**1NC**

**T**

**A] Interpretation – the affirmative must reduce IP protections for medicines, not medical technology**

**1] Medicines are consumable substances that treat or prevent disease**

**Kurrer 21** [Christian Kurrer, Policy Analyst at European Parliament. "Medicines and Medical Devices," European Parliament, 05-2021, accessed 9-2-2021, https://www.europarl.europa.eu/factsheets/en/sheet/50/medicines-and-medical-devices] HWIC

A. General rules on medicines

A medicinal product (medicine) is a substance or combination of substances that is used for the treatment or prevention of diseases in human beings. With the aim of safeguarding public health, the market authorisation, classification and labelling of medicines has been regulated in the EU since 1965. The evaluation of medicines has been centralised through the European Medicines Agency (EMA) since its creation in 1993 and a centralised authorisation procedure was put in place in 1995 to guarantee the highest level of public health and to secure the availability of medicinal products. The main pieces of legislation in this area are Directive 2001/83/EC[1] and Regulation (EC) No 726/2004[2], which lay down the rules for establishing centralised and decentralised procedures.

**2] CRISPR is a gene editing platform, it can help develop medicine(s) but it is not medicine**

**Editas No Date**

(Editas Medicine is a leading genome editing company focused on translating the power and potential of the CRISPR/Cas9 and CRISPR/Cpf1 (also known as Cas12a) genome editing systems into a robust pipeline of medicines for people living with serious diseases around the world. https://www.editasmedicine.com/crispr-gene-editing/)

CRISPR (pronounced “crisper”) is an acronym for “Clustered, Regularly Interspaced, Short Palindromic Repeats,” and refers to a recently developed gene editing technology that can revise, remove, and replace DNA in a highly targeted manner. CRISPR is a dynamic, versatile tool that allows us to get to and edit nearly any location in the genome, and has the potential to **help us develop medicines** for people with a wide variety of diseases. We view CRISPR as a “**platform” technology** because of its ability to target DNA in any cell or tissue. CRISPR uses a combination of 2 types of molecules to edit disease-related genes or to modify cells: a nuclease (the gene editor) and guide RNA (which helps the nuclease find the right place to edit). CRISPR’s ability to only edit intended DNA targets and avoid off-target editing is known as its specificity. Achieving high levels of specificity requires the right combination of nuclease and guide RNA.

**3] Process, not drug**

**Khatri, MD, 19**

(Minesh, https://www.webmd.com/cancer/guide/crispr-facts-overview, 10-14)

It might sound like something you’d find in the grocery store between the potato chips and cheese puffs, but CRISPR is state-of-the-art medicine. It might one day help cure conditions from cystic fibrosis to lung cancer. **CRISPR isn’t a drug. It’s a technique**. The goal is to cut out and fix glitches in your genes that threaten your health. Although it’s not the first gene-editing method scientists have tried, it’s the simplest, fastest, and most accurate. And that makes it a game-changer.

**B] Violation- the plan reduces protections on medical research technology, not medicine.**

**C] Standards –**

**1] Precision – prefer qualified evidence from experts with intent to define over contextual evidence from journalists that is less precise**

**2] Ground – they arbitrarily jettison "medicine" from the topic which turns and o/w aff clash arguments bc one-sided topic education doesn't matter if we can't engage w/ it**

**3] Limits – expanding beyond a strict definition of medicine opens the floodgates and makes neg prep impossible –**

**FDA Fact Sheet No Date** https://www.fda.gov/about-fda/fda-basics/fact-sheet-fda-glance

There are over 20,000 prescription drug products approved for marketing.FDA oversees over 6,500 different medical device product categories. There are over 1,600 FDA-approved animal drug products. There are about 300 FDA-licensed biologics products.

**4] Extra topicality and effects T are voting issues – vague plan mechanisms cause 2NR meltdown as we are forced to go for T or a CP to get back to square one**

**D] Topicality is a voting issue for predictable limits- it tells the negative what they do and do not have to prepare for. Use competing interpretations – reasonability causes a race to the bottom for questionable argumentation**

**At best it means they don't solve bc the plantext is the therapeutic technique / base protein that other drugs are derived from, not the drugs themselves**

**Innovation**

**1NC – Disease**

**Pharma industry innovation is up but profit margins are razor thin**

**Young 9-14-21**

(Peter, CEO and President of Young & Partners, and a member of Pharm Exec’s Editorial Advisory Board. https://www.pharmexec.com/view/fishawack-health-appoints-new-ceo-jonathan-koch)

Business. The business outlook for pharma manufacturers is positive with regard to drug development and the **volume and quality of promising drugs in the pipeline**. The industry’s innovations in drug development and productivity **have improved**. Combined with indirect R&D pursuits through the biotech industry, overall development activity has been **strong and should continue to be strong**. There has been a shift in emphasis toward orphan drugs, oncology therapies, new innovations such as mRNA, gene therapy, CAR-T, immune system solutions, CRISPR, etc. The current pandemic has been a plus for the reputation of the industry, but a negative with regard to the ability to execute clinical trials and to maintain industry supply chains. Generic pharma companies are **under severe profit pressures** and will continue to consolidate, cut costs, and try to push selectively into higher value and more protected product areas. They are under intense pricing and competitive pressure.

**CRISPR is K2 pharma research and R&D for future drugs and medicines—pharma already knows and is investing in CRISPR infrastructure already.**

**Enzmann and Wronski 19**

Brittany L. Enzmann, PhD and Ania Wronski, PhD; scientific communications manager and engineered cells product manager at Synthego; “How CRISPR Is Accelerating Drug Discovery”; Genetic Engineering & Biotech News; January 11, 2019, 2021; https://www.genengnews.com/insights/how-crispr-is-accelerating-drug-discovery/; EMJ

CRISPR holds **tremendous potential** in advancing pharmacological research, with its impact **spanning the entire preclinical drug discovery** pipeline. Because CRISPR makes gene editing more tractable and precise, **drug targets can be identified faster**, and disease models can be generated that are more realistic. An increasing number of **collaborations between industry and academia** are sure to further advance the role of CRISPR in drug development. Pharmaceutical companies are also **investing in CRISPR infrastructure** to develop the next generation of drugs. In parallel, CRISPR is also being used to develop novel gene- and cell-based therapies that modulate genes directly within the patient or through ex vivo methods. For example, chimeric antigen receptor T (CAR-T) cells are being engineered to target cancer. CRISPR not only holds promise for **developing therapies faster and at lower cost**, but also facilitates the advancement of personalized medicine. Soon, the tailoring of therapies to individual patients may no longer be just an idea, but a distinct reality.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that **without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations**.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

**COVID incentivizes engineered bioterror.**

**Walsh, 20** -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: **New tech**nology like **gene editing** and **DNA synthesis** has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, **engineered pandemics** are widely considered the **biggest existential risk facing humanity**.

