## 1

#### The meta-ethic is practical reason—

#### [1] Inescapability— I can question why to follow or the validity of an ethical theory, which concedes the authority of reason as if I question reason, I use reason to question. Outweighs on validity—any other truth risks falsity Reality may be fake, our experiences may be arbitrary, and experience may be descriptive not normative, but questioning the validity of reason requires reason, conceding its validity. Any other ethic begs the question of why, meaning it’s arbitrary and nonbinding

#### [2] Action theory— Only reason can explain why we take transitional action to an overall end. For example, setting the end of tea provides me a reason to unify the necessary actions to produce tea, like getting a pot, filling it with water, etc. Any other explanation fails since it can’t give meaning to why we take transitioning action – freezing action. 2 Impacts—

#### [a] That’s a side constraint on the AC—ethics is a guide to action so it must appeal to a structure of action.

#### [b] Bindingness—reason is intrinsic to actions since only it can provide value to transitioning action, which justifies universality

#### That justifies universality—

#### If we are all reasoners, we must all be able to determine if an action is good. An action that maximizes my freedom at the cost of others then would have to be recognized as good by everyone, but that leads to a contradiction where everyone takes other’s freedoms to maximize theirs, making it impossible to reach my end

#### Thus, the standard is respecting a system of inner and outer freedom

#### Now Negate:

#### Negates, reducing intellectual property violates rights to property

Riccardo Pozzo 06 [January 2006, "Immanuel Kant on intellectual property," https://www.researchgate.net/publication/250048266\_Immanuel\_Kant\_on\_intellectual\_property] // WW DL

**\*We do not endorse the author’s gendered language**

Corpus mysticum, opus mysticum, propriété incorporelle, proprietà letteraria, geistiges Eigentum. All these terms mean intellectual property, the existence of which is intuitively clear because of the unbreakable bond that ties the work to its creator. The book belongs to whomever has written it, the picture to whomever has painted it, the sculpture to whomever has sculpted it; and this independently from the number of exemplars of the book or of the work of art in their passages from owner to owner. The initial bond cannot change and it ensures the author authority on the work. Kant writes in section 31/II of the Metaphysics of Morals: “Why does unauthorized publishing, which strikes one even at first glance as unjust, still have an appearance of being rightful? Because on the one hand a book is a corporeal artifact (opus mechanicum) that can be reproduced (by someone in legitimate possession of a copy of it), so that there is a right to a thing with regard to it. On the other hand a book is also a mere discourse of the pub 1 Lecturer (Full Professor) of History of Philosophy at University of Verona. Article received on oct/ 06 and approuved for publication on dec/06. 12 Trans/Form/Ação, São Paulo, 29(2): 11-18, 2006 lisher to the public, which the publisher may not repeat publicly without having a mandate from the author to do so (praestatio operae), and this is a right against a person. The error consists in mistaking one of these rights for the other” (Kant, 1902, t.6, p.290). The corpus mysticum, the work considered as an immaterial good, remains property of the author on behalf of the original right of its creation. The corpus mechanicum consists of the exemplars of the book or of the work of art. It becomes the property of whoever has bought the material object in which the work has been reproduced or expressed. Seneca points out in De beneficiis (VII, 6) the difference between owning a thing and owning its use. He tells us that the bookseller Dorus had the habit of calling Cicero’s books his own, while there are people who claim books their own because they have written them and other people that do the same because they have bought them. Seneca concludes that the books can be correctly said to belong to both, for it is true they belong to both, but in a different way. The peculiarity of intellectual property consists thus first in being indeed a property, but property of an action; and second in being indeed inalienable, but also transferable in commission and license to a publisher. The bond the author has on his work confers him a moral right that is indeed a personal right. It is also a right to exploit economically his work in all possible ways, a right of economic use, which is a patrimonial right. Kant and Fichte argued that moral right and the right of economic use are strictly connected, and that the offense to one implies inevitably offense to the other. In eighteenth-century Germany, the free use came into discussion among the presuppositions of a democratic renewal of state and society. In his Supplement to the Consideration of Publishing and Its Rights, Reimarus asked writers “instead of writing for the aristocracy, to write for the tiers état of the reader’s world.” (Reimarus, 1791b, p.595). He saluted with enthusiasm the claim of disenfranchising from the monopoly of English publishers expressed in the American Act for the Encouragement of Learning of May 31, 1790. Kant, however, was firm in embracing intellectual property. Referring himself to Roman Law, he asked for its legislative formulation not only as patrimonial right, but also as a personal right. In Of the Illegitimity of Pirate Publishing, he considered the moral faculties related to intellectual property as an “inalienable right (ius personalissimum) always himself to speak through anyone else, the right, that is, that no one may deliver the same speech to the public other than in his (the author’s) name” (Kant, 1902, t.8, p.85). Fichte went farther in the Demonstration of the Illegitimity of Pirate Publishing. He saw intellectual property as a part of his metaphysical construction of intellectual activity, which was based on the principle that thoughts “are not transmitted hand to hand, they are not paid with shining cash, neither are they transmitted to us if we take home the book Trans/Form/Ação, São Paulo, 29(2): 11-18, 2006 13 that contains them and put it into our library. In order to make those thoughts our own an action is still missing: we must read the book, meditate – provided it is not completely trivial – on its content, consider it under different aspects and eventually accept it within our connections of ideas” (Fichte, 1964, t.I/1, p.411).

