# 1

#### Brink. US/PRC on the brink of nuclear confrontation.

Gerson 8/4/2021 {Joseph, Executive Director of the Campaign for Peace, Disarmament and Common Security and Vice-President of the International Peace Bureau] “IN A DANGEROUS TIME: TOWARD PREVENTING A DISASTROUS U.S.-CHINA WAR,” **Foreign Policy in Focus** <https://fpif.org/in-a-dangerous-time-toward-preventing-a-disastrous-u-s-china-war/EDM>

U.S.-Chinese relations are worse than at any time since the renewal or relations began in the early 1970s. As in the late 1940s, we are witnessing, and suffering, the restructuring of the global disorder into a new, extremely dangerous, and totally unnecessary confrontation analogous, but not identical, to the Cold War. As Zhu Zhiqun, my colleague at the Committee for a SANE U.S.-China Policy has written, “the Biden Administration has convinced itself that China is an existential threat to US national interests and…must be pushed back at all costs.” Trump, and now Biden, Blinken and others, blinded by their self-righteousness, have forged a new Washington and national consensus: China poses an existential threat to freedom and democracy around the world; therefore the U.S. must aggressively defend freedom and democracy – militarily, diplomatically, technologically, and otherwise. That the United States has enforced an Asia-Pacific empire since 1898, that human rights do not exist in Guantanamo, that racist Republicans – like Modi, Washington’s new partner in India – are disenfranchising minority voters, and that the United States is deeply allied with repressive governments around the world are inconvenient truths consigned to an Orwellian memory hole. At root are the inevitable tensions between rising and declining powers, the Thucydides Trap, that many times in history has climaxed in catastrophic wars. Compounding the Cold War analogy, there are disturbing parallels to the years before World War I: tensions between rising and declining powers and complex alliance structures that now include the QUAD, intense nationalism with attendant hatreds, territorial disputes, arms races with new technologies, international economic integration and competition, autocracies, and wild-card actors. Like the 1914 Sarajevo gunshots, an incident, accident, or miscalculation –a collision of warships in the South or East China Seas or near Taiwan – could escalate to a major, potentially nuclear, war.

#### China manipulates the WTO process. WTO = China steals tech and manipulates trade.

Wemer 2019 [David A., Assistant director, editorial, at the Atlantic Council] “What is wrong with the WTO?” **The Atlantic Council** <https://www.atlanticcouncil.org/blogs/new-atlanticist/what-is-wrong-with-the-wto/EDM>

Criticisms of the WTO by the United States and others, such as the European Union and Japan, fall into three major categories: the ability of WTO members to self-identify as “developing” countries in order to receive special treatment, the failure of many WTO members to properly notify the WTO and other WTO members of government subsidies in accordance with specific agreement rules, and alleged overreach by the Appellate Body. Much of this criticism is directed at the actions of China, which the United States and other WTO members say is skirting WTO rules in the behavior of state-owned enterprises, dumping products, and stealing intellectual property.

#### Surrendering US IP benefits to WTO members kills US competitive edge. SQ IPR best.

Atkinson 2019 [Robert, Founder and president of the Information Technology and Innovation Foundation] “China’s Biopharmaceutical Strategy: Challenge or Complement to U.S. Industry Competitiveness?” **Information Technology & Innovation Foundation** <https://itif.org/publications/2019/08/12/chinas-biopharmaceutical-strategy-challenge-or-complement-us-industry/EM>