That's in part because a pathogen could be **engineered** in a lab **for maximum contagiousness and virulence**, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The **democratization of biotech**nology could unleash a **wave of** creativity and **innovation**, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they **do not rule** the possibility **out** entirely. Although rare, there are recorded instances of **species going extinct due to disease**—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

**Case**

**crispr**

**Crispr causes extinction— lack of verification on projects.**

**Pandya 19** [(Jayshree, Ph.D., the founder and chief executive officer of Risk Group LLC is working passionately to define a new security centric operating system for humanity. Her efforts towards building a strategic security risk intelligence platform are to equip the global strategic security community with the tools and culture to collectively imagine the strategic security risks to our future and to define and design a new security centric operating system for the future of humanity) “Evolution Or Extinction: Where Will The Gene Editing Revolution Take Us” Forbes, 6/9/19. https://www.forbes.com/sites/cognitiveworld/2019/06/09/evolution-or-extinction-where-will-the-gene-editing-revolution-take-us/?sh=12fff3897b06] TDI

There is no doubt that gene editing tools bring great potential for the future of humanity. However, it is a dual-use technology and can be used for both good and bad. While it will likely revolutionize disease treatment, perhaps enhance intelligence, and give control to humans to evolve on our terms and timeline, **it can also become a powerful tool of destruction and maybe even extinction**. The emerging potential of the **“democratization of destruction”** amidst a do-it-yourself movement is a cause of great concern as **there is no way of knowing what changes are being** **made to the human or any living biological species genome,** **where, by who, with what intention, and with what consequences.**

The human ecosystem will inevitably move beyond natural evolution as scientists across nations are already using gene editing tools like CRISPR-Cas9. Gene editing in human embryos is frankly a reality now, as gene editing, genome editing, or genomic engineering processes -- in which DNA is inserted, deleted, modified, or replaced by making use of specific proteins that can cut DNA precisely in selected targeted locations -- is already being reported from across nations. **These examples already show us the potential for danger in gene editing.** In 2018, He Jiankui, a now-disgraced Chinese scientist, announced that he had successfully used CRISPR to give two twin baby girls immunity against HIV. However, scientists worldwide condemned not only the ethical ramifications of his work but also the results, noting that he likely focused on too specific of a mutation to properly give the babies immunity and that the gene he used has been linked with premature death. That brings us an important question: what security implications are emerging from gene editing, and are we prepared for the evolutionary implications?

Since DNA is involved in many biological processes: from building cells and controlling their number and type, to energy production, metabolism regulation, disease immunity, and so on, when gene editing is on its way to disrupting fundamental biological processes, it is vital to understand and evaluate its risks by evaluating how genome editing is used today. Acknowledging this emerging reality, Risk Group initiated a much-needed discussion on The Rise of Gene Editing with Dr. Rajesh Chowdhury Ph.D., on Risk Roundup.

While the process of natural biological evolution involves a series of natural changes over time that causes a species to evolve, adapt to the environment, or become extinct, the question is whether the ongoing gene editing revolution accelerates our timeline of evolution or extinction.

We, informed, intelligent, and conscious individuals across nations, must control our species’ evolutionary future. The scientist within us needs to be cautious of our actions with the human species (and any other biological species) and focus on security—to help us get through the expected turmoil brought on by gene editing tools, technological transformation, revolution, and evolution.

Let us be cautious and evolve with caution.

**Harmonization doesn't solve – 1] they don't fiat that it happens 2] the turn is about about misapplication not patents**

**Patents don’t hamper research, plan causes a shift to trade secrets**

**Cynober 19**

(Timothe, Former regulatory scientist at Voisin Consulting Life Sciences in Paris. https://www.labiotech.eu/in-depth/crispr-patent-dispute-licensing/, 11-2)

As more and more patents are granted, individual patent claims will **become narrower** and might have less value, which would make them harder to enforce. In this context, it is difficult to evaluate the weight of each patent for each technology and application. This situation may prompt some to rely on trade secrets to protect their assets rather than on patent protection.

**Patents don’t hamper research, plan causes a shift to trade secrets**

**Cynober 19**

(Timothe, Former regulatory scientist at Voisin Consulting Life Sciences in Paris. https://www.labiotech.eu/in-depth/crispr-patent-dispute-licensing/, 11-2)

As more and more patents are granted, individual patent claims will **become narrower** and might have less value, which would make them harder to enforce. In this context, it is difficult to evaluate the weight of each patent for each technology and application. This situation may prompt some to rely on trade secrets to protect their assets rather than on patent protection.