#### Reducing IP law uses people as a means to an end violating their freedom.

**Kornyo, 14** (Emmanuel Kornyo, 9-11-2014, accessed on 8-14-2021, Journals.library.columbia, "Patent Protection and the Global Access to Essential Pharmaceuticals during Patent Infringements under TRIPS| Voices in Bioethics", https://journals.library.columbia.edu/index.php/bioethics/article/view/6467)WWPP

When I think of a categorical imperative I know at once what it contains. For, since the imperative contains, beyond the law, only the necessity that the maxim be in conformity with this law, while the law contains no condition to which it would be limited, nothing is left with which the maxim of action is to conform but the universality of a law as such ... There is, therefore, only a single categorical imperative and it is this: act only in accordance with thatmaxim through which you can at the same time will that it become a universal law.[xiv] In addition, the principle of deontology imposes an obligation on all people to never use another human being as a means to attain an end. In other words, the end does not justify the means. Hence, in dire humanitarian crises such as the HIV case, by breaking the patent, the government of these countries “used” the intellectual property of these patents to attain their own local or national needs. One cannot use the larger interest of the population to the exclusion of the investors or patent holders who have rights as well.[xv

## 2

#### Biden PC is key to getting Manchin & Sinema on board – continued negotiations tentatively get their votes – it’s try or die for Tuesday’s vote

Edmondson & Cochrane 10/24 [Catie Edmondson is a reporter in the Washington bureau of The New York Times, covering Congress, Emily Cochrane is a correspondent based in Washington. She has covered Congress since late 2018, focusing on the annual debate over government funding and economic legislation, ranging from emergency pandemic relief to infrastructure, “Biden Meets With Manchin and Schumer as Democrats Race to Finish Social Policy Bill”, 10-24-2021, New York Times, https://www.nytimes.com/2021/10/24/us/politics/biden-manchin-schumer-spending-bill.html]//pranav

WASHINGTON — President Biden huddled with key Democrats on Sunday to iron out crucial spending and tax provisions as they raced to wrap up their expansive social safety net legislation before his appearance at a U.N. climate summit next week. Speaker Nancy Pelosi of California said Democrats were close to completing the bill, displaying confidence that the negotiations over issues like paid leave, tax increases and Medicare benefits that have bedeviled the party for months would soon end. “We have 90 percent of the bill agreed to and written. We just have some of the last decisions to be made,” Ms. Pelosi said on CNN’s “State of the Union,” adding that she hoped to pass an infrastructure bill that had already cleared the Senate and have a deal in hand on the social policy bill by the end of the week. “We’re pretty much there now.” Her comments came as Mr. Biden met with Senators Chuck Schumer of New York, the majority leader, and Joe Manchin III of West Virginia, one of the critical centrist holdouts on the budget bill. The White House called the breakfast at Mr. Biden’s Wilmington home a “productive discussion.” For weeks, intraparty divisions over the scope and size of their marquee domestic policy plan have delayed an agreement on how to trim the initial $3.5 trillion blueprint Democrats passed this year. In order to bypass united Republican opposition and pass the final bill, Democrats are using an arcane budget process known as reconciliation, which shields fiscal legislation from a filibuster but would require every Senate Democrat to unite behind the plan in the evenly divided chamber. The party’s margins in the House are not much more forgiving. Facing opposition over the $3.5 trillion price tag, White House and party leaders are coalescing around a cost of up to $2 trillion over 10 years. They have spent days negotiating primarily with Mr. Manchin and Senator Kyrsten Sinema, Democrat of Arizona and another centrist holdout. House Democratic leaders hope to advance both a compromise reconciliation package and the $1 trillion bipartisan infrastructure package. Liberals have so far balked at voting on the bipartisan deal until the more expansive domestic policy package — which is expected to address climate change, public education and health care — is agreed upon. But Democrats are facing a new sense of urgency to finish the legislation before Mr. Biden’s trip to a major United Nations climate change conference, where he hopes to point to the bill as proof that the United States is serious about leading the effort to fight global warming. “The president looked us in the eye, and he said: ‘I need this before I go and represent the United States in Glasgow. American prestige is on the line,’” Representative Ro Khanna, a California Democrat who met with Mr. Biden last week at the White House, said on “Fox News Sunday.” Democrats are also increasingly eager to deliver the bipartisan legislation to Mr. Biden’s desk before elections for governor in Virginia and New Jersey on Nov. 2, to show voters the party is making good on its promise to deliver sweeping social change. And a number of transportation programs will lapse at the end of the month without congressional action on either a stopgap extension or passage of the infrastructure bill, leading to possible furloughs.

