Framework

I value morality, because the verb "ought" implies a moral obligation.

My criterion is utilitarianism.

Only utilitarianism can legitimately justify policies to the public, since they inevitably entail trade-offs. Though perhaps appropriate for individuals, rule-based moral codes create irresolvable bureaucracy when applied to governments.

Gary Woller [BYU Prof., "An Overview by Gary Woller", A Forum on the Role of Environmental Ethics, June 1997, pg. 10]

Moreover, virtually all public policies entail some redistribution of economic or political resources, such that one group's gains must come at another group's ex- pense. Consequently, public policies in a democracy must be justified to the public and especially to those who pay the costs of those policies. Such justification cannot simply be assumed a priori by invoking some higher-order moral principle. Appeals to a priori moral principles such as environmental preservation, also often fail to acknowledge that public policies inevitably entail trade-offs among competing values. Thus since policymakers cannot justify inherent value conflicts to the public in any philosophical sense, and since public policies inherently imply winners and losers, the policymakers' duty to the public interest requires them to demonstrate that the redistributive effects and value trade-offs implied by their polices are somehow to the overall advantage of society. At the same time, deontologically based ethical systems have severe practical limitations as a basis for public policy. At best, a priori moral principles provide only general guidance to ethical dilemmas in public affairs and do not themselves suggest appropriate public policies, and at worst, they create a regimen of regulatory unreasonableness while failing to adequately address the problem or actually making it worse. For example, a moral obligation to preserve the environment by no means implies the best way, or any way for that matter, to do so, just as there is no a priori reason to believe that any policy that claims to preserve the environment will actually do so. Any number of policies might work, and others, although seemingly consistent with the moral principle, will fail utterly. That deontological principles are an inadequate basis for environmental policy is evident in the rather significant irony that most forms of deontologically based environmental laws and regulations tend to be implemented in a very utilitarian manner by street-level enforcement officials. Moreover, ignoring the relevant costs and benefits of environmental policy and their attendant incentive structures can, as alluded to above, actually work at cross purposes to environmental preservation. (There exists an extensive literature on this aspect of regulatory enforcement and the often perverse outcomes of regulatory policy. See, for example, Ackerman, 1981; Bartrip and Fenn, 1983; Hawkins, 1983, 1984; Hawkins and Thomas, 1984.) Even the most die-hard preservationist/deontologist would, I believe, be troubled by this outcome. The above points are perhaps best expressed by Richard Flathman, The number of values typically involved in public policy decisions, the broad categories which must be employed and above all, the scope and complexity of the consequences to be anticipated militate against reasoning so conclusively that they generate an imperative to institute a specific policy. It is seldom the case that only one policy will meet the criteria of the public interest (1958, p. 12). It therefore follows that in a democracy, policymakers have an ethical duty to establish a plausible link between policy alternatives and the problems they address, and the public must be reasonably assured that a policy will actually do something about an existing problem; this requires the means-end language and methodology of utilitarian ethics. Good intentions, lofty rhetoric, and moral piety are an insufficient though perhaps at times a necessary, basis for public policy in a democracy.

Prefer utilitarianism for two additional reasons.

First, the government derives its legitimacy from a social contract, in which individuals give up freedom in exchange for protection from harm. Therefore, a government that doesn't look after its citizens' well-being would be illegitimate.

Second, death is the greatest denial of freedom since it destroys all possibilities and life projects – this means that life is the greatest impact under utilitarianism and relevant under any other ethical framework.

Bauman 95 [Zygmunt Bauman (University of Leeds Professor Emeritus of Sociology). "Life In Fragments: Essays In Postmodern Morality." p. 66-71. 1995]

The being for is like living towards the future: a being filled with anticipation, a being aware of the abyss between future foretold and future that will eventually be; it is this gap which, like a magnet, draws the self towards the Other,as it draws life towards the future, making life into an

activity of overcoming, transcending, leaving behind. The self stretches towards the Other, as life stretches towards the future; neither can grasp what it stretches toward, but it is in this hopeful and desperate, never conclusive and never abandoned stretching toward that the self is ever anew created and life ever anew lived. In the words of M. M. Bakhtin, it is only in this not yet accomplished world of anticipation and trial, leaning toward stubbornly an other Other, that life can be lived not in the world of the `events that occurred'; in the latter world, `it is impossible to live, to act responsibly; in it, I am not needed, in principle I am not there at all." Art, the Other, the future: what unites them, what makes them into three words vainly trying to grasp the same mystery, is the modality of possibility. A curious modality, at home neither in ontology nor epistemology; itself, like that which it tries to catch in its net, `always outside', forever `otherwise than being'. The possibility we are talking about here is not the all too familiar unsure of itself, and through that uncertainty flawed, inferior and incomplete being, disdainfully dismissed by triumphant existence as `mere possibility', `just a possibility'; possibility is instead `plus que la reahte' both the origin and the foundation of being. The hope, says Blanchot, proclaims the possibility of that which evades the possible; `in its limit, this is the hope of the bond recaptured where it is now lost."' The hope is always the hope of being fu filled, but what keeps the hope alive and so keeps the being open and on the move is precisely its unfu filment. One may say that the paradox of hope (and the paradox of possibility founded in hope) is that it may pursue its destination solely through betraying its nature; the most exuberant of energies expends itself in the urge towards rest. Possibility uses up its openness in search of closure. Its image of the better being is its own impoverishment . . . The togetherness of the being for is cut out of the same block; it shares in the paradoxical lot of all possibility. It lasts as long as it is unfulfilled, yet it uses itself up in never ending effort of fulfilment, of recapturing the bond, making it tight and immune to all future temptations. In an important, perhaps decisive sense, it is selfdestructive and self defeating: its triumph is its death. The Other, like restless and unpredictable art, like the future itself, is a mystery. And being for the Other, going towards the Other through the twisted and rocky gorge of affection, brings that mystery into view makes it into a challenge. That mystery is what has triggered the sentiment in the first place but cracking that mystery is what the resulting movement is about. The mystery must be unpacked so that the being for may focus on the Other: one needs to know what to focus on. (The `demand' is unspoken, the responsibility undertaken is unconditional; it is up to him or her who follows the demand and takes up the responsibility to decide what the following of that demand and carrying out of that responsibility means in practical terms.) Mystery noted Max Frisch (and the Other is a mystery), is an exciting puzzle, but one tends to get tired of that excitement. `And so one creates for oneself an image. This is a loveless act, the betrayal." Creating an image of the Other leads to the substitution of the image for the Other; the Other is now fixed soothingly and comfortingly. There is nothing to be excited about anymore. I know what the Other needs, I know where my responsibility starts and ends. Whatever the Other may now do will be taken down and used against him. What used to be received as an exciting surprise now looks more like perversion; what used to be adored as exhilarating creativity now feels like wicked levity. Thanatos has taken over from Eros, and the excitement of the ungraspable turned into the dullness and tedium of the grasped. But, as Gyorgy Lukacs observed, `everything one person may know about another is only expectation, only potentiality, only wish or fear, acquiring reality only as a result of what happens later, and this reality, too, dissolves straightaway into potentialities'. Only death, with its finality and irreversibility, puts an end to the musical chairs game of the real and the potential it