**Alternatives to CRISPR solve**

**Reader 20**

(Ruth, https://www.fastcompany.com/90561762/nobel-prize-jennifer-doudna-emmanuelle-charpentier-crispr-patent-lawsuit)

That litigation hasn’t entirely stopped CRISPR exploration. **In fact, a whole industry of apparatuses** and chemicals has emerged to facilitate CRISPR gene edits. CRISPR Cas-9 is showing promising results as a treatment for rare diseases such as sickle cell anemia as well as an implement for biomanufacturing. But the litigation may be shifting gene-editing research. Like any technology, CRISPR Cas-9 is not perfect. It’s not as precise as some scientists would like, and it can have unanticipated effects outside of the desired outcome. Scientists who don’t already have a claim to the CRISPR Cas-9 system may be more inclined to seek out **other gene-editing** opportunities rather than improve Cas-9. Conley says scientists may be wary of pushing the technology ahead. “It has absolutely put fear in the minds of many scientists who frankly could do great things for society,” says Conley. “They are living in terror of, well, if I go down this road a) am I going to be sued? And b) is there any commercial outlet where I’m going to have trouble raising money, because there’s fear and loathing around the CRISPR component?” Much of the new science surrounding CRISPR Cas-9 has come from scientists with a stake in the intellectual property. Last year, David Liu, a scientist at the Broad Institute and cofounder of gene-editing therapeutics company Editas Medicine, published a way of making more precise edits with fewer unintended effects using a new process called prime editing. One of Doudna’s companies, Scribe Therapeutics, is engineering CRISPR molecules, rather than using the ones found in nature, in order to do away with the natural aspects that get in the way of putting it to good use as a targeted gene editor. The company just raised $20 million and signed a deal with pharmaceutical company Biogen to implement its technology. Meanwhile, many researchers are seeking alternative gene-editing mechanisms, whether because of the litigation or because of the **imperfection of CRISPR Cas-9 itself**. There is an effort to find enzymes that perform many of the same cutting functions as the Cas-9 protein but are less entrenched in a legal morass. Conley thinks that eventually this avenue of research will push gene editing far beyond what CRISPR Cas-9 is capable of.

**SQ Voluntary licensing solves**

**GenomeWeb 3-10**-21 https://www.genomeweb.com/business-news/ers-genomics-licenses-crispr-patents-setsuro-tech#.YTTye45KhhE

ERS Genomics said on Wednesday that it has granted Japanese biotechnology startup Setsuro Tech a non-exclusive license to its CRISPR-Cas9 patent portfolio in Japan, which Setsuro said it will use to develop and supply cell and animal models. Financial and other terms of the deal were not disclosed. Dublin-based ERS Genomics was **founded to provide access** to CRISPR-Cas9 intellectual property held by Emmanuelle **Charpentier.** The IP is shared between her, Jennifer Doudna and the University of California, and the University of Vienna and is separate from genome editing patents held by the Broad Institute. Setsuro has developed a high-throughput genome editing method for mammalian embryos, which it calls genome editing by electroporation of Cas9 protein (GEEP). Using this method, the company is able to rapidly produce genetically engineered mice at low cost. Setsuro said it plans to use the ERS CRISPR technology to create genome-edited cell and animal models based on its customers' requirements. "Our technology enables us to provide researchers with genome-edited models quickly and at relatively low cost," Setsuro CEO Shinichiro Takezawa said in a statement. "The license from ERS expands our portfolio and having access to advanced technologies such as CRISPR-Cas9 will allow us to continue our high-quality offerings that combine CRISPR-Cas9 with our patent-pending technologies." ERS has signed **many similar licensing** deals for its CRISPR-Cas9 patent portfolio. Its most recent agreement was with Japanese drugmaker Otsuka Pharmaceutical at the beginning of March, for Otsuka's internal research and development programs to address areas of unmet medical need.

**Sub-licensing and “safe harbor” provisions mean patents don’t deter research**

**Mullin 16**

(Emily is a science and biotech journalist based in Maryland. https://www.technologyreview.com/2016/12/13/155448/crispr-patent-outcome-wont-slow-innovation/ 12-13)

Last week a panel of judges at the U.S. Patent and Trademark Office in Alexandria, Virginia, heard arguments as to who should own the rights to the century’s biggest biotechnology invention to date, a precise gene-editing system called CRISPR-Cas9 that has the potential to treat serious human genetic disorders and create designer crops that resist drought and pathogens. Embroiled in the dispute are the Broad Institute of MIT and Harvard, which holds 13 CRISPR-related patents, and the University of California, Berkeley, which believes it is the true inventor of the technology. Groups at the two universities are fighting for ownership of CRISPR gene editing in eukaryotic cells (those of humans, plants, and animals), which represents the most lucrative uses of the technology. At stake are billions of dollars tied up in numerous commercial agreements with biomedical and agricultural companies. The outcome of the so-called patent interference could render some of those contracts invalid. But the patent judges’ decision—expected in early 2017—is not likely to put any CRISPR companies out of business or even slow the lightning pace of research and development in commercial laboratories, experts say. “The success or failure of any company is not determined by patents alone,” says Mark Shtilerman, an intellectual-property lawyer at Deerfield Management, which has invested $20 million in Editas Medicine. Rather, he says, a company’s pipeline is more important. While Editas has exclusive licensing rights to use CRISPR technology from the Broad Institute to make medical treatments, other companies, including Intellia Therapeutics, CRISPR Therapeutics, and Caribou Biosciences, **hold licenses or sublicenses** to the rival intellectual property controlled by the University of California and several European inventors. Even with the fate of key patents up in the air, these companies have attracted a combined total of more than $1 billion in venture capital and are racing to develop therapeutics that use DNA editing to correct disease-causing genetic alterations. Editas, Intellia, and CRISPR Therapeutics declined to comment for this story. If the patent judges decide that the Broad is the official inventor of CRISPR and upholds all its patents, it’s likely that most other companies would then need to license the technology from the Broad or Editas, since these patents are fundamental to using CRISPR in eukaryotic cells, Shtilerman says. But it’s possible the judges could rule in favor of the University of California, in which case Editas and other companies aligned with the Broad would have to negotiate new license agreements. Harvard genetics professor George Church, a CRISPR researcher who is also a founding member of Editas, says he hopes that if the Broad wins, Editas will grant what is known as a sublicense to other companies developing CRISPR-related biotech drugs so they can “get on with their work.” He says he would be surprised if the winner of the patent battle didn’t dole out such licenses. “I don’t see the point in having winners and losers,” Church says. The more companies working on this technology, the greater the chance for one of them to develop a blockbuster drug, he says. In exchange for a sublicense, companies would agree to share a certain portion of profits with the patent holder. In the agricultural sector, DuPont has licensed CRISPR technology from Caribou Biosciences, and Monsanto has licensed patents from the Broad Institute. DuPont is already working to commercialize a CRISPR-edited corn product that it says will be available in five years. Neal Gutterson, vice president of research and development at DuPont Pioneer, said in a statement that the company does not speculate on ongoing legal proceedings. But he acknowledged that DuPont “has a strategy in place to position our business as a leader in the application of CRISPR-Cas in agriculture.” Colleen Tracy James, an intellectual-property lawyer specializing in life sciences at the firm Mayer Brown, says it could take as little as a few weeks for companies to negotiate and get a new license from the official inventor, if needed. She says the **winner “has an incentive to do it quickly and get the revenue**.” A third possible outcome of the patent hearing is that the judges could award patent rights to both the Broad Institute and the University of California. In that case, the companies licensing CRISPR technology would need to determine which institution owns the rights to the specific application they are using. Until then, companies developing potentially life-saving drugs are legally protected under what’s known as a “safe harbor” exemption, Shtilerman says. **The exemption means that companies can conduct research using a patented invention even if they don’t hold a license to use that technology.**