America’s strong IP system—including allowing 12 years of data exclusivity for biologics and providing a period of marketing exclusivity for drugs independent of exclusive patent rights, as well as providing patent linkage and patent term extension through the Hatch-Waxman Act—has helped spur investment. Robust funding for the National Institutes of Health (NIH), especially the doubling of funding in the late 1990s and early 2000s, has helped lay the groundwork for robust biopharma innovation.22 The United States also benefits greatly from having a drug-pricing system that permits companies to earn sufficient revenues from one generation of biomedical innovation to reinvest in the next. That matters greatly because, as the Organization for Economic Cooperation and Development (OECD) has written, “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”23 Limited government price controls also make investing in the United States more attractive than in many other nations.24 The lesson of the U.S. gain in global competitive advantage in the biopharmaceutical industry should be clear. It was not based on absolute advantage (e.g., some nations being good in agriculture because they have a lot of arable land). Rather, it was and is based on competitive advantage (e.g., factors that are malleable by policy, such as a strong drug-approval system and reasonable drug pricing). As such, have competitive advantage in industries such as biopharmaceutical is something that has to be earned and worked at to retain. As some European nations and nations such as Japan found to their distress, competitive advantage is not a birthright; it can be lost. That should be the message for the United States: while the United States is doing well in the industry now, it could easily lose that advantage, particularly to China, which has targeted the industry for global leadership. This means that the United States needs to keep in place the right policies and make them even stronger while at the same time continuing to press China to roll back its innovation mercantilist practices in this industry.

#### Medical edge increases PRC military

Kuo 17 [Mercy A; Executive Vice President at Pamir Consulting; “The Great US-China Biotechnology and Artificial Intelligence Race,” The Diplomat; 8/23/17; <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>EDM

Trans-Pacific View author Mercy Kuo regularly engages subject-matter experts, policy practitioners, and strategic thinkers across the globe for their diverse insights into the U.S. Asia policy. This conversation with Eleonore Pauwels – Director of Biology Collectives and Senior Program Associate, Science and Technology Innovation Program at the Wilson Center in Washington D.C. – is the 104th in “The Trans-Pacific View Insight Series.” Explain the motivation behind Chinese investment in U.S. genomics and artificial intelligence (AI). With large public and private investments inland and in the U.S., China plans to become the next AI-Genomics powerhouse, which indicates that these technologies will soon converge in China. China’s ambition is to lead the global market for precision medicine, which necessitates acquiring strategic technological and human capital in both genomics and AI. And the country excels at this game. A sharp blow in this U.S.-China competition happened in 2013 when BGI purchased Complete Genomics, in California, with the intent to build its own advanced genomic sequencing machines, therefore securing a technological knowhow mainly mastered by U.S. producers. There are significant economic incentives behind China’s heavy investment in the increasing convergence of AI and genomics. This golden combination will drive precision medicine to new heights by developing a more sophisticated understanding of how our genomes function, leading to precise, even personalized, cancer therapeutics and preventive diagnostics, such as liquid biopsies. By one estimate, the liquid biopsy market is expected to be worth $40 billion in 2017. Assess the implications of iCarbonX of Shenzhen’s decision to invest US$100 million in U.S.-company PatientsLikeMe relative to AI and genomic data collection. iCarbonX is a pioneer in AI software that learns to recognize useful relationships between large amounts of individuals’ biological, medical, behavioral and psychological data. Such a data-ecosystem will deliver insights into how an individual’s genome is mutating over time, and therefore critical information about this individual’s susceptibilities to rare, chronic and mental illnesses. In 2017, iCarbonX invested $100 million in PatientsLikeMe, getting a hold over data from the biggest online network of patients with rare and chronic diseases. If successful, this effort could turn into genetic gold, making iCarbonX one of the wealthiest healthcare companies in China and beyond. The risk factor is that iCarbonX is handling more than personal data, but potentially vulnerable data as the company uses a smartphone application, Meum, for customers to consult for health advice. Remember that the Chinese nascent genomics and AI industry relies on cloud computing for genomics data-storage and exchange, creating, in its wake, new vulnerabilities associated with any internet-based technology. This phenomenon has severe implications. How much consideration has been given to privacy and the evolving notion of personal data in this AI-powered health economy? And is our cyberinfrastructure ready to protect such trove of personal health data from hackers and industrial espionage? In this new race, will China and the U.S. have to constantly accelerate their rate of cyber and bio-innovation to be more resilient? Refining our models of genomics data protection will become a critical biosecurity issue. Why is Chinese access to U.S. genomic data a national security concern? Genomics and computing research isinherentlydual-use**,** therefore a strategic advantagein a nation’s security arsenal. Using AI systems to understand how the functioning of our genomes impacts our health is of strategic importancefor biodefense. This knowledge will lead to increasing developments at the forefront of medical countermeasures, including vaccines, antibiotics, and targeted treatments relying on virus-engineering and microbiome research. Applying deep learning to genomics data-sets could help geneticists learn how to use genome-editing (CRISPR) to efficiently engineer living systems, but also to treat and, even “optimize,” human health, with potentialapplications in military enhancements. A $15 million partnership between a U.S. company, Gingko Bioworks, and DARPA aims to genetically design new probiotics as a protection for soldiers against a variety of stomach bugs and illnesses. China could be using the same deep learning techniques on U.S. genomics data to better comprehend how to develop, patent and manufacture tailored cancer immunotherapies in high demand in the United States. Yet, what if Chinese efforts venture into understanding how to impact key genomics health determinants relevant to the U.S. population? Gaining access toincreasingly largeU.S. genomicdata-sets gives China aknowledge advantage into leading the next stepsin bio-military research**.** Could biomedical data be used to develop bioweapons? Explain. Personalized medicine advances mean that personalized bio-attacks are increasingly possible. The combination of AI with biomedical data and genome-editing technologies will help us predict genes most important to particular functions. Such insights will contribute to knowing how a particular disease occurs, how a newly-discovered virus has high transmissibility, but also why certain populations and individuals are more susceptible to it. Combining host susceptibility information with pathogenic targeted design, malicious actors could engineer pathogens that are tailored to overcome the immune system or the microbiome of specific populations.

