# 1NC

## 1

#### Interpretation– “medicines” are substances that prevent, diagnose, or treat harms

MRS 20 [(MAINE REVENUE SERVICE SALES, FUEL & SPECIAL TAX DIVISION) “A REFERENCE GUIDE TO THE SALES AND USE TAX LAW” <https://www.maine.gov/revenue/sites/maine.gov.revenue/files/inline-files/Reference%20Guide%202020.pdf> December 2020] SS

[Medicines](https://www.lawinsider.com/dictionary/medicines) means antibiotics, analgesics, antipyretics, stimulants, sedatives, antitoxins, anesthetics, antipruritics, hormones, antihistamines, certain “dermal fillers” (such as BoTox®), injectable contrast agents, vitamins, oxygen, vaccines and other substances that are used in the prevention, diagnosis or treatment of disease or injury and that either (1) require a prescription in order to be purchased or administered to the retail consumer or patient; or (2) are sold in packaging.

#### Violation – CRISPR is a gene-editing tool, NOT a medicine – it’s also used in a variety of non-medical fields.

NewScientist 20 "What is CRISPR" <https://www.newscientist.com/definition/what-is-crispr/> //Elmer

**CRISPR is a technology** **that can be used to edit genes** and, as such, will likely change the world. The essence of CRISPR is simple: it’s a way of finding a specific bit of DNA inside a cell. After that, the next step in CRISPR gene editing is usually to alter that piece of DNA. However, CRISPR has also been adapted to do other things too, such as turning genes on or off without altering their sequence. There were ways to edit the genomes of some plants and animals before the CRISPR method was unveiled in 2012 but it took years and cost hundreds of thousands of dollars. CRISPR has made it cheap and easy. CRISPR is already widely **used for** scientific research, and in the not too distant future many of the **plants** and **animals** in our **farms**, gardens or homes may have been altered with CRISPR. In fact, some people already are eating CRISPRed **food**.

#### It's used in drug discovery but isn’t a drug – makes the Aff effects-Topical.

Enzmann and Wronski 19 Brittany Enzmann and Ania Wronski 1-11-2019 "How CRISPR Is Accelerating Drug Discovery" <https://www.genengnews.com/insights/how-crispr-is-accelerating-drug-discovery/> (scientific communications manager at Synthego)//Elmer

Subsequent cellular repair facilitates knockouts, knockins, or the exchange of nucleotides. Because these types of modifications are made endogenously, scientists can study the subsequent changes to mRNA and protein at native, physiologically relevant levels. Variations of **CRISPR** can be **used for** other modifications, including the activation and inhibition of gene expression. Due to its increased ease and versatility, CRISPR shows promise in overcoming many of the technical challenges of **drug discovery**. Here, we summarize some of the ways in which CRISPR is advancing the stages of preclinical drug development. Drug discovery workflow The drug discovery process often starts with basic scientific **research** and involves many steps before new therapeutics are approved for clinical use. While each pharmaceutical company approaches the discovery and development of new drugs differently, the major steps common to most preclinical processes are **target identification and validation**, high-throughput compound **screening**, **hit validation**, and **lead drug candidate optimization** (Figure 2). All of these steps, and the ways **CRISPR** is **accelerating progress through them**, are discussed below.

#### Here's the burden for the Violation – Medicine must be substances that are used to treat diseases. CRISPR is a technology to find or create those substances BUT isn’t used to treat diseases itself which means it’s not Topical.

#### Answering their Pre-empts:

#### AT Vidyasagar – This says it’s a DNA – a] that’s not a substance and b] it cuts DNA, it’s not a medicine itself – which is our Effects-T offense.

#### AT Sfera – 1] This proves our Extra-T offense – simply being able to be used as a drug doesn’t mean it’s a medicine – this identifies a singular CRISPR tool, CTX001 as a drug, but CRISPR itself isn’t one and 2] Creating medicines is distinct from being a medicine.

#### 3] The Standard is Limits – They explode the topic to include therapies, research areas, treatments, drug discovery techniques, etc. that eviscerate a stable locus of predictability. Limits is a sequencing question to Clash and in-depth Education since we’re only able to prepare if there’s stable core controversies. Independently, massive caselists make debate inaccessible to small school debaters, whose lack of resources make writing individualized disads impossible

#### 4] TVA Solves – reduce IP protections on gene-based medicines.

#### 5] Paradigm Issues –

#### A] Topicality is Drop the Debater – it’s a fundamental baseline for debate-ability.

#### B] Use Competing Interps – 1] Topicality is a yes/no question, you can’t be reasonably topical and 2] Reasonability invites arbitrary judge intervention and a race to the bottom of questionable argumentation.

#### C] No RVI’s - 1] Forces the 1NC to go all-in on Theory which kills substance education, 2] Encourages Baiting since the 1AC will purposely be abusive, and 3] Illogical – you shouldn’t win for not being abusive.

## 2

#### Counterplan Text – Member states of the World Trade Organization ought to consult the World Health Organization on whether or not to [do the Plan]. The World Health Organization ought to publicly declare that their decision on [the Plan] will represent their future decisions on all intellectual property protections on medicines.

#### The Plan’s unilateral action by the WTO on medical IP undermines WHO legitimacy – forcing a perception of WHO action against Patents is key to re-assert it – they say yes.

Rimmer 4, Matthew. "The race to patent the SARS virus: the TRIPS agreement and access to essential medicines." Melbourne Journal of International Law 5.2 (2004): 335-374.

<https://law.unimelb.edu.au/__data/assets/pdf_file/0007/1681117/Rimmer.pdf> (BA (Hons), LLB (Hons) (Australian National University), PhD (New South Wales); Lecturer at ACIPA, the Faculty of Law, The Australian National University)//SidK + Elmer

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as ‘one of the biggest success stories in public health in recent years’.206 However, it **was less active in the debate over patent law** and public health epidemics. The 56th World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.207 However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of aspirational statements about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate. Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency didnoteven seem aware of the patent proceedings, leaving individual research institutions without guidance. Spokesman Dick Thompson said: ‘What we care about is [that] the international collaboration continues to function. Patents, they don’t really concern us’.208 The director of WHO’s Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: ‘I don’t think this will undermine the collaborative spirit of the network of labs’.209 However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: ‘At a certain point of time you have to give way for competitive pharmaceutical companies’.210 On a policy front, the WHO remained deferential to the WTO over the debate over patent law and access to essential medicines, observing: Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.211 In such a statement, the WHO appears diffident, unwilling to take on more than a spectator role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the **TRIPS** Agreement on public health concerns. The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the WHO **should not be limited to a mere spectator role in such policy discussions. It** needstoplay an active advocacy role in the debate over patent law and access to essential medicines. The WHO released a position statement on ‘Patent Applications for the SARS Virus and Genes’ on 29 May 2003.212 The organisation stressed that it had no per se objection to the patenting of the SARS virus: Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.213 Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research: The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.214 The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.215 The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed: In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.216 It maintained that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.219 The Assembly requested that the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer.220 The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.221 It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.222 The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.223 The Director-General of the WHO, Dr Gro Harlem Brundtland, **told the World Health** Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘**Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation** is a critical challenge — whether the target is SARS or any other threat to human health’.224 Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said: If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.225 She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure that, once developed, they are available in both industrialised and developing countries.226 C Summary The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on ‘Intellectual Property Rights, Innovation, and Public Health’.227 He maintains that the Assembly could have addressed ‘practical examples, like SARS’ and cites the report in The Washington Post that notes that a number of commercial companies are investing in SARS research.228 The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: ‘As the world’s leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should **do much more’**.229 The WHO should become a vocal advocate for public health concerns at the WTO and its TRIPS Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines. The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as ‘defensive patenting’ — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus: The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.230 There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus. There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, ‘[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application’.231 There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry. The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate over patent law and access to essential medicines. Not only could it mediate legal disputes over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the Doha Declaration on the TRIPS Agreement and Public Health. Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes: SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20th century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.232 Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.233 There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.234

#### WHO Cred key to Global Right to Health – medicine access is critical.

* Note the Bottom Paragraph is at the bottom of the PDF – I put a paragraph break to indicate it as such – no words are missing.