#### Big Pharma hates the plan – empirics – err neg our ev literally cites their press releases

PhRMA ’21 [The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading innovative biopharmaceutical research companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier and more productive lives. Since 2000, PhRMA member companies have invested nearly $1 trillion in the search for new treatments and cures, including an estimated $83 billion in 2019 alone, “PhRMA Statement on WTO TRIPS Intellectual Property Waiver”, 05-05-2021, https://www.phrma.org/coronavirus/phrma-statement-on-wto-trips-intellectual-property-waiver]//pranav

WASHINGTON, D.C. (May 5, 2021) – Pharmaceutical Research and Manufacturers of America (PhRMA) president and CEO Stephen J. Ubl made the following statement after the United States Trade Representative expressed support for a proposal to waive patent protections for COVID-19 medicines: “In the midst of a deadly pandemic, the Biden Administration has taken an unprecedented step that will undermine our global response to the pandemic and compromise safety. This decision will sow confusion between public and private partners, further weaken already strained supply chains and foster the proliferation of counterfeit vaccines. “This change in longstanding American policy will not save lives. It also 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. This decision does nothing to address the real challenges to getting more shots in arms, including last-mile distribution and limited availability of raw materials. These are the real challenges we face that this empty promise ignores. “In the past few days alone, we’ve seen more American vaccine exports, increased production targets from manufacturers, new commitments to COVAX and unprecedented aid for India during its devastating COVID-19 surge. Biopharmaceutical manufacturers are fully committed to providing global access to COVID-19 vaccines, and they are collaborating at a scale that was previously unimaginable, including more than 200 manufacturing and other partnerships to date. The biopharmaceutical industry shares the goal to get as many people vaccinated as quickly as possible, and we hope we can all re-focus on that shared objective.”

#### They lash out against infra and use COVID clout to kill it – they have public support, and a win now postpones reform indefinitely which turns case

Fuchs et al. 09/02 [Hailey Fuchsattended Yale University and was an inaugural Bradlee Fellow for The Washington Post, where she reported on national politics**,** Alice Ollstein is a health care reporter for POLITICO Pro, covering the Capitol Hill beat. Prior to joining POLITICO, she covered federal policy and politics for Talking Points Memo, Megan Wilson is a health care and influence reporter at POLITICO, “Drug industry banks on its Covid clout to halt Dems’ push on prices”, 09-02-2021, https://www.politico.com/news/2021/09/02/drug-prices-democrats-lobbying-508127]//pranav

As Democrats prepare a massive overhaul of prescription drug policy, major pharmaceutical companies are mounting a lobbying campaign against it, arguing that the effort could undermine a Covid fight likely to last far longer than originally expected. In meetings with lawmakers, lobbyists for the pharmaceutical industry have issued warnings about the reconciliation package now moving through both chambers of Congress that is set to include language allowing Medicare to negotiate the price of some drugs, which could generate billions of dollars in savings. In those conversations, K Street insiders say, lobbyists have explicitly mentioned that the fight against the coronavirus will almost certainly extend beyond the current surge of the Delta variant. And they’re arguing that now isn’t the time to hit the industry with new regulations or taxes, particularly in light of its successful efforts to swiftly develop vaccines for the virus. “For years, politicians have been saying that the federal government can interfere in the price of medicines and patients won’t suffer any harm,” said Brian Newell, a spokesperson for the Pharmaceutical Research and Manufacturers of America, or PhRMA, in a statement. “But in countries where this already happens, people experience fewer choices and less access to prescription medicines. Patients know if something sounds too good to be true, then it usually is.” The escalating warnings from the pharmaceutical industry are part of what is expected to be one of the more dramatic and expensive lobbying fights in recent memory, and a heightened repeat of the industry’s pushback to actions by former President Donald Trump to target drug prices. The proposal now under consideration in Democrats’ reconciliation package could save the federal government hundreds of billions of dollars by leveraging its ability to purchase prescription drugs, according to a report from the Congressional Budget Office. Without those funds, Democrats won’t be able to pay for the rest of the health care agenda they’ve promised to voters, including expansions of Medicare, Medicaid and Obamacare. But the plan has political power as more than a revenue raiser. Party leaders — from President Joe Biden to Senate Budget Chair Bernie Sanders (I-Vt.) — are touting it as one of the most important components of the $3.5 trillion package, with the potential to lower out-of-pocket health spending for tens if not hundreds of millions of people. Outside advocates have also zeroed in on it as the most consequential policy fight on the horizon. “This is the best chance that we have seen in a couple of decades to enact meaningful reforms to drug pricing policy in the United States that will lower the prices of prescription drugs, and it’s very clear that the drug companies are going all out to stop it,” said David Mitchell, founder of Patients for Affordable Drugs. “This is Armageddon for pharma.” Progressive Democrats and their outside allies believe they’re closer than they’ve been in decades to imposing some price controls, and worry that failure to do so this year will delay progress indefinitely given the possibility of the party losing one or more chambers of Congress in the 2022 midterms. In April, the House passed a fairly aggressive version — H.R. 3 (117) — though a handful of moderate Democrats friendly to the industry have threatened to block it when it comes back to the floor for a vote later this fall. Leadership has largely shrugged off this threat, banking on the fact that the most vulnerable frontline Democrats are vocally in favor of the policy, while most of the dissenters sit in safe blue districts. The Senate is designing its own version, outlined by Sen. Ron Wyden (D-Ore.) in June, as a middle ground between HR3 and the more narrow, bipartisan bill he and Sen. Chuck Grassley (R-Iowa) put forward last Congress. A senior Senate Democratic aide confirmed to POLITICO that the bill is nearly complete and that they’re in the process of shopping it around to undecided senators to make sure it has enough support to move forward in the 50-50 upper chamber. “It makes sense to get buy-in before releasing it rather than releasing it with fingers crossed and then tweaking it once members complain,” the aide said. But the reform push is coming at a time when the pharmaceutical industry is working hand-in-hand with government officials to combat the pandemic and enjoying a boost in public opinion as a result, even as drug costs continue to rise. The companies claim that fundamental changes to their bottom line — in addition to the Medicare provision, the reconciliation bill will likely raise corporate tax rate significantly, as high as 28 percent (a jump of 7 percentage points) — will threaten its current investments in research and development at a historically critical juncture. With the final draft of the bill expected in the coming weeks, the Pharmaceutical Research and Manufacturers of America, the lobbying arm of the pharmaceutical industry, is taking its case public. The group has recently spent at least seven figures on ads pressuring Congress not to change Medicare drug policy.