#### Threshold: The closer to reaching US technological edge, the higher risk of war in SCS.

Leigh et al. 2020 [12/17, Karen**]** “Troubled Waters: Where the US and China could clash in the SCS,” **Bloomberg** <https://www.bloomberg.com/graphics/2020-south-china-sea-miscalculation/EDM>

Perhaps nowhere do the U.S. and Chinese militaries come closer to each other than in the South China Sea. And the brinkmanship in the waters could soon rise under President-elect Joe Biden. As the world’s biggest economies spar on everything from trade to the coronavirus, fears have grown that a miscalculation between warships could spark a wider military confrontation. Although top defense officials from the U.S. and China have maintained communication even as broader relations have deteriorated, more fervent nationalism in both countries raises the political stakes of any crisis. President Donald Trump’s administration has increased the number of “freedom of navigation operations”—known as FONOPs—in the South China Sea to challenge China’s sovereignty claims. The current round of maneuvers, which involve naval vessels sailing within territorial limits of land features claimed by China, reached a new high of 10 last year after a total of just five in the last two years of the Obama administration. Biden looks set to maintain or even expand the number of FONOPs. Jake Sullivan, his pick for national security adviser, last year lamented the U.S.’s inability to stop China from militarizing artificial land features in the South China Sea, and called for the U.S. to focus more on freedom of navigation. “We should be devoting more assets and resources to ensuring and reinforcing, and holding up alongside our partners, the freedom of navigation in the South China Sea,” Sullivan told ChinaTalk, a podcast hosted by Jordan Schneider, an adjunct fellow at the Washington-based Center for a New American Security. “That puts the shoe on the other foot. China then has to stop us, which they will not do.” The U.S. has played a key role in maintaining security in Asian waters since World War II. Yet Beijing’s military buildup, combined with moves to fortify its hold on disputed territory in the South China Sea, has raised fears that it could look to deny the U.S. military access to waters off China’s coastline. In turn, the U.S. has increasingly sought to demonstrate the right to travel through what it considers international waters and airspace. That’s led to a handful of tense encounters. Back in 2001, a mid-air collision between a U.S. Navy reconnaissance plane and a Chinese fighter jet prompted an international incident, with the American crew held for 10 days on Hainan island. During a close call in 2018 between China’s Luyang destroyer and the USS Decatur, the Chinese warship warned the American vessel it would “suffer consequences” if it didn’t change course, according to the South China Morning Post. “We certainly don’t want to go to war over some coral rocks, but then again we don’t want to let China change the rules with their presence,” said Joe Felter, former deputy assistant secretary of defense for South Asia, Southeast Asia and Oceania in the Trump administration. “They’re going to push it as far as they can.” China claims more than 80% of the South China Sea, one of the world’s busiest shipping routes, based on a 1947 map showing vague markings that has since become known as the “nine-dash line.” The U.S. estimates that more than 30% of the global maritime crude oil trade passes through the waters. Besides China, five other governments claim land in the South China Sea: Vietnam, the Philippines, Brunei, Malaysia and Taiwan. Efforts to resolve the disputes have made little progress: Talks with Southeast Asian nations on a code of conduct in the waters have dragged on for about two decades. Beijing has also rejected a dispute resolution mechanism under the United Nations