Bluestone 3, Ken. "Strengthening WHO's position should be a priority for the new Director-General." The Lancet 361.9351 (2003): 2. (Senior Policy Adviser, Voluntary Service Overseas (VSO))//Elmer

To meet these challenges, WHO must strengthen its resolve to maintain its **independence and lead its member states**, **even at the risk of causing controversy**. A meaningful example is the role that WHO can have in **ensuring access to medicines** for the world’s poorest people. WHO is the only global institution that has the **remit to drive this agenda forward**, yet has failed to do so convincingly. The new Director-General must support and reinvigorate the advocacy efforts of the organisation and provide a proper counterbalance to the interests of the pharmaceutical industry and wealthy member states. As the new Director-General takes office, they will face the dual challenge of **seeing that** the broadest possible public health interpretation of the World Trade Organization’s Doha Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) **is not lost, and** of seizing an opportunity to bring about an international framework for sustainable and predictable tiered pricing of medicines. Without the active intervention of a public health advocate at the level of WHO, there is a risk that both of these initiatives **could founder.** Some people in positions of power still do not have high expectations of WHO or its new Director-General. But for the world’s poorest people, the overwhelming majority of whom live in developing countries, this person’s legacy could literally make the difference between life and death. Ken Bluestone Senior Policy Adviser, Voluntary Service Overseas (VSO)

New leader should re-establish WHO’s credibility The credibility of WHO’s advocacy of the right to health for all has been eroded in recent years. A large reason is WHO’s **failure to challenge the pharmaceutical** industry on access to medicines for people with HIV/AIDS and other diseases. WHO’s collaboration with the industry in the “Accelerated Access” programme on antiretroviral medicines sounds good. In fact, the programme has served as a cover for the organisation’s frequent acceptance of industry arguments for restricting treatment access. To re-establish WHO’s credibility, the new Director-General must lead the organisation to stand consistently with those most deprived of health services. Kenneth Roth, Executive Director, Human Rights Watch.

#### Right to Health solves Nationalist Populism.

Friedman 17 Eric Friedman March 2017 “New WHO Leader Will Need Human Rights to Counter Nationalistic Populism” <https://www.hhrjournal.org/2017/03/new-who-leader-will-need-human-rights-to-counter-populism/> (JD, Project Leader of the Platform for a Framework Convention on Global Health at the O’Neill Institute for National and Global Health Law at the Georgetown University Law Center in Washington, DC)//Elmer

The need for WHO leadership on human rights—and for global leadership on health and human rights beyond WHO—has always been present, yet has become ever more pressing. A reactionary, nationalist populism has been gaining momentum, particularly in the United States and parts of Europe, and some of its most disturbing features, such as xenophobia and disregard for international law and institutions, are surfacing elsewhere. Persisting health challenges—such as immense national and global health inequities, with universal health coverage and the Sustainable Development Goals offering some hope of lessening them—and growing threats such as outbreaks of infectious disease, worsening antimicrobial resistance, and climate change demand the type of leadership that the right to health entails. In this immensely challenging environment, WHO needs to become a 21st century institution that has the gravitas and credibility to carve a path through these obstacles towards global health justice. The next WHO Director-General, to be elected in May, must lead the organization there. The right to health can light the way ahead, with reforms to, and driven by, WHO. These reforms must develop an internal governance that is far more welcoming of civil society, with WHO member states significantly increasing contributions so work on the social determinants of health can expand, and with enhanced transparency and accountability. Furthermore, reforms are needed so that WHO leads on global health equity and human rights, including through national health equity strategies and, above all, the Framework Convention on Global Health (FCGH). The FCGH could help bring the right to health to the next level by capturing core aspects of the right to health, such as: 1) participation and accountability, setting clear standards for people’s participation in health policy-making at all levels, and establishing multi-layered health accountability frameworks with standards to which all nations would be held; 2) equity, including by catalyzing national health equity strategies—which must be developed through broad participation, itself a potentially empowering process—and advancing data disaggregation and more equitable financing; 3) financial resources, with global norms on national and international health financing responsibilities; and 4) respecting and promoting the right to health in all policies, from setting standards on health impact assessments—including participatory processes in developing them, human rights standards, an equity focus, and follow-up processes—to firmly ensuring the primacy of the right to health in other legal regimes that may undermine. From an earlier WHO treaty, the Framework Convention on Tobacco Control, we know the power of international law to significantly advance health, with the transformative power of legally binding global health norms. As a treaty, the FCGH would increase political accountability and accountability through the courts, while helping protect health other treaty-based international regimes, such as trade. It would also be a bold assertion of global solidarity for global justice, as so urgently needed, “demonstrating that the community of nations are indeed stronger together.” One candidate for the WHO Director-General election, David Nabarro, has recognized the value and civil society support that FCGH has already received, and the need to further explore the treaty (mentioned at 1:46:38 mark). A good first step would be establishing a WHO working group on the FCGH, with broad participation, particularly from states, civil society, and representatives of communities most affected by health inequities, along with relevant international agencies. We see signs of resistance of the dangerous nationalist populism, from protests that persist and judicial checks on one of the administration’s vilest acts (an immigration and refugee travel ban, with its effects falling heaviest on Muslims) in the United States to the rejection of the far-right candidate in the elections in the Netherland. Such resistance can prevent some of the worst impacts on the right to health, from discrimination against migrants to cuts to programs vital for health. Meanwhile, let’s construct an edifice for the future of health and human rights, even as we stand against its destruction. WHO, right to health, and FCGH leadership ought to be a core part of that endeavor.

#### Populism is an existential threat.

de Waal 16 Alex de Waal 12-5-2016 “Garrison America and the Threat of Global War” <http://bostonreview.net/war-security-politics-global-justice/alex-de-waal-garrison-america-and-threat-global-war> (Executive Director of the World Peace Foundation at the Fletcher School at Tufts University)//Elmer

Polanyi recounts how economic and financial crisis led to global calamity. Something similar could happen today. In fact we are already in a steady unpicking of the liberal peace that glowed at the turn of the millennium. Since approximately 2008, the historic decline in the number and lethality of wars appears to have been reversed. Today’s wars are not like World War I, with formal declarations of war, clear war zones, rules of engagement, and definite endings. But they are wars nonetheless. What does a world in global, generalized war look like? We have an unwinnable “war on terror” that is metastasizing with every escalation, and which has blurred the boundaries between war and everything else. We have deep states—built on a new oligarchy of generals, spies, and private-sector suppliers—that are strangling liberalism. We have emboldened middle powers (such as Saudi Arabia) and revanchist powers (such as Russia) rearming and taking unilateral military action across borders (Ukraine and Syria). We have massive profiteering from conflicts by the arms industry, as well as through the corruption and organized crime that follow in their wake (Afghanistan). We have impoverishment and starvation through economic warfare, the worst case being Yemen. We have “peacekeeping” forces fighting wars (Somalia). We have regional rivals threatening one another, some with nuclear weapons (India and Pakistan) and others with possibilities of acquiring them (Saudi Arabia and Iran). Above all, today’s generalized war is a conflict of destabilization, with big powers intervening in the domestic politics of others, buying influence in their security establishments, bribing their way to big commercial contracts and thereby corroding respect for government, and manipulating public opinion through the media. Washington, D.C., and Moscow each does this in its own way. Put the pieces together and a global political market of rival plutocracies comes into view. Add virulent reactionary populism to the mix and it resembles a war on democracy. What more might we see? Economic liberalism is a creed of optimism and abundance; reactionary protectionism feeds on pessimistic scarcity. If we see punitive trade wars and national leaders taking preemptive action to secure strategic resources within the walls of their garrison states, then old-fashioned territorial disputes along with accelerated state-commercial grabbing of land and minerals are in prospect. We could see mobilization against immigrants and minorities as a way of enflaming and rewarding a constituency that can police borders, enforce the new political rightness, and even become electoral vigilantes. Liberal multilateralism is a system of seeking common wins through peaceful negotiation; case-by-case power dealing is a zero-sum calculus. We may see regional arms races, nuclear proliferation, and opportunistic power coalitions to exploit the weak. In such a global political marketplace, we would see middle-ranking and junior states rewarded for the toughness of their bargaining, and foreign policy and security strategy delegated to the CEOs of oil companies, defense contractors, bankers, and real estate magnates. The United Nations system appeals to leaders to live up to the highest standards. The fact that they so often conceal their transgressions is the tribute that vice pays to virtue. A cabal of plutocratic populists would revel in the opposite: applauding one another’s readiness to tear up cosmopolitan liberalism and pursue a latter-day mercantilist naked self-interest. Garrison America could opportunistically collude with similarly constituted political-military business regimes in Russia, China, Turkey, and elsewhere for a new realpolitik global concert, redolent of the early nineteenth-century era of the Congress of Vienna, bringing a façade of stability for as long as they collude—and war when they fall out. And there is a danger that, in response to a terrorist outrage or an international political crisis, President Trump will do something stupid, just as Europe’s leaders so unthinkingly strolled into World War I. The multilateral security system is in poor health and may not be able to cope. Underpinning this is a simple truth: the plutocratic populist order is a future that does not work. If illustration were needed of the logic of hiding under the blanket rather than facing difficult realities, look no further than Trump’s readiness to deny climate change. We have been here before, more or less, and from history we can gather important lessons about what we must do now. The importance of defending civility with democratic deliberation, respecting human rights and values, and maintaining a commitment to public goods and the global commons—including the future of the planet—remain evergreen. We need to find our way to a new 1945—and the global political settlement for a tamed and humane capitalism—without having to suffer the catastrophic traumas of trying everything else first.