#### Big pharma always wins – independently kills aff solvency bc it causes the plan to be watered down so much that de facto monopolies can survive

Florko & Facher ‘19 [Nicholas Florko is a Stat News Washington correspondent and Lev Facher is Stat News health and life sciences writer, “How pharma, under attack from all sides, keeps winning in Washington”, 07-16-2019, Stat News, https://www.statnews.com/2019/07/16/pharma-still-winning/]//pranav

It does not seem to matter how angrily President Trump tweets, how pointedly House Speaker Nancy Pelosi lobs a critique, or how shrewdly health secretary Alex Azar drafts a regulatory change. The pharmaceutical industry is still winning in Washington. In the past month alone, drug makers and the army of lobbyists they employ pressured a Republican senator not to push forward a bill that would have limited some of their intellectual property rights, according to lobbyists and industry representatives. They managed to water down another before it was added to a legislative package aimed at lowering health care costs. Lobbyists also convinced yet another GOP lawmaker — once bombastically opposed to the industry’s patent tactics — to publicly commit to softening his own legislation on the topic, as STAT reported last month. Even off Capitol Hill, they found a way to block perhaps the Trump administration’s most substantial anti-industry accomplishment in the past two years: a rule that would have required drug companies to list their prices in television ads. To pick their way through the policy minefield, drug makers have successfully deployed dozens of lobbyists and devoted record-breaking sums to their federal advocacy efforts. But there is also a seemingly new strategy in play: industry CEOs have targeted their campaign donations this year on a pair of vulnerable Republican lawmakers — and then called on them not to upend the industry’s business model. In more than a dozen interviews by STAT with an array of industry employees, Capitol Hill staff, lobbyists, policy analysts, and advocates for lower drug prices, however, an unmistakable disconnect emerges. Even though Washington has stepped up its rhetorical attacks on the industry, and focused its policymaking efforts on reining in high drug prices, the pharmaceutical industry’s time-honored lobbying and advocacy strategies have kept both lawmakers and the Trump administration from landing any of their prescription-drug punches. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers,” Sen. Dick Durbin (D-Ill.) said in a statement to STAT. Durbin, who recently saw the industry successfully oppose his proposal to curtail some of the industry’s patent maneuvering, added that, “Pharma’s billions allow them to continue to rip off American families and taxpayers.” The industry doesn’t get all the credit; it has also benefited from a fractured Congress and discord between President Trump’s most senior health care advisers. PhRMA, the drug industry’s largest lobbying group here, declined to comment for this article. But industry leaders have broadly argued against efforts to rein in the industry’s practices in terms of price hikes and patents, making the case that that could irreparably stifle medical innovation. The battle is far from over, and industry representatives and lobbyists are quick to hypothesize that the worst, for them, is yet to come. They point to several ongoing legislative initiatives, including in the Senate Finance Committee, that could take more concerted direct aim at their pricing strategies in Medicare. They’re waiting, too, to see if House Democrats can cut a drug pricing deal with the White House to empower Medicare to negotiate at least some drug prices. Another pending regulation, loathed by drug makers, might tie their pricing decisions in Medicare to an index of international prices. They’ve also bemoaned the Trump administration’s decision last week to abandon a policy change that would have ended drug rebates — which, the pharmaceutical industry has said, could have given drug makers more space to lower their prices voluntarily. “We’re getting killed!” one pharma lobbyist told STAT. Of course, the Trump administration’s supposedly devastating decision to abandon that proposal simply maintains the status quo. “Big Pharma has replaced Big Tobacco as the most powerful brute in the ranks of Washington power brokers.” n Valentine’s Day, Sen. Thom Tillis (R-N.C.) enjoyed a showering of love that is familiar in Washington: a flood of campaign contributions, many at the federal limit of $2,800 for a candidate or $5,000 for an affiliated political committee. One donation came from Pfizer’s CEO, Albert Bourla, who donated $5,000 to Tillis and another $10,000 to Sen. John Cornyn (R-Texas) and associated campaign committees. Another came from Kenneth Frazier, the top executive at Merck. The Tillis campaign committee eventually cashed checks from CEOs and other high-ranking executives at those companies as well as Amgen, Eli Lilly, Sanofi, and Bristol Myers-Squibb, plus two high-ranking officials at the advocacy group PhRMA. Six lobbyists at one firm that works with PhRMA, BGR, also combined to contribute $100,000 to a bevy of Republican lawmakers and the party’s campaign arms. Tillis raised an additional $64,500 from drug industry political action committees in the past quarter, according to disclosures released on Monday. A Pfizer spokeswoman declined to comment about Bourla’s contributions, and representatives for the other companies did not respond to STAT’s request for comment. Tills was one of few individual lawmakers — in many cases, the only one — to whom the executives had written personal checks during the current election cycle. While drug industry CEOs frequently contribute to political committees for congressional leadership, the breadth of executives who donated Tillis specifically is notable, particularly considering his outspoken role on pharmaceutical industry issues. While lobbyists pushed back on the notion that campaign contributions directly influence votes, the donations targeted so specifically to a particular candidate could be seen as a prime example of Washington’s system for rewarding loyalty and how industries protect their interests. The same PhRMA PAC that donated to Tillis has given generously in recent years: nearly $200,000 in the 2018 campaign cycle, roughly 58% of which was targeted toward Republicans. Drug industry PACs donated $10.3 million in total in that cycle, according to the Center for Responsive Politics. The figure two years before was even higher: a total of $12.2 million from industry-aligned PACs alone. It is no accident that the pharmaceutical industry has maintained its reputation among the nation’s most powerful lobbies, said Sheila Krumholz, the executive director of the Center for Responsive Politics, an organization that tracks political influence. “Their access and influence goes beyond this Congress or even the administration,” Krumholz said in an interview, adding that she “was struggling to think of evidence” it had waned. Pharma has a reputation