of companies,' said Professor Belkhir. He added: 'It also raises questions about the sincerity of these companies' strategies and actions in reducing their contribution to climate change.' Researchers encountered challenges in accurately assessing the emissions from some companies, such as Bayer AG, who lump together its emission data from across its pharmaceutical, medical equipment and agricultural product divisions Finally, the research duo estimated by how much the pharmaceutical sector would have to cut back on its greenhouse gas emissions in order to meet the targets established by the 2016 Paris Climate agreement. 'We found that by 2025, the overall pharma sector would need to reduce its emissions intensity by about 59 percent from 2015 levels,' Professor Belkhir said.

#### Climate change leads to extinction *by 2050*

Specktor 19 [Brandon Specktor Senior Writer Brandon Specktor writes about the science of everyday life for Live Science, and previously for Reader's Digest magazine, where he served as an editor for five years. ] “Human Civilization Will Crumble by 2050 If We Don’t Stop Climate Change Now, New Paper Claims.” livescience.com. June 04, 2019 https://www.livescience.com/65633-climate-change-dooms-humans-by-2050.html.~Anop

It seems every week there's a scary new report about how man-made climate change is going to cause the collapse of the world's ice sheets, result in the extinction of up to 1 million animal species and — if that wasn't bad enough — make our beer very, very expensive. This week, a new policy paper from an Australian think tank claims that those other reports are slightly off; the risks of climate change are actually much, much worse than anyone can imagine. According to the paper, climate change poses a "near- to mid-term existential threat to human civilization," and there's a good chance society could collapse as soon as 2050 if serious mitigation actions aren't taken in the next decade. Published by the Breakthrough National Centre for Climate Restoration in Melbourne (an independent think tank focused on climate policy) and authored by a climate researcher and a former fossil fuel executive, the paper's central thesis is that climate scientists are too restrained in their predictions of how climate change will affect the planet in the near future. The current climate crisis, they say, is larger and more complex than any humans have ever dealt with before. General climate models — like the one that the United Nations' Panel on Climate Change (IPCC) used in 2018 to predict that a global temperature increase of 3.6 degrees Fahrenheit (2 degrees Celsius) could put hundreds of millions of people at risk — fail to account for the sheer complexity of Earth's many interlinked geological processes; as such, they fail to adequately predict the scale of the potential consequences. The truth, the authors wrote, is probably far worse than any models can fathom. How the world ends What might an accurate worst-case picture of the planet's climate-addled future actually look like, then? The authors provide one particularly grim scenario that begins with world governments "politely ignoring" the advice of scientists and the will of the public to decarbonize the economy (finding alternative energy sources), resulting in a global temperature increase 5.4 F (3 C) by the year 2050. At this point, the world's ice sheets vanish; brutal droughts kill many of the trees in the Amazon rainforest (removing one of the world's largest carbon offsets); and the planet plunges into a feedback loop of ever-hotter, ever-deadlier conditions. "Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of lethal heat conditions, beyond the threshold of human survivability," the authors hypothesized. Meanwhile, droughts, floods and wildfires regularly ravage the land. Nearly one-third of the world's land surface turns to desert. Entire ecosystems collapse, beginning with the planet's coral reefs, the rainforest and the Arctic ice sheets. The world's tropics are hit hardest by these new climate extremes, destroying the region's agriculture and turning more than 1 billion people into refugees. This mass movement of refugees — coupled with shrinking coastlines and severe drops in food and water availability — begin to stress the fabric of the world's largest nations, including the United States. Armed conflicts over resources, perhaps culminating in nuclear war, are likely. The result, according to the new paper, is "outright chaos" and perhaps "the end of human global civilization as we know it." How can this catastrophic vision of the future be prevented? Only with the people of the world accepting climate change for the emergency it is and getting to work — immediately. According to the paper's authors, the human race has about one decade left to mount a global movement to transition the world economy to a zero-carbon-emissions system. (Achieving zero-carbon emissions requires either not emitting carbon or balancing carbon emissions with carbon removal.) The effort required to do so "would be akin in scale to the World War II emergency mobilization," the authors wrote. The new policy paper was endorsed with a foreword by Adm. Chris Barrie, a retired Australian defense chief and senior royal navy commander who has testified before the Australian Senate about the devastating possibilities climate change poses to national security and overall human well-being. "I told the [Senate] Inquiry that, after nuclear war, human-induced global warming is the greatest threat to human life on the planet," Barrie wrote in the new paper. "Human life on Earth may be on the way to extinction, in the most horrible way."