## 3

#### Text – Member nations of the World Trade Organization ought to

#### - Maintain patent protection over Clustered Regularly Interspaced Short Palindromic Repeats (CRISPR).

#### - Purchase CRISPR patents and distribute associated technology developed from CRISPR research.

#### - Intervene and force licenses if market prices of CRISPR technology is too high.

#### - Create an advisory committee for gene-editing patents to reviewing and regulating CRISPR patents in accordance to 1NC Parthasarathy.

#### - Ensure Transparency and Certainty in the Patent-filing and application process.

#### - Invest in University-level research on Genome Patenting through licenses.

#### - Officially change and announce the WTO stance and rulings on Genomic Editing to allow patent protection on Genomic Editing.

#### Patents are necessary to guide what functions and uses CRISPR takes – state control and regulation is key to actively guide development paths.

Parthasarathy 18 Shobita Parthasarathy 10-23-2018 "Use the patent system to regulate gene editing" <https://www.nature.com/articles/d41586-018-07108-3> (professor and director of the Science, Technology, and Public Policy Program at the Gerald R. Ford School of Public Policy, University of Michigan, Ann Arbor, Michigan, USA.)//Elmer

Next month, researchers, policymakers, ethicists and social scientists will meet in Hong Kong for the second International Summit on Human Gene Editing. Since the first summit, held in Washington DC nearly three years ago, **researchers** have continued to **apply** the versatile **gene-editing** technology **CRISPR**–Cas9 **to diverse domains** — from crop enhancement and pest eradication to human disease. Many have flagged the ethical, economic and environmental concerns raised by manipulating plant and animal genomes, including our own. But, so far, **governments** have **struggled to develop** **viable approaches to regulation**. **A crucial part of the arsenal** **for shaping the future of gene editing is** hiding in plain sight: **the patent system**. In the **past**, **patents** have **played** an **important part in regulating new technologies** and research, **from** the **atom bomb to** work involving human embryonic **stem cells**. Some organizations and individual researchers using CRISPR–Cas9 are already creating licensing agreements that reflect their own moral codes. In my view, **government-driven efforts centred on national patent systems should be deployed to help regulate gene editing**. New laws needed Last year, the US National Academies of Science, Engineering, and Medicine recommended that clinical trials involving gene editing in human eggs, sperm or embryos should be permitted only for the treatment and prevention of serious disease or disability. They also urged that a “stringent oversight” system be developed to limit the use of the technology in this context1. In July, the Nuffield Council on Bioethics, a highly respected bioethics body in the United Kingdom, similarly stated that the use of heritable genome editing “could be ethically acceptable” only after appropriate governance measures are put in place2. These recommendations haven’t yet translated into legal frameworks or formal governance structures. And the history of regulating emerging biotechnologies suggests that such laws could be a long time coming, if they end up being formed at all3. For now, when it comes to editing genes in humans and other organisms, the United States and the United Kingdom — along with many other countries — **rely on laws and policies that cover existing genetic-engineering technologies**. Or, as in the case of human germline editing in the United States, the government **simply bans the use of federal funds for such research**. Such policies have been criticized for decades as **being inadequate4**. Their insufficiencies are considerably more problematic in the context of gene editing, which, largely thanks to the development and uptake of CRISPR–Cas9 (see ‘Invention protection’), promises to have much greater societal impact than previous technologies for modifying genomes. In the United States, for instance, the oversight provided by the ‘coordinated framework’ (developed in the 1980s to deal with genetically engineered organisms) handles only immediate risks. The framework covers the management of altered plants and animals that have already been created, and does not consider the socio-economic, ecological or ethical consequences of creating organisms not found in nature. Likewise, since 2016, a condition in the budget for the US Food and Drug Administration has prohibited the agency from authorizing clinical trials in which a “human embryo is intentionally created or modified to include a heritable genetic modification”. But there is nothing to stop US researchers using private funds to edit the genes of human embryos in the lab. Historical precedents How could **patents** help? These legal instruments — which give inventors the right to prevent others from commercializing their technologies — are usually seen solely as contracts that incentivize innovation. In fact, they can do much more, directly and indirectly. They can lead to higher prices for products, for instance, and reduce people’s access to important technologies if inventors use them to establish and maintain monopolies. Perhaps most importantly, they **can shape innovation trajectories**. Patent laws were a **major factor in the ‘war of the currents’** in the 1880s, driving people to favour engineer George Westinghouse’s alternating current (AC) over the direct-current system invented by Thomas Edison. (Westinghouse licensed the US patents for AC from inventor Nikola Tesla.) The **decisions that governments make about** whether to grant **patents** implicitly **demonstrate** their moral **approval of an invention** and indicate what types of technology are likely to generate exclusive markets5. The idea that governments could use patent systems to shape both the development of a technology and its impact on society is not new. In **the 1940s, the US Congress used the patent system to control the development and commercialization of atomic weaponry**. To try to reduce the possibility of private actors developing atomic bombs, or of US intelligence leaking, Congress created a three-tier system of non-patentable, government patentable and privately patentable technologies in the Atomic Energy Act of 19546. The US Patent and Trademark Office offered standard patents for technologies that fell into the ‘privately patentable’ category. But inventions that would be useful only in the production of fissionable material, or when using such material or atomic energy in a military weapon, were non-patentable. The government (specifically, the Atomic Energy Commission) could also step in and require ‘compulsory licenses’ for technologies deemed to be in the public interest. Even further back, in the nineteenth century, the governments of several European countries, including France, Switzerland and Italy, limited or even banned patents on foods and pharmaceuticals to ensure that people had sufficient access to these products7. Existing frameworks Biotechnology, including gene editing, is already regulated to some degree through patents. In 1998, the European Parliament and Council passed a directive on the legal protection of biotechnological inventions. This harmonized Europe’s approach to patents in the emerging field; it covers all European Union countries and the 38 member countries of the European Patent Office. It also addressed people’s concerns about the moral and socio-economic implications of individuals being able to obtain patents on living entities, such as human embryos or genetically engineered plants and animals. The directive states that governments can grant patents on animals that have been modified only if the resulting benefit to humankind outweighs the animal’s suffering. It even includes prohibitions on patenting processes that could be used to modify human sperm, eggs or embryos. Moreover, some scientific organizations and researchers who use CRISPR–Cas9 have themselves recognized the power of patents to govern gene editing, and are writing their own licensing agreements. For example, the Broad Institute of MIT and Harvard, in Cambridge, Massachusetts, is a non-profit research institution that holds expansive patents on CRISPR–Cas9 technology. It prohibits its licensees from using CRISPR–Cas9 to modify human embryos, alter ecosystems or modify tobacco plants8. Similarly, Kevin Esvelt at the Massachusetts Institute of Technology (MIT), also in Cambridge, holds a patent on a ‘gene drive’ that could be used to spread a particular genomic alteration throughout an animal population. He requires those who wish to license this patent to disclose their proposed use, and has suggested that other scientists working on gene drives do the same. He argues that this will enable public discussion9. What I’m calling for, however, is different: more-**formal**, **comprehensive**, **government-driven regulation using the patent system**. This would **cover all domains of gene editing**, not just certain areas of research. It would have **more transparency and political legitimacy** than individual efforts ever could, **by involving government institutions** that are explicitly charged with representing the public interest. And it would **enable** governments to exploit the **unique vantage point that patent offices** **have on the early stages of scientific fields and industries.**