once and for all closes the embrace of togetherness which was before invitingly open and tempted the lonely self." `Creating an image' is the dress rehearsal of that death. But creating an image is the inner urge, the constant temptation, the must of all affection . . . It is the loneliness of being abandoned to an unresolvable ambivalence and an unanchored and formless sentiment which sets in motion the togetherness of being for. But what loneliness seeks in togetherness is an end to its present condition an end to itself. Without knowing without being capable of knowing that the hope to replace the vexing loneliness with togetherness is founded solely on its own unfulfilment, and that once loneliness is no more, the togetherness (the being for togetherness) must also collapse, as it cannot survive its own completion. What the loneliness seeks in togetherness (suicidally for its own cravings) is the foreclosing and pre empting of the future, cancelling the future before it comes, robbing it of mystery but also of the possibility with which it is pregnant. Unknowingly yet necessarily, it seeks it all to its own detriment, since the success (if there is a success) may only bring it back to where it started and to the condition which prompted it to start on the journey in the first place. The togetherness of being for is always in the future, and nowhere else. It is no more once the self proclaims: `I have arrived', `I have done it', `I fulfilled my duty.' The being for starts from the realization of the bottomlessness of the task, and ends with the declaration that the infinity has been exhausted. This is the tragedy of being for the reason why it cannot but be death bound while simultaneously remaining an undying attraction. In this tragedy, there are many happy moments, but no happy end. Death is always the foreclosure of possibilities, and it comes eventually in its own time, even if not brought forward by the impatience of love. The catch is to direct the affection to staving off the end, and to do this against the affection's nature. What follows is that, if moral relationship is grounded in the being-for togetherness (as it is), then it can exist as a project, and guide the self's conduct only as long as its nature of a project (a not yet-completed project) is not denied. Morality, like the future itself, is forever not yet. (And this is why the ethical code, any ethical code, the more so the more perfect it is by its own standards, supports morality the way the rope supports the hanged man.) It is because of our loneliness that we crave togetherness. It is because of our loneliness that we open up to the Other and allow the Other to open up to us. It is because of our loneliness (which is only belied, not overcome, by the hubbub of the being with) that we turn into moral selves. And it is only through allowing the togetherness its possibilities which only the future can disclose that we stand a chance of acting morally, and sometimes even of being good, in the present.

Contention 1 – innovation

The aff drives down pharmaceutical innovation – companies rely on patent protections to secure RnD funding – comparative study

Cockburn et al ’15: Iain Cockburn and Genia Long. “The importance of patents to innovation: updated cross-industry comparisons with pharmaceuticals”. *Critical Reviews in Biotechnology*. April 30th, 2015.
https://www.tandfonline.com/doi/full/10.1517/13543776.2015.1040762
Due to distinctive economic characteristics, patents and regulatory exclusivity have long been considered essential to prescription drug development. These characteristics include the costly,

lengthy, and risky nature of innovative research and development (R&D) and the much lower investment required for generic drugs. Because of this disparity, without patent protection and regulatory exclusivity, particularly in the USA, innovators would be unlikely to make the substantial investments required to bring new drugs to market. Whereas drug development is global, patent law and regulation are country-specific. In the USA, regulatory exclusivity operates in parallel with patents, defining when generics or biosimilars may not submit abbreviated applications and/or enter the market. Generic imitation may require several million dollars, whereas the cost to bring a single FDA-approved drug to market (including the cost of failed attempts) has been estimated at $1.4 billion in out-of-pocket costs and $2.6 billion including the cost of capital [1,2]. New drug R&D requires more than a decade, including pre-clinical testing, clinical trials, and US regulatory approval [1,2]. In comparison, clinical testing is not required for generics; manufacturers need only demonstrate bioequivalence to an already-approved drug. Risk is also high; the vast majority of candidates are eliminated, most before clinical testing. For those that begin clinical testing, the probability of proceeding to approval averages only 12% [2,3]. Therefore, R&D must be funded by a few successful, on-market medicines [4]. Generally, in the USA, once patent protection and any 180-day generic exclusivity end, multiple generics launch, and generic share increases rapidly. For all new molecular entities experiencing first generic entry in 2011–12, the average brand's unit share of molecule sales declined to 16% 12 months after generic entry, versus 44% in 1999–00 [5]. In 2013, generics represented 86% of all US prescriptions [6]. In addition to distinctive R&D and market competition economic characteristics, biopharmaceuticals are also distinguished from other industries by a large gap between the statutory patent term (20 years from the effective patent filing date) and the effective patent term (years remaining at launch), even after any patent term restoration and additional regulatory exclusivity (e.g., for pediatric studies). The average time between brand launch and first generic sale for drugs experiencing initial generic entry in 2011–12 was 12.6 years for drugs with sales greater than $100 million (in 2008 dollars) in the year prior to generic entry, and 12.9 years overall [5]. In contrast, assuming < 3 years for the US Patent and Trademark Office to examine and approve a patent application (overall average of 29 months for FY2013), the remaining duration (assuming 20 years from the effective patent filing date) would be > 17 years in other industries [7]. Finally, patents serve other particularly important economic functions in biopharmaceuticals, developing robust markets for technology and 'signaling' to potential investors the quality of pre-market assets [8]. Since the 1980s, a number of scientific, economic, and legal developments have created the modern-day US biopharmaceutical sector [9]. In addition to scientific discoveries creating new areas of life sciences research, patent law developments made obtaining and enforcing patents for genes and recombinant entities possible, the Bayh-Dole Act encouraged university licensing of government-sponsored research, and a venture capital industry emerged, supporting early phase companies. Between 1980 and 2012, life sciences venture investments totaled $108 billion in 4,600 start-ups (19% of all US venture investment then) [10]. Potential start-up investors weigh patents heavily, including expected effective patent terms of molecules in development, and patent strength for proprietary technology.
PARAGRAPHS OMITTED Since the 1980s, US-focused researchers have found patents to be relatively more important to R&D than other forms of IP protection (trademarks, copyrights, confidential trade secrets, confidential or non-confidential know-how) and strategic complementary assets (such as lead time, sales and service, and manufacturing advantages) in biopharmaceuticals than in other industries. The most recent data from US government and annual US and Canada licensing professional surveys are consistent with these findings.