#### Warming is incremental— any climate reform is key to *saving millions*

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It’s not too late. In fact, it never will be. Whatever you may have read over the past year — as extreme weather brought a global heat wave and unprecedented wildfires burned through 1.6 million California acres and newspaper headlines declared, “Climate Change Is Here” — global warming is not binary. It is not a matter of “yes” or “no,” not a question of “fucked” or “not.” Instead, it is a problem that gets worse over time the longer we produce greenhouse gas, and can be made better if we choose to stop. Which means that no matter how hot it gets, no matter how fully climate change transforms the planet and the way we live on it, it will always be the case that the next decade could contain more warming, and more suffering, or less warming and less suffering. Just how much is up to us, and always will be. A century and a half after the greenhouse effect was first identified, and a few decades since climate denial and misinformation began muddying our sense of what scientists do know, we are left with a set of predictions that can appear falsifiable — about global temperatures and sea-level rise and even hurricane frequency and wildfire volume. And there are, it is true, feedback loops in the climate system that we do not yet perfectly understand and dynamic processes that remain mysterious. But to the extent that we live today under clouds of uncertainty about the future of climate change, those clouds are, overwhelmingly, not projections of collective ignorance about the natural world but of blindness about the human one, and they can be dispersed by human action. The question of how bad things will get is not, actually, a test of the science; it is a bet on human activity. How much will we do to forestall disaster and how quickly? These are the disconcerting, contradictory lessons of global warming, which counsels both human humility and human grandiosity, each drawn from the same perception of peril. There’s a name for those who hold the fate of the world in their hands, as we do — gods. But for the moment, at least, many of us seem inclined to run from that responsibility rather than embrace it. Or even admit we see it, though it sits in front of us as plainly as a steering wheel. That climate change is all-enveloping means that it targets us all and that we must all share in the responsibility so we do not all share in the suffering — at least not share in so suffocatingly much of it.Since I first began writing about climate a few years ago, I’ve been asked often whether I see any reason for optimism. The thing is, I am optimistic. But optimism is always a matter of perspective, and mine is this: No one wants to believe disaster is coming, but those who look, do. At about two degrees Celsius of warming, just one degree north of where we are today, some of the planet’s ice sheets are expected to begin their collapse, eventually bringing, over centuries, perhaps as much as 50 feet of sea-level rise. In the meantime, major cities in the equatorial band of the planet will become unlivable. There will be, it has been estimated, 32 times as many extreme heat waves in India, and even in the northern latitudes, heat waves will kill thousands each summer. Given only conventional methods of decarbonization (replacing dirty-energy sources like coal and oil with clean ones like wind and solar), this is probably our best-case scenario. It is also what is called — so often nowadays the phrase numbs the lips — “catastrophic warming.” A representative from the Marshall Islands spoke for many of the world’s island nations when he used another word to describe the meaning of two degrees: genocide. You do not need to contemplate worst-case scenarios to be alarmed; this best-case scenario is alarming enough. Two degrees would be terrible, but it’s better than three, at which point Southern Europe would be in permanent drought, African droughts would last five years on average, and the areas burned annually by wildfires in the United States could quadruple, or worse, from last year’s million-plus acres. And three degrees is much better than four, at which point six natural disasters could strike a single community simultaneously; the number of climate refugees, already in the millions, could grow tenfold, or 20-fold, or more; and, globally, damages from warming could reach $600 trillion — about double all the wealth that exists in the world today. We are on track for more warming still — just above four degrees by 2100, the U.N. estimates. So if optimism is always a matter of perspective, the possibility of four degrees shapes mine. It is unlikely, I think, that we reach four degrees this century. But this is what it would take to stay under two: a comprehensively decarbonized economy, a perfectly renewable energy system, a reimagined system of agriculture, perhaps even a planet without meat-eaters. We also need overhauls of the world’s transportation systems and infrastructure. Every year the average American emits enough carbon to melt 10,000 tons of ice in the Antarctic ice sheets — enough to add 10,000 cubic meters of water to the ocean. Every minute, we each add five gallons. If the task of reversing all that seems incomprehensibly big, it is. The scale of the technological transformation required dwarfs every technological revolution ever engineered in human history, including electricity and telecommunications and even the invention of agriculture 10,000 years ago. By definition, it dwarfs them, because it contains all of them — every single sector needs to be rebuilt from the foundation, since every single one breathes on carbon like it’s a ventilator. In October, the U.N.’s Intergovernmental Panel on Climate Change warned that the world has only a dozen years to halve its carbon emissions to safely avoid two degrees of warming and all those “catastrophic” impacts. Is it possible? The short answer is, technically speaking, maybe — though just maybe. But speaking practically, and politically, is another matter