**Best science proves no warming impact.**

**Idso et al, PhDs, 18**

(Craig, Geography@ArizonaState, David Legates, Climatology@Delaware, ProfClimatology@Deleware, Fred Singer, Physics@Princeton, ProfEnviroScience@Virginia, Climate Change Reconsidered II: Fossil Fuels, NIPCC, Ch.2, p. 108-109, Chapter Contributors: Joseph Bast, FormerPresident@HeartlandInstitute, Patrick Frank, PhD Chemistry@Stanford, Kenneth Haapala, MS Econ, President@Science+EnvironmentalPolicyProject, Jay Lehr, PhD Hyrdrology@Arizona, Patrick Moore, Co-Founder@Greenpeace, PhD Ecology@UniversityBrittishColumbia, Willie Soon, PhD AerospaceEngineering@USC, Chapter Reviewers: Charles Anderson, PhD Biology@Stanford, AssocProfBiolofy@PennState, Dennis Avery, DirectorFoodSecurity@Hudson, FormerUSDeptAg, Timothy Ball, PhD Climatology@QueenMary, FormerProfGeography@Winnipeg, David Bowen, PhD Geology@UCBoulder, ProfGeology@MontanaState, David Burton, MA CompSci@UTAustin, Mark Campbell, PhD Chemistry@JohnsHopkins, ProfChemistry@USNavalAcademy, David Deming, PhD PublicPolicy@Harvard, ProfPublicPolicy@Harvard, Rex Fleming, PhD AtmosphericScience@Michigan, Lee Gerhard, PhD Geology@Kansas, François Gervais, PhD Physics@UniversityNewOreleans, ProfPhysics@FrançoisRabelaisUniversity, Laurence Gould, ProfPhysics@UniversityHatford, PhD Physics@Temple, Kesten Green, PhD Managment@VictoriaManagmentSchool, Hermann Harde, PhD Engineering@UniversityOfKaiserslautern, Howard Hayden, PhD Physics@DenverUniversity, Ole Humlum, PhD GlacialGeomorphology@UniversityCopenhagen, ProfGeography@Oslo, Richard Keen, PhD Climatology@Colorado, ProfAtmosphericScience@Colorado, William Kininmonth, MSc@Colorado, FormerHead@AustralianBureauOfMeteorologyNationalClimateCenter, Anthony Lupo, PhD AtmosphericScience@Purdue, ProfAtmosphericScience@Missouri, Robert Murphy, PhD Chemistry@MIT, ProfPharmacology@Colorado, David Nebert, MD@UniversityOregon, ProfEnvironmentalHealth@Cincinati, Norman Page, PhD Geology@Illinois, Frederick Palmer, JD@Arizona, Gath Paltridge, PhD AtmosphericPhysics@UniversityMelbourne, ChiefResearchScientist@CSIRODivisionAtmosphericResearch, Jim Petch, PhD Geography@KingsCollegeLondon, Jan-Erik Solheim, MA PoliSci@Oslo, FormerExecDirectorUNEnvironmentProgram, Peter Stilbs, PhD Chemistry@RoyalInstituteTechnology, Roger Tattersol, BA History+PhilosophyOfScience@Leeds, Frank Tipler, PhD Physics@Maryland, ProfPhysics@Tulane, Ftitz Vahrenholt, PhD Chemistry@Munster, Art Viterito, PhD Climatology@Denver, ProfGeography@Maryland, Lance Wallace, PhD Physics@CUNY)