Convention on the Law of the Sea, known as Unclos. In a case unilaterally brought by the Philippines, the Permanent Court of Arbitration in The Hague ruled in 2016 that there was no legal basis for China to claim historic rights to resources in seas falling within the nine-dash line, and man-made structures don’t generate zones of sovereignty. In a military fight, China could easily take the islands from its fellow claimants. The U.S. and Japan are the only countries that “stand a chance” against China while Southeast Asian nations can only hope to “inflict a bloody nose,” said Bill Hayton, associate fellow with the Asia-Pacific Program at Chatham House and author of “The South China Sea: The Struggle for Power in Asia.” U.S. sailors conduct flight operations on the deck of the aircraft carrier USS Carl Vinson. American Navy aircraft carrier strike groups regularly patrol regional waters, fueling tensions in the South China Sea. Photographer: Mass Communication Specialist 3rd Class Matt Brown/U.S. Navy via Getty Images “We’re getting to a kind of brinkmanship phase now,” he said. “The U.S. has an edge technologically, but the closer the Chinese come to thinking they can match the U.S. the closer we get to confrontation.”

#### Chinese aggression = SCS invasion and nuclear war.

Flournoy and Chefitz 2020 [Michèle A., Former undersecretary of defense for policy, and Gabrielle, senior associate at WestExec Advisors] “China's military capabilities are gaining on the U.S. The Pentagon needs to take bold steps,” **Think** <https://www.nbcnews.com/think/opinion/china-s-military-capabilities-are-gaining-u-s-pentagon-needs-ncna1234383/EDM>

The next U.S. administration will face an increasingly emboldened and aggressive China — one that has shown a growing willingness to use coercive measures to stake its territorial claims from the South China Sea to Taiwan to the Indian border region. Although neither Washington nor Beijing wants a war, there is a real risk that miscalculation could cause a crisis to spiral into a conflict between these two nuclear-armed powers. Although neither Washington nor Beijing wants a war, there is a real risk that miscalculation could cause a crisis to spiral into a conflict between these two nuclear-armed powers. To prevent conflict, the United States must maintain the military capability to deter China by demonstrating the ability to deny the success of such aggression or impose costs so high that Beijing steps back from the brink. The problem is this: If the Pentagon's own reported war games and analysis are to be believed, the current force may well be insufficient to deter or defeat Chinese aggression in the future. The Pentagon's analysis shows that the U.S. military is equipped to fight the last war. But many of the weapon systems that gave U.S. forces the edge in conflicts in the Middle East are incredibly vulnerable to attack by the advanced electronic warfare, cyber-capabilities and precision-guided missiles of China and Russia. The U.S. must take urgent action to reverse this worrying trend. Maintaining and ultimately extending its military-technological edge over great-power competitors like China must become the Pentagon's highest investment priority — or it could lose that edge within the decade. To stay on top, the next secretary of defense must advance a much bolder vision for sharpening the U.S. military-technology edge, as recommended in our recent Center for a New American Security report, "Sharpening the U.S. Military's Edge: Critical Steps for the Next Administration." Few U.S. national security challenges are of greater consequence and urgency than preventing conflict with China and promoting a peaceful Asia-Pacific region. It is fundamental to safeguarding global trade and shipping routes, democratic norms and ideals, the future of technological governance and the security and independence of key partners and allies.