here for winning on policy — often thanks to the lawmakers who are among the biggest recipients of the millions that drug corporations, employees, and the industry political arms donate each year. Even as the rhetoric has escalated, the industry has quietly worked to insulate itself from any major legislative changes. Take, for example, a recent about-face from Cornyn, the Texas Republican who took in some campaign cash alongside Tillis. As recently as February, Cornyn seemed to be positioning himself as a rare Republican figurehead for anti-pharma congressional wrath. At a widely publicized hearing before the Senate Finance Committee, he went head-to-head with AbbVie CEO Richard Gonzalez, pressing him to explain why the company had filed more than 100 patents on its blockbuster arthritis drug Humira. Cornyn introduced legislation soon after the skirmish to crack down on patent “thicketing,” a term for a drug company tactic to accumulate tens, if not hundreds, of patents to shield a drug from potential generic competition. Pharma sprung into action. They recruited congressional allies, including Tillis, to pressure Cornyn to significantly rework the bill, and they succeeded. The version of the bill that eventually cleared the Senate Judiciary Committee was stripped of language that would have empowered the Federal Trade Commission to go after patent thicketing. Instead, the bill limited how many patents a drug maker could assert in a patent lawsuit. The new version of the bill lost “a lot of teeth” and “solves a narrower problem in a narrow way,” advocates told STAT when the change was first introduced. It is far from the only example of the industry’s aggressive interventions to water down legislation. “In lots of ways they’re like the [National Rifle Association], because they have an incredible power to squash out any negative opinion, nor to feel any of the ill effects of those things,” said Pallavi Damani Kumar, an American University crisis communications professor who once worked in media relations for drug manufacturers. “It just speaks to how incredibly savvy they are.” Pharmaceutical industry lobbyists also successfully fought to keep another anti-drug industry patent proposal from Sen. Bill Cassidy (R-La.) and Dick Durbin (D-Ill.) out of a bipartisan drug pricing package moving through the Senate HELP Committee. The legislation would have allowed the FDA to approve cheaper versions of drugs, even when the more expensive product was protected by certain patents. Cassidy’s proposal never even made it into the HELP package. As the lobbyist who bemoaned the withdrawal of the rebate rule put it, Cassidy “simmered down” in the face of industry pressure. In recent weeks, the industry had targeted Cassidy in particular, in recent weeks, for fear he would break with many of his GOP colleagues to support a cap on some price hikes for drugs purchased under Medicare, a proposal so far pushed only by Democrats. “Sen. Cassidy doesn’t care what lobbyists think — he is going to do what’s best for patients,” said Ty Bofferding, a Cassidy spokesman. “Sen. Cassidy fought for the committee to include the REMEDY Act in the package, despite strong opposition from the pharmaceutical industry.” The committee eventually included half the bill’s provisions, he added, as well as four other pieces of legislation meant to prevent the industry from taking advantage of the patent system. The drug industry also notched a win by watering down another proposal in that package from Sen. Susan Collins (R-Maine) that would have blocked drug makers from suing over patents they didn’t disclose to the FDA. The version of the bill that actually made it into the package doesn’t block drug makers from suing, but instead directs the FDA to create a public list of companies that fail to disclose their patents. “This change is a big win for drug makers,” Michael Carrier, a Rutgers University professor and expert on patent gaming, told STAT. “Shaming is something drug makers don’t seem worried about.” Matthew Lane, the executive director of the Coalition Against Patent Abuse, likewise added that the altered bill “doesn’t seem to be doing much anymore.” Not all of the pharma-endorsed changes, however, are self-serving. Patent experts and federal regulators too had raised concerns with some of the bill being proposed. Cornyn’s patent bill was particularly controversial. “These provisions encourage ‘fishing expeditions’ by zealous bureaucrats, politically motivated by the popularity of efforts to reduce drug prices and garner the political benefits of being seen to be pursuing these ends,” Kevin Noonan, a patent lawyer at McDonnell Boehnen Hulbert & Berghoff wrote in a recent blog post, referring to the original Cornyn bill. Drug-pricing advocates said lobbyists have even managed to convince lawmakers to introduce some legislation they say has explicitly favored the drug industry, including intellectual property-focused legislation that would allow drug makers to patent human genes. That particular bill would “undo the bipartisan effort underway to fix pharma’s exploitation of the patent system,” said the Coalition Against Patent Abuse. And they were far from the only group raising concerns. The American Civil Liberties Union and more than 150 other groups wrote to lawmakers last month opposing the bill. Pharma’s list of policy victories goes on: Drug companies and allied patient groups forced the Trump administration to back off a proposal to make relatively minor changes to Medicare’s so-called protected classes policy. Currently, Medicare is required to cover all drugs for certain conditions, including depression and HIV. The Trump administration proposed in November that private Medicare plans should be able to remove certain drugs in those classes from their formularies, if the drugs were just new formulations of a cheaper, older version of the same drug, or when a drug spiked in price. But drug industry opposition helped convince the administration to spike that effort. A week ago, the industry struck its biggest blow yet. Three of the country’s largest pharmaceutical companies —Amgen, Eli Lilly, and Merck — prevailed in a lawsuit to strike down a Trump administration requirement that they disclose list prices in television advertisements. The lack of congressional action — despite the Democratic enthusiasm and bipartisan appetite — is still further evidence of industry’s ability to stave off defeat. As the dozens of Democrats running for president ramp up their anti-pharma rhetoric, both Trump and progressives have begun to fret that Washington’s efforts have proven to be all bark and no bite. With two weeks remaining before the August recess and an escalating 2020 campaign, some advocates fear that the window for bold action is closing quickly. “It’s appalling that we are six months into this Congress and we haven’t seen meaningful legislation passed on American’s number one issue for this congress,” said Peter Maybarduk, who leads drug-pricing initiatives for the advocacy group Public Citizen. “Congress needs to get its act together.”