(Inventors usually file patent applications before they try to get regulatory approval for new technologies.) In the United States, Congress could authorize a working group to convene an **advisory committee** for gene-editing patents. The working group could include: individuals from the Environmental Protection Agency, who are trained in assessing ecosystem impacts; staff from the Department of Commerce, which oversees the US Patent and Trademark Office; personnel from the Department of Health and Human Services, who have deep understanding of biomedical research, health-care costs and research ethics; and staff from the Government Accountability Office, which in the past few years has developed expertise in technology assessment. The advisory committee should also comprise scientists, physicians, ethicists, social scientists, historians, lawyers and representatives from the private sector. Building on existing laws such as the 1954 Atomic Energy Act, the committee could put together a regulatory framework for reviewing and awarding patents related to gene editing. It would need to **incorporate** the **perspectives of citizens** at every step10, and might **place inventions into distinct categories**. **Perhaps** the **use of CRISPR**–Cas9 **for editing human embryos would not receive patent protection**, for instance, **whereas** the **use** of the technology **to correct a common mutation that causes heart failure would**. Under such a framework, the committee could identify inventions that are likely to be so important to the public interest that the government should monitor closely how associated patents are used and licensed, and **step in to** **force broad licensing** **if** a patent holder charges **too high a price** for access to their invention. (Currently, the 1980 Bayh–Dole Act gives the US government ‘march-in’ rights in the case of taxpayer-funded research, although it has never been used in this way11.) The EU directive on the legal protection of biotechnological inventions already provides Europe with some guidance on which gene-editing processes and products to exclude from patentability5. But 20 years on, additional oversight is needed. To develop a more detailed governance framework, the European Patent Office should convene an advisory committee to develop a framework, similar to the one proposed for the United States. This could then by adopted by the European Patent Office and EU member countries. Ultimately, patent law will need to be just one of many regulatory schemes. Some developers might still create and use ethically problematic technology, even if they are unable to patent it. But existing approaches, and the entities that are conventionally tasked with overseeing areas of scientific research, seem ill-equipped to address complex societal and value-based concerns in an increasingly privatized world. Patents, which affect the thousands of investigators now using CRISPR–Cas9 in both the private and public sector, should be part of the mix.

#### Absent Government regulation, gene editing is dominated by the market which is used to reduce genetic diversity – that causes Extinction.

Wolfe 9 Christian Wolfe 7-27-2009 “Human Genetic Diversity and the Threat to the Survivability of Human Populations” <https://www.ohio.edu/ethics/2003-conferences/human-genetic-diversity-and-the-threat-to-the-survivability-of-human-populations/> (Associate Editor for American Association of Inside Sales Professionals)//re-cut by Elmer

Through advances in reproductive technologies humans will eventually have the ability to utilize nearly fully artificial selection on human populations. These technologies raise many ethical and theological concerns. I will address one of the pragmatic ethical concerns, the potential loss of genetic diversity. **Genetic diversity has a direct relation to the** fitness and **survivability of** various **species** and populations; as genetic diversity decreases within a population, so does the fitness and survivability of that population. An examination of the genetic diversity argument (GDA) reveals that there is not strongly persuasive evidence regarding the effects on genetic diversity of the reproductive technologies on human populations. The only method available to produce the required evidence is through a very complex form of human experimentation. The type of human experiment that would produce the evidence is incompatible with present ethical codes of conduct. Therefore, any implementation of these technologies on human populations should be banned. There are many emerging technologies that could potentially affect genetic diversity. These include **genetic testing** and screening, selective breeding, population control, sterilization, selective abortion, embryo testing and selection, sperm donation, egg donation, embryo donation, surrogate pregnancy, fertility drugs, contraception, cloning embryos, and germ line or somatic cell manipulation (Resnik 2000, 454). Each of these reproductive technologies **affects** **the** composition of the human **gene pool by** increasing or **decreasing the frequency of different genotypes** or combinations of genotypes (Resnik 2000, 454). The germ-cell line, or just germ-line, constitutes a cell line through which genes are passed from generation to generation (World of Genetics 322). Germ-line therapy is often differentiated from somatic cell therapy, which is the alteration of non-reproductive cells. This distinction is not as clear as much of the literature supposes, but the problems with the germ-line/somatic cell distinction are beyond the scope of this paper. The focus of this paper includes the screening of embryos with the possibility of destruction of certain embryos, the modification of DNA (deoxyribonucleic acid) of early stage embryos through in-vitro fertilization (IVF), and the modification of parent gametes (Zimmerman 594-5). These technologies pose the clearest threat to genetic diversity of human populations. Genetic testing and screening examines the genetic information contained in a person’s cells to determine whether that person has or will develop a certain disease, is more susceptible to certain environmental risks, or could pass a disease on to his or her offspring (World 305). Parents could subject themselves to testing to determine whether or not to reproduce based on the likelihood of their potential children inheriting their genetic maladies. Also, embryos can be subjected to testing and screening to determine the likelihood that the future individual will develop a genetic disease. From that information, parents can decide to destroy the embryo, alter the embryo, or leave the embryo unmodified and risk that the child will develop a genetic disease. Germ-line gene therapy (GLGT) is germ-line manipulation on the genetic level in order to prevent genetic diseases in future persons (Richter and Bacchetta 304). The goal of GLGT is to treat human diseases by correcting the genetic defects that underlie the genetic disorders (Anderson and Friedmann 907). Therapy presents an alternative to destroying embryos likely to develop genetic disease by actually correcting genetic defects. Also available is the alteration of parent gametes in order to eliminate the possibility of passing on genetic disease to their offspring. GLGT allows for the alteration of either the early stage embryo or the parent gametes to prevent genetic disease. By either eliminating those genotypes that are likely to produce genetic disease or by altering the genome to actually prevent the genetic disease from developing, these technologies have great potential to affect the genetic diversity of a population. Genetic diversity is the variety and frequency of different genotypes or combinations of different genotypes within a population. A population is a geographically, socially, or culturally linked group whose reproductive decisions affect those within the group. Genetic diversity is measured by genetic variability, which diminishes in a population when the number of different phenotypes or the number of different combinations of genotypes decreases. Since populations are composed of individuals that carry genotypes, individual reproductive outcomes affect the genetic variability within specific populations (Resnik 2000, 452). Genetic diversity provides the resource for phenotypic variation that is integral in determining the rate of evolutionary change in an environment. A population that lacks genetic diversity will be poorly equipped to meet environmental changes and demands (Resnik 2000, 452). The importance of genetic diversity is undeniable; the survivability of a population is directly related to genetic diversity. While genetic diversity has no intrinsic value, genetic diversity has a clear instrumental value. Humans place positive value in genetic diversity as it promotes the extrinsic value of survivability. There is an ethical duty to prevent decreases in the genetic diversity of populations because of its importance in the survivability of those populations. Decreases in genetic diversity in populations are ethically undesirable because actions that reduce the survivability of the population are unethical. The genetic diversity argument (GDA) starts from the fact that scientific and technological developments in the realm of genetics and human reproduction will greatly affect the genetic diversity of human populations. There are both pessimistic and optimistic versions of the argument. I will briefly describe both versions of the GDA. The pessimistic version of the argument contends that the increased ability to control human reproduction will result in a loss of genetic diversity that will threaten the health and survivability of human populations (Resnik 2000, 451). **This threat to** health and **survivability is due to a decrease in the populations’ ability to adapt to environmental changes and demands**. In effect, these technologies have the potential to make the pool of available phenotypic traits limited enough so that human populations will not be able to respond to changes in environmental demand. This version of the GDA warns that germ-line altering reproductive technologies will reduce populations’ gene pools and eliminate potentially useful genes. Genetic diversity provides a resource of these useful genes. **Evolutionary change** is blind and **has no way to know which genes are useful**, therefore it is potentially **damaging** **to** population **survivability to eliminate genes of any sort.**