Turns case – innovation has widespread impacts on public health and sustainability of health care systems

Zozaya et al '19: Neboa Zozaya, Bleric Alcala, and Jhon Galindo. "The offset of pharmaceutical innovation: a review study". Sage Journals. September 14th, 2019. FD.
It is well known that pharmaceutical innovation has improved the health and quality of life of patients. It is however sometimes forgotten that new drugs also have the potential of improving the **efficiency and the sustainability of the healthcare system**. The objective of this review is to shed light on the magnitude of the offset effect that drugs may have in the realm of the healthcare system and for society as a whole. A narrative literature review was carried out. This review demonstrated that a growing body of literature has tried to measure the magnitude of the offset effect associated with pharmaceutical innovation, both at the aggregate level and for different diseases. There is evidence that the aggregate use of new drugs can generate net savings to the healthcare system and to society, as they may release both healthcare and non-healthcare resources for alternative uses. A high degree of heterogeneity in the magnitude of the effect has been found across different pathologies and different types of drugs. By improving the patients' health status, the use of new drugs is

often translated into a decrease in the utilization of healthcare resources, such as hospitalizations, medical visits, and concomitant medication, leading to financial savings, or releasing resources for other uses within the healthcare system. A growing body of literature has tried to measure the magnitude of this offset effect that is associated with PI, both at the aggregate level and for different concrete pathologies. Lichtenberg was one of the first authors who quantified the offset effect of drugs at the general level, leading to the notion that PI's economic and social contribution could significantly exceed its costs. In a study published in 2001, the author estimated that if a 15-year-old drug was to be replaced by a 5.5-year-old one, per capita pharmaceutical expenditure in the United States would increase by USD 18 on average, while non-pharmaceutical expenditure would decrease by USD 72, leading to a savings ratio of almost 4 times the cost of the introduction of the newest drug.4 He later updated his analysis for the years 1997 and 1998 and obtained a savings ratio of 7.2 in the entire population and 8.3 for the population covered by Medicare, basically due to savings in hospitalizations.5 In another study, Lichtenberg6 estimated that, even under a most conservative cost methodology, the net cost of new drugs was negative, as they would generate savings in hospitalization and nursing home costs equivalent to 2.4 times the cost of the drugs. Other authors later found that the magnitude of the aggregate offset effect of new drugs in the United States actually amounted to intermediate values. For example, Civan and Koksal focused on Medicare- and Medicaid-covered population and obtained a net per capita savings ratio of 5.5 when using newer drugs (actually, when the average age of the drug being assessed was reduced in 1 year). However, the authors also found significant heterogeneity among different drug classes.7 In another study, Santerre (2011) obtained estimations for the United States and six other Organisation for Economic Co-operation and Development (OECD) countries and found larger offset effects in the long run than in the short run. Indeed, according to the author, the marginal effect of commercializing a new medication was equivalent to net per capita savings in healthcare costs of USD 5.9 in the short run and USD 11.4 in the long run. These findings implied aggregated savings at the national level of USD 1800 million and USD 3400 million in the short and long run, respectively.8 Public organizations like the Congressional Budget Office have also validated the offset effect of PI in the United States. Their study highlighted that, in the case of the Medicare-covered population, a 1% increase in the number of annual prescriptions translated into a 0.2% decrease in annual healthcare costs.9 Based on this finding and on the volume of prescriptions filled in 2014, Lakdawalla et al.10 estimated that each additional prescription led to savings of USD 94 in DHC in that same year. The existence of an offset effect associated with PI has also been confirmed in other countries. For example, in Canada, Crémieux et al.11 estimated that each additional dollar invested in new drugs yields an average reduction of CAD 4.7 in hospital expenditure and of CAD 1.5 in global healthcare expenditures. In Spain, an increase of 10% in hospital drugs expenditure between 1995 and 2005 led to net per capita savings of EUR 1.1 in total hospital expenditures.12 Savings by therapeutic area Many studies have analysed the economic impact that drugs have in specific therapeutic areas, finding that in those cases, PI also often translates into net savings in costs. In what follows, we summarize some examples found in the literature. In the oncology area, drugs that were commercialized between 1980 and 1997 in Canada avoided 1.7 million hospitalization days per year, which translated into savings that approximated CAD 4700 million (base year 2012), a significantly higher amount than the annual expenditure in cancer drugs in that country.13 Likewise, in the United States, a study estimated that cancer treatments launched between 1989 and 2005 avoided 1.55 million hospitalization days in 2013, thereby reducing hospitalization costs by USD 4800 million in that same year.14 There is also evidence that oncological PI increased healthcare cost savings in Australia. Multiple examples of offset effects have also been found in the cardiovascular area. In OECD countries, pharmaceutical expenditure in cardiovascular illnesses increased by USD 24 per capita between 1995 and 2004, which in turn led to estimated hospitalization savings of USD 89 per capita.16 A study by the British National Health Service estimated that treating atrial fibrillation patients with anticoagulant therapy was associated with net per capita savings of GBP 412 in the short run and GBP 2408 throughout the patient's lifetime. This same study found additional savings for society of GBP 94 and GBP 1379 in the short and long run, respectively.17 Likewise, according to a clinical trial conducted in the United States, the use of statins has led to a 27% reduction in other healthcare costs related to illness management, thereby allowing for an 11% reduction in total cardiovascular healthcare costs.18 Another study found that the use of antihypertensive medication was associated with a benefit–cost ratio of 6:1 in women and of 10:1 in men.19 Other examples can be found for other illnesses, such as depression, asthma and HIV/AIDS. In the United States, the total net healthcare cost per patient diagnosed with depression was reduced during the 1990s by 18%, mainly due to the decrease in hospitalization costs that was produced by innovations in drug treatment.20 In Ireland, the use of new monoclonal antibodies in asthmatic patients led to a reduction in exacerbations and allowed for a decrease of 14.5% in net DHC.21 Finally, studies have demonstrated that while the use of antiretroviral therapy has increased drug expenditure in patients with HIV/AIDS, it has also decreased other healthcare costs, leading to net savings of 10%.22