#### Infra’s k2 stopping existential climate change – warming is incremental and every change in temperature is vital

Higgins 8/16 [Trevor, Senior Director, Domestic Climate and Energy, “Budget Reconciliation Is the Key to Stopping Climate Change”, 08-16-2021, https://www.americanprogress.org/issues/green/news/2021/08/16/502681/budget-reconciliation-key-stopping-climate-change/]//pranav

The United States is suffering acutely from the chaotic changes in climate that scientists now directly attribute to the burning of fossil fuels and other human activity. The drought, fires, extreme heat, and floods that have already killed hundreds this summer across the continent and around the world are a tragedy—and a warning of worsening instability yet to come. However, this week, the Senate initiated an extraordinary legislative response that would set the world on a different path. Enacting the full scope of President Joe Biden’s Build Back Better agenda would put the American economy to work leading a global transition to clean energy and stabilizing the climate. A look at what’s coming next through the budget reconciliation process reveals a ray of hope that is easy to miss amid the fitful negotiations of recent months: At long last, Congress is on the verge of major legislation that would build a more equitable, just, and inclusive clean energy economy. This is our shot to stop climate change. Building a clean energy future must start now Until the global economy stops polluting the air and instead starts to draw down the emissions of years past, the world will continue to heat up, blundering past perilous tipping points that threaten irreversible and catastrophic consequences. Stemming the extent of warming at 1.5 degrees Celsius rather 2 degrees or worse will reduce the risk of crossing such tipping points or otherwise exceeding the adaptive capacity of human society. Every degree matters. Stabilizing global warming at 1.5 degrees Celsius starts with cutting annual greenhouse gas emissions in the United States to half of peak levels by 2030. This isn’t about temporary offsets or incremental gains in efficiency—it’s about the rapid adoption of scalable solutions that will work throughout the world to eliminate global net emissions by 2050 and sustain net-negative emissions thereafter. Building this better future will tackle climate change, deliver on environmental justice, and create good jobs. It will give us a shot to stop the planet from continuously warming. It will alleviate the concentrated burdens of fossil fuel pollution, which are concentrated in systemically disadvantaged, often majority Black and brown communities. It will empower American workers to compete in the global clean energy economy of the 21st century. There is no time to lose in the work of building a clean energy future.