As Glenn McGee notes, “The point of the GDA is that human beings also have no way of knowing which genes will be useful in the future or in different environments” (cited in Resnik 2000, 456). For instance, genetically homogenous populations of corn face problems with blight due to lack of genetic diversity. Although human populations have an ever-increasing level of control over the environment, the pessimistic response still turns on the inability to determine which genes will be useful in the future. The optimistic version of the genetic diversity argument contends that these reproductive technologies could lead to increases in human health and survivability resulting in an improvement of the well being of populations (Resnik 2000, 457). The basis for this response rests on the historical fact that advances in technology increase humans’ ability to control nature. The ability to control nature often leads to positive changes in the adaptability and survivability of human populations. The optimistic GDA relies on this historical fact and the seemingly obvious inference that the above technologies will increase the ability to affect the genetic diversity of human populations (Resnik 2000, 457). A commonly cited example of how genetic diversity can be increased with the implementation of such technologies is the incredible diversity of canines. Of course, there are important dissimilarities such as the explicit intention to increase phenotypic diversity. **A major factor** **in whether these reproductive technologies** **will** increase or **decrease genetic diversity is what model they are implemented under, free market or state control**. Each model addresses the concerns and motivations of those affected differently. The **free market** model is based upon the reproductive decisions of a diverse group of potential parents with separate interests, motivations, and means. The free market is the method by which many consumer decisions are made in the United States. This model is fundamentally **based on** the interaction between **supply and demand**. If a market demands diversity of a product, then the market will often supply the desired diversity. If the market demands the standardization of goods, such as building supplies, then that homogeneity is likely to be supplied. Also, markets create new preferences and demands by introducing new goods and services to the market. Most often, advancements in technology increase market variability, except of course if that development results in the formation of a monopoly. The diversity of goods in the free market system of America seemingly justifies the inference that a free market model for reproductive technologies would lead to increases, not decreases, in the genetic diversity of human populations. Both J. Glover and W. Gardner’s individual studies conclude, “Increases in our ability to control human reproduction will result in more genetic diversity in the human population because parents will have a variety of preferences and values that they can use in selecting offspring” (cited in Resnik 2000, 458). Just as technological advancements have increased the availability of diverse consumer products, germ-line altering technologies could increase the available options in reproduction and therefore increase the diversity of human populations. Nevertheless, confounding factors such homogeneity of desirable characteristics makes the above inference much more dubious than it first appears. The **major problem with** the free **market** model **is** the potential **emergence of the homogeneity of desirable characteristics**. Many characteristics such as intelligence, athleticism, and health, are almost universally accepted as desirable. Other characteristics such as height, eye color, and hair color, also have particular value attached to them. Genetic homogeneity could arise if the consumers of reproductive technologies have similar preferences for traits. As Resnik states, “If most people want tall, intelligent, healthy children with blonde hair and blue eyes, then parental choices could produce a phenotypically and genetically homogeneous population” (2000, 459). This problem is only exacerbated when one considers the phenomenon of fads. **Societal pressures and obligations may** also **produce conformity**. While these social effects may not take hold immediately, it seems possible, if not probable that these pressures would eventually affect reproductive decisions. Genetic homogeneity may be an unintended consequence of a population sharing common values (Resnik 2000, 459). If most people within a population have similar characteristic preferences and a desire to conform, genetic homogeneity is almost inevitable. Of course much of this line of reasoning depends on genetic determinism, which is incredibly naïve and misinformed. Environmental factors often play a decisive role in which phenotypes are displayed. If certain desirable traits, such as intelligence or health, were strongly linked to environmental factors regardless of genotype, then the inference from individual choices to phenotypic characteristics would be dramatically weakened (Resnik 2000, 465). On the other hand, **if certain genes** or series of genes **are linked to a trait**, and that genotype is most frequently selected, it would still **poses** the potential **threat of** a **genetically** **homogeneous population**, although not phenotypically homogeneous.

#### Genetic Diversity outweighs – hurts resilience to shock which allows exogenous factors to cause Extinction – specifically turning disease.

Becker 17 Rachel Becker 10-9-2017 “Sex, disease, and extinction: what ancient DNA tells us about humans and Neanderthals” <https://www.theverge.com/2017/10/9/16448412/neanderthal-stone-age-human-genes-dna-schizophrenia-cholesterol-hair-skin-loneliness> (Verge Contributor)//Elmer

The findings help explain what exactly Neanderthal DNA is doing in many modern human genomes, and how it affects our health. Piecing together the sex lives of our human ancestors may also help us understand how and when these genes were exchanged. All together, the three **studies** — published in various journals last week — **contribute** key clues to the mystery of **why humans survived to populate the globe, even as** our close cousins, the **Neanderthals, died out.** Modern humans, or Homo sapiens, and Neanderthals shared a common ancestor roughly half a million years ago. They then split and evolved in parallel: humans in Africa, and Neanderthals on the Eurasian continent. When humans finally ventured to Eurasia, they had sex with Neanderthals, swapping DNA around. Today, people who aren’t of African descent owe roughly 2 percent of their DNA to their Neanderthal ancestors. “The first question that anyone ever asks is ‘Well, what does it do?’” says Janet Kelso, a bioinformatician who studies genome evolution at the Max Planck Institute in Germany. Previous studies have linked Neanderthal DNA to a big range of health conditions in modern-day people, including depression, nicotine addiction, and skin disorders. But it’s not all bad: understanding which stretches of Neanderthal DNA stuck around might also help scientists tease apart which traits might have helped ancient humans survive in Eurasia, like changes to skin and hair, or resistance to certain diseases. There’s also another mystery to solve: Neanderthals went extinct about 40,000 years ago, while Homo sapiens did not. Why? There are a lot of theories, including that alliances between modern humans and dogs helped humans hunt food better, essentially starving Neanderthals out of Europe. Or, humans might have reproduced faster than Neanderthals, multiplying and edging them out. “It’s still one of those unsolved and really interesting questions,” says Martin Sikora, a geneticist at the University of Copenhagen. “Were we more successful because we had better technology, or was it just a consequence of pure numbers?” To piece the story together, scientists are searching for more **Neanderthal genomes** locked in ancient bones, and for more Neanderthal DNA hiding in present-day genomes. The studies published last week have uncovered both. A NEW ANCIENT NEANDERTHAL GENOME The first study, published in Science, describes a bone fragment called Vindija 33.19, which was found in a Croatian cave of the same name in the 1980s. Now, researchers have finally been able to sequence the DNA locked inside, discovering it belonged to a female Neanderthal who lived 52,000 years ago. Researchers found that the Vindija Neanderthal was very similar genetically to another Neanderthal who died about 122,000 years ago in the Altai mountains of Siberia (dubbed the Altai Neanderthal). The fact that two Neanderthals separated by more than 3,700 miles and 70,000 years were so similar suggests that Neanderthal communities were tiny, with very **little genetic diversity**. “It’s quite amazing when you think about it,” says study author Kay Pruefer, at the Max Planck Institute. “They are really so closely related that **you cannot find any two people** on this planet that are **this close**.” That could support the theory that Neanderthals’ **low** genetic **diversity** may have **contributed to** their **extinction**. Genetic diversity forms the basis for natural selection. **If everyone** in a population **had the exact same** versions of the same **genes**, then **one plague** **or one hard winter could wipe everyone out**. And then **there’d be no survivors** to pass on the genes that would give their offspring a chance to survive the next plague or harsh winter. Incest can also lead to genetic abnormalities: the Altai Neanderthal was the daughter of two half-siblings, and while the Vindija Neanderthal’s parents weren’t related, they were very, very genetically similar.