# 2

#### Plan: The US, EU, China, Russia, Canada and India will join the WHO patent pools for infectious disease research [CTAP and MPP], providing economic support and compliance with the pool. Pool resources will be devoted to addressing inequality of access to medicines and vaccines worldwide. Funding and enforcement guaranteed.

#### WHO patent pool = best solvency. Protects innovation. Need US and others to join.

Davey 2021 [Neil, Science Writer, 2/26] “Increasing global access to COVID-19 vaccines and treatments through patent pools,” **Jolt Digest** <https://jolt.law.harvard.edu/digest/increasing-global-access-to-covid-19-vaccines-and-treatments-through-patent-pools/EDM>

Given that the Global North is responsible for a [majority of the world’s biotechnology innovation](https://science.sciencemag.org/content/294/5550/2289.3) and thereby owns most of the intellectual property (“IP”) for these technologies, a fine balance must be achieved between increasing international access to care without deterring essential [R&D]Research & Development investment. The World Health Organization (“WHO”) has created a [voluntary patent pool](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool/solidarity-call-to-action/) in an attempt to resolve this tension. Known as the [COVID-19 Technology Access Pool](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov/covid-19-technology-access-pool) (“C-TAP”), this effort [led by Costa Rica and the WHO](https://www.who.int/news/item/29-05-2020-international-community-rallies-to-support-open-research-and-science-to-fight-covid-19) aims to leverage collective research and incentivize international cooperation to address the pandemic. The goal of such a patent pool is to bundle multiple pieces of IP together so as to [reduce the transaction costs](https://www.thinkglobalhealth.org/article/patent-pools-and-pandemic-renewed-debate) of knowledge sharing on a patent-by-patent basis. Signatory nations to this proposal agree to sharing data, knowledge, and IP surrounding COVID-19 detection, prevention, and treatment. Thus far, [35+ countries have signed](https://www.bioworld.com/articles/435437-who-launches-covid-19-patent-pool-backed-by-35-countries), but many of the world’s leading biotechnology innovators (including the US, UK, France, Germany, China, Russia, Canada, and India) have [not joined the international effort](https://www.statnews.com/pharmalot/2020/05/29/who-covid19-coronavirus-patents/). Importantly, such a voluntary patent pool is preferable to the pharmaceutical industry relative to a compulsory licensing approach, in which countries could entirely circumvent the patents of innovator pharmaceutical companies and allow domestic generic companies to manufacture and distribute the products.

#### Pools solve red tape issues that hinder innovation. Restricting IP inefficient. Pools fast-track innovation.

Eldin 2011 [Chris, Themba Pharmaceuticals] “The importance of patent sharing in neglected disease drug discovery,” **Future Science** <https://www.future-science.com/doi/pdf/10.4155/fmc.11.101/EDM>