Contention 2 – Hegemony

The plan weakens US hegemony – China and Russia will capitalize on new biotech

Lauder et al ’21: David Lauder and Andrea Shalal, Carl O’Donnell. “US Wants COVID Vaccine Patent Waiver to Benefit the World, Not Boost China Biotech”. Reuters. May 8th, 2021. https://www.reuters.com/world/china/us-wants-covid-vaccine-patent-waiver-benefit-world-not-boost-china-biotech-2021-05-08/. FD.

May 8 (Reuters) - The Biden administration is examining ways to ensure that a waiver of COVID-19 vaccine patents to aid poor countries will not hand sensitive U.S. biopharmaceutical technology to China and Russia, responding to a chorus of concerns, U.S. and industry officials say. President Joe Biden on Wednesday backed the U.S. entering negotiations at the World Trade Organization for the waiver of intellectual property rights as a means to boost vaccine supplies by allowing poorer countries to make their own. So far, vaccines have gone overwhelmingly to richer nations, which scooped up contracts for them earlier this year. COVID-19 infection rates inr wealthy countries have dropped as vaccination rates increased this year, but infections are still rising in 36 countries, with India’s daily cases skyrocketing to nearly 400,000 a day. Western pharmaceutical companies, many of which have received government support to develop vaccines, strongly oppose the transfer of intellectual property to make them. They say poorer countries will be slow to set up manufacturing capacity and compete for scarce supplies, hitting production. Albert Bourla, CEO of Pfizer Inc, said on Friday that the proposed waiver would disrupt progress made so far in boosting vaccine supplies. “It will unleash a scramble for the critical inputs we require in order to make a safe and effective vaccine. Entities with little or no experience in manufacturing vaccines are likely to chase the very raw materials we require to scale our production, putting the safety and security of all at risk.” Many companies and now some U.S. officials fear the move would allow China to leapfrog years of research and erode the U.S. advantage in biopharmaceuticals. A senior Biden administration official said that while the priority is saving lives, the United States "would want to examine the effect of a waiver on China and Russia before it went into effect to ensure that it's fit for purpose." A question and answer document produced by the administration and shared with industry representatives also acknowledges concerns that intellectual property sharing could damage the United State's competitive advantage over China, an industry source familiar with the discussions told Reuters. The contents of the document read to a Reuters reporter by an industry representative said the Biden administration believes it can address those concerns through the WTO negotiations, but did not specify how. The source added that some agencies in the Biden administration have conflicting views of how to address the concerns in negotiations that are expected to take months. Spokespersons at the White House and U.S. Trade Representative's office had no immediate comment on the matter. Pfizer and Moderna spokespersons did not respond to requests for comment on technology transfer concerns, while a Novavax spokesperson referred Reuters to the company's statement opposing the waiver on Friday, which said proposals to "weaken intellectual property protections would not achieve equitable vaccine access." Enforcing limits on use of the technology could be very difficult, once handed over, some analysts say. Messenger RNA, used in COVID-19 vaccines by leaders Pfizer/BioNTech and Moderna, is a newly developed biotechnology that holds promise for treatments far beyond vaccines. China and Russia have their own vaccines that do not use this biotechnology. "It took Pfizer and Moderna years and years of research to develop these vaccines," said Gary Locke a former U.S. ambassador to China and U.S. Commerce Secretary. "China, Russia, India, South Africa and others want to gain access. Their intention is to get the underlying know-how so they can use it to develop further vaccines," Locke said. China's Fosun Pharma has struck a deal with BioNTech on COVID-19 vaccine product development, which would potentially give it access to some of the technology. China has high ambitions for its pharma industry and already is developing its own mRNA vaccine. Patents themselves are publicly accessible, noted James Pooley, intellectual property attorney and former deputy director general of the United Nations' World Intellectual Property Organization. But trade secrets developed by Pfizer/BioNTech, Moderna and others, "cook books" of manufacturing processes such as temperature and growing conditions, have not been made public. That may ultimately be a dual problem for negotiators. Before they protect the knowledge, U.S. officials would have to ensure access to it. Those companies would need to be persuaded to come to the bargaining table to give up such trade secrets. “What happens when it turns out that the U.S. can’t actually deliver the information that is critically important to implementing the inventions?” Pooley asked. “This will be seen as another failure by the U.S. and other rich countries to keep their promises

US Primacy is key to stop arms races, land grabs, rogue states, and great power war – reject old defense that ignores emerging instability and compounding risk

Brands 18 [Hal, Henry Kissinger Distinguished Professor at Johns Hopkins University's School of Advanced International Studies and a senior fellow at the Center for Strategic and Budgetary Assessments." American Grand Strategy in the Age of Trump." Page 129-133]

Since World War II, the United States has had a military **second to none**. Since the Cold War, America has **committed** to having **overwhelming military primacy**. The idea, as George W. Bush declared in 2002, that America must possess "strengths beyond challenge" has featured in every major U.S. strategy document for a quarter century; it has also been reflected in concrete terms.6

From the early 1990s, for example, the **U**nited **S**tates consistently accounted for around 35 to 45 percent of world defense spending and maintained **peerless global power-projection capabilities**.7 Perhaps more important, U.S. primacy was also unrivaled in key overseas **strategic regions**—**Europe, East Asia, the Middle East**. From **thrashing Saddam** Hussein's million-man Iraqi military during Operation Desert Storm, to deploying—with impunity—two carrier strike groups off Taiwan during the China-Taiwan crisis of 1995– 96, Washington has been able to project military power **superior** to anything a **regional rival** could employ even **on its own geopolitical doorstep.**

This **military dominance** has constituted the **hard-power backbone** of an ambitious global strategy. After the Cold War, U.S. policymakers committed to averting a return to the **unstable multipolarity** of earlier eras, and to perpetuating the more favorable unipolar order. They committed to building on the successes of the postwar era by further advancing **liberal political values** and an open international **economy**, and to **suppressing** international scourges such as **rogue states**, **nuclear proliferation**, and catastrophic **terrorism**. And because they recognized that military force remained the ultima ratio regum, they understood the **centrality** of military preponderance.

Washington would **need** the **military power** necessary to **underwrite** worldwide **alliance commitments**. It would have to preserve **substantial overmatch** versus any potential **great-power rival.** It must be able to answer the sharpest challenges to the international system, such as Saddam's invasion of Kuwait in 1990 or jihadist extremism after 9/11. Finally, because prevailing global **norms** generally reflect **hard-power realities**, America would need the superiority to assure that its own **values remained ascendant**. It was impolitic to say that U.S. strategy and the international order required "**strengths beyond challenge**," but it was not at all inaccurate.

American primacy, moreover, was eminently affordable. At the height of the Cold War, the United States spent over 12 percent of GDP on defense. Since the mid-1990s, the number has usually been between 3 and 4 percent.8 In a historically favorable international environment, Washington could enjoy primacy—and its geopolitical fruits—on the cheap.

Yet U.S. strategy also heeded, at least until recently, the fact that there was a limit to how cheaply that primacy could be had. The American military did shrink significantly during the 1990s, but U.S. officials understood that if Washington cut back too far, its primacy would erode to a point where it ceased to deliver its geopolitical benefits. **Alliances** would **lose credibility**; the stability of key **regions** would be **eroded**; **rivals would be emboldened**; **international crises would go unaddressed**. American primacy was thus like a **reasonably priced insurance policy**. It

required nontrivial expenditures, but protected against far costlier outcomes.9 Washington paid its insurance premiums for two decades after the Cold War. But more recently American primacy and strategic solvency have been imperiled.

THE DARKENING HORIZON For most of the post–Cold War era, the international system was— by historical standards—remarkably benign. Dangers existed, and as the terrorist attacks of September 11, 2001, demonstrated, they could manifest with horrific effect. But for two decades after the Soviet collapse, the world was characterized by **remarkably low levels of great-power competition,** high levels of **security** in key theaters such as **Europe** and **East Asia**, and the **comparative weakness** of those "**rogue" actors**—Iran, Iraq, North Korea, al-Qaeda—who most aggressively challenged American power. During the 1990s, some observers even spoke of a "strategic pause," the idea being that the end of the Cold War had afforded the United States a respite from normal levels of geopolitical danger and competition. Now, however, **the strategic horizon is darkening**, due to four factors.

First, **great-power military competition is back**. The world's two leading authoritarian powers—**China** and **Russia**—are seeking **regional hegemony**, contesting global norms such as nonaggression and freedom of navigation, and developing the **military punch** to underwrite these ambitions. Notwithstanding severe economic and demographic problems, Russia has conducted a major military **modernization** emphasizing **nuclear weapons**, high-end conventional capabilities, and rapid-deployment and special operations forces— and utilized many of these capabilities in conflicts in Ukraine and Syria.10 China, meanwhile, has carried out a **buildup of historic proportions,** with constant-dollar defense outlays rising from US$26 billion in 1995 to US$226 billion in 2016.11 Ominously, these expenditures have funded development of **power-projection** and antiaccess/area denial (**A2/AD) tools** necessary to threaten China's neighbors and complicate U.S. intervention on their behalf. Washington has grown accustomed to having a generational military lead; Russian and Chinese modernization efforts are now creating a **far more competitive environment.**

Second, the **international outlaws** are no longer so **weak**. **North Korea's** conventional forces have atrophied, but it has amassed a growing **nuclear arsenal** and is developing an intercontinental delivery capability that will soon allow it to threaten not just America's regional allies but also the **continental United States**.12 **Iran** remains a **nuclear threshold state,** one that continues to develop ballistic missiles and A2/AD capabilities while employing **sectarian** and **proxy forces** across the Middle East. The Islamic State, for its part, is headed for defeat, but has displayed military capabilities **unprecedented** for any **terrorist group**, and shown that **counterterrorism** will continue to place **significant operational demands** on U.S. forces whether in this context or in others. Rogue actors have long preoccupied American planners, but **the rogues are now more capable** than at any time in decades.

Third, the **democratization of technology** has allowed more actors to **contest American superiority** in dangerous ways. The spread of **antisatellite** and **cyberwarfare** capabilities; the proliferation of man-portable air defense systems and ballistic missiles; the increasing availability of key elements of the precision-strike complex— these phenomena have had a **military leveling effect** by giving weaker actors **capabilities** which were **formerly unique** to technologically advanced states. As such technologies "**proliferate worldwide**," Air Force Chief of Staff General David Goldfein commented in 2016, "the **technology** and **capability gaps** between America and our adversaries are **closing dangerously fast**."13 Indeed, as these capabilities spread, fourth-generation systems (such as F-15s and F-16s) may provide **decreasing utility** against even **non-great-power competitors**, and **far more fifth-generation capabilities may be needed to perpetuate American overmatch**.

Finally, the number of challenges has **multiplied**. During the 1990s and early 2000s, Washington faced rogue states and jihadist extremism—but not intense great-power rivalry. America faced conflicts in the Middle East—but East Asia and Europe were comparatively secure. Now, the old threats still exist—but the more **permissive conditions** have **vanished**. The **U**nited **S**tates confronts **rogue states**, lethal **jihadist organizations**, and **great-power competition**; there are severe challenges in all **three Eurasian theaters**. "I don't **recall a time** when we have been confronted with a **more diverse array of threats**, whether it's the nation state threats posed by **Russia** and **China** and particularly their substantial nuclear capabilities, or non-nation states of the likes of ISIL, Al Qaida, etc.," Director of National Intelligence James Clapper commented in 2016. Trends in the strategic landscape constituted a veritable "**litany of doom**."14 The United States thus faces not just more significant, but also more numerous, challenges to its **military dominance** than it has for at least a **quarter century**.
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Contention 3 – Alternatives to the aff

Licensing solves global vaccination better than a patent waiver – multiple warrants

Silverman ’21: Rachel Silverman. Policy Fellow at the Center for Global Development. “Waiving Vaccine Patents Won’t Help Inoculate Poorer Nations”. Washington Post. March 15, 2021.

The coronavirus vaccine rollout in the United States is quickly ramping up: The Biden administration now promises enough supply for every American adult by the end of May. Yet as we look forward to family reunions, summer barbecues and rescheduled weddings, the world’s poorest countries still face a dire situation. Only in recent weeks did such nations as Ghana, Cambodia and Nigeria welcome their first vaccine shipments — and only enough to cover about 2 percent of their populations. One grim projection suggests that most poor countries will have to wait years — until at least 2023 — to achieve mass vaccination. According to some activists, the solution to this inequity is relatively simple: By suspending protections on covid-19 vaccine patents, the international community “could help break Big Pharma monopolies and increase supplies so there are enough doses for everyone, everywhere,” claims the People’s Vaccine Alliance. Indeed, 58 low- and middle-income countries have mobilized in support of a proposed World Trade Organization waiver that would temporarily exempt coronavirus-related intellectual property from normal international rules and protections. And while the effort to waive IP protections has been a global health hot topic for months, it gained a high-profile endorsement in the United States recently from Sen. Bernie Sanders (I-Vt.). In a March 10 video statement, Sanders called upon President Biden to support the IP suspension while slamming “huge, multibillion-dollar pharmaceutical companies [that] continue to prioritize profits by protecting their monopolies.” The logic of the argument seems clear and intuitive — at first. Without patents, which serve narrow commercial interests, companies all over the world could freely produce the vaccine. Sure, Big Pharma would lose money — but this is a pandemic, and human life comes before private profit, especially when vaccines receive substantial public financing to support research and development. As with HIV drugs in years past, widespread generic production would dramatically increase supply and drive down prices to levels affordable even in the developing world. **Reality is more complicated**, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have little effect. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would not enforce IP rights on its coronavirus vaccine — and yet it has taken no steps to share information about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the company’s direct control within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario. Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items. There are better options than broadly waiving IP rules — notably, encouraging (and pressuring) vaccine manufacturers to cooperate

and share knowledge with partners across the globe. Voluntary licensing is one route: It's a common arrangement in which developers enter into binding contractual agreements with generic producers. Generic manufacturers get permission, know-how and assistance from the patent-holder to produce the vaccine for sales in specified markets; in exchange, the patent-holder can ensure quality of the generic product and may receive royalties on its sales, usually representing less than 10 percent of sales value. These royalties may be lower than the profit margin on direct sales; for example, Pfizer expects a 25 to 30 percent profit on its vaccine sales, or roughly $5 for every $19.50 dose. (The U.S. government has agreed to buy 300 million doses at that price.) But voluntary licensing deals offer a new revenue stream that would otherwise be captured by competitors — not to mention good publicity. Already, voluntary licensing deals from AstraZeneca and Novavax are facilitating large-scale production in India, Japan and South Korea; many of the resulting vaccines are destined for lower-income countries through Covax. The best route to vaccine equity involves creating the conditions to facilitate more of these voluntary deals. How can governments and activists help push things in the right direction? By lifting the export curbs on materials such as filters and bioreactor bags intended to protect domestic supply, countries can help lubricate supply chains, creating a better environment for cross-national collaboration. Governments and development-finance institutions can invest to build up the capabilities of potential vaccine manufacturing plants, making it easier for originators to say yes. Domestically, the Biden administration did something like this when it invested $269 million under the Defense Production Act to prepare Merck's manufacturing facilities to produce the Johnson & Johnson vaccine — a crucial plank of the joint production deal announced this month. Similar efforts are underway abroad. On March 12, for example, the "Quad" — the United States, India, Japan and Australia — announced a joint pledge to produce and disseminate 1 billion vaccine doses; as part of this effort, the Biden administration announced that it would help finance an Indian generic manufacturer to make coronavirus vaccines, including the Johnson & Johnson product. The contractual language of licensing deals can explicitly protect IP from broader dissemination, helping originators feel more comfortable sharing commercially valuable information. In praise of vaccine selfies Sticks as well as carrots can facilitate partnerships. Under existing World Trade Organization rules, countries already have the right to issue "compulsory licenses" in certain cases pertaining to public health, allowing them to produce or import generic health products without permission from the patent-holder. Advocates correctly point out that countries face potential retaliation from industry and wealthy governments when they try to use these tools — a strong disincentive. (In 2006-2007, Thailand's use of compulsory licenses to access more affordable AIDS drugs led the United States to revoke preferential trade status for some Thai exports.) **This should change.** The Biden administration and other global leaders should make clear that they will support legitimate compulsory licensees of coronavirus vaccines in cases where a valid voluntary license request has been rejected or ignored. But compulsory licensing is vastly inferior to voluntary deals in the case of vaccines, because with the former the generic producer would still need to figure out how to make the vaccines without the originator's assistance — again, an extraordinarily difficult task. It is useful mainly as a threat held in reserve, paired with the "carrots" of subsidies to local plants and so on. Firms may choose to play ball on voluntary licensing deals rather than face a mess of legal challenges and bad publicity. This month, for example, Canadian biotech firm Biolyse Pharma publicly requested a voluntary license to manufacture the Johnson & Johnson vaccine for global distribution. If Johnson & Johnson is unwilling, Biolyse made clear in its announcement, the company will appeal to the Canadian government for a compulsory license. The ball is now in Johnson & Johnson's court — but this seems like the type of offer it should choose to accept, both for the global good and its self-interest. Scaling up vaccine production is an imperative for equitable global access and an end to the pandemic. But it is smart incentives for sharing knowledge, not the wholesale elimination of intellectual-property rights, that will get us to the finish line.

Case Turns

Patent waivers won’t speed up vaccine production or boost supply – disrupted supply chains and lack of compliance

Bhuyan 5-17: Anoo Bhuyan. “Patent Waivers for COVID won’t speed up vaccine supply”. India Speed. May 17th, 2021. https://www.indiaspend.com/covid-19/patent-waivers-for-covid-19-wont-speed-up-vaccine-supply-749417. FD.

New Delhi: Sharing vaccine formulae for COVID-19 with developing countries will not help mitigate the global pandemic crisis as many of these countries did not have the capacity to manufacture COVID-19 vaccines adequately. Bill Gates, one of the world's leading billionaires and philanthropists, said on April 25. A few days later, the Bill and Melinda Gates Foundation, of which he is co-chair, issued astatement saying they support a "narrow intellectual property waiver for COVID-19 vaccines during the pandemic". The Gates Foundation has been involved with vaccine-development efforts since early into the COVID-19 pandemic. Intellectual property rights (IPR) on drugs and vaccine formulae give creators an exclusive right over inventions for a certain period of time, and prevent multiple pharmaceutical companies from making the same items. This typically keeps prices high, and when drugs go off patents and multiple companies can make them, prices crash, making them more accessible and affordable. The conversation on patent waivers began in the first year of the pandemic, when India and South Africa made a proposal at the World Trade Organization (WTO) on October 2, 2020, for IPR exemptions on several items for COVID-19, including drugs, vaccines, protective gear, ventilators and diagnostic kits. The WTO is the ultimate authority on global trade rules, including IPR, and enabler of international trade agreements for 164 member countries including India. Internationally, IPR are governed by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), which would have to be waived as an exception, per the proposal. The proposal recommended that these exemptions be in place until "the majority of the world's population has developed immunity" and until "widespread vaccination is in place globally". At the time, the World Health Organization's director general, Tedros Adhanom Ghebreyesus, had also said that he supported this move as it would "ease international & intellectual property agreements on COVID-19 vaccines, treatments & tests in order to make the tools available to all who need them at an affordable cost". Public health advocates have supported the proposal. The tide has begun to turn in favour of the proposal only as of this month. Apart from the divergence between Bill Gates and his foundation, the United States government has also come out in support of a waiver. On May 5, the United States Trade Representative said the government "supports the waiver of those protections for COVID-19 vaccines" in "service of ending this pandemic". The United States is home to several COVID-19 vaccine-makers including Pfizer, Johnson & Johnson, Merck, Novavax and Moderna. In a day's time, several other countries indicated they would support a waiver, including France, Russia and New Zealand. Any waiver by the WTO would have to be by consensus among member states. The European Commission said it would begin discussions on waivers but Germany, home to BioNTech, the firm that created the vaccine being marketed by Pfizer, said it opposed a waiver because "the protection of intellectual property is a source of innovation and must remain so". Waiving intellectual property rights without technology transfer "is like saying 'From tomorrow we will make space travel free'," said Gopakumar Nair, a former pharmaceutical industry executive and an expert on IPR. "The patent waiver at the global level is a good move. Indian companies will be able to step in and make more COVID-19 vaccines," said Sudarshan Jain, secretary general of the Indian Pharmaceutical Alliance (IPA), which represents 24 leading pharmaceutical companies. The next step must be to ensure transfer of technology, without which the first step is meaningless, he said. India's generics industry has for decades reverse-engineered drugs to sell cheaper, mass-produced generic versions. But vaccines, especially those using the newer mRNA technology, require a higher order of scientific knowhow, Nair said, which is the reason why technology transfer will be key. Yet, pharmaceutical companies may not want to comply with WTO waivers, even if they come through--the WTO's next meeting to discuss IPR is in June, and the next is slated in October. Experts believe vaccine production after waivers will take well over a year to ease the current shortage. The most effective solution is for patent holders themselves to issue voluntary licenses to other companies, Jain said, adding that the recent announcements have created an environment where patent holding companies will have to recognise this as a real and imminent issue. "For generic companies wishing to make COVID-19 drugs and vaccines, it is important that they not only have access to the patent information but also have some sort of partnership or license with the innovator companies to figure out how to develop the item. This will help them arrange the necessary equipment, infrastructure, technical skills, technology, software, laboratories and raw materials," said Shivangi Mittal, senior associate at Koan Advisory. "Companies who receive these licenses from the innovator companies, to make the drug or vaccine on contract basis, will also avoid going through clinical trials again, which will not be the case for a generic company that develops the entire technology, product and process for the item on its own without a technology transfer," said Mittal. Amid this, the Indian government's statement in court has drawn criticism. "We may think that big pharmaceutical companies are bluffing about not wanting to allow patent waivers, but it is the Indian government who is bluffing by

saying these contradictory statements abroad and in India on whether it will support waiving patents," said Murali Neelakantan, a lawyer, and formerly the legal counsel for Cipla and Glenmark. "How can Indian companies have confidence that they will not be sued for patent infringement, when the government sends different signals?" he said. There are other reasons why those opposing patent waivers say they will not be immediately beneficial, as a May 2021 report from research and brokerage firm Sanford Bernstein highlights. One reason they cite is that unless the waiver comes with technology-transfer, it will take longer for Indian manufacturers to themselves develop the technology needed, end-to-end, especially for the mRNA vaccines such as from Pfizer and Moderna. Another reason they cite is that the existing manufacturing capacity in India is already in use, with very little idle capacity. Big foreign pharmaceutical companies and their industry-associations are not yet on board with the waiver, or convinced that it will solve any of the current supply problems. They point out that a waiver could disrupt existing supply chains of raw materials and manufactured vaccines, and result in a suboptimal use of limited resources at a critical time. For instance, a statement from the Pharmaceutical Research and Manufacturers of America (PhRMA) pointed out that patent waivers would not solve the limited availability of raw materials or provide solutions to actually distribute the various vaccines thus produced. Trade barriers and supply-chain constraints are a more worrisome problem than patents, according to the International Federation of Pharmaceutical Manufacturers and Associations. Companies who want to manufacture COVID-19 vaccines and governments interested to make this happen must ensure that raw materials are available, adequate infrastructure and equipment are available, that high levels of quality control are maintained and that a large enough and skilled workforce is available, a report in the British Medical Journal said on May 10, 2021. However, drawing it all together, "the patent is still the critical barrier", said Davinder Gill, an expert on vaccines and former vice president for global biotherapeutics at Pfizer. "If you compare India with other countries in the sub-continent, and if the same waiver was provided to all countries, India would be the one to perform well. In India there is the capacity, and experience, to make drugs and vaccines." Without technology transfer, it may take longer, but Indian companies will be able to develop the vaccines, he said, adding, "But the patent is still the critical barrier which poses the risk and is preventing companies from jumping in."

The patent waiver harms developing countries – upholding IPR is a better means of inoculating the world

Roberts 6-9-21: James Roberts. “Biden’s wink at global theft of US vaccine patents is bad for America and the world”. The Heritage Foundation. June 9th, 2021. https://www.heritage.org/economic-and-property-rights/report/bidens-wink-global-theft-us-vaccine-patents-bad-america-and-the. FD.

The Biden Administration claims that its IPR policy is compassionate in that it will theoretically make available more plentiful and cheaper COVID-19 vaccines to needy countries around the world. Actually, **the opposite is true**. Protecting vaccine IPR will incentivize production of enough vaccines to inoculate the world. Another important reason for the U.S. to oppose waiving TRIPS is that doing so could hobble future advances in mRNA technology. As the CDC notes, “Future mRNA vaccine technology may allow for one vaccine to provide protection for multiple diseases, thus decreasing the number of shots needed for protection against common vaccine-preventable diseases.”21 U.S. Centers for Disease Control and Prevention, “Understanding mRNA COVID-19 Vaccines,“ March 4, 2021, https://www.cdc.gov/coronavirus/2019-ncov/vaccines/different-vaccines/mrna.html (accessed May 19, 2021). Waiver of TRIPS protection under Article 31bis, then, threatens not only COVID-19 vaccines, but also **future vaccines**. Efforts that would hamper and disincentivize the creation and availability of future vaccines would be a terrible outcome for the world. The U.S. government should join other developed countries opposing the waiver of TRIPS patent protection under Article 31bis. **Waiving TRIPS hinders, not helps, developing countries** as they seek to purchase vaccines and improve their own pharmaceutical manufacturing sectors’ ability to produce them.

IP protections stifles pandemic response by hindering innovation – a TRIPS waiver would set the opposite precedent

Lindsey ’21: Brink Lindsey, Vice President of Niskanen Center. June 11th, 2021. “*Why Intellectual Property and Pandemics don’t mix*”. Brookings Institute. https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/.
When we take the longer view, we can see **a fundamental mismatch** between the policy design of intellectual property protection and the policy requirements of effective pandemic response. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing **a TRIPS waiver for COVID-19 vaccines** and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices.

Top-Level:

1] A vaccine waiver greenlights counterfeit medicine – independently turns Case by increasing vaccine hesitancy.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" https://archive.is/vsNXv#selection-5353.0-5364.0 (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine**, **and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

2] Lack of key supplies

Tepper 21 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital

components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK's jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline's plant at Barnard Castle to be put into vials for distribution. "The first hurdle is showing it works and we don't have that hurdle any more," Erck said. But he added there were others still to overcome. "There's the media that the cells have to grow in," Erck said. "You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count." Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. "We started working on our part of the supply chain in summer last year," he said. "We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled." Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK's vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: "We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags. We typically run out at 16 weeks to get a custom bioreactor bag out to a customer." He said ABEC was still managing to fulfil orders at roughly that rate. "The bag manufacturing capacity can't meet demand right now," he added. "And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time." ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and "vaccine nationalism" by operating on four continents, with 20 facilities in nine countries. "One year ago, we had exactly zero manufacturing capacity," Erck said. "We're self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands." There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports.

Turns the Aff – Delta Variant proves current vaccines aren't enough – we need new innovations.

Guarino 8-18 Ben Guarino 8-18-2021 "Vaccines show declining effectiveness against infection overall but strong protection against hospitalization amid delta variant" https://archive.is/pvuzL#selection-747.0-750.0 (Education: University of Pennsylvania, BSE in bioengineering; New York University, MA in journalism)//Elmer

Results from a trio of studies, published in the CDC's weekly report, **motivated** the **Biden** administration **to consider booster shots**. **Three studies published** Wednesday by the Centers for Disease Control and Prevention **show** that **protection against the coronavirus from vaccines declined** in the midsummer months **when** the more contagious **delta variant rose** to dominance in the United States. At the same time, protection against hospitalization was strong for weeks after vaccination, indicating the shots will generate immune fighters that stave off the worst effects of the virus and its current variations. Data from these studies persuaded the Biden administration to develop a plan for additional doses to bolster the immune systems of people vaccinated months earlier. The trio of reports, published Wednesday in the Morbidity and Mortality Weekly Report, the CDC's scientific digest, also **reinforce** the **idea** that **vaccines alone will be unable to lift the nation out of the pandemic**. Masks and other precautions should be part of "a layered approach centered on vaccination," wrote researchers from the New York State Department of Health and the University at Albany School of Public Health in their study of vaccine effectiveness across New York state. All three reports measure vaccine effectiveness, which compares the rates of infection or hospitalization among vaccinated people with the rates among people who had not been vaccinated. Until now, evaluations of vaccine effectiveness amid delta largely relied on observations from outside the United States. A recent New England Journal of Medicine study concluded the Pfizer vaccine was 88 percent effective against infections that caused symptoms in England. Others, such as **a study in Israel**, **found larger declines in protection against infection**. One U.S. report that has not yet gone through peer review, collecting data from Mayo Clinic Health System facilities in five states, **found** a **drop in** the **Pfizer**-BioNTech **vaccine's effectiveness against delta infections to 42 percent**. The other mRNA vaccine, made by Moderna, was 76 percent effective. The new study from New York is the first to assess vaccine protection against coronavirus infection across the entirety of a U.S. state amid delta. The study authors found a modest drop in effectiveness: It descended from 92 percent in May to 80 percent in late July. Twenty percent of new infections and 15 percent of hospitalizations from covid-19, the disease caused by the coronavirus, were among vaccinated people. The second of the three studies published Wednesday by the CDC found effectiveness against infection declined for nursing home residents after delta emerged. It dropped from 75 percent in March through May to 53 percent in June and July. Vaccination for visitors and staff is crucial, the study authors wrote, and "additional doses of COVID-19 vaccine might be considered for nursing home and long-term care facility residents." The third report, an analysis of patients at 21 hospitals in 18 states, found sustained protection against hospitalization. Effectiveness was steady at 86 percent, even in the midsummer months when delta outcompeted other variants of concern. For adults who do not have compromised immune systems, that effectiveness stood at 90 percent.

4] Skill Disparities and Trade Secrets – Moderna proves IP isn't the root cause.

Silverman 3-15 Rachel Silverman 3-15-2021 "Waiving vaccine patents won't help inoculate poorer nations" https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/ (Rachel Silverman is a policy fellow at the Center for Global Development)//Duong

Reality is more complicated, however. Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have **little effect**. It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents. The

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