## 3

#### CP: Member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over reducing intellectual property protections by implementing a one-and-done approach for patent protection. Member nations will support the proposal and adopt the results of consultation.

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation displays strong leadership, authority, and cohesion among member states which are key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

# Case

### Framing

#### Problem of induction—I predict based on past experiences, but there’s no justification for why those past experiences are true besides they worked in the past, which is based on experiences and is circular

#### Infinite consequences—each action has a consequence which leads to another consequence—if I drop a pen, that could lead to a hurricane so there is no consequence that can be predicted

#### Pain and pleasure arbitrary and not a stasis point—people have different interps on whether 3 headaches or a migraine is worse

#### Util relies on internalism, which has no bindingness since I could say I did an action because I didn’t know that the result would be bad since no one knows my experiences

### Solvency

**[1] No solvency and reject "empirical" claims -- vaccines require complex infrastructure to manufacture, not just patents**

**Hotez 5/10** [Peter J. Hotez, Maria Elena Bottazzi, and Prashant Yadav. "Producing a Vaccine Requires More Than a Patent," Foreign Affairs, 5-10-2021, accessed 8-8-2021, https://www.foreignaffairs.com/articles/united-states/2021-05-10/producing-vaccine-requires-more-patent] HWIC

On May 5, President Joe Biden announced that the United States would support an international bid to waive intellectual property rights to vaccines for the duration of the coronavirus pandemic, thereby ostensibly allowing other countries to ramp up production even of the sophisticated technology behind the Pfizer-BioNTech and Moderna vaccines against COVID-19. Many in the global health community and developing world welcomed the decision as a victory for greater equity in vaccine distribution, in which middle- and low-income countries are lagging far behind wealthy ones. But the jubilation may be premature. The drive for intellectual property waivers originates in part from the world’s experience fighting the last war, against HIV/AIDS. Patent pools, intellectual property waivers, and other liberalizing mechanisms were urgent in assuring equity of access to lifesaving drugs during that epidemic. But these tools are better suited to medicines and other pharmaceuticals than to vaccines. Producing vaccines—particularly those as technologically complex as the messenger RNA (mRNA) inoculations against COVID-19—requires not only patents but an entire infrastructure that cannot be transferred overnight. The sharing of patents is an important and welcome development for the long term, but it may not even be the most pressing first step. JUST OPEN THE SPIGOT At the turn of the millennium, multinational pharmaceutical companies were charging $10,000 per patient for a daily drug regimen that could keep those infected with HIV/AIDS alive. Those in low- and middle-income countries in Africa and elsewhere could access this cocktail only under limited circumstances. Then, in 2001, the Indian drug manufacturer Cipla Limited began producing versions of a triple antiretroviral drug cocktail for a mere $350. Cipla, in collaboration with Médecins Sans Frontières (Doctors Without Borders), helped usher in a new era of global access to essential medicines—one that justified relaxing or even ignoring international patents and other property rights to produce and distribute an important and lifesaving drug as a generic. Since that time, global health advocacy organizations have found increasingly sophisticated ways to work with multinationals in ensuring access to essential medicines for low- and middle-income countries. In the 2010s, the global health initiative Unitaid helped create a Medicines Patent Pool, in which pharmaceutical companies from all over the world offered antiretroviral drug licenses, thereby creating a path for developing generic versions so long as the patent holders received royalties. The mechanism supplied voluntary licenses to new producers even while protecting the legal rights of the drugs’ original manufacturers. Companies such as Gilead, for example, have supplied voluntary licenses for their antivirals directly to generic manufacturers, allowing for tiered pricing across countries. Barely any COVID-19 vaccines have been administered in the African continent or in low- or middle-income countries in Asia and Latin America. Global health professionals have understandably sought to ascertain whether a similar approach could help make the distribution of COVID-19 vaccines less lopsided. More than one billion vaccine doses have now been administered—but overwhelmingly to people living in just a few countries. More than half have been administered in the United States (250 million) and China (290 million) alone, followed by India (160 million), the United Kingdom (51 million), and Germany (32 million). In contrast, for all practical purposes, barely any COVID-19 vaccines have been [administered](https://www.nytimes.com/interactive/2021/world/covid-vaccinations-tracker.html) in the African continent or in low- or middle-income countries in Asia and Latin America. Global health advocates have responded to this inequity by seeking to apply the lessons they learned from antiretroviral drugs and demanding patent pools or other intellectual property waivers for COVID-19 vaccines. In March 2021, Médecins Sans Frontières organized protests at the World Trade Organization (WTO) headquarters in Geneva, unfurling a banner that read, “No COVID Monopolies—Wealthy Countries Stop Blocking TRIPS Waiver,” referring to the organization’s Agreement on Trade-Related Aspects of Intellectual Property