## Case

### Advantage 1

#### Top-Level:

#### 1] No solvency – 1AC Sherkow isolates the reason for lack of CRISPR research as lack of funding, but the aff removes all potential for revenue because there aren’t any more patents

#### 2] No impact – the patent disputes will be resolved, at which point all the 1AC innovation begins – make them prove that it’s try or die now

#### The Aff causes Bioterrorism – two internal links –

#### 1] Eliminating CRISPR Patents cause rise of unethical biohacking.

Zettler 19, Patricia J., Christi J. Guerrini, and Jacob S. Sherkow. "Regulating genetic biohacking." Science 365.6448 (2019): 34-36. (Ohio State University Moritz School of Law)//Elmer

Genetic **biohacking** is also potentially **subject to U.S. laws that are enforced by private** rather than government **actors**. These may fill some of the gaps in public regulators’ ambit (9). **Patent owners**, for example, **can impose ethical restrictions on licensees,** such as the Broad Institute’s licenses for its CRISPR patents to Bayer (formerly Monsanto), **with conditions that** Bayer **avoid research activities that are potentially harmful to public health**, **including** **tobacco research and germline editing** (10). **Such license restrictions can**—and should—**be used to police commercial manufacturers of genome-editing kits and reagents popular in biohacking communities**, just as they have previously been used to prevent activities that pose national security, environmental, or public health risks (11). Even without a license in place, **patent owners can enforce restrictions through threats of patent infringement litigation against any recalcitrant biohackers or manufacturers of biohacking products**. A similar model was proposed as an attempt to restrict the use of “gene drive technology”—inheritable versions of CRISPR designed to drive a specific allele through generations of a population (12). Beyond patents, people injured by genetic biohacking materials could potentially bring tort law claims against biohackers and component suppliers to seek compensation for their injuries. A person injured while using a DIY CRISPR kit, for example, would likely be able to sue the seller of the kit —a potentially strong deterrent to marketers of unsafe biohacking materials.

#### Expanded Biohacking risks Bioterrorism.

Wikswo 14, J., S. Hummel, and V. Quaranta. "The Biohacker: A Threat to National Security." CTC Sentinel 7.1 (2014). (a biological physicist at Vanderbilt University. He was born in Lynchburg, Virginia, United States. Wikswo is noted for his work on biomagnetism and cardiac electrophysiology.)//Elmer

The **ability of non-scientists to create** and deploy **a biological weapon** highlights the emergence of **a new threat, the “biohacker.”** “Biohacking” is not necessarily malicious and could be as innocent as a beer enthusiast altering yeast to create a better brew. Yet the **same technology** **used by** a benign **biohacker** **could** easily **be transformed into** a tool for the disgruntled and disenfranchised12 to modify existing or emerging **biological warfare agents** **and employ them as bioterrorism**. A 2005 Washington Post article by Steve Coll and Susan Glasser presciently stated that “one can find on the web how to inject animals, like rats, with pneumonic plague and how to extract microbes from infected blood…and how to dry them so that they can be used with an aerosol delivery system, and thus how to make a biological weapon. If this information is readily available to all, is it possible to keep a determined terrorist from getting his hands on it?”13 This article argues that the biohacker is a real and existing threat by examining evasive biohacking strategies and limitations of current detection methods. The article finds that more active measures are required to stem the growing, long-term threat of modified BW agents employed by individuals. The **biohacker is** not only **a credible threat**, but also one that can be checked through improved detection and by disrupting BW agent delivery methods.

#### 2] CRIPR access leads to democratization of biotech – makes bioweapons more available.

Antonio Regalad. February 9, 2016. Top U.S. Intelligence Official Calls Gene Editing a WMD Threat. https://www.technologyreview.com/2016/02/09/71575/top-us-intelligence-official-calls-gene-editing-a-wmd-threat/

Gene editing refers to several novel ways to alter the DNA inside living cells. The most popular method, CRISPR, has been revolutionizing scientific research, leading to novel animals and crops, and is likely to power a new generation of gene treatments for serious diseases (see “Everything You Need to Know About CRISPR’s Monster Year”). It is gene editing’s relative ease of use that worries the U.S. intelligence community, according to the assessment. “Given the broad distribution, low cost, and accelerated pace of development of this dual-use technology, its deliberate or unintentional misuse might lead to far-reaching economic and national security implications,” the report said. The choice by the U.S. spy chief to call out gene editing as a potential weapon of mass destruction, or WMD, surprised some experts. It was the only biotechnology appearing in a tally of six more conventional threats, like North Korea’s suspected nuclear detonation on January 6, Syria’s undeclared chemical weapons, and new Russian cruise missiles that might violate an international treaty. The report is an unclassified version of the “collective insights” of the Central Intelligence Agency, the National Security Agency, and half a dozen other U.S. spy and fact-gathering operations. Although the report doesn’t mention CRISPR by name, Clapper clearly had the newest and the most versatile of the gene-editing systems in mind. The CRISPR technique’s low cost and relative ease of use—the basic ingredients can be bought online for $60—seems to have spooked intelligence agencies. “Research in genome editing conducted by countries with different regulatory or ethical standards than those of Western countries probably increases the risk of the creation of potentially harmful biological agents or products,” t

he report said. The concern is that biotechnology is a “dual use” technology—meaning normal scientific developments could also be harnessed as weapons. The report noted that new discoveries “move easily in the globalized economy, as do personnel with the scientific expertise to design and use them.” Clapper didn’t lay out any particular bioweapons scenarios, but scientists have previously speculated about whether CRISPR could be used to make “killer mosquitoes,” plagues that wipe out staple crops, or even a virus that snips at people’s DNA. “Biotechnology, more than any other domain, has great potential for human good, but also has the possibility to be misused,” says Daniel Gerstein, a senior policy analyst at RAND and a former under secretary at the Department of Homeland Defense. “We are worried about people developing some sort of pathogen with robust capabilities, but we are also concerned about the chance of misutilization. We could have an accident occur with gene editing that is catastrophic, since the genome is the very essence of life.”

#### The Disease Impact –

#### 1] They can’t solve it – their impact is about future pandemics BUT their CRISPR I/L is about prior-known disease that we can find genetic cures to.

#### 2] The Aff will say “CRIPSR solves their turns” – that’s incorrect – CRISPR isn’t a silver bullet for Disease.

Radcliffe 17 Shawn Radcliffe 8-26-2017 "Will Gene Editing Allow Us to Rid the World of Diseases?" <https://www.healthline.com/health-news/will-gene-editing-allow-us-to-rid-world-of-diseases> (Shawn Radcliffe is a science writer and yoga teacher in Ontario, Canada.)//Elmer

Safety and ethical concerns **CRISPR**-Cas9 is a powerful tool, but it also **raises several concerns**. “There’s a lot of discussion right now about how best to detect so-called ‘**off-target effects**,’” said Hochstrasser. “This is what happens when the [Cas9] protein cuts somewhere similar to where you want it to cut.” Off-target cuts could lead to **unexpected genetic problems** that cause an embryo to die. An **edit** **in the wrong gene** **could** also **create an entirely new genetic disease that would be passed onto future generations**

. Even using CRISPR-Cas9 to modify mosquitoes and other insects raises safety concerns — like what happens when you make large-scale **changes to an ecosystem** or a trait in a population that **gets out of control**. There are also many ethical issues that come with modifying human embryos. So will **CRISPR**-Cas9 help rid the world of disease? There’s no doubt that it will make a sizeable dent in many diseases, but it’s **unlikely to cure all** of them any time soon. **We** already **have tools for avoiding genetic diseases** — like early genetic screening of fetuses and embryos — but these are not universally used. “**We still don’t avoid** tons of genetic diseases, **because** a lot of **people don’t know that they harbor mutations that can be inherited**,” said Hochstrasser. **Some** genetic mutations also **happen spontaneously**. This is the case with many cancers that result from environmental factorsTrusted Source such as UV rays, tobacco smoke, and certain chemicals. People also make choices that increase their risk of heart disease, stroke, obesity, and diabetes. So unless scientists can use CRISPR-Cas9 to find treatments for these lifestyle diseases — or genetically engineer people to stop smoking and start biking to work — **these diseases will linger** in human society. “Things like that are always going to need to be treated,” said Hochstrasser. “I don’t think it’s realistic to think we would ever prevent every disease from happening in a human.”