Methodology The Scientific Method is a series of requirements imposed on scientists to ensure the integrity of their work. **The IPCC has not followed established rules** that guide scientific research. Appealing to consensus may have a place in science, but not as a means of shutting down debate. Uncertainty in science is unavoidable but must be acknowledged. Many declaratory and predictive statements about the global climate are **not warranted by science**. Observations Surface air temperature is governed by energy flow from the Sun to Earth and from Earth back into space. Whatever diminishes or intensifies this energy flow can change air temperature. Levels of carbon dioxide and methane in the atmosphere are governed by processes of the carbon cycle. Exchange rates and other climatological processes are poorly understood. The geological record shows temperatures and CO2 levels in the atmosphere **have not been stable**, making untenable the IPCC’s assumption that they would be stable in the future in the absence of human emissions. Water vapor is the dominant greenhouse gas owing to its abundance in the atmosphere and the wide range of spectra in which it absorbs radiation. Carbon dioxide (CO2) absorbs energy only in a very narrow range of the longwave infrared spectrum. Controversies Reconstructions of average global surface temperature differ depending on the methodology used. The warming of the twentieth and early twenty-first centuries has **not been shown to be beyond the bounds of natural variability.** General circulation models (GCMs) are unable to accurately depict complex climate processes. They do not accurately hindcast or forecast the climate effects of human-related greenhouse gas emissions. Estimates of equilibrium climate sensitivity (the amount of warming that would occur following a doubling of atmospheric CO2 level) range widely. The IPCC’s estimate is higher than many recent estimates. **Solar irradiance, magnetic fields, UV fluxes, and cosmic rays** are poorly understood and may have greater influence on climate than general circulation models currently assume. Climate Impacts There is **little evidence** that the warming of the twentieth and early twenty-first centuries has caused a general increase in severe weather events. Meteorological science suggests a warmer world will see **milder weather patterns**. Arctic ice is losing mass, but melting commenced before there was a human impact on climate and is not unprecedented. Antarctica is either gaining ice mass or is unchanged. Best available data show **sea-level rise is not accelerating**. Local and regional sea levels continue to exhibit typical natural variability. The link between warming and drought is weak, and by some measures drought decreased over the twentieth century. Changes in the hydrosphere of this type are regionally highly variable and show a closer correlation with multidecadal climate rhythmicity than they do with global temperature. Plants have responded positively to rising temperatures and carbon dioxide levels in the atmosphere, a trend that is likely to continue beyond the twenty-first century. Why Scientists Disagree Climate is an interdisciplinary subject requiring insights from many fields of study. Very few scholars have mastery of more than one or two of these disciplines. Fundamental uncertainties arise from insufficient observational evidence and disagreements over how to interpret data and how to set the parameters of models. Many scientists trust the Intergovernmental Panel on Climate Change (IPCC) to objectively report the latest scientific findings on climate change, but it has failed to produce balanced reports and has allowed its findings to be misrepresented to the public. Climate scientists, like all humans, can have tunnel vision. Bias, even or especially if unconscious, can be especially pernicious when data are equivocal and allow multiple interpretations, as in climatology. Appeals to Consensus Surveys and abstract-counting exercises that are said to show a “scientific consensus” on the causes and consequences of climate change **invariably ask the wrong questions or the wrong people**. No survey data exist that support claims of consensus on important scientific questions. Some survey data, petitions, and peer-reviewed research show deep disagreement among scientists on issues that must be resolved before the man-made global warming hypothesis can be accepted. Some **31,000 scientists** have signed a petition saying “there is no convincing scientific evidence that human release of carbon dioxide, methane, or other greenhouse gases is causing or will, in the foreseeable future, cause catastrophic heating of the Earth’s atmosphere and disruption of the Earth’s climate.” Prominent climate scientists have said repeatedly that there is no consensus on the most important issues in climate science.

The Earth is cooling, and CO2 only controls two percent of global temperature – prefer NASA and professors over alarmists.

**Shedlock ‘19**

(Michael, https://moneymaven.io/mishtalk/economics/amidst-global-warming-hysteria-nasa-expects-global-cooling-SJDpCv3V4EqKSOY11A378Q/, January 29) BW

\*\*GAT = global average temperature

Those promoting CO2 as the reason for global warming are hucksters and those taken in by hucksters. Please consider NASA Sees Climate Cooling Trend Thanks to Low Sun Activity. **“We see a cooling trend,”** said Martin Mlynczak of NASA’s Langley Research Center. “High above Earth’s surface, near the edge of space, our atmosphere is **losing heat energy.** If current trends continue, it could soon set a Space Age record for cold.” “The new data is coming from NASA’s Sounding of the Atmosphere using Broadband Emission Radiometry or SABER instrument, which is onboard the space agency’s Thermosphere Ionosphere Mesosphere Energetics and Dynamics (TIMED) satellite. SABER monitors infrared radiation from carbon dioxide (CO2) and nitric oxide (NO), two substances that play a vital role in the energy output of our thermosphere, the very top level of our atmosphere. “The thermosphere always cools off during Solar Minimum. It’s one of the most important ways the solar cycle affects our planet,” said Mlynczak, who is the associate principal investigator for SABER. The new NASA findings are in line with studies released by UC-San Diego and Northumbria University in Great Britain last year, both of which predict a **Grand Solar Minimum in coming decades** due to low sunspot activity. Both studies predicted sun activity similar to the Maunder Minimum of the mid-17th to early 18th centuries, which coincided to a time known as the Little Ice Age, during which temperatures were much lower than those of today. If all of this seems as if NASA is contradicting itself, you’re right — sort of. After all, NASA also reported last week that Arctic sea ice was at its sixth lowest level since measuring began. Isn’t that a sure sign of global warming? All any of this “proves” is that we have, at best, a cursory understanding of Earth’s incredibly complex climate system. So when mainstream media and carbon-credit salesman Al Gore breathlessly warn you that we must do something about climate change, it’s all right to step back, take a deep breath, and realize that we don’t have the knowledge, skill or resources to have much effect on the Earth’s climate.” Incredibly Complex Systems See the problem? Alarmists take one variable, **CO2** that is only a **tiny part of extremely long cycles** and make projections far into to the future based off it. When I was in grade school, the alarmists were worried about global cooling. Amusingly, I recall discussing in science class the need to put soot on the arctic ice to melt it to stop the advance of glaciers. ​The latest Intergovernmental Panel on Climate Change (IPCC) Report said we have only 12 years left to save the planet. It triggered the usual frantic and ridiculous reactions. NBC News offered this gem: “A last-ditch global warming fix? A man-made ‘volcanic’ eruption” to cool the planet.” Its article proclaimed, “Scientists and some environmentalists believe nations might have to mimic volcanic gases as a last-ditch effort to protect Earth from extreme warming.” Geo-engineering: Ignoring the Consequences Watts Up With That discusses Geo-Engineering: Ignoring the Consequences. “From 1940 to almost 1980, the average global temperature went down. Political concerns and the alleged scientific consensus focused on global cooling. Alarmists said it could be the end of agriculture and civilization. Journalist Lowell Ponte wrote in his 1976 book, The Cooling. The problem then was – and still is now – that people are educated in the false philosophy of uniformitarianism: the misguided belief that conditions always were and always will be as they are now, and any natural changes will occur over long periods of time. Consequently, most people did not understand that the cooling was part of the natural cycle of climate variability, or that changes are often huge and sudden. Just 18,000 years ago we were at the peak of an Ice Age. Then, most of the ice melted and sea levels rose 150 meters (490 feet), because it was warmer for almost all of the last 10,000 years than it is today. During the cooling “danger,” geo-engineering proposals included: \* building a dam across the Bering Straits to block cold Arctic water, to warm the North Pacific and the middle latitudes of the Northern Hemisphere; \* dumping black soot on the Arctic ice cap to promote melting; \* adding carbon dioxide (CO2) to the atmosphere to raise global temperatures. “Taking carbon dioxide out of the atmosphere,” as advocated by the IPCC in its October 8 news conference, is also foolish. Historic records show that, at about 410 parts per million (ppm), the level of CO2 supposedly in the atmosphere now, we are near the lowest in the last 280 million years. As plants evolved over that time, the average level was 1200 ppm. That is why commercial greenhouses boost CO2 to that level to increase plant growth and yields by a factor of four.” **The IPCC has been wrong in every prediction it’s made since 1990.** It would be a grave error to use its latest forecasts as the excuse to engage in geo-engineering experiments with the only planet we have. ​Global Warming Errs Badly Next, please consider Extreme weather not proof of global warming, NASA on global cooling “To understand the great confusion about global warming or climate change, my most lucid guide has been Dr. Richard Lindzen — a former Alfred P. Sloan professor of meteorology at MIT and member of the US National Academy of Sciences — and his now famous lecture for the Global Warming Policy Foundation last October 8. In just a number of segments of his lecture, Dr. Lindzen crystallized for me why the church of global warming errs so badly in its dogma. Global warming promoters fostered the popular public perception of the science of climate change as quite simple. It is that here’s one phenomenon to be explained (“global average temperature,” or GAT, which, says Lindzen, is a thoroughly unscientific concept). And there’s one explanation for it: the amount of CO2 in the atmosphere. GAT is only one of many important phenomena to measure in the climate system, and CO2 is only one of many factors that influence both GAT and all the other phenomena. **CO2’s role in controlling GAT is at most perhaps 2 percent,** yet climate alarmists think of it as the “control knob.” Most people readily confuse weather (short-term, local-scale temperature, humidity, precipitation, wind, cloudiness, and more) with climate (long-term, large-scale of each) and think weather phenomena are driven by climate phenomena; they aren’t. Consequently, as Lindzen says, the currently popular narrative concerning this system is this: The climate, a complex multifactor system, can be summarized in just one variable, the globally averaged temperature change, and is primarily controlled by the 1 to 2 percent perturbation in the energy budget due to a single variable — carbon dioxide — among many variables of comparable importance.” Big Chill Did You Know the Greatest Two-Year Global Cooling Event Just Took Place? “Would it surprise you to learn the greatest global two-year cooling event of the last century just occurred? From February 2016 to February 2018 (the latest month available) **global average temperatures dropped 0.56°C.** You have to go back to 1982-84 for the next biggest two-year drop, 0.47°C—also during the global warming era. All the data in this essay come from GISTEMP Team, 2018: GISS Surface Temperature Analysis (GISTEMP). NASA Goddard Institute for Space Studies (dataset accessed 2018-04-11 at ). This is the standard source used in most journalistic reporting of global average temperatures. The 2016-18 Big Chill was composed of two Little Chills, the biggest five month drop ever (February to June 2016) and the fourth biggest (February to June 2017). A similar event from February to June 2018 would bring global average temperatures below the 1980s average. February 2018 was colder than February 1998. If someone is tempted to argue that the reason for recent record cooling periods is that global temperatures are getting more volatile, it's not true. The volatility of monthly global average temperatures since 2000 is only two-thirds what it was from 1880 to 1999.

**WTO**

**They do not solve harmonization. Their evidence says:**

1. **The “new EU trade restrictions” were passed in 2019, which means their impact should’ve already happened.**
2. **Their card says that European legislation is the only way to solve.**

**We read blue.**

**Menz et al. 20** [(Dr. Jochen Menz, of Julius Kühn-Institut, Federal Research Centre for Cultivated Plants) Modrzejewski (Dominik PhD, Julius Kühn-Institut, Institute for Biosafety in Plant Biotechnology) Hartung (Frank, Julius Kühn-Institut, Institute for Biosafety in Plant Biotechnology) Wilhelm (Ralf, Kühn-Institut, Institute for Biosafety in Plant Biotechnology) Sprink (Thorben, Julius Kühn-Institut, Institute for Biosafety in Plant Biotechnology) “Genome Edited Crops Touch the Market: A View on the Global Development and Regulatory Environment” Front Plant Sci, 10/9/2020. https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7581933/] BC

WTO: Committee on Sanitary and Phytosanitary Measures

In November 2018, the delegations of Australia, Argentina, Brazil, Canada, the Dominican Republic, Guatemala, Honduras, Paraguay, the United States of America, and Uruguay signed the international statement on agricultural applications of precision biotechnology in the WTO Committee on Sanitary and Phytosanitary Measures (**CSPM**). The delegations agreed to engage for the exploration of science based opportunities for regulatory frameworks and the avoidance of trade barriers for products derived from genome editing (Commitee on Sanitary and Phytosanitary Measures, 2018). **In their declaration the states affirmed that cultivars derived from genome editing should be regulated similar to conventional cultivars due to their high similarity**. Deregulation of genome editing techniques offers new opportunities for SMEs and national research institutions. Thus, **a harmonization at national and international level should be ensured to exploit the full potential of genome editing.** Furthermore, within the CSPM the United States with support from Argentina and Paraguay raised specific trade concerns (STC 452) **about restrictions from the E**uropean **U**nion **resulting from the implementation of the CJEU Ruling in** **C**ommitee on **S**anitary and **P**hytosanitary **M**easures **(2019). The implementation would lead to unjustified barriers to trade in products of genome editing.** It **stifles** the agricultural **research** and innovation necessary to prevent hunger and malnutrition in the coming decades, while ensuring environmental sustainability of agricultural activities. **Without any changes in European legislation the issue stays unresolved.**

**Their scenario makes no sense. They have seriously misread and mistagged their Horton and Hopewell card.**

1. **It does NOT say that the EU is the glue that holds the WTO together. This article says that the EU is the best place to act when the US and China fight about trade.**
2. **At best, this card says the EU is better than China and the US when it comes to leadership. But it doesn’t say the WTO will crumble due to a single CRISPR dispute.**
3. **We won’t re-read their card, but seriously screen this piece Horton and Hopewell evidence to find a clear warrant that supports their argument.**

**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.”

**Regionalism promotes trade and stops war – avoids their impact because our regionalism is different than protectionist blocs.**

**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

Besides those advocating the optimistic or pessimistic view on regionalism effect on global trade liberalization, some economists, such as Frankel and Wei, hold a neutral position, in a way. Frankel and Wei believe that forms and achievements of international economic integrations can vary and that, for this reason, regionalism can be – depending on circumstances – linked to greater or smaller global trade liberalization. In the years-long period of regional integration development, four periods have been identified during which the integration processes were becoming particularly intensive and which have therefore been named "waves of regionalism". The first wave was taking place during the capitalism development in the second half of the 19th century, in the course of British sovereign domination over the world market. Economic integrations of the time primarily had the form of bilateral customs unions; however, owing to the comparative openness of international trading system based on the golden standard automatism, this period is called the "era of progressive bilateralism". The next two waves of **regionalism** occurred in the years following the world wars. Since the disintegration processes caused by the wars usually spawned economic nationalisms and autarchic tendencies, it is not surprising that post-war regionalisms were marked by discriminatory international economic integrations, primarily at the level of so-called negative integration, with expressedly “beggar-thy-neighbor” policies that resulted in considerable trade deviations. This particularly refers to the regionalism momentum after the First World War, which was additionally burdened by the consequences of Big Economic Crisis. The current wave of regionalism started in late 1980s and spread around the world to a far greater extent than any previous one did: it has covered almost all the continents and almost all the countries, even those which have mis to join all earlier regional initiatives, such as the USA, Canada, Japan and China. Integration processes, however, do not show any signs of flagging. Up till now, over 200 RTAs have been registered with GATT/WTO, more than 150 of them being still in force, and most of these valid arrangement have been made in the past ten years. Specific in many ways, this wave was dubbed "new regionalism". The most specific **characteristics** of new regionalism **include: geographic spread** **of RTAs** **in** terms of **encompassing entire continents;** **greater speed**; integration forms success; deepening of integration processes; **and**, the most important for this theoretical discussion, generally **non-negative impact on outsiders, world economy as a whole, and** the **multilateral liberalization** process. Some theorists (Gilpin) actually distinguish **between** the "**benign**" **and** "**malign**" **regionalism**. On the one hand, **regionalism can advance** the **international economic stability**, multilateral liberalization **and world peace**. On the other, it can have mercantilist features leading to economic well-being degradation and increasing international tensions and conflicts. Analyses of trends within the contemporary integration processes show that they mainly have features of "benign" regionalism. Reasons for this are numerous. **Forces driving** the **contemporary** **regionalism** development **differ from** those that used to drive **earlier** regionalism periods in the 20th century. The **present regionalism emerged in** the period characterized by the **increasing economic inter-dependence** between different world economy subjects, countries attempts to resolve trade disputes and multilateral framework of trade relations. As opposed to the 1930s episode, contemporary regional initiatives represent **attempts to make** the members' **participation in the world economy easier**, rather than make them more distant from it. As opposed to 1950s and 1960s episode, new **initiatives** are **less frequently motivated** **exclusively by political interests**, and are **less frequently** being used **for mercantilist purposes**. After the Second World War, more powerful countries kept using the economic integration as a means to strengthen their political influence on their weaker partners and outsiders. The examples include CMEA and European Community arrangements with its members' former colonies. As opposed to this practice, the new regionalism, mostly driven by common economic interests, yielded less trade diversion than previous one, and has also **contributed to** the **prevention of military conflicts of greater proportions**. Various analyses have shown that many regional integrations in earlier periods resulted in trade deviations, particularly those formed between less developed countries and between socialist countries. In recent years, however, the newly formed or revised regional **integrations** primarily seem to **lead to trade creation**. Contrary to the “beggar thy- neighbor” model of former international economic integrations, the integrations now offer certain advantages to outsiders as well, by stimulating growth and spurring the role of market forces. The analyses of contemporary trends in world economy also speak in favor of the "optimistic" proposition. The structural analysis shows that the world trade is growing and that this growth results both from the increase in intra-regional and from the increase in extra-regional trade value (Anderson i Snape 1994.)28. Actually, the intraregional trade has been growing faster, both by total value and by its share in world GDP. The extra-regional trade share in GDP was increasing in some regions – in North America, Asia-Pacific and Asian developing countries. However, the question arises as to whether the extra-regional trade would be greater without regional integrations or not? The answer would primarily depend both on the estimate of degree of some countries' trade policy restrictedness in such circumstances, and on factors such as geographic distance, transport communications, political relations among states. One should also take into account certain contemporary integration features – the primarily economic, rather than strategic motivation, and continuous expansion, which mostly includes countries that are significant economic partners. With respect to NAFTA, many believe that the negative effects on outsiders will be negligible, since the USA and Canada have actually been highly integrated economies for a long time already, while the Mexican economy is relatively small. The same view was pointed out by the EU, with respect to its expansion. It particularly refers to the inclusion of the remaining EFTA countries, because this will actually only complete, in institutional terms, the EU strong economic ties with these countries. Most EFTA countries have been part of the European economic area (EEA), i.e. the original EC-EFTA agreement, for a few years already, and conduct some 70% of their total international exchange with the Union countries. EU countries are also the most significant foreign-trade partners of Central and East Europe countries, and the recent joining the Union of several of them is not expected to cause a significant trade diversion. Besides, according to some earlier studies, during the previous wave of regionalism, in the 1967-70 period, the creation of trade in EEC was far greater than trade diversion: trade creation ranged from 13 to 23% of total imports, while trade diversion ranged from 1 to 6%. In Latin America, the new regionalism resulted in the faster growth of intra-regional trade, while the extra-regional exports and imports also continued to grow. Since early 1990s, the value of intra-regional imports registered the average annual growth of 18%. In the same time, the extra-regional exports were also growing, although at a lower rate of 9% average a year; its share in the total Latin America exports at the end of decade amounted to 18% as compared to 12% in 1990. In the 1990-1996 period, the intraregional imports grew by some 18% a year. The extra-regional imports were also growing very fast, reaching the 14% rate. These data reflect a great unbalance in the trade with extra-regional markets, since the imports from countries outside the region grew much faster the exports.30 Since the described trends point to the continued growth of extra-regional imports and exports, they also show that regional integration in Latin America has had the open regionalism character. Besides, the pending establishment of FTAA – Free Trade Area of Americas will gather, in the same group, the so-called "natural" trade partners – countries that have had an extremely extensive mutual exchange for years already, and the outsiders are therefore unlikely to be affected by strengthening of regionalism in this part of the world. Contemporary research shows that intra-regional trade is growing, however, same as interdependence between North America and East Asia and between the EU and East Asia. It can also be seen that the biggest and the **most powerful** countries, i.e. **blocs**, **are extremely dependent** **on the rest of the world in terms of trade.** For the EU, besides the intra-European trade, which is ranked first, foreign trade has the vital importance since it accounts for 10% of European GDP. In early 1990s, EU exchanged 40% of its foreign trade with non-members, 16% out of which with North America and East Asia together. EU therefore must keep in mind the rest of the world as well. The growing EU interest in outsiders is confirmed by establishing "The Euro-Med Partnership", which proclaimed a new form of cooperation between the EU and the countries at its South periphery32. Besides, the past few years witnessed a series of inter-regional agreements between the EU on the one hand, and certain groups from other regions on the other (MERCOSUR, CARICOM, ASEAN and GCC). In case of North America the ratio between intra-regional and inter-regional trade is 40:60, and in East Asia, it is 45:55. Any attempt to move towards significantly closed blocs ("fortresses") would require overcoming the significant inter-dependence between major trading blocs. Besides the analysis of contemporary trends in extra- and intra-regional trade, other research was conducted that was supposed to point to the reasons why the **new regionalism has** mainly a **non-negative impact on** outsiders and **global liberalization**. The distinctive features of new regionalism were also affected to characteristics of international economic and political environment it sprouted in. In the 1980s, economic nationalisms were not so expressed as in the interventionism years following the Second World War; however, the neo-liberalism represented by GATT activities did not find the "fertile ground” in all parts of the world. Regionalism growth in the circumstances of multilateral system existence is, among other things, the consequence of distrust in multilateralism. „The revival of the forces of regionalism stemmed from frustration with the slow pace of multilateral trade liberalization... If the world trade regime could not be moved ahead, then perhaps it was time for deeper liberalization within more limited groups of like-minded nations... Such efforts would at least liberalize some trade... and might even prod the other nations to go along with multilateral liberalization.“33 Kennedy's round and Tokyo round of trade negotiations under GATT auspices brought a certain progress in the global trade liberalization. However, the 1980s witnessed significant changes in the world economy that the GATT trade system was not up to. Besides. GATT had not yet managed to cover the entire trade in goods, since there were still exceptions in the trade in agricultural and textile products that particularly affected the USA and developing countries. GATT system of conflict resolutions, and its organizational and administrative mechanism in general also required revision. In this vacuum that was created in promoting trade and investment multilateralism from the point when GATT inadequacy became obvious until the start of the Uruguay round and the establishment of World Trade Organization, the wave of regionalism started spreading across the world again. Prodded by the Single European Act and the success of European integration, many countries turned to an alternative solution – establishment of new or expansion and deepening of the existing economic integrations. Even the USA, the multilateralism bastion until then, made a radical turn in their foreign-trade policy and started working on designing a North American integration.

**That outweighs—multilateral trade causes wars with a larger impact**

**Thoma 7** Mark Thoma July 2007 “Trade Liberalization and War” http://economistsview.typepad.com/economistsview/2007/07/trade-liberaliz.html (Economics Professor at the University of Oregon)//Elmer

Globalisation is by construction an increase in both bilateral and multilateral trade flows. What then was the net effect of increased trade since 1970? We find that it **generated an increase in the probability of a bilateral conflict by** around **20%** for those **countries separated by less than 1000kms,** the group of countries for **which the risk of disputes that can escalate militarily is the highest.** The effects are much smaller for countries which are more distant. Contrary to what these results (aggravated by our nationality) may suggest, we are not anti-globalisation activists even though we are aware that some implications of our work could be (mis)used in such a way. The result that bilateral trade is pacifying brings several more optimistic implications on globalisation. First, if we think of a world war as a war between two large groups or coalitions of countries, then globalisation makes such a war less likely because it increases the opportunity cost of such a conflict. Obviously, this conclusion cannot be tested but is a logical implication of our results. From this point of view, our work suggests that globalisation may be at the origin of a change in the nature of conflicts, less global and more local. Second, our results do confirm that increased trade flows **created by regional trade agreements** (such as the EU) are indeed **pacifying** as intended. Given that most military conflicts are local, because they find their origins in border or ethnic disputes, **this is not a small achievement**. These beneficial political aspects of regional trade agreements are not usually considered by economists who often focus on the economic distortions brought by their discriminatory nature. Given the huge human and economic costs of wars, this political effect of regional trade agreements should not be discounted. This opens interesting questions on how far these regional trade agreements should extend – a topical issue in the case of the EU. The entry of Turkey in the EU would indeed pacify its relations with EU countries (especially Greece and Cyprus), but also increase the probability of a conflict between Turkey and its non-EU neighbours. However, our simulations suggest that in this case, the first effect dominates the second by a large margin. More generally, our results should be interpreted as a word of caution on some political aspects of globalisation. As it proceeds and weakens the economic ties of proximate countries, those with the highest risk of disputes that can escalate into military conflicts, local conflicts may become more prevalent. Even if they may not appear optimal on purely economic grounds, regional and bilateral trade agreements, by strengthening local economic ties, may therefore **be a necessary political counterbalance to economic globalisation**.