Rights. The assumption underlying such demands is that intellectual property is a crucial barrier blocking vaccine developers, especially in low- and middle-income countries, from producing COVID-19 vaccines to scale—particularly the high-performing mRNA vaccines that Pfizer-BioNTech and Moderna currently produce. These vaccines elicit more than 90 percent protective immunity against both symptomatic illness and documented infection, including asymptomatic infection, with COVID-19. They are successfully driving the recovery of the United States, Israel, and other nations. But so far, mRNA vaccines are mostly invisible to Africa, Latin America, and low- and middle-income countries in other regions. The hope of those pushing for TRIPS waivers and patent pools is that these will unleash the technology to make the recovery global. IT TAKES A WHOLE ECOSYSTEM Intellectual property sharing may be helpful in the long term. But producing complicated biologics, especially innovative ones such as mRNA or adenovirus-vectored vaccines, is not solely a matter of patent access. Small-molecule antiviral drugs are comparatively straightforward: the multistep chemical processes through which they are synthesized are often fully detailed in published patents or scientific papers. Chemists and formulation experts can often synthesize and scale up production just from knowing the drug structure. But vaccines are different. Producing and manufacturing lipid-encased mRNA molecules, recombinant adenoviruses, or even the proteins or whole inactivated viruses used in older-generation vaccines requires a far higher level of sophistication than is needed for producing small-molecule drugs. Moreover, vaccine production must meet stringent requirements for quality control, quality assurance, and regulatory oversight. The **effective transfer of such complex technology requires a receiving ecosystem that can take years, sometimes decades, to build**. Countries seeking to ramp up vaccine production will need to train staff scientists and technicians. They will also need scientific administrators versed not only in basic research and development but also in detailed record keeping, including specific documentation practices such as batch production records. Moreover, they will need strong quality control systems and regulatory guardrails. Building such an infrastructure requires intensive training and often considerable financial investment and risk. It also takes time—by some estimates, vaccine development requires at least 11 years, and even then the probability that such efforts will result in bringing a vaccine to market is less than ten percent. Consider that the COVID-19 vaccines were themselves the outcome of decades of research and development. Few nations are prepared to take such risks. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. Only a handful of low- or middle-income countries currently have the capacity to produce new vaccines. The most notable and largest is India, which currently makes the adenovirus-vectored vaccines developed by Janssen and by Oxford and AstraZeneca, as well as an older-technology recombinant protein vaccine and a whole inactivated virus vaccine. Manufacturers in Brazil, Cuba, and some Southeast Asian countries have experience producing childhood vaccines and may be able to develop the capacity to make COVID-19 vaccines as well. Other possibilities may develop elsewhere, including in the Middle East and Africa. But in the near term, such manufacturers will require financing, access to very large amounts of raw materials and supplies (possibly including relaxation of export controls), and some technical expertise in manufacturing and quality control if they are to produce the existing vaccines against COVID-19. Vaccinating India alone will require almost two billion doses, and more than 12 billion doses will be required to vaccinate the world. The emergence of new variants and the need for booster doses may increase demand even further. Whether mRNA vaccine technology can be scaled to produce billions of doses in 2021, or even by early 2022, remains entirely unknown, but the goal is worth pursuing. To this end, some kind of patent relaxation may be necessary, but far from sufficient. Would-be producers will need technical know-how, regulatory controls, and components that are currently in very short supply, such as nucleotides and lipids.

#### [2] Evergreened drugs vs new drugs are impossible to distinguish, there is no brightline between the difference of an evergreened drug and a new drug, that turns the aff.

#### [b] none of the 1AC is reverse casual -even if they read ev abt stopping evergreening there is no ev abt how that solves drug prices or innovation

### 1NC – AT: AMR

#### 1] Low prices independently cause AMR.

Babu and Suma 6 Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

#### Evolving superbugs trigger extinction.

Srivatsa ’17 (Kadiyali; specialist in pediatric intensive and critical care medicine in the UK. Invented the bacterial identification tool ‘MAYA’; 1-12-2017; "Superbug Pandemics and How to Prevent Them", American Interest; https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/, Accessed: 8-31-2021; AU)

It is by now no secret that the human species is locked in a race of its own making with “superbugs.” Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, we must now invent new and effective antibiotics faster than deadly bacteria evolve—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, humanity faces an existential threat largely of its own making in the absence of malign intentions. As threats go, this one is entirely predictable. The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons.2 A pandemic is a quintessential gray rhino, for it is no longer a matter of if but of when it will challenge us—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race,” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine,