## 1NC – Offs

### 1

#### Interp – if affs don’t defend the exact text of the resolution, they must provide a counter solvency advocate.

#### Violation – they don’t – here’s the brightline – it must have members of the WTO as the actor, intellectual property, and medicine.

1AC Feldman 3 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but **not all of the above** and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

#### 1] Feldman 3 says legislative changes to the FDA’s drug approval system but that’s only the US

#### 2] they reference drugs – that’s distinct from medicine.

Singh 18 [Arvind Singh (Banaras Hindu University). “What is the difference between a medicine and drug?” 30th Dec, 2018. Accessed 8/30/21. <https://www.researchgate.net/post/What-is-the-difference-between-a-medicine-and-drug> //Xu]

Medicine is a substance or preparation used in treating disease, while drug is any chemical compound either synthesized in laboratory or of plant, animal or marine origin which is intended to bring change in normal physiological functions of body. All medicines are drugs but all drugs are not medicines.

#### Prefer –

#### 1] Predictable Limits – not having a clear solvency advocate should be a signal that topic lit on this aff is marginal – allowing them to jettison random words in the rez lets them cherry pick the best and unpredictable aff with little neg ground which skews clash and prep.

#### 2] Shiftiness – a blurry advocacy means they aren’t held to a detailed interpretation of the topic – allows them to shift out of 1NC args, disincentivizes substantial case engagement, and causes circumvention cuz companies don’t know what the plan entails which is a terminal solvency deficit to the aff.

#### Drop the debater—the abuse has already occurred and my time allocation which leads to severance in the 1ar which ow/s on magnitude

#### Competing interps – a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm

#### No RVIs – a) illogical – you shouldn’t win for being fair – it’s a litmus test for engaging in substance b) norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms,

### 2

#### Text – On September 28th, 2021, States ought to individually domestically establish single-payer national health insurance.

#### Solves evergreening and drug prices while avoiding our innovation turns.

Narayanan 19 Srivats Narayanan 8-15-2019 "Medicare for All and Evergreening" <https://medium.com/@srivats.narayanan/medicare-for-all-and-evergreening-cb84c930e0ea> (UMKC School of Medicine)//Elmer

Drug companies rake in massive profits. The pharmaceutical industry has some of the largest profit margins among American industries. Unfortunately, pharmaceutical giants don’t always have patients’ best interests in mind — they make a big portion of their money by exploiting the patent process instead of making breakthrough drugs that would meaningfully improve patients’ lives. Pharmaceutical corporations aren’t as innovative as one might expect. Although the Food and Drug Administration (FDA) has been consistently approving new (and expensive) drugs every year, most of these drugs aren’t impacting healthcare much. Many studies have revealed that a whopping 85–90% of new drugs since the mid-1990s “provide few or no clinical advantages.” This is because pharmaceutical firms are spending their time and money on a technique known as “evergreening.” Evergreening is when drug companies produce redundant drugs that are nothing but minor modifications of old drugs. By making slight alterations to their medicines, biotech companies continue to hold patents for drugs with minimal spending on research and development (R&D). Pharmaceutical companies then use those patents to prevent competitors from selling generic versions of their drugs. Without any competition, these corporations get away with ridiculously high drug pricing and can thus make big profits on their drugs. The companies simultaneously justify their absurd drug prices by pointing to the inflated R&D costs of producing new drugs. This excuse has been used time and again by the profit-hungry pharmaceutical industry, and it’s coming at the expense of patients who struggle to afford their medicines. A well-known example of evergreening pertains to the anticonvulsant medication gabapentin, which was first sold by Pfizer under the brand name Neurontin. When the drug became available as a generic medication over a decade ago, Pfizer created a very similar medicine, pregabalin (Lyrica), that didn’t have any significant benefits over the original drug. As a result, Pfizer has kept a control over the market for anticonvulsant drugs with negligible innovation. The drug industry’s reliance on evergreening is undoubtedly stifling innovation. This is where **Medicare for All**, **which would impose the government as the only health insurer**, **would be useful**. **In our current system**, **there are many insurers** **and they each have** **little market power** **and** consequently **little negotiating power** **to reduce** treatment **prices**. **Since the government would have** **consolidated control over healthcare financing** under Medicare for All, **its stronger bargaining power would force drug companies to charge lower prices for their products**. In addition, prescription drugs would be paid for by the government and not by patients under Medicare for All. **Medicare for All would prevent evergreening**. **National healthcare financing** **would align** **how much the government pays a drug company with how much patients benefit** from the company’s drugs. **If a new drug had more clinical benefits** than an older version, **the government would pay more** for it. If a new drug produced the same results as an older version, the government wouldn’t pay more for the new drug. So, Medicare for All would **encourage** pharmaceutical **companies to pursue truly innovative drugs because such drugs would be more profitable**. The policy would incentivize companies to invest in R&D for more useful drugs, instead of just producing redundant and expensive medications. A national healthcare plan would prioritize “patient and community needs” and match up pharmaceutical companies’ interests with actually improving public health. Evergreening has become the name of the game for the pharmaceutical industry. A major solution to the evergreening problem is Medicare for All. **A single-payer system** like Medicare for All **would sharply curtail evergreening**, since drug companies wouldn’t be able to profit from it. Medicare for All would **usher** in **a new era of medical innovation**.

#### The CP solves but now is key for the infrastructure DA

Melissa Quinn, 8-24-2021, (Politics Reporter at CBSNews.com)"House approves $3.5 trillion budget plan, sets deadline for infrastructure vote," *CBS News*, <https://www.cbsnews.com/news/budget-reconciliation-plan-house-representatives-infrastructure-vote/> Cho

Washington — The House on Tuesday voted to advance the $1 trillion bipartisan infrastructure bill while simultaneously approving a $3.5 trillion budget blueprint that clears the way for Democrats in Congress to take action on a sweeping package that includes President Biden's key domestic policy proposals. Lawmakers voted along party lines 220 to 212 to approve a rule that deemed the budget framework as passed, a key step toward enacting Mr. Biden's broader families plan, and set a September 27 deadline for the House to pass the infrastructure measure. The procedural resolution also moved forward a voting rights bill, a major priority for congressional Democrats, and a vote to pass that legislation is expected later Tuesday. "Passing this rule paves the way for the Building Back Better plan, which will forge legislative progress unseen in 50 years, that will stand for generations alongside the New Deal and the Great Society," House Speaker Nancy Pelosi said on the House floor ahead of the vote. "Any delay in passing the rule threatens the Build Back Better plan, as well as voting rights reform, as well as the bipartisan infrastructure bill. We cannot surrender our leverage."

### 3

#### Biden’s infrastructure bill will pass through reconciliation but absolute Dem Unity is key.

* Turns Structural Violence

Pramuk and Ranck 8-25 Jacob Pramuk and Thomas Franck 8-25-2021 "Here’s what happens next as Democrats try to pass Biden’s multitrillion-dollar economic plans" <https://www.cnbc.com/2021/08/25/what-happens-next-with-biden-infrastructure-budget-bills-in-congress.html> (Staff Reporter at CNBC)//Elmer

WASHINGTON — **House Democrats just patched up a party fracture** **to take a critical step forward with a mammoth economic agenda**. But the **path ahead could get trickier** as party leaders try to thread a legislative needle to pass more than $4 trillion in new spending. **In** the **coming weeks**, **Democrats** **aim to approve** a $1 trillion bipartisan **infrastructure** plan and up to $3.5 trillion in investments in social programs. Passing both **will require a heavy lift**, as leaders will need to **satisfy** **competing demands of centrists** wary of spending **and progressives** who want to reimagine government’s role in American households. The House is leaving Washington **until Sept. 20** after taking key steps toward pushing through the sprawling economic plans. The chamber on Tuesday approved a $3.5 trillion budget resolution and advanced the infrastructure bill, as House Speaker Nancy Pelosi, D-Calif., promised centrist Democrats to take up the bipartisan plan by Sept. 27. The Senate already passed the infrastructure legislation, so **a final House vote would send it to Biden’s desk for his** signature. Now that both chambers have passed the budget measure, **Democrats can move without Republicans** to push through their spending plan **via reconciliation**. Party leaders want committees to write their pieces of the bill by Sept. 15 before budget committees package them into one massive measure that can move through Congress. Committees could start marking up legislation in early September. Party leaders **face a challenge** in coming up with a bill that will satisfy centrists who want to trim back the $3.5 trillion price tag and progressives who consider it the minimum Congress should spend. As **one defection in the Senate** — **and four in the House** — **would sink legislation,** **Democrats have to satisfy a diverse range of views** to pass their agenda. “We write a bill with the Senate because it’s no use doing a bill that’s not going to pass the Senate, in the interest of getting things done,” Pelosi told reporters on Wednesday. Given the magnitude of the legislation, passing it quickly could prove difficult. To appease congressional progressives who have prioritized passage of the budget bill, Democrats could move to pass both proposals at about the same time. While Pelosi gave a Sept. 27 target date to approve the infrastructure plan, the commitment is not binding. Still, she noted Wednesday that Congress needs to pass the bill before surface transportation spending authorization expires Sept. 30. “We have long had an eye to having the infrastructure bill on the President’s desk by the October 1, the effective date of the legislation,” she wrote in a separate letter to Democrats on Wednesday. Democrats say the bills combined will provide a jolt to the economy and a lifeline for households. Supporters of the Democratic spending plan, including Pelosi and Senate Budget Committee Chair Bernie Sanders, I-Vt., have cast it as the biggest expansion of the U.S. social safety net in decades. “This is a truly historic opportunity to pass the **most transformative** and consequential **legislation for families** in a century, and will stand alongside the New Deal and Great Society as pillars of **economic security**,” Pelosi wrote to colleagues Wednesday. The plan would **expand Medicare**, **paid leave** and child care, extend enhanced household tax credits and encourage **green energy adoption**, **while hiking taxes on corporations and the wealthy**. Democrats hope to sell a wave of new support for families as they campaign to keep control of Congress in next year’s midterms. Those elections, though, have helped to generate staunch opposition on the other side of the aisle. The GOP has cited the trillions in new spending and the proposed reversal of some of its 2017 tax cuts in trying to take down the Democratic budget bill. Republicans and some Democrats have in recent weeks said that another $4.5 trillion in fiscal stimulus could not only boost economic growth but have the adverse effect of fueling inflation.

#### They choose Infrastructure as backlash – they bill costs Pharma millions – lobbyists can derail the Agenda.

Brennan 8-2 Zachary Brennan 8-2-2021 "How the biopharma industry is helping to pay for the bipartisan infrastructure bill" <https://endpts.com/how-the-biopharma-industry-is-helping-to-pay-for-the-bipartisan-infrastructure-bill/> (Senior Editor at Endpoint News)//Elmer

Senators on Sunday finalized the text of **a massive, bipartisan infrastructure bill** that contains little **that might** **impact the biopharma industry** other than two ways the legislators are planning to pay for the $1.2 trillion deal. On the one hand, senators are **seeking to** further **delay** a **Trump-era Medicare** Part D **rule** **related to drug rebates**, this time until 2026. Senators claim the rule could end up saving about $49 billion (and that number increased this week to $51 billion), but the PBM industry has attacked it as it would remove rebates from a safe harbor that provides protection from federal anti-kickback laws. The **pharmaceutical industry**, however, is in favor of the rule and **opposes this latest delay** as it continues to point its finger at the PBM industry for the rising cost of out-of-pocket expenses. Debra DeShong, EVP of public affairs at PhRMA, said via email: Despite railing against high drug costs on the campaign trail, lawmakers are threatening to gut a rule that would provide patients meaningful relief at the pharmacy. If it is included in the infrastructure package, this proposal will provide health insurers and drug middlemen a windfall and turn Medicare into a piggybank to fund projects that have nothing to do with lowering out-of-pocket costs for medicines. This would be an unconscionable move that robs patients of the prescription drug savings they deserve to help fill potholes and fund other infrastructure projects. The **other provision** **in the infrastructure bill**, which is estimated to save about $3 billion, **would save money for Medicare** **on discarded medications** from large, single-use drug vials. **Manufacturers will be required to pay refunds** for such discarded drugs, and each manufacturer will be subject to periodic audits on the refunds issued. If manufacturers don’t comply, HHS can fine them the refund amount that they would have paid plus 25%. Drugs that will be excluded from these refund payments include radiopharmaceuticals or imaging agents, as well as those that require filtration during the drug preparation process. So do these two pay-fors mean that the pharma industry is getting off without any serious drug pricing reforms? Not quite, according to Alex Lawson, executive director of Social Security Works. Lawson told Endpoints News in an interview that he still fully expects major drug pricing reforms to make their way through Congress between now and the end of September as Sen. Ron Wyden (D-OR) refines his plan, part of an early fall spending package. Senate Majority Leader Chuck Schumer has promised both the infrastructure and spending package will pass before the Senate leaves for August recess. At the very least in terms of drug pricing provisions, expect to see a combination of the Wyden bill he co-wrote with Sen. Chuck Grassley (R-IA) last year, alongside further Medicare negotiations, Lawson said. “Talk is still optimistic,” Lawson said on the prospects of a drug pricing deal getting done, while noting that **pharmaceutical** company **lobbyists** are **swarming Capitol Hill** at the moment because of **not just drug pricing plans**, but **tax provisions** and the **TRIPS waiver** that the biopharma industry is worried about. “These are **challenges to their entire existence**, **so they’re willing to protect them at any cost**,” Lawson said, noting the target for drug pricing is about $500 billion in savings. As the House has jetted off to enjoy what might be an abbreviated summer recess, the Senate has just this week to get its work done, unless its recess is cut short too. “There’s a **real possibility** that **the whole thing blows up** and we get nothing on either side,” Lawson said.

#### Democrat Senators in Big Pharma’s pocket derails the Plan.

Sirota 8-23 David Sirota 8-23-2021 "Dem Obstructionists Are Bankrolled By Pharma And Oil" <https://www.dailyposter.com/dem-obstructionists-are-bankrolled-by-pharma-and-oil/> (an American journalist, columnist at The Guardian, and editor for Jacobin. He is also a political commentator and radio host based in Denver. He is a nationally syndicated newspaper columnist, political spokesperson, and blogger)//Elmer

The **small group of conservative Democratic lawmakers** that has been **threatening to** help Republicans **halt** **Democrats’ budget package** have **raked in more than $3 million from donors in the pharmaceutical** and fossil fuel **industries** that could see reduced profits if the plan passes. As the House reconvenes today to tackle the budget reconciliation process, nine Democrats legislators have been promising to kill their party’s $3.5 trillion budget bill until Congress first passes a separate, smaller infrastructure spending measure, which has garnered some Republican support and which some environmental advocates say would exacerbate the climate crisis. Indeed, an ExxonMobil lobbyist was recently caught on tape saying the company had worked to strip climate measures out of the infrastructure bill. “**We will vote against a budget resolution** if the infrastructure package isn’t brought up first,” Democratic **Rep**. Josh **Gottheimer** **told** the Washington Post this weekend, **though** the American Prospect reported on Sunday that “**several**” of the **legislators** now **indicated they could back down**. **In the narrowly divided House**, **obstructionism from these** conservative Democrats **could decouple the infrastructure** and budget **measures** from one another. Many believe that would kill the latter by letting conservative Democrats in the Senate such as Kyrsten Sinema (D-Ariz.) and Joe Manchin (D-W.Va.) get the infrastructure bill they want without having to provide the votes necessary to enact the much larger and more progressive budget measure. “If we were to pass the bipartisan [infrastructure] bill first, then we lose leverage,” Democratic Rep. Ritchie Torres (NY) told the Wall Street Journal. Along with Gottheimer, the eight other Democrats who have threatened to obstruct the budget bill are Carolyn Bordeaux (Ga.), Ed Case (Hawaii), Jim Costa (Calif.), Henry Cuellar (Texas), Jared Golden (Maine), Vicente Gonzalez (Texas), Kurt Schrader (Ore.), and Filemon Vela (TX). The U.S. Chamber of Commerce — Washington’s most powerful corporate lobby group — has been airing digital ads thanking the nine Democrats for their maneuvers. Eight of the nine Democrats represent congressional districts won by President Joe Biden, who supports the reconciliation package. Big Pharma’s Big Allies The reconciliation bill is still being negotiated, and many Democratic lawmakers — including those in key swing districts — are pushing for it to include long-promised legislation to allow Medicare to use its enormous purchasing power to negotiate lower prices for prescription drugs. The **pharmaceutical industry** has **aggressively lobbied against the initiative**, which the Congressional Budget Office has estimated would save Medicare $345 billion in medicine costs. The nine House Democrats threatening to derail the reconciliation bill have raked in nearly $1.2 million from donors in the pharmaceutical and health products industries, according to data compiled by OpenSecrets. Among them are two of the Democratic Party’s **top recipients of health care industry money**: **Gottheimer** ($228,186) **and Schrader** ($614,830). Schrader’s third biggest career donor is Pfizer’s political action committee, and his former chief of staff is now a registered lobbyist for the Pharmaceutical Researchers and Manufacturers Association, the pharmaceutical industry’s main lobbying group. Both Gottheimer and Schrader signed a letter earlier this year slamming Democratic leaders’ legislation to lower prescription drug prices. Eight out of the nine Democrats threatening to kill the budget bill also declined to sponsor Democrats’ standalone legislation to let Medicare negotiate lower drug prices. In the Senate, Sinema’s renewed threat to vote down a final reconciliation bill came after she received $519,000 from donors in the pharmaceutical and health products industries.

#### Infrastructure solves existential climate change – spill-over.

USA Today 7-20 [7-20-2021 "Climate change is at 'code red' status for the planet, and inaction is no longer an option". Editorial Board @ USA Today. Accessed 8/30/21. <https://www.usatoday.com/story/opinion/todaysdebate/2021/07/20/climate-change-biden-infrastructure-bill-good-start/7877118002/> //Recut Xu from Elmer]

Not long ago, climate change for many Americans was like a distant bell. News of starving polar bears or melting glaciers was tragic and disturbing, but other worldly. Not any more. Top climate scientists from around the world warned of a "code red for humanity" in a report issued Monday that says severe, human-caused global warming is become unassailable. Proof of the findings by the United Nations' Intergovernmental Panel on Climate Change is a now a factor of daily life. Due to intense heat waves and drought, 107 wildfires – including the largest ever in California – are now raging across the West, consuming 2.3 million acres. Earlier this summer, hundreds of people died in unprecedented triple-digit heat in Oregon, Washington and western Canada, when a "heat dome" of enormous proportions settled over the region for days. Some victims brought by stretcher into crowded hospital wards had body temperatures so high, their nervous systems had shut down. People collapsed trying to make their way to cooling shelters. Heat-trapping greenhouse gases Scientists say the event was almost certainly made worse and more intransigent by human-caused climate change. They attribute it to a combination of warming Arctic temperatures and a growing accumulation of heat-trapping greenhouse gases caused by the burning of fossil fuels. The consequences of what mankind has done to the atmosphere are now inescapable. Periods of extreme heat are projected to double in the lower 48 states by 2100. Heat deaths are far outpacing every other form of weather killer in a 30-year average. A persistent megadrought in America's West continues to create tinder-dry conditions that augur another devastating wildfire season. And scientists say warming oceans are fueling ever more powerful storms, evidenced by Elsa and the early arrival of hurricane season this year. Increasingly severe weather is causing an estimated $100 billion in damage to the United States every year. "It is honestly surreal to see your projections manifesting themselves in real time, with all the suffering that accompanies them. It is heartbreaking," said climate scientist Katharine Hayhoe. Rising seas from global warming Investigators are still trying to determine what led to the collapse of a Miami-area condominium that left more than 100 dead or missing. But one concerning factor is the corrosive effect on reinforced steel structures of encroaching saltwater, made worse in Florida by a foot of rising seas from global warming since the 1900s. The clock is ticking for planet Earth. While the U.N. report concludes some level of severe climate change is now unavoidable, there is still a window of time when far more catastrophic events can be mitigated. But mankind must act soon to curb the release of heat-trapping gases. Global temperature has risen nearly 2 degrees Fahrenheit since the pre-industrial era of the late 19th century. Scientists warn that in a decade, it could surpass a 2.7-degree increase. That's enough warming to cause catastrophic climate changes. After a brief decline in global greenhouse gas emissions during the pandemic, pollution is on the rise. Years that could have been devoted to addressing the crisis were wasted during a feckless period of inaction by the Trump administration. Congress must act Joe Biden won the presidency promising broad new policies to cut America's greenhouse gas emissions. But Congress needs to act on those ideas this year. Democrats cannot risk losing narrow control of one or both chambers of Congress in the 2022 elections to a Republican Party too long resistant to meaningful action on the climate. So what's at issue? A trillion dollar infrastructure bill negotiated between Biden and a group of centrist senators (including 10 Republicans) is a start. In addition to repairing bridges, roads and rails, it would improve access by the nation's power infrastructure to renewable energy sources, cap millions of abandoned oil and gas wells spewing greenhouse gases, and harden structures against climate change. It also offers tax credits for the purchase of electric vehicles and funds the construction of charging stations. (The nation's largest source of climate pollution are gas-powered vehicles.) Senate approval could come very soon. Much more is needed if the nation is going to reach Biden's necessary goal of cutting U.S. climate pollution in half from 2005 levels by 2030. His ideas worth considering include a federal clean electricity standard for utilities, federal investments and tax credits to promote renewable energy, and tens of billions of dollars in clean energy research and development, including into ways of extracting greenhouse gases from the skies. Another idea worth considering is a fully refundable carbon tax. The vehicle for these additional proposals would be a second infrastructure bill. And if Republicans balk at the cost of such vital investment, Biden is rightly proposing to pass this package through a process known as budget reconciliation, which allows bills to clear the Senate with a simple majority vote. These are drastic legislative steps. But drastic times call for them. And when Biden attends a U.N. climate conference in November, he can use American progress on climate change as a mean of persuading others to follow our lead. Further delay is not an option.

### 4

#### Coercive power relations have shifted from the local to the global creating biodiplomacy which facilitates liberal expansion and development.

Constantinou and Opondo 15, Constantinou, Costas M., and Sam Okoth Opondo. "Engaging the ‘ungoverned’: The merging of diplomacy, defence and development." Cooperation and Conflict 51.3 (2016): 307-324. (Professor of International Relations @ University of Cyprus, Sam Okoth Opondo, Professor of Political Science and Africana Studies)//Elmer

Ultimately, this military-diplomatic apparatus presents something more than a state’s or empire’s attempt to ‘enhance its value’ at the periphery of the international system. By **managing** poverty and scarcity and supporting ‘good’ **living conditions around the globe**, the apparatus **maintains** old and extends new ‘**relations of subjection’** and governance while creating new sites of diplomatic engagement that exceed the governmental domain (Mbembe, 2001: 24). Connecting domains of administration and negotiation, but also violence and multiple attempts to curtail it, the apparatus is part of a milieu in which governmental and diplomatic practices are synergized and instituted. Beyond its strategic concern with the optimization of lives and livelihoods, the **entanglement of governmental** **and diplomatic** conduct **registers**, we believe, **an ontological shift from biopolitics to biodiplomacy**. Emerging from the liberal will to self-regulation and governance and specifically addressing the politics of life, biopolitics, Michel Foucault tells us, involves ‘control over relations between the human race, or human beings insofar as they are a species, insofar as they are living beings, and their environment, the milieu in which they live’ (Foucault, 2003: 245). Going beyond the juridical conception of sovereignty and law enforcement, **biopolitics concentrates on** the **management of populations through** the **production of knowledge** about life and ways of living, as well as the enhancement of methods of supporting and controlling them. Unlike juridical sovereignty, which was predominantly defined by the right of rulers to ‘take life and let live’, biopolitics follows a governmental logic of ‘**making live and letting die’** (Foucault, 2003: 247). Whereas biopolitics has expanded its reach and deepened its governmental methods to multiple domains around the globe – not only enhancing conditions of living but also determining who is made to live and who is let to die – biodiplomacy underscores the continuous **negotiation of life** that **accompanies** this **global expansion** and that has brought **shifts in** **strategies of control**, discourses of legitimation and forms of co-optation and cohabitation beyond governance. We have examined the theoretical and ethical ramifications of biodiplomacy in more detail in a separate paper (Constantinou and Opondo, 2014). The focus on biodiplomacy provokes us to ask if there is something more going on beyond ‘liberal governance’, the ‘liberal way of war’ or the ‘**merging of security with development’**. Specifically it allows us to inquire how groups, like the Jeldessa villagers or other groups who are acted upon by the powerful, play out their agency and the forms of diplomacy that enable them to do so. Do they create new diplomacies as they enact their lives in the spaces and times where biopolitical regimes operate? Or is the biopolitical formation creating new forms of diplomatic subjects? Posing the question not only of biopolitics but of biodiplomacy makes it possible for us to seriously think how lives and worlds are not just ‘governed’ but ‘negotiated’, how certain lives and worlds become plausible, and others implausible, and this not through centralized command, control and exercise of power. To be sure, biodiplomacy does not ensure symmetrical negotiation, particularly where the USA is involved. Over the last 10 years, the cultivation of outreach and the exploitation of new civilian partnerships have been keenly pursued through the US Transformational Diplomacy initiative, extending operations beyond the traditional centres of power and intergovernmental relationships. For instance, a plethora of projects have been promoted under the auspices of US Africa Command (AFRICOM) in a manner that exemplifies both the biopolitical and biodiplomatic dimensions of the military-diplomatic apparatus. Such projects are sometimes frank and cynical about their goal. VETCAP, for example, currently operates in Djibouti, Ethiopia, Kenya, Morocco, Tanzania and Uganda and aims to ‘deliver veterinary programs in support of strategic military objectives’.3 Although there is no public explanation as to what the specific strategic military objectives are in each country and how they are linked to the vaccination of livestock, the engagements are indicative of the new civilian partnerships that the US Defense and State Departments are developing worldwide as well as of what has been termed as the merging of diplomacy, defence and development (3D) – the ‘three pillars’ of US foreign policy in the post-9/11 era. In short, there is a clear policy reorientation towards supporting ‘foreign’ life that is openly admitted and promoted, but whose global implications and replications are yet to be fully understood.

#### Medicine is the next tool of colonization by glorifying western medical advancement in contrast to the “backwards” third word – saving everything paradoxically results in the elimination of the very lives they seek to preserve.

Yau 7, Wing-kit. "Representing illness: patients, monsters, andmicrobes." HKU Theses Online (HKUTO) (2007). (Medical Graduate Student at Hong Kong University)//Elmer

History shows that political and economic colonialism that took over geographical area can be justified with a utopian vision, and the modernisation that follows eventually improve the standard of the colonised up to that of the coloniser. **Medical colonisation**, in the same vein, can also be considered as **a humanitarian endeavour**. Western medicine ‘**colonises’** the **field of medicine**, **taking over traditional** and other indigenous medical **practices** **and render them** as ‘**unscientific’** and ‘superstitious’ while celebrating the achievement of scientific method that is the basis for our bio-medical culture as the real life savour. 91 Fortunately or unfortunately, Frank believes this period of medical colonisation has probably ended. He regards this new era medical post-colonisation when political issues and national security are now closely allied and fusing with the medical curriculum, further **alienating** the **patients** and turning the city space into a space of thoroughly-sanitised, isolating environs. It also means that in medical post-colonisation, the meaning of public health is now synonymous with global health. Under this new name, its area of administration reaches beyond the microscopic world of biological border-crossing virus and germs to the border-crossing people and other political agenda as well. Different from other diseases, infectious disease does not confine itself to a particular stigmatisable population. Take SARS for example, it is quite different from other re-emerging diseases that are, to this date, still a regional plague limited to third-world countries (where medical facilities are inadequate and people are living under deprived conditions). The primary risk group during the outbreak in Hong Kong, however, is not the stigmatised ‘other’ – typically the poor or the under-privileged class, but the medical workers in hospitals – who are usually esteemed as professionals and from a prestigious group in our society even today. Christine Loh sums up the impact of SARS and the fusing of medicine with politics in the following way: Events happened quickly. Healthcare professionals had to face enormous personal risks in fighting the disease on the frontline […] Need has been the mother of a number of useful inventions, such as the contact tracing system developed in Hong Kong. SARS also touched almost every other aspect of personal and community life in affected areas [including Toronto, Singapore and Taiwan]. Ministers and officials lost their jobs. Many businesses suffered. Ordinary people were forced to reassess their priorities. Communities had to find useful ways of coping with panic while continuing to fight the disease.92 Paul Virilio has already warned us that the fear of contamination by a viral agent is not, and should not be the sole object of horror in this day and age, but the fear of extinguishments engendered by the hyperfragility of the technological process of our society.93 Although infectious disease is only a viral contamination, and it is by no means comparable to the kind of weapon that is designed to function as another network to cause a wide-spread breakdown of our existing life-dependent networks (such as power supplies), Peter Chan’s Memory has shown how this fear of risk has undergone a series of re-configuration, from being contaminated by the foreign invasion of a virus, to the fear of isolation and incommunicability. Perhaps it is helpful to compare this change of our subject of anxiety in terms of the colonial-era ideologies of medicine and post-colonial ideologies of global health, as there is increasing emphasis on information and commodity exchange networks intertwining with space and territoriality, as Nicholas B King puts it: While colonial anxiety revolved around fears of contamination as certain (white, European, male) bodies moved into vulnerable places and faced novel contaminating environments and (non-white, non-European, female) peoples, postcolonial anxiety revolves around the contamination of space itself by mobile bodies and motile environments. This is not the horror of matter (or bodies) out of place, which presupposed the identification of a place for matter; instead, it is the horror of places no longer mattering, of a ‘third-worlding’ at home.94 The horror in Memory is not the ghostly figure played by Tony Leung. It is true that while he is wandering and happens to see the masked Eugenia Yuan sitting by herself staring out of a café’s window, there is a brief moment of tacit recognition, or as another film critic remarks, it is a moment when Leung and the Yuan (who plays a ghostly figure in another Peter Chan’s film Going Home) meets and it dawns on the audience that Leung, too, is a ghost.95 Nonetheless, the ‘ghosts’ here are just as powerless as the imprisoned people in the building in the sick, infected city. They no more understand the snow in Hong Kong, nor the hearses that are passing by than we do. That is to say, they are not from another world different to ours. The real horror comes from the uniqueness of SARS and the new realisation that it came with – not only does it mean that **biomedicine is no longer the guarantee for health**, but it also paints a grimmer picture of reality that says this new epidemic cannot be reduced to just another ‘difficult time’ for the local people to overcome, and that it, like so many adversities in the past decades, can be overcome. That explains why critics of the 1:99 Short Film Series have been negative, mostly toward the films’ focus on the disease as an ‘adversary’ that Hong Kong people are facing collectively rather than treating SARS as a unique, (un)timely disease.96 In Hong Kong is the Best (Dir. Alan Mak Siu-Fai, Andrew Lau Wai-Keung), for example, SARS is even treated as an equivalent to other pandemics/disasters in the past, as if the disease were just another difficult time that the locals can, and will go through collectively, that what it causes (the other) will not destroy us (the self) because, as the title suggests, Hong Kong is the best. Memory addresses the post-SARS trauma by showing how the disease has caught Hong Kong people getting weary of human-to-human contact – everyone is imprisoned in the round windows in solitude, expressionless and masked. These people have been through mass anxiety and paranoia about the disease, and panic over being infected with the virus, which, like the rest of the influenza viral strain, is still not preventable. In Hystories, Elaine Showalter remarks that mass hysteria usually takes place within a community, especially a tight-knit one like that of Hong Kong, where rumours can develop with the social network to sustain it.97 In the example of SARS, there was once a time when rumour first hit the locals that a mysterious flu has killed people in Guangzhou. And the locals were seen as reacting with irrational fear by stocking up white vinegar98 and the market also reacted by increasing the prices of all kinds of disinfectants, such as Clorox, Dettol and even masks. Interestingly, such mass hysteria did not last long. As masks are being discarded, fear is also being forgotten. Our memories do not seem to hold on for long to our previous experience and soon drifts into oblivion before it disappears completely. As a result, the epidemic itself never plays a major role in shaping the Hong Kong society, and there leaves very little room for artistic production in response to its devastating period of outbreak.99 [cont.] It has become increasingly clear that health and the proper management of illness (especially of infectious diseases) are now individual moral responsibilities in real life. Individuals (lay people) are expected to have improved assess to (medical) knowledge through popular science and mass media that would enable them to better self-surveillance, risk assessment, and ultimately, prevention. In the meantime, we have what Adele E. Clarke et al. calls the ‘biomedicalisation’ process that, ‘through the complex, multisided, multidirectional process of medicalisation and application of technoscience,’ has given us both new individual and collective identities according to our ‘risk status’, DNA profiles, or whether we are ‘Syndrome X sufferers,’ etc.106 Interestingly, if medicalisation is a process in which ‘unwanted’ social phenomenon or behaviours are passed from the jurisdiction of law to that of medicine, (e.g. branding/classifying someone as sick just because (s)he does not fit the social norm, and thereby treating it as an illness and disease), then biomedicalisation can be understood as a process that medicalises health (e.g. classifying somebody as belonging to a ‘high-risk’ group based on lifestyle and genetic make-up or even social class, and treating it as a cause of illness and disease). Disease used to be conceptualised at the level of organs and cells, so that when there is a disease in the heart or the liver, we are simply known as the heart disease patient, or liver disease patient, etc. However, today’s risks and **diseases are** conceptualised at the level of genes and molecules, which are the **codes from which our biological identity is constituted**. As noted by Clarke et al., **health policy is no longer about problem-solving** (i.e., patients visits the physicians with a physical symptoms, with clear test results and unambiguous diagnosis, followed by treatment that cures the disease by removing the symptoms) **but** more about **problem finding** (i.e. patients are tested and classified by risks, for instance, high cholesterol, too skinny, too fat, etc).107 In other words, physical condition becomes a disease to be treated. Thus, it is not difficult to see that selling disease and commodifying health are basically two sides of the same coin. Therefore, the notion of ‘safe space’ in terms of our understanding of Carol’s environmental illness becomes an encapsulation of what biomedicine (and even environmentalists and alternative medicine) are preoccupied with today – that of bodies and space. Peter Donning, the Wrenwood guru, in his welcoming speech to the new ‘long-timers’, made the following statements: ‘what you’re seeing outside is a reflection of what you feel from within,’ and, ‘I’ve stopped reading the papers. I’ve stopped watching the news on TV…I’ve seen their fatalistic, negative attitude and I’ve finally realised once and for all, I don’t need it. So I transform that negative stimulus into something that will not do harm to me.’ The sole reason why Donning calls Wrenwood an ‘environmentally safe place’ is due to his belief that how he feels in his head can directly or indirectly influence his organs (especially his immune system) to behave in a certain way. In other words, within this space, safety is ensured – it is only you and your thinking that is hazardous to your health. Once again, it shows that the spaces and the bodies that inhabit or travel within these spaces have become the primary concern for health maintenance. Film critics like Roddy Reid remarks that Safe is about the experience of our bodies understood as sites of struggle between medical discourses, health-care practices, pathogens, and visual inscriptions108. It is a struggle because we are most disturbed by the opacity of the environment and the ‘unfathomable mystery’ of the body. With the body and the surrounding disappearing into the internal psychological space, one’s past and history have become an alternative form of toxin where repressed dark memories are dug up and turned into an enemy. With new enemy, de-toxification can then begin in yet another form of speech to cleanse the body ‘system’ in the name of ‘self-love.’ However, such promise of speech and self-knowledge is just as groundless as the belief that a fruit diet Carol is on can cleanse the body of the toxins one cannot avoid taking in everyday. The more transparent our body and space is, the easier for surveillance, so that barriers can be set; risks can be assessed. **We are**, in effect, **living as the Boy in the Bubble**, or in Jean Baudrillard’s own words, it is ‘a transparent envelope in which we have taken refuge and where we remain, bereft of everything yet overprotected, **doomed to artificial immunity**, continual transfusions and, at the slightest contact with the world outside, instant death.’109 As a result, the proliferating health product and alternative treatment, in cooperation with the transnational pharmaceutical industry, has now made even high-cholesterol and osteoporosis a disease. Consequently, we are self-conscious of the level of cholesterol in what we eat; the level of pollutants in the air we breathe and the water we drink. But how much transparency is transparent enough? In order to see and know what is doing harm to our bodies, we are **obsessed with information**, and one of the examples would be labels on food packages. Borrowing again from Baudrillard’s idea of ‘absolute communication’ in which the ultra-rapid circulation of signs is operating so fast for the sole reason that it never passes via the mediation of meaning, we may also understand body and health as contaminated by the same sign-circulation process: meat is bad, vegetables are good; city air is polluted, country air is more healthy. The **transparency** of food products **makes us feel safe**, at the same time such transparency corresponds to the pervasiveness of our body which made us believe that we are vulnerable to the invisible killers such as germs, chemical compounds and smoke, and that makes us ‘un-safe’. This conflict illustrates nicely the paradox of the Freudian pleasure principle, which Slavoj Zizek sarcastically remarks: You have a society which is ostensibly oriented toward pure pleasure, but you pay for it through a whole series of "you can't." The hidden prohibitions: eat whatever you want, but beware of fat and cholesterol; smoke, but beware of nicotine; sex, but safe sex. Yet the ultimate consequence of this pleasure principle is that **everything is prohibited** in a way; you can't smoke: there's nicotine; you can't eat: there's fat; you can't have sex: you'll get sick. So this is a kind of everyday confirmation of the Lacanian paradox.111 These are all telling us that nothing is safe. At first glance, it is no wonder why the Wrenwood Centre is a ‘perfect safe space’ – it is toxin-free: no exhaust, no aerosol, no fumes – our desire for transparency has landed us into a vacuum that is also known as a sanatorium. There is finally no prohibition – because it is ubiquitous, it seems like safety is found in this nostalgia afforded by this pre-modern space. However, after all external aggressions are eliminated by a place like Wrenwood; the body has become the Other and become its own internal virulence: Carol’s reaction appears to have been alleviated at Wrenwood but she is becoming more visibly sick as evidenced by her lesions and swollen eyes. In the final scene, Carol succumbs to Wrenwood’s preaching about self-love, and starts to practise saying ‘I love you’ in front of the mirror. However, there is no reconciliation between the utterance and the mirrored image,112 instead, it is more like one more letting down by speech and knowledge, uncovering the same emptiness within the inner psychic realm in which she attempts to create protection. Her facial expression remains bland and vacuous, and all we can see is the Carol that is metamorphosing into ‘the other.’ The sentence ‘I love you’ carries no weight in it because what is there to refer to in a vacuum that is now within and around her? She has not yet become the ‘other’ but we do not have the chance to see this metamorphoses completed as the film ends with a black-out, leaving us in this permanent stage of disease with Carol and with her image in the mirror. Medical sociologist Deborah Lupton argues that due to our dependence on rationality and individualism which is the legacy of Western societies ever since the Enlightenment, together with “**the turn to biomedicine** and science **as** the ultimate **weapons** **against** illness, **disease** and premature death have **generated** **discourses** and practices **which** tend to **deny the fragility** and mortality **of the human body**.”113 But are we really as innately fragile as we think we are? In our attempt to create a safe environment, we are setting up more and more barriers against risks such as toxins and pollutants that are the natural basis of the industrial, modernised society. Yet at the same time, we are **letting our bodies** become **increasingly vulnerable** because bodies are, too, a transparent, porous entity. In such transparent space where everything is made visible, and our visual world has required us to by-pass the mediation of consciousness and meaning, disease soon becomes the only escape(ade) for us to let our natural defence system, i.e. our antibodies, fight against virulence, the same way Carol runs away from her well-protected middle class home in a Californian suburban valley to find salvation in a sanatorium in a New Mexican desert – an excursion on Carol’s part that she is actively doing something about her unknown, undetermined illness . However, there is no escape; just as there is no outside to our environment, nor is there an alternative outside to the existing system into which we can adventure. Outside the Bubble means instant death, thus, there can only be Bubble after Bubble. The same goes for the audience, if watching Safe is a process of immersing ourselves into a world of unknown, unforeseeable environmental risks, a threatened sense of safety and partial knowledge, we are also destined to reach a vacuum with Carol where every last bit of materiality in our environmental space is made to disappear (through speech and discourse on risk and surveillance) into a vacuum where there is no more ‘other’. Disease becomes dis-ease when there are no longer any barriers to put up against anything except the vacuous self that can only be pacified by a self-resistance against an imagined ‘other’114. However, we should also take into consideration the fact that the (female, suffering) body is not just an abstracted object belonging always to someone else, which means also the clinical gaze. The body is also what phenomenologist Vivian Sobchack so forcefully argues, in her collection of essays on the body and illness entitled Carnal Thoughts, that it is also a lived body as ‘objective subject’ and the ‘subjective object,’ with materialised capacities and the agency to make sense of, to feel, both ourselves and the others. She also points out that embodiment is never ‘a priori to historical and cultural existence.’115 Sobchack’s perspective on the lived body shows that suffering is part of our capacities to make sense of, and to feel the body, and therefore, should be taken as a part of life, but it is also something that high technological intervention and our expanding scientific knowledge base would like to deny. What we subsequently have is what Arthur Kleinman calls ‘the facile expectations that psychotherapy and psychopharmacology can relieve residual pain and suffering. In this respect, the culture of biomedicine, which does not value the core illness experience at the same level as the diagnosis and treatment of disease pathology, conspires with the popular culture to treat death as the enemy’ especially for the chronically ill and people suffering from cancer. In Medicine as Culture, Lupton draws from the way medicine is experienced, perceived and socially constructed to provide different theoretical perspectives on the socio-cultural dimension of medicine, illness, and the body. She comments that scientific medicine is merely disillusionment. According to her, ‘the construction of the medical practitioner as omnipotent inevitably leads to disappointment and disillusionment when things go wrong […] there are few explanations that can provide meaning to the [unexpected happenings].’117 Part of the disillusionment also comes from our increasing dependence upon biomedicine (the use of biotechnologies, geneticization, nanoscience, genetic engineering, etc), and we respond by idealizing the physicians as the final saviour.118 While diseases like cancer and chronic illness are today’s worst fear among the ageing population, Jean Baudrillard finds **medicine the real culprit for** the cause of their **incurability**, as he tells us: ‘[**medicine**] **treats cancer or AIDS** **as** if they were **conventional** illnesses, **when** in fact **they are** illnesses **generated by** the **very success of** prophylaxis and **medicine**, illnesses bred of the disappearance of illnesses, of elimination of pathogenic forms.’119 By conventional illness, it means the kind of illness that is believed to be caused by pathogens-bacteria or biochemical imbalance; its symptoms are common enough to be dealt with by conventional treatments – ones that are done by scientific tests for diagnosis and medications and surgery are the key methods of treatment. The problem with treating ‘unconventional’ illnesses the ‘conventional’ way is that when you have somebody like Safe’s Carol in the Safe Room, it is simply denying her physical experience and regarding her as an object – by placing it somewhere safe in the hope that it can become well again through regular monitoring and examination, and elimination of all other invading pathogenic forms. However, environmental illness is not like tuberculosis or liver disease, where the patient can travel to a mountainous area to breathe cleaner air to relieve his/her symptoms, or to have a liver transplant to replace the ailing one. Patients with a disease of an organ can seek help externally, for example, by changing one’s living environment or eating habits, or even taking medicine in order to heal; or in some cases, have the organ replaced or removed surgically, as in the case of cancer. Environmental illness, on the other hand, is not a disease of the organ. It affects the organs but it is not organ-specific. One cannot say that it is the organ that has failed so that there are symptoms, rather, it is something that has gone wrong with the body’s system and it is manifested through the body symptomatically. Environmental illness cannot look to the external for help, for it is not a conventional, scientifically defined disease by traditional Western medicine. This makes way for an easy shift of focus from the body to the soul, especially when the disease is believed to be caused by the mind, or ‘psychological weaknesses’ – the way we tend to explain and understand Carol’s sickness. The idea of the shift from the suffering of the body to the suffering of the mind resonates with the classical study of punishment and the prisoner’s body in Foucault’s Discipline and Punish. During the 18th century when La Mettrie first published Man the Machine, the human body was understood as the materialist reduction of the soul and there was an emphasis of the body as ‘docile’, as Foucault himself writes after La Metrrie: ‘The classical age discovered the body as object and target of power. It is easy enough to find signs of the attention then paid to the body – to the body that is manipulated, shaped, trained, which obeys, responds, becomes skilful and increases its forces.’120 Because of the need to exert control and power over the people that are being governed ‘without the slightest detail escaping [Napoleon’s] attention’, rigorous discipline had to be imposed under his reign, and from here on, Foucault believes that discipline has to proceed from the ‘distribution of individuals in space’, as he explains: ‘Discipline sometimes requires enclosure, the specification of a place heterogeneous to all others and closed in upon itself. It is the protected place of disciplinary monotony.’ 121 Let us now perceive the environment as such a ‘disciplinary space.’

#### Liberal Governance produces Endless War through a biopolitics of security that culminates in extinction.

Evans 16, Brad. "Liberal Violence: From the Benjaminian Divine to the Angels of History." Theory & Event 19.1 (2016). (a senior lecturer in international relations at the School of Sociology, Politics & International Studies)//Elmer

Liberal War as Divine Violence Despite universal claims to peaceful co-habitation, **liberal regimes** have been compelled to **make war on whatever threatens it** 40 . This is why the liberal account of freedom has depended upon a lethal principle, which discursively **wrapped in** the **language of** rights, **security** and justice, inaugurated planetary state of warfare and siege. It has promoted an account of freedom that, in the process of taking hold of the problem of the planetary life of political subjects, linked human potentiality to the possibility of its ruination. If liberal violence has then produced a necessary lethal corollary in its mission to foster the peace and prosperity of the species in order to alleviate unnecessary suffering; so it has also needed to foster a belief in the necessity of violence in the name of that suffering and vulnerability to which it continually stakes a claim. The Liberal wars of the past two decades in particular have revealed a number of defining principles41 . Aside from relying upon technological supremacy and universal claims to truth, they have been overwhelmingly **driven by** a **bio-political imperative**, which has displaced concerns with Sovereign integrities with forms of violence carried out **in the name of an endangered humanity**. In this regard, they have destroyed the Westphalia pretence, seeing the catastrophes of our global age in fact as a condition of possibility to further the liberal will to rule. Since incorporation in this setting has proceed on the basis that all life should necessarily be included within its strategic orbit, the veritable evisceration of any sense of “the outside” (as conceived in terms of its political imaginary) has led to the **blurring of all** conventional **demarcations** between friends/enemies, citizens/soldiers, times of war/times of peace. What is more, as life itself became increasingly central to questions of security, issues of development as broadly conceived would no longer be regarded as peripheral to the war effort. It would in fact become a central motif as most notably articulated in the strategic mantras “War by Other means” and “War for Hearts and Minds”. Not only would this point to new forms of de-politicisation which, less about Schmittean exceptionalism, were more explicable in terms of the fundamental political and social transformation of societies. It would also lead to the production of violent subjects, as the recourse to violence became sure testament to a conception of humanity realised through the wars fought in its name. **Liberal violence**, in other words, proved to be **unbounded**, **unlimited** and without conventional Sovereign warrant – namely revealing of the fundamental principles of what Benjamin once elected to term “the divine”. Diagnosing the liberal wars of the past two decades as a form of divine violence offers a more disturbing reading of the violence of the liberal encounter. If the violence of political realism, at least in theory, appreciated the value of limits and boundaries, what seems to define the lethality of liberal freedom has been a commitment to war without boundaries, hence limitless. As Dillon and Julian Reid acutely observed: [L]iberal peacemaking is lethal. Its violence a necessary corollary of the aporetic character of its mission to foster the peace and prosperity of the species ... There is, then, a martial face to liberal peace. The liberal way of rule is contoured by the liberal way of war ... Liberalism is therefore **obliged to** **exercise** **a** **strategic calculus of necessary killing**, in the course of which calculus ought to be able to say how much killing is enough... [However] it has no better way of saying how much killing is enough, once it starts killing to make life live, than does the geopolitical strategic calculus of necessary killing’42 . This brings us to Steven Pinker’s Better Angels of Our Nature43 . Reworking the well-rehearsed liberal peace thesis, for Pinker, the reason we have become less warlike today can be account for in terms of our liberal maturity. Leaving aside the evident theological undertones to Pinker’s work, along with the numerous empirical flaws in his thesis, his not so original thesis at least accredits its all too Euro-centric sources of inspiration on matters of civility: ‘The reason so many violent institutions succumbed within so short a span of time was that the arguments that slew them belong to a coherent philosophy that emerged during the Age of Reason and the Enlightenment. The ideas of thinkers like Hobbes, Spinoza, Descartes, Locke, David Hume, Mary Astell, Kant, Beccaria, Smith, Mary Wollstonecraft, Madison, Jefferson, Hamilton and John Stuart Mill coalesced into a worldview that we can call Enlightenment humanism’. John Gray has been rightly suspicious of the entire project and claims being made here: The idea that a new world can be constructed through the rational application of force is peculiarly modern, animating ideas of revolutionary war and pedagogic terror that feature in an influential tradition of radical Enlightenment thinking. Downplaying this tradition is extremely important for Pinker. Along with liberal humanists everywhere, he regards the core of the Enlightenment as a commitment to rationality. The fact that prominent Enlightenment figures have favoured violence as an instrument of social transformation is—to put it mildly—inconvenient... No doubt we have become less violent in some ways. But it is easy for liberal humanists to pass over the respects in which civilisation has retreated. Pinker is no exception. Just as he writes off mass killing in developing countries as evidence of backwardness without enquiring whether it might be linked in some way to peace in the developed world, he celebrates “re-civilisation”... without much concern for those who pay the price of the re-civilising process44 . Gray showed his evident concerns here with the promissory nature of liberal violence. Indeed, what he elsewhere terms the violence of the liberal missionary, reposes Nietzsche’s further instance that ‘god is dead and man has killed him’ with a devastating humanistic critique45 . Such violence, in the end, however has proved to be politically, ethically and economically narcissistic. Just as liberal advocates in the zones of crises now increasingly find themselves operating within fortified protectorates as part of a great separation from the world46 , this has been matched, albeit it ways that initially appear disconnected, by new forms of violence which also takes place almost exclusively at a distance. Indeed, as liberal actors increasingly give up on the idea that the world may be transformed for the better, new modalities of violence are emerging which seem to be more logically in fitting with the new politics of catastrophe that increasingly defines our terrifyingly normal times. As the promise of violence and catastrophe now appears inescapable, **insecurity** is becoming **normalised**, dystopian realism becoming the prevailing imaginaries for political rule, and once cited claims to emancipation, unending progress and lasting security for peoples all but abandoned47 . The politics of catastrophe and its relationship to “end of times” narratives adds another layer to our theological enquiry. As Jacob Taubes once noted48 , there is perhaps something theologically different at work here between the pre-modern apocalyptic movements and the catastrophic reasoning now defining the contemporary moment. For all their nihilism and monotheistic servitude, at least the apocalyptic movements of yesteryear could imagine a better world than already existed. There is therefore a vast difference between the subjects which names its disaster ‘apocalypse’ to that which reads disaster in terms of ‘catastrophe.’49 Unlike apocalypse, there is no beyond the catastrophic. Its mediation on the “end of times” is already fated. Catastrophe denies political transformation. It demands instead a forced partaking in a world that is deemed to be insecure unto the end. The upshot being, as all things become the source of endangerment, the human becomes the source of our veritable undoing. Angels of History Every war produces its casualties. Some of these stand out in terms of the sheer body count. The horror of mass warfare reduced to the most banal forms of inhuman quantification. Others, no less important, are its political and philosophical losses. What is increasingly clear is that the past two decades of liberal warfare, punctured but not initially determined by the tragedy of the events of September 11th 2001, ultimately put the very concept of war into question. The reluctance to officially declare war, even when our involvement in the politically motivated violence appears to be all too evident, now demands a move beyond the dominant frames which have shaped discussions for the past two decades. There is an important caveat to address here. What happened during last decade of the Global Wars on Terror cannot simply be inserted into a post 9/11 frames for analysis. Much of what passed for post 9/11 justice or military excessiveness was slowly maturing in the global borderlands for some considerable time. If there is a departure it needs to be accounted for against this broader post-Cold War humanitarian sensibility through which liberalism absorbed local crises into its political fabric to further condition its violent interventions. It has been all too easy for political and social theorists to put the blame for the violence and atrocities of the Global Wars on Terror onto the shoulders of George Bush and Dick Cheney. This has allowed liberals to appropriate Schmitt as one of their own, hence reducing the entire war effort to the reductionist measures of “US hegemony/exceptionalism”. Such retreats back into state centric models have not only proved unhelpful in terms of questioning the normalization of violence, they have failed to grasp the complexity of war – especially how questions of universality, economy, power and the formation of political subjectivities can be rethought through violent encounters. What is more, the limits of these analyses have been further evidenced by the complete lack of engagement with political theology, failing to recognize the violence of universal ambitions, along with the need to put the contemporary legacy of Kant on trial. Let us not forget Tony Blair and Barack Obama have embodied the liberal Kantian idea of political leadership better than any others throughout the history of liberalism. Any change in liberal fortunes must be understood in this context. We have witnessed in recent times profound changes in the violent cartography of what is a post-Iraq liberal influence. Instead of actively and one-sidedly engaging the world, humanely, violently or otherwise, what we are now encountering are new political arrangements shaped by forms of distancing and technological realignment. Just as liberal agents in the dangerous borderland areas increasingly find themselves operating within fortified protectorates as part of a great separation from the world, this is matched, albeit it ways that initially appear disconnected, by new forms of violence that also take place at a distance. The political and philosophical significance of this should not be underestimated. The technological and strategic confluence between the remote management of populations (notably surveillance) and new forms of violence are indicative of the narcissism of a liberal project that reeks of the worst excesses of technological determinism. Instead of looking with confidence towards a post-liberal commitment to transforming the living conditions of the world of peoples, what has taken its place is an intellectually barren landscape offering no alternative other than to live out our catastrophically fated existence. This is instructive regarding how we might envisage “the end of liberal times” as marked out and defined by this incommensurable sense of planetary siege. It also demands new thinking about the relationship between violence, technology and theology in these uncertain times. The **liberal wars** of the past decade have been **premised on** two notable claims to superiority. The first was premised on the logic of technology where it was assumed that high-tech sophistry could replace the need to suffer casualties. The second was premised upon a more **humanitarian ethos**, which **demanded** **local** knowledge and **engagement with dangerous populations**. The narcissistic violence of the Global War on Terror has put this secondary vision into lasting crises as the violence of liberal encounter has fatefully exposed any universal commitment to rights and justice. Not only did we appear to be the principle authors of violence, thereby challenging the notion that underdevelopment was the true cause of planetary endangerment, populations within liberal societies have lost faith in worldly responsibilities. **Metaphysical hubris displaced by a catastrophic reasoning** that quite literally **places us at the point of extinction**. Violence as such has assumed non-locatable forms as liberalism is coming to terms with the limits to its territorial will to rule. Physically separated from a world it no longer understands, it is now left to the digital and technological recoupment of distance to shape worldly relations with little concern for human relations. Drone violence is particularly revealing of this shift in the liberal worldview. While the first recorded drone strike was authorised by President George Bush in Pakistan on 18th June 2004, it has been during the Presidency of Obama that the use of the technology has become the more favoured method for dealing with recalcitrant elements in the global borderlands. Indeed, it seems, whilst the Bush administration favoured extraordinary rendition, detention and torture, the Obama policy for preventing the growth of inmates in camps such as Guantanamo has been their execution. Hence inhumane torture and barbarity replaced by the more dignified and considerate method of targeted assassination! While debates on drone violence tend to centre on questions its legality, especially whether it fits within established rules of war, little attention is given to the wider political moment and how the violence points to the changing nature of liberal power and its veritable retreat from the world of people. Whereas Bush and Blair launched a one-sided territorial assault on Iraq and Afghanistan in order to promote ‘civilisation’, Obama has waged his war in the deregulated atmospheric shadows where technological supremacy allows for the continuation of uninhibited forms of violence, while addressing the fact that the previous interventions failed by any given measure. Hence, this time, out of respect for public sensibilities a ‘precise’ or ‘surgical’ form of violence is delivered remotely to its distant adversaries. We should not forget however that the technologies, infrastructures and aesthetics essential for remote warfare are essentially the same as those that support the economy and consumer society. Targeted drone-strikes and the advertising that maintains the consumer hothouse essentially rely on the same computer-based technologies and algorithmic sense-making tools. Put another way, how Amazon mechanically predicts your next book purchase is not fundamentally different from how adversarial behavioural patterns are isolated in authoring a signature-kill. Drone technologies are not simply a new tool of warfare that allow for legal or strategic reassessment. They are paradigmatic to the contemporary stages of liberal rule. As technological advance compensates for the “soldiers on the ground” militaristic retreat, they further radicalise the very idea of the territorial front line such that any Schmittean notion of inside/outside appears like some arcane remnant of an out-dated past. What takes its place is an atmospheric gaze that further eviscerates the human. From the perspective of violence, displacing the primacy of human agency from the act of killing represents more than the realisation of the military’s dream of zero casualties. It reveals more fully the dominance of dystopian realism as the defining rationality shaping the political landscape in the here and now, and beyond50 . Demanding then of a new conceptual vocabulary that allows us to critique what happens when violence is neither orderly nor progressive, but is simply tasked to mitigate the demise liberal power and ambition in an uncertain world seems more pressing than ever.

#### The Alternative is affirming exilic spaces that breaks out of the Aff’s political imaginary dominated by an apparatus of control.

Vodovnik and Grubacic 15, Ziga, and Andrej Grubacic. "" Yes, we camp!": Democracy in the age of Occupy." Lex Localis 13.3 (2015): 537. (Associate Professor at University of Ljubljana, Faculty of Social Sciences and Andrej, Ph.D., Associate Professor, California Institute of Integral Studies)//Elmer

When Occupy Wall Street initially burst onto the political scene in September 2011, igniting approximately 1400 occupation encampments across the globe – from New York City to Frankfurt, from Ljubljana to the docks of Oakland – it reminded us once again that we should understand social movements as something more than just “orgasms of history” (Fremion 2002). As Raul Zibechi points out, in relation to recent revolutionary movements in Latin America: in the daily life of divided societies, public time dominates the scene; the only audible voices are those of the economic, political and union elites. For this reason the Argentine insurrection was both “unexpected” and “spontaneous” to those elites, who could not hear the underground sounds, despite the fact that for more than a decade the voices had been echoing from below anticipating the approaching event (2010: 213). Social movements are always in the making for a longer time than we can see (or want to see), and we are therefore always surprised by their sudden “eruption.” In this “becoming” even the symbolism is not missing. It was definitely not missing in front of the Ljubljana Stock Exchange (borza), where the vibrations of the 15O protests caused the letter R to fall off the façade of the building, to be replaced only moments later by an improvised letter J. The message of this détournement was clear: borza (stock exchange) was transformed into boj za (struggle for). The Newest Social Movements (NSM), a term coined by Richard J.F. Day (2005) to distinguish the new incarnations of social movements which began to emerge around the turn of the millennium, are assessing political choices – both tactical and strategic – following a new logic. If in the past their actions and choices were organized toward producing effects on the powers that be, today their actions and choices consider the impact on themselves. It is not, therefore, struggle against (boj proti), but increasingly struggle for (boj za). If we are concrete, it is **a struggle for a new “democratized democracy**” which is both plural and inclusive. Although local circumstances, grievances, and idiosyncrasies varied from encampment to encampment, there was nevertheless an overarching context in which the occupations were emerging: the current economic moment, in which **polities and democracy are** being **forced to redefine their** position and **purpose**. The structure of the global economy, based on **Western hegemony** in the interstate system, **appears to be in** a serious **crisis**. However, as many commentators have already pointed out, what Occupy activists shared was more than just the rejection of a particular economic model (cf. Eisenstein in Kennedy, 2012: xiii). Specifically, the **occupations** were not inspired by the narrow economic reductionism and determinism which results in the fetishization of economic exploitation and class antagonisms. Rather, they were **putting** **emphasis on the crisis of** representative **democracy** at global, national, and local levels. Their **tactics highlighted the presence of** **hierarchy and domination** that run throughout all of these levels, and consequently addressed forms of exploitation that may not necessarily have any economic meaning at all. We build on the recent scholarly attention given to the notion of **nonstate spaces,** which we have chosen to call **exilic spaces** (Gray, 2004; Grubacic & O’Hearn, forthcoming) because they **are** populated by communities that voluntarily or involuntarily attempt escape from both state regulation (the focus of much anarchist analysis) and capitalist accumulation (the focus of Marxism). Exilic spaces can be defined as those **areas** of social and economic life **wherein people** and groups **attempt to** **extricate themselves from** **capitalist** economic **processes**, whether by territorial escape or by attempting to build structures that are **independent of** capitalist accumulation and **social control**. This is important because of the centrality of the spatial aspect of occupations – i.e. the idea of occupying public spaces, symbolically proclaiming: “This country is for everyone” (Eisenstein in Kennedy, 2012: xiii). Saskia Sassen (2012) agrees that the question of public space was central for the politics of Occupy, since “**to occupy is to remake**, even if temporarily, territory’s **embedded** and often deeply undemocratic **logics of power**, and to redefine the role of citizens, mostly weakened and fatigued after decades of growing inequality and injustice.” We will return to the exilic politics of Occupy later on, but here we can point out that, in Bookchin’s (2007) terms, the occupations raised much broader and more important questions related to understanding social change as something that should transcends the standard ways we live, work, make love, and collaborate. The exilic character of occupied spaces was not something that was immediately understood. After the occupation of Zuccotti park and the first encampments of the 15O protests, occupy soon became a buzzword, a hashtag. So much so that the American Dialect Society named it “The Word of the Year” for 2012, while in Germany the term Wutbürger (angry citizen) became the word of the year in the Gesellschaft für deutsche Sprach. But despite the vast amounts of media coverage and books and articles on the various “Occupy” movements, we argue that the movement’s most important political (exilic) aspirations have still not been properly addressed. To some degree we can understand epistemological myopia, since reflecting something so recent and dynamic as Occupy is always an optical challenge par excellence (cf. Appadurai, 2002; Tormey, 2012). As Saul Newman (2014: 94) points out, political theory has to catch up with this new terrain, since it “generally looks for visible, representative identities situated on an ontological field organized by sovereign power; it is concerned with how we are governed, or with the normative principles or constitutive logics upon which political power is founded.” Indeed, we argue that the new politics of Occupation reveals the need for a wider epistemological and methodological transformation. Too many theoretical concepts and political praxes invented by these new unruly subjects are too elusive for traditional disciplines, theories, and epistemologies. Therefore, their analysis must be founded on a new, more flexible epistemology and methodology. Paraphrasing Eduardo Restrepo and Arturo Escobar (2005), such an epistemological transformation calls for a critical awareness of both the larger epistemic and political field in which disciplines have emerged and continue to function, and of the micro-practices and relations of power within and across different locations and traditions of individual disciplines. In our reading of occupations we will follow James C. Scott’s theory of infrapolitics, but with some important modifications. In Scott’s terminology, infrapolitics is “an unobtrusive realm of political struggle” (Scott, 1990: 183) that includes a “wide variety of low-profile forms of resistance that dare not speak in their own name” (ibid., 38). **Infrapolitics** is essentially a strategic form of resistance that subjects must assume under conditions of great peril (ibid., 199). They provide a “**structural underpinning** for more visible political action, not as a substitute, but as its condition” (ibid., 58). We believe that infrapolitics should be understood as a political process articulated on two distinct levels. In it’s “micropolitical” sense, infrapolitics can assist us in highlighting how many aspects of the politics of Occupy were overlooked, or marginalized at best, since, “like infrared rays,” they were “beyond the visible end of the spectrum” (ibid., 201). Michael Greenberg (2012: 271) argues that “occupation presented **politics** not as a set issues but **as a way of being**. It offered a **release from subjectivity.”** For the political Right and Left, advocating real political action means action via political parties, protests or other conventional forms of collective action. They do not find alternative political praxes such as occupations fascinating and tend to dismiss them as: (1) unorganized, unsystematic, and individual; (2) opportunistic and self-indulgent; and (3) lacking in real potential/consequences. Furthermore, their own solutions always imply accommodation with the existing system of domination (Scott, 1985: 292). Following Scott we will try to recuperate “subaltern” aspects of occupations as providing “much of the cultural and structural underpinning of the more visible political action on which our attention has generally been focused” (Scott, 1990: 184). Our suggestion here is that we must shift our attention from the most visible - and consequently the most mediatized - aspects of Occupy to redefinitions of democracy and political membership that lie in the “immense political terrain … between quiescence and revolt” (ibid., 200). On the “macropolitical” level, infrapolitics is a process of producing forms of place-based politics **within cracks** **of the** global capitalist **system**. Infrapolitics of the capitalist world economy describes the effort of breaking from systemic processes of state and capital. It is a process of (self-)organization of relatively autonomous and only partially-incorporated spaces, and the resulting antagonistic relationship which emerges between exilic spaces and the hierarchical organizations of a capitalist world economy. It is also a predictable response to an enduring logic of exit and capture inscribed in the longue duree of historical capitalism. Instead of ruptures and breaks, we see a long-term, large-scale historical process of state making and state breaking, of state formation and state de-formation, of ongoing and uneven incorporation and exilic re-appropriation and recovery. The rise of the global mass assembly movement and the politics of occupation, should be understood in this larger historical context. The purpose of the article is twofold. First, we examine political practice and imagination of Occupation, focusing on redefinitions of democracy as practiced in encampments and squares, where various collectives and movements developed a genuinely new political alternative, and with it also a new understanding of politics that is worked out on a more manageable scale, that is to say, within local communities. We start from the supposition, that in the Occupy Movement we can find the beginning of a trans-local yet truly global network of direct democracy that, in its struggle against social exclusion and the trivialization of citizenship, recuperates an idea of prefiguration and direct democracy. We will explore further Newman’s (2014) suggestion that we should understand Occupy as a distinct form of politics and a new mode of democratic organization, involving the creation of autonomous spaces, rather than a distinct social movement. Finally, we consider the intersection between political/democratic and physical/spatial aspects of occupations. We examine the reaffirmation of spatiality and, with it, a redefinition of political membership as one of the most important aspects of the politics of Occupation.2 In a way, the movements of Occupation initiated a paradigm shift in political thought and practice, especially if we bear in mind various debates on global/cosmopolitan democracy from the mid-90s onwards. We argue that Occupy imagined new concepts of political participation constituted beyond the nation-state, sometimes in opposition to it, but always transcending the parochial forms of political membership that make global connectedness impossible. 2 Becoming political We can agree with the thesis that two main discourses can be found in contemporary discussions on democracy. The first understands democracy as a word whose roots lie in Ancient Greece and whose etymological origin poses new dilemmas, while the second examines democracy as an egalitarian decisionmaking procedure and everyday practice which in antiquity gradually became labeled “democratic” (Graeber, 2007: 340).3 The results of this dualism are “diachronous” discussions on democracy and, ultimately, a series of debates on the level of democracy of institutions and institutes which by their very essence counterpoise democratic practices. These and similar misconceptions also gave rise to a hegemonic notion of democracy which only recuperated the word while rejecting its contents. What was genuinely new about Occupy, were in fact distinct forms of politics, involving the creation of autonomous spaces. Occupy should be, according to Newman, seen **not** so much as **a movement**, **but** “as a **tactic**, a **practice**, a mode of organisation and **rhizomatic mobilization**, one that spreads spontaneously throughout the nerve centres of capitalist societies, involving the occupation and transformation of physical, symbolic and social spaces.” (Newman, 2014: 94; cf Smucker, 2012). Whether in the US, Slovenia, or elsewhere, what we have seen is a collective re-imagining of democracy. Since one of the key features of Occupy was the link between political struggle and its objectives—“the means are the goals in the making”— it is not surprising that the theory and practice of prefigurative politics developed as a new democratic spirit of encampment. Prefiguration means an attempt to use methods of political organization and action to create the future in the present, or at least, to some extent, foresee and manifest the social changes we are striving for. As explained by Tim Jordan (2002), it means acting in the present the ways we would want to act in the future, or acting as if the world in which we aspire to live has already materialized. It is a brief attempt to delegitimize the existing system and to build up its alternative from the bottom up. In this perspective, the encampments were not important only for their physical disposition, but rather as symbolic spaces for acting out new political structures and norms. For Peter Marcuse (2012: 16), an occupied square offers “a physical presence, a locational identity, a place that can be identified with the movement that visitors can come to, and where adherents can meet. It also has a second function: it is an opportunity to try out different forms of self-governance, the management of a space and, particularly if the physical occupation is overnight and continuous, of living together.”

## 1NC – Case

#### Reasonability on 1AR shells – 1AR theory is very aff-biased because the 2AR gets to line-by-line every 2NR standard with new answers that never get responded to

#### DTA on 1AR shells - They can blow up blippy 20 second shells in the 2AR while I have to split my time and can’t preempt 2AR spin which necessitates judge intervention

#### RVIs on 1AR theory – 1AR being able to spend 20 seconds on a shell and still win forces the 2N to allocate at least 2:30 on the shell o/w quantifiability

#### Different times for different allocations means aff theory doesn’t ow

### Innov

#### Evergreening is an incoherent concept AND anti-trust solves it

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

“**Evergreening**” – an **Incoherent Concept** Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a **secondary patent** somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a **false** assumption — a patent on an **improved formulation**, for example, is limited to that improvement and does **not extend** patent protection for the original formulation. Once the patents covering the **original formulation** have **expired**, generic companies are free to **market** a **generic** version of the original product, and patients willing to forgo the benefits of the improved formulation can **choose to purchase** the generic product, **free of** any **constraints** imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and **third-party** payers who **determine** whether the **value** of the improvement justifies the costs. Of course, this **assumes** a reasonably **well-functioning** pharmaceutical **market**. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then **antitrust** and **competition** laws should be **invoked** to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that **misuse** of the patent system which should be addressed directly, **rather than** through what amounts to an attack on the patent **system** itself.

#### Secondary and Follow-on patents are key.

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

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

#### One-and-done doesn’t solve international evergreening – alt causes aren’t included in patent, an orphan drug designation, a period of data exclusivity named by Feldman 3.

Hennebry PhD 18 [Sarah Hennebry (BA, BSc (Hons), PhD, MIP Law). “When a 20 year patent term just isn't enough: Market and data exclusivity”. FPA Patent Attorneys. 2018-01-31. Accessed 8/31/21. <https://www.fpapatents.com/resource?id=483> //Xu]

2. Europe In addition to periods of data exclusivity, the European Medicines Agency (EMA) also provides for periods of market exclusivity. Market exclusivity refers to a period where a party wishing to sell a follow-on product is prohibited from doing so, even if regulatory approval has been obtained. a) Data exclusivity Current European regulations provide 8 years of data exclusivity for pharmaceutical products. The period of exclusivity commences from the first marketing authorisation date and relates to the preclinical tests and clinical trials on a medicine that are provided to the EMA to obtain first regulatory approval of a product. During the period of data exclusivity, a third party wishing to obtain regulatory approval of a biosimilar or generic product, may not rely on the data submitted to the EMA in respect of the regulatory approval of an originator product. b) Marketing exclusivity The 8 year data exclusivity period referred to at a) above, is followed by a 2 year market exclusivity period. Ostensibly, this provides the innovator company with a 10 year period from the time of obtaining regulatory approval wherein market entry of a competitor is prohibited. There are no difference between the data and marketing exclusivity periods provided to small molecule pharmaceuticals or biologic pharmaceuticals under the provisions of the EMA. c) Extra market protection The cumulative 10 year period (8 years' data exclusivity plus 2 year marketing exclusivity) may further be extended by 1 year for certain new indications that are demonstrated to provide additional clinical benefit over previous indications. This is often referred to as “extra market protection”. The 1 year extra market protection can be obtained if approval for a new indication is obtained during the initial 8 year period and: there are no existing therapies for that indication; or there are existing therapies for that indication, but there is a significant clinical benefit to using the drug for which the extra market protection is sought. d) Orphan designation The EMA assigns orphan designation to a pharmaceutical product that is approved for the treatment of: a rare condition, where < 5 individual in 10,000 are at risk of the condition; and the condition is serious (ie life threatening or chronically debilitating). The period of market exclusivity for an orphan designated pharmaceutical product is 10 years (rather than 8 years of data exclusivity plus 2 years marketing exclusivity if no orphan designation). This means that a competitor cannot rely on any information submitted to the EMA in respect of the regulatory approval of a follow-on product, until 10 years after the initial marketing approval of the originator product. Market exclusivity is extended by a period of 2 years if the orphan designation also relates to a Paediatric indication. The market exclusivity provisions in respect of pharmaceuticals with orphan designation run in parallel with the data and marketing exclusivity provisions for other pharmaceuticals. For more information on market and data exclusivity in Europe, please see: European Medicines Agency Data Exclusivity 3. Japan There are no data or marketing exclusivity provisions for pharmaceutical products in Japan. However, the effect of post market pharmacovigilance provisions is to ostensibly act as a data exclusivity provision and prevent any generic from coming onto the market during the Post Marketing Surveillance period. Post Market Surveillance is a process whereby the Japanese regulatory authority (Pharmaceuticals and Medical Devices Agency) re-examines the safety and efficacy of new chemical entities and previously approved pharmaceuticals later approved for new indications. The re-examination period lasts for between 4 to 10 years, during which time any data submitted to the regulatory authority by the drug sponsor which relates to the safety of the drug cannot be obtained by generic companies. It is not until after the conclusion of this period that a generic company is able to commence marketing of their product. The re-examination period is 8 years for new chemical entities, and 4 years for new indications. The re-examination period for orphan drugs is 10 years. For more information on post-marketing surveillance in Japan, please see: Post-marketing Safety Measures in Japan 4. Australia The period of data exclusivity is with respect to confidential information submitted to the Therapeutic Goods Administration (TGA) or the Australian Pesticides and Veterinary Medicines Authority (APVMA) by a first sponsor, for the purposes of obtaining regulatory approval of a new product containing a pharmaceutically active ingredient for human use, or products containing active ingredients for veterinary or agricultural use. During the data exclusivity period, the confidential information provided to the TGA or AVPMA cannot be used by a third party, without the consent of the first sponsor. The Therapeutics Goods Act (1989) provides that certain information is ‘protected’ if it meets the following criteria: the information concerns an active component (but not a device) which is contained in an application to register a therapeutic good; the information is not in the public domain and the sponsor has not given written permission for the Secretary to use the information; at the time the application for regulatory approval was lodged, no goods containing the active ingredient were (or had ever been) included in the ARTG; and the therapeutic good has been included in the Register for less than 5 years. Under the Therapeutic Goods Act (“the Act”), the Secretary (of the ARTG) is prohibited from using information that is deemed protected under the Act, when evaluating therapeutic goods (ie other therapeutic goods) for registration in the ARTG. This is slightly different to the situation in other jurisdictions, such as Europe, where the data exclusivity provisions prevent the review or submission of any generic or biosimilar product during the relevant period. Under the Australian provisions, such regulatory approval may still be sought by a competitor during the data exclusivity period, however, the applicant may not rely on any confidential information provided to the TGA in support of the subsequent approval. (In other words, if a third party wishes to obtain approval of a generic or biosimilar product during the data exclusivity period, a full data package must be submitted to the TGA). The period of data exclusivity is 5 years from the date a new product is registered under the Act. Unlike the US and Europe, the Australian data exclusivity regime is restricted to confidential information associated with the registration of new chemical entities. Confidential information associated with the registration of new dosage forms, new routes of administration, new indications or combination products is not eligible for protection by data exclusivity provisions. The result of this is that the first applicant to register, for example, a new indication of a known drug, must rely solely on patent protection to block a competitor from entering the market.

#### AMR patents are primary not secondary patents

Maria Abud et. al, 15 [Maria Abud, (School of International and Public Affairs, Columbia University, New York, United States of America)]. "An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile." 4-27-2015, Accessed 8-31-2021. https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0124257 // duongie

Table 3 shows the number of primary and secondary patents associated with each therapeutic class (the total number of entries in the table is 1,246 because there can be more than one class for a given patent—see also Tables A-7-A-9 in the online appendix). The shares of primary patents vary considerably: recall that product patents were not available in Chile before 1991. This means that classes like anti-depressants and anti-ulcer (gastrointestinal agents) which had important patents prior to that date are covered largely by secondary patents. In contrast, newer areas like anti-virals and anti-neoplastics (anti-cancer) have a large share of primary patents. One of way of assessing the importance of secondary patents for extending market exclusivity is to analyze whether there are any differences in the use of secondary patents by type of patent owner – in particular distinguishing between for-profit companies and not-for-profit research institutes and universities. In Fig 10 we distinguish between these two types of assignees. The figure shows that the share of secondary patents among patent-protected active ingredients is significantly larger for companies than for universities/not-for-profit research institutes. There are only 5 secondary patents that are assigned to universities and not-for-profit research institutes. However, with the exception of one secondary patent which is assigned to the Wellcome Foundation, all other secondary patents are co-assigned to universities/not-for profit research institutes and private companies. This suggests that secondary patents are almost exclusively used by private companies as a tool to achieve exclusivity. That said, universities tend to focus on early stage research which is less likely to lead to the filing of secondary patents. Taking a closer look at patenting companies, we find that 76 out of 123 companies (62%) only file secondary patents whereas 25 companies (20%) only file primary patents (22 companies file both types of patents). Conclusion Our objective was to take a first look at patenting of pharmaceuticals in Chile, with a particular focus on the distinction between primary and secondary patents. We provide a number of descriptive findings that show that pharmaceutical patents associated with drugs that have received market approval are almost exclusively the domain of foreign originator companies. Overall, we find that only a subset of drugs with market approval is protected by patents, a much larger number of products are protected by trademarks. We also find that foreign originator companies rely on a patent-trademark combination whereas domestic companies rely only on trademarks. Nevertheless, we also find a substantial number of ISP registrations that are not protected either by a patent or a trademark. When we take a closer look at ISP registrations protected by patents, we find that the majority are protected only by secondary patents (few active ingredients are protected by more than 1–3 patents). This is especially true before the change to the patent law in 1991, although it takes a few years for the number of primary patents to become significant. We also find that nearly all primary patents on active ingredients were filed before a drug containing the active ingredient was registered with the ISP. Secondary patents in contrast often follow with a lag of several years, that is, secondary patents are often filed after primary patents and after a drug has been registered at the ISP. The timing is also reflected in the fact that secondary patents dominate “older” therapeutic classes like anti-ulcer and anti-depressants. In contrast, newer areas like anti-virals and anti-neoplastics (anti-cancer) have a much larger share of primary patents. Our data also reveal that secondary patents are almost exclusively a tool used by private companies whereas universities and not-for-profit research institutes concentrate on primary patent protection. This study is only a first step towards a better understanding of pharmaceutical patents in Chile. We have assembled a dataset that combines pharmaceutical products, active ingredients, patents, trademarks, and information on the corresponding companies. These data enable us to substantially deepen our understanding of the impact of patents on the pharmaceutical industry in Chile. Still, our approach and data have a number of obvious limitations. Perhaps most importantly, we only observe whether a drug has obtained market approval, but we have no information on actual demand or prices. This limits our ability to account for the importance of different drugs other than through their therapeutic classes. We plan to extend this work to assess the impact that the combined use of primary and secondary patents has had on the ability of Chilean companies to compete in the generics industry. Such analysis could produce relevant insights for the current debate on secondary patents.

#### NAS 8 has no warrant for why pharma spills over to climate change make them read new ev

#### No uq to medicine diplomacy Russia and China have rapidly filled in the voids through COVID medicines and would be equally affected by the plan since they’re also members of the WTO

#### No extinction from pandemics

* Death rates as high as 50% didn’t collapse civilization
* Fossil fuel record caps risk at .1% per century
* health, sanitation, medicine, science, public health bodies, solve
* viruses can’t survive in all locations
* refugee populations like tribes, remote researchers, submarine crews, solve

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Are we safe now from events like this? Or are we more vulnerable? Could a pandemic threaten humanity’s future?10 The Black Death was not the only biological disaster to scar human history. It was not even the only great bubonic plague. In 541 CE the Plague of Justinian struck the Byzantine Empire. Over three years it took the lives of roughly 3 percent of the world’s people.11 When Europeans reached the Americas in 1492, the two populations exposed each other to completely novel diseases. Over thousands of years each population had built up resistance to their own set of diseases, but were extremely susceptible to the others. The American peoples got by far the worse end of exchange, through diseases such as measles, influenza and especially smallpox. During the next hundred years a combination of invasion and disease took an immense toll—one whose scale may never be known, due to great uncertainty about the size of the pre-existing population. We can’t rule out the loss of more than 90 percent of the population of the Americas during that century, though the number could also be much lower.12 And it is very difficult to tease out how much of this should be attributed to war and occupation, rather than disease. As a rough upper bound, the Columbian exchange may have killed as many as 10 percent of the world’s people.13 Centuries later, the world had become so interconnected that a truly global pandemic was possible. Near the end of the First World War, a devastating strain of influenza (known as the 1918 flu or Spanish Flu) spread to six continents, and even remote Pacific islands. At least a third of the world’s population were infected and 3 to 6 percent were killed.14 This death toll outstripped that of the First World War, and possibly both World Wars combined. Yet even events like these fall short of being a threat to humanity’s longterm potential.15 In the great bubonic plagues we saw civilization in the affected areas falter, but recover. The regional 25 to 50 percent death rate was not enough to precipitate a continent-wide collapse of civilization. It changed the relative fortunes of empires, and may have altered the course of history substantially, but if anything, it gives us reason to believe that human civilization is likely to make it through future events with similar death rates, even if they were global in scale. The 1918 flu pandemic was remarkable in having very little apparent effect on the world’s development despite its global reach. It looks like it was lost in the wake of the First World War, which despite a smaller death toll, seems to have had a much larger effect on the course of history.16 It is less clear what lesson to draw from the Columbian exchange due to our lack of good records and its mix of causes. Pandemics were clearly a part of what led to a regional collapse of civilization, but we don’t know whether this would have occurred had it not been for the accompanying violence and imperial rule. The strongest case against existential risk from natural pandemics is the fossil record argument from Chapter 3. Extinction risk from natural causes above 0.1 percent per century is incompatible with the evidence of how long humanity and similar species have lasted. But this argument only works where the risk to humanity now is similar or lower than the longterm levels. For most risks this is clearly true, but not for pandemics. We have done many things to exacerbate the risk: some that could make pandemics more likely to occur, and some that could increase their damage. Thus even “natural” pandemics should be seen as a partly anthropogenic risk. Our population now is a thousand times greater than over most of human history, so there are vastly more opportunities for new human diseases to originate.17 And our farming practices have created vast numbers of animals living in unhealthy conditions within close proximity to humans. This increases the risk, as many major diseases originate in animals before crossing over to humans. Examples include HIV (chimpanzees), Ebola (bats), SARS (probably bats) and influenza (usually pigs or birds).18 Evidence suggests that diseases are crossing over into human populations from animals at an increasing rate.19 Modern civilization may also make it much easier for a pandemic to spread. The higher density of people living together in cities increases the number of people each of us may infect. Rapid long-distance transport greatly increases the distance pathogens can spread, reducing the degrees of separation between any two people. Moreover, we are no longer divided into isolated populations as we were for most of the last 10,000 years.20 Together these effects suggest that we might expect more new pandemics, for them to spread more quickly, and to reach a higher percentage of the world’s people. But we have also changed the world in ways that offer protection. We have a healthier population; improved sanitation and hygiene; preventative and curative medicine; and a scientific understanding of disease. Perhaps most importantly, we have public health bodies to facilitate global communication and coordination in the face of new outbreaks. We have seen the benefits of this protection through the dramatic decline of endemic infectious disease over the last century (though we can’t be sure pandemics will obey the same trend). Finally, we have spread to a range of locations and environments unprecedented for any mammalian species. This offers special protection from extinction events, because it requires the pathogen to be able to flourish in a vast range of environments and to reach exceptionally isolated populations such as uncontacted tribes, Antarctic researchers and nuclear submarine crews. 21 It is hard to know whether these combined effects have increased or decreased the existential risk from pandemics. This uncertainty is ultimately bad news: we were previously sitting on a powerful argument that the risk was tiny; now we are not. But note that we are not merely interested in the direction of the change, but also in the size of the change. If we take the fossil record as evidence that the risk was less than one in 2,000 per century, then to reach 1 percent per century the pandemic risk would need to be at least 20 times larger. This seems unlikely. In my view, the fossil record still provides a strong case against there being a high extinction risk from “natural” pandemics. So most of the remaining existential risk would come from the threat of permanent collapse: a pandemic severe enough to collapse civilization globally, combined with civilization turning out to be hard to re-establish or bad luck in our attempts to do so.