### Advantage 2

#### Low WTO causes regional trade – yes trade-off

Isfeld 14 Gordon Isfeld 3-17-2014 business.financialpost.com/2014/03/17/with-rise-of-shot-gun-trade-agreements-is-the-wto-even-relevant-anymore/ “With the rise of 'shot-gun' trade agreements, is the WTO even relevant anymore” //Elmer

OTTAWA — It’s getting awfully crowded out there in the free-trading world. The seemingly endless hunt for new global partners is redefining the traditional and hard-fought rules of engagement between nations. So much so, observers say, the old world order — remember the WTO, and GATT before it — has increasingly become a sideshow to the proliferation of bilateral, **trilateral** **and**, often, **multi-lateral** agreements. Even the term “free trade” no longer accurately describes the “new world” of negotiations — one that encompasses far more than what and how products are permitted to slide under domestic tariff radars. For Canada, we can now add South Korea and the European Union — deals long in the making but only weeks in the signing — after a string of minor agreements since the landmark free trade act 25 years ago with the United States, and later to include Mexico. Now, as the growing mass of country-to-country, region-to-region agreements has made apparent, it’s open season on anything that moves between borders — not only products, investments and intellectual property, but also new rules on competition, and the inclusion of labour laws and environmental guidelines. These are just some of the areas of possible disputes that the World Trade Organization “does not deal with,” said Debra Steger, a professor of law at University of Ottawa, specializing in international trade and development. “These are new models. These are not traditional trade agreements, per se.” Ms. Steger, who worked for the federal government on the Uruguay Round of negotiations that led to formation of the WTO, said the framework of recent deals goes “way beyond subjects that NAFTA dealt with.” “Trade, even in the WTO, isn’t only about tariffs. It’s not just about customs and border measures,” she said. “But it’s not about behind-the-border regulatory matters, like environmental regulation and labour standards, competition policy and human rights, corruption, and on and on it goes.” Free trade, between where ever, has become the go-to issue for politicians, business leaders, public-policy makers and private interest groups. Note, this month’s sudden but long-rumoured announcement by the Harper government of a free-trade deal with South Korea, nearly 10 years after talks began and stumbled, and resumed again. Arguably, the deal was finally done as a result of the resolution to Canada’s drawn-out dispute with Seoul over our beef exports — the so-called “mad cow” disease leading to a ban in that county and others. Of course, the United States, the European Union and Australia, among others, already had agreements in hand with South Korea. A few months earlier, Ottawa inked its EU deal — the Comprehensive Economic and Trade Agreement — which was again the outcome of a seemingly endless circle of negotiations that still left Canada trailing similar pacts by the U.S. and others. Even so, these pacts “affect the WTO and WTO negotiations for a number of reasons. That’s a major problem,” said Ms. Steger. “The major developed countries have gone off and started these efforts to negotiate these big FTAs [free trade agreements] as a response to the declining situation in the Doha Round. The WTO — reborn in 1995 out of the General Agreement and Tariffs and Trade, the original body created in 1948 — has been struggling to maintain its relevance as the global arbiter of trade agreements and dispute resolution. The cachet of the 159-member body, however, has been diminished in recent years as countries moved to seal their own free-trade deals with major partners in the absence, some would argue, of any significant movement by the WTO on its own 2001 trade liberalization initiative, launched in Doha, Qatar. Late last year, members managed to agree to only limited movement on trade under the Doha Round of talks. Even now, details remain to be worked out. “One of the reasons why we’re seeing this sort of shot-gun approach [to trade agreements outside of the WTO] is because a number of countries are concerned that the big global deals are probably next to impossible at this stage, given how the Doha Round went and what we ended up with there, which was next to nothing,” said Douglas Porter, chief economist at BMO Capital Markets in Toronto. “They did manage to reach a tiny deal when all was said and done, but it was very modest in terms of its scope.” The move toward bilateral or multi-lateral agreements “is a symptom of the problems that we were running into at the WTO,” Mr. Porter said. “Important players are probably quietly questioning the future for the WTO…. Is it that death knell for the WTO? I don’t think so. [But] it just means we might not be able to accomplish grand, global deals in the future.” However, “there’s really no other way to approach trade disputes with, say, a country like China, then through that body at this point.” “Even 10 years ago, I think it was more straightforward to come to global trade rules. You had two major players, Europe and the U.S., and a few next tier players, including Japan,” Mr. Porter said. “Now, though, you have all kinds of important big players that have a huge chunk of global trade, and have very different goals and aims, and it might be the nature of the global economy now — the reality that we have many different groups in many different regions. “It might be impossible to square that circle.” Over the course of 25 years, Canada has piled on more than a dozen free trade agreements. The first — taking effect on Jan. 1, 1989 — was with the United States. A heated political issue in the 1988 federal election, which Brian Mulroney’s Conservatives won, the FTA was expanded in 1994 to include Mexico and rebranded as NAFTA. Other free trade deals, though much smaller, were signed in subsequent years, some yet to take effect: Israel, Jordan and Chile, followed later by Costa Rica, Peru, Panama, Honduras and Colombia, leading up to the pacts with EU and South Korea. Negotiations are ongoing for at least another dozen agreements. For countries such as Colombia, which has had an agreement in effect with Canada since 2011, the goal is “to insert our economy into the world economy,” said Alvaro Concha, trade commissioner of Proexport Colombia, based in Toronto. “At the beginning of this decade, we had only our preferential access to over 500 million consumers,” Mr. Concha said. “With all the potential FTAs we’ve been signing with potential markets and with potential partners, we believe that not just the potential buyers of our products, but also the potential investors in our country, we have opened our preferential access to over 1.5 billion consumers.” Likely to push the WTO further into the shadows of global trade will be the Trans Pacific Partnership. “In many ways, the Trans Pacific Partnership will be, if it is successful, an updating of the NAFTA, because the U.S. and Mexico are involved, as well as some [trading] partners we already have within Latin America, like Peru,” said Ms. Steger, at the University of Ottawa. “But [there are] also some key countries in Asia that we don’t have agreements with yet. And some other developed countries in that regional, New Zealand and Australia, that we don’t have agreements with,” she adds. “So that [TPP] agreement is very, very important. It’s also the first major plur-lateral agreement that the world has seen.”

#### Economy Impact – Regionalism solves it – the internal link is interdependence which we solve.

#### Group the Trade Impact:

#### 1] Current Regional Trade isn’t Great Power Competition – it’s regional integration that’s far more open which takes out their Exclusion I/L – that’s 1NC Brkic.

#### 2] Regionalism solves – it’s a building block – prefer gradual change to immediate ones.

Brkić 13, Snježana, and Adnan Efendic. "Regional Trading Arrangements–Stumbling Blocks or Building Blocks in the Process of Global Trade Liberalization?." 5th International Conference «Economic Integration, competition and cooperation», Croatia, Opatija. 2013. papers.ssrn.com/sol3/papers.cfm?abstract\_id=2239275 (Economics Prof at U of Sarajevo) //Elmer

There are **over 180 independent states** in the modern world, most of which **differ** enormously **in economic development and power**. World economy is therefore a battlefield of varied interests expressed in the action of different national economic policies. In such conditions, **attempts to integrate** world **economy** **by global liberalization of** international **trade cannot yield** significant **results overnight.** Global free trade is considered the first best solution, but is not feasible immediately and at once, since too many people believe that they would lose with global liberalization. According to the view believed to be optimistic, creation of international economic integrations could be a distinctive inter-step in the process of free world market creation. Lester Thurow points out: "In the long run, **regionalism** development **could be favorable** for the world. **Free trade within regions** and regulated trade between regions **could be** the **proper road to free world trade in a long term**. The shift from national to world economy at once would be too big a jump. One should first make a few smaller inter-steps, and pseudo-trading blocs coupled with regulated trade could be such a necessary inter-step." The essential rationale of this view is actually the speed of reforms - the gradual versus “big bang” approach. Many contemporary economists, in their analyses of world economy trends, conclude that political forces behind regional integration show signs of consistency with those acting towards global world trade. According to the optimistic view, the multilateralization process is slowed down by different standpoints on the free trade usefulness, by economic nationalisms, even by varying political interests, and therefore another way had to be found in order to achieve the world market integration – a slower one, but more effective in the existing constellation of international economic relations. This view denies the opposition between regionalism and multilateralism, and explains it as follows: Since integration improves economic relations between members through removing trading and other barriers, and since all these integrated regions are part of the world territory, the advancement of economic relations within regions can be understood as the advancement of global economic relations. Regional trading, i.e. economic blocs would in this case be only a bypass towards the creation of unified world market. "... What could not be achieved in global relations was achieved within regions, through multilateralization of the European economic area. These achievements were later followed by many countries in other world regions, in their mutual relations practice. Practically, we thus got regional multilateralisms." Regionalism advocates also point out that the formation of economic integrations could facilitate the pending WTO negotiation rounds. Actually, the Uruguay round was partly protracted due to a great number of participants and the "free riders" issue. Viewed in broader context, one could say that regionalism contributes to overall globalization as well, since these are processes motivated from the same source. Both regionalism and globalization are driven by big capital interests, and that these two phenomena are actually ways to make the centuries-long capitalism aspiration – unified world market - come true. According to this view, the globalization process as a process of world economy functional integration under the circumstances of imperfect market and hegemony weakening early in the 20th century has to be supported by the institutional component, either on a multilateral basis through international organizations and institutions such as the World Bank, IMF and WTO, or on regional scale through regional trading arrangements.

#### The Lake Evidence - Their card concedes a] the impact isn’t inevitable BUT driven by contingent choices which we control the U/Q that countries won’t by driven by those Great Power competitions and b] protectionism is driven by domestic forces – if that’s true, then WTO credibility doesn’t matter and they’ll defy the WTO anyways – here’s a re-highlighting.

1AC Lake 18. [(David Lake is a Professor of Social Sciences and Distinguished Professor of Political Science at the University of California, San Diego. "Economic Openness and Great Power Competition: Lessons for China and the United States,” April 30, 2018. <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3171196/>] TDI

I develop two central arguments. First, historically, great power competition has been driven primarily by exclusion or fears of exclusion from each power’s international economic zone, including its domestic market. Great powers in the past have often used their international influence to build zones in which subordinate polities – whether these be colonies or simply states within a sphere of influence – are integrated into their economies. These economic zones, in turn, are typically biased in favor of the great power’s firms and investors, with the effect of excluding (in whole or part) the economic agents of other great powers. These other great powers, in response, are then compelled to develop or expand their own exclusive economic zones. The “race” for economic privilege can quickly divide the world up into economic blocs. Like the security dilemma, great powers need not actually exclude one another from their zones; the fear of exclusion alone is enough to ignite the process of division. The race for privilege then draws great powers into over-expanding into unprofitable regions and, more important, militarized competition. Economic and military competition are thus linked, with the former usually driving the latter. The most significant military crises have, historically, been over where to draw the boundaries between economic zones and subsequent challenges to those boundaries. Economic closure and fear of closure have been consistent sources of great power conflict in the past – and possibly will be in the future. The **major exception** to this trend **was** the **peaceful transfer of** **dominance** **in Latin America** from Britain to the United States in the late nineteenth century. This suggests that **economic closure and great power competition** **is not inevitable**, **but a choice of the great powers themselves**. Second, this **international competition is driven**, in turn, **by domestic**, rent-seeking groups and their economic **interests**. In all countries, scarce factors of production, import competing sectors, and domestically-oriented firms have concentrated and intense preferences for market restricting policies, including tariffs and the formation of exclusive economic zones. Consumers and free trade-oriented groups have diffuse preferences for market enhancing policies, and thus tend to lose at the ballot box and in the making of national policy. This inequality in preference intensity does not mean protectionists always win; after 1934, the United States insulated itself by shifting authority to the executive and negotiating reductions through broad, multi-product international agreements.8 Yet, as the recent return to economic nationalism of the Trump administration suggests, protectionism often wins out. Rent-seeking is **a central tendency, not an inevitable success.** Contemporary great power relations are at a critical juncture. As China’s influence expands, the role of special economic interests in China is especially worrisome. In pursuit of stability, political support, or private gains, the government will always be tempted to create economic zones that favor its nationals. In this way, China will be no different than the majority of great powers before it. But, given the expansive role of the state in the Chinese economy, especially its backing of outward foreign investments by its state-owned enterprises (SOEs), and the close ties between business elites and its authoritarian political leaders, however, it will be even harder for China to resist biasing any future economic zone to benefit its own firms. Although China has gained greatly from economic openness, its domestic political system will be prone to rent-seeking demands by important constituents in areas of future influence. Critically, the United States is also moving toward economic closure with the election of President Trump on a platform of economic nationalism. Demands for protection against Chinese goods have been growing over time.9 The “China shock” that followed Beijing’s joining the World Trade Organization was a huge disruption to the international division of labor, U.S. comparative advantage, and especially U.S. industry.10 The Trans-Pacific Partnership, though now defunct, was “marketed” by President Barak Obama as a means of “containing” China, both economically and militarily, but was opposed by virtually all of the candidates in the 2016 presidential election for its trade-enhancing potential. President Trump has already signaled a much more hostile and protectionist stance toward China – as well as calling for the repeal of NAFTA and even questioning the utility of the European Union. Not only has he imposed tariffs on washing machines, solar panels, steel and aluminum, dangerously declaring the latter two issues of national security, he is making exceptions on these tariffs for friends and allies. 11 Implicitly targeting China, these protectionist moves by the administration risk creating preferential trading blocs not seen since the 1930s. He has also now proposed punitive tariffs on over $60 billions of imports from China into the United States.12 Acknowledging his inconsistencies on many policy issues, Trump’s economic nationalism has remained the core of his political agenda. The threat to the liberal international economy is not only that China might seek an economic bloc in the future, but that the United States itself is turning more exclusionary. For each great power to fear that the other might seek to exclude it from its economic zone is not unreasonable. If so, great power competition could break out in the twenty-first century not because of bipolarity or any inevitable tendency toward conflict, but because neither great power can control its own protectionist forces nor signal to the other that it would not exclude it from its economic zone. The British-U.S. case, again, suggests that exclusion and competition are not inevitable, but the current danger of economic closure is real and increasing. This article is synthetic in its theory and merely suggestive in its use of historical evidence. The theory aims to integrate current work on political economy and national security, not to develop a completely original take on this relationship. In turn, rather than testing the theory in any rigorous sense or delving into particular cases to show the theoretical mechanisms at work, so to speak, it surveys selected historical episodes to illustrate central tendencies. It is the recurring pattern across multiple cases that suggests why we should worry today. The remainder of this essay is divided in three primary sections. Section I briefly outlines the analytics of economic openness and great power competition. Section II focuses on historical instances of great power competition, highlighting the role of economic openness as a central cleavage in international politics. Section III examines contemporary policies in and between China and the United States. The conclusion suggests ways that the potential for conflict may be mitigated. The Open Economy Politics of Great Power Competition All states have a tendency towards protectionism at home and exclusive economic zones abroad. A tendency, though, is not an inevitability. The pursuit of protection and economic zones by domestic interests is conditioned by the political coalition in power at any given time and institutions that aggregate and bias the articulation of social groups. 13 The tendency is also influenced, however, by the actions of other countries. Protectionism can sour great power relations, but it is the desire for exclusive economic zones that drives great power competition and, given the possibility of coercion, influences grand strategy. Thus, the theory sketched here integrates insights from international political economy (see below), the literature on domestic politics and grand strategy,14 and systemic theories of international relations.15