It is widely acknowledged that insufficient resources are allocated globally to [R&D] research and development covering new ways to reduce the disease burden in developing countries, and particularly neglected tropical diseases (NTDs). In order to address this problem, several organizations have sought innovative ways to increase the availability of funding for such research. For instance, the WHO established the Expert Working Group on Research and Development: Coordination and Financing to “examine current financing and coordination of research and development, as well as proposals for new and innovative sources of financing to stimulate research and development”, related to diseases predominantly affecting the developing countries [101. Sharing patents and their associated data and know-how is another example of such an initiative. According to patent law, a traditional patent pool is a consortium of at least two companies agreeing to cross-license or make available patents relating to a particular technology or innovation. The creation of a patent pool can save patentees and licensees time and money, and, in the case of blocking patents, it may also be the only reasonable method for making the invention available to the public [1]. In the NTD space, mechanisms for sharing patents should be established to make the patents and, at the discretion of a pool contributor, the know-how of companies and organizations more widely available for the development of therapeutics for NTDs. For such patent pools to achieve their maximum impact, the entire process from inflow to outflow of technology and collaborations needs to be carefully managed. In particular, the following principles should be implemented: n Core values for the patent pool should be established to manage: incoming patents and technology, incoming requests to join the pool and exploit any technology, license and royalty agreements of any innovation resulting from exploitation of information, or know-how in the pool and ownership of any intellectual property (IP) that results from pool collaborations; n A clearly defined process map should be produced to handle requests for participation in the pool; n A method should be implemented that measures the success of the pool (e.g., number of investigational new drug filings and hit series generated). In the case of NTD research, where there is a pressing requirement for new medicines but little to no market for commercial development, there is a need for novel discovery and development models to be identified, developed and pursued. Traditional, industry-driven approaches to drug discovery are less appropriate in the NTD discovery space because the investment required to protect and develop medicines is not likely to be recouped through sales of drugs following regulatory approval [2]. Patent pools represent one way that knowledge and know-how can be shared in order to fast-track medicine development.

Advantage: WHO Leadership

#### Only WHO effectively promotes innovation. Overlapping involvement by WTO = policy failure. Makes the problem worse. CP solves. Gets better coordination.

Taylor 2002 [Allyn, Health policy Advisor, WHO] “Global governance, international health law and WHO: looking towards the future,” **Bulletin of the World Health Organization** <https://scielosp.org/pdf/bwho/v80n12/8012a12.pdf/EDM>

The WTO’s [TRIPs} Convention on Trade-related Aspects of Intellectual Property establishes standards for protection of [IP] intellectual property applicable to biotechnology; several other WTO agreements also apply to biotechnology related trade disputes. The United Nations Education, Scientific and Cultural Organization has announced the ‘‘possible preparation’’ of an ‘‘international instrument on genetic data’’ and a ‘‘universal instrument on bioethics’’ as a follow-up to its Universal Declaration on the Human Genome and Human Rights (32); it is unclear whether these proposed instruments would be designed as binding international law. Most recently, in December 2001, the United Nations General Assembly established an Ad Hoc Working Group of the Sixth Committee to consider an international treaty to ban reproductive cloning of human beings (20)…International law in biotechnology is thus emerging in a fragmented and amorphous manner in which intergovernmental organizations with overlapping jurisdictions are addressing sector-specific aspects of the genetics revolution in a piecemeal and incomplete manner. The splintered legal process exacerbates uncertainties about the legal regime that governs biotechnology. This is partly because standards adopted under the auspices of different international organizations are being developed in increasingly contradictory ways, including conflicting legal standards related to intellectual property (33, 34). The experience of international lawmaking in biotechnology strongly suggests that the current decentralized organizational framework is ill-equipped to deal with international legal aspects of the massive public health implications of new genetic technologies and other realms of global public health. Taking the agenda forward: WHO and international health law An international health law mandate for WHO: coordination and collective management A larger role for WHO, involving coordination of the international health law enterprise, is essential for rational development and effective implementation of international health law policy.

#### CP solves China and globalization best. WHO is proper place for US-China collaboration. Failure to support WHO governance drives crisis.

Xinhua 2020 [5/8] “Responding to crisis requires cooperation between China, U.S.: expert,” <http://www.xinhuanet.com/english/2020-05/08/c_139040592.htm/EDM>

Gu cited how coronavirus pandemic outbreak took place in an era of globalization, where people, information and resources flow through a market-oriented global system. However, when a major infectious disease occurs and its enormous negative externality causes the market-oriented global trading system fail, there is an "urgent need" for a strong international governance body to step in, said Gu. Unfortunately, effective global leadership and global collective action has not emerged from this crisis, he added. For instance, The [WHO] World Health Organization, as the coordinating body for global public health, has not had the support of some of the major powers to deal with such a major global public health crisis, said Gu. Gu called the spread of this epidemic as a crisis of global governance, not a crisis of globalization" and that the aftermath of this lack of global governance has been "disastrous." In fact, globalization has played a crucial role in the fight against the epidemic, said Gu. The world has provided China with scarce medical supplies. Likewise, when the United States and Europe situation worsened, the international community, led by China, provided much support as well. This process of mutual support therefore illustrates the importance of global production and supply chain systems in supporting global disasters, and in allowing for international aid to reach disaster areas quickly, said Gu. Some might think that a shortage for medical emergency supplies like masks due to more demand is a problem caused by the global supply chain and that the future solution is to localize medical supplies, Gu said. In times of crisis, however, the reality is that the principle of efficiency or timely supply of critical goods cannot be guaranteed. "Because the probability of such rare public health emergencies occurring frequently is very small, we can't know in advance which country the crisis will occur," he said. While political interference may affect globalization in the short term, globalization will not end, as long as enterprises seek to maximise profits, and consumers pursue their interests. Hence, as globalization is inevitable, countries should make strengthening global governance their top priority, because globalization without global governance is "fragile and even dangerous," said Gu. The world has undergone fundamental changes, with the growth of developing countries which still lack a voice on global governance. As the power of the U.S. continues to wane, it cannot sustain its unipolar hegemony, and is further weakened by Trump administration's decision to pull out in many areas of global governance, said Gu. The most important need now is for the world to form a multi-polar system of governance as soon as possible, he said. This can be done through a reform of the existing governance system, as well as establishing new institutions. But either way, multilateralism and the participation of developing countries should be important elements, said Gu. For this to happen, cooperation between the two major powers of China and the United States is essential to solve many of the existential crisis facing the world.

# 3

#### Infrastructure and reconciliation are the priority now. they’ll pass by new deadline

Alemany 10/12 [Jacqueline Alemany and Theodoric Meyer, "The new deadline to pass Biden's agenda is coming up fast", 10/12/21, https://www.washingtonpost.com/politics/2021/10/13/new-deadline-pass-biden-agenda-is-coming-up-fast/]

New deadline, old problems: Less than two weeks after House Democrats missed a deadline to hold a vote on the infrastructure bill, the party is staring down another one.

House Speaker Nancy Pelosi and Senate Majority Leader Chuck Schumer say they’re aiming to pass the $1.2 trillion infrastructure bill and a larger package stuffed full of Democrats’ child care, health care and climate change priorities by Oct. 31, when a short-term extension of highway funding is set to run out.

Coincidentally, Oct. 31 is the day before the much-anticipated United Nations climate summit kicks off in Glasgow, where administration officials are eager to show off legislation that would establish credibility in negotiations with foreign governments. White House press secretary Jen Psaki told reporters last month that Biden expected the reconciliation bill — much of which is focused on fighting climate change — would “move forward in advance of that.”

(Asked about it on Tuesday, Psaki said Biden would tout the administration's commitment to combating climate change in Glasgow “regardless of where the package stands.”)

And two days later, Virginians will head to the polls to elect a new governor in a contest lawmakers and the White House are watching closely. Former Democratic Gov. Terry McAuliffe has implored Democrats in Washington to pass the infrastructure bill by Election Day.

The 18-day sprint

Can Democrats really pass two massive bills in the next 18 days?

“Yes,” Rep. Gerry Connolly (D-Va.) told The Early yesterday evening. “Will it is a different matter. But can it? Yeah. We’re experts at coming right up against the edge and pulling a miracle.”

#### Pushing a WTO takes time, energy, and political capital away from domestic legislation – big pharma and EU allies

**Bhadrakumar 5/9** M K Bhadrakumar is a former Indian diplomat. "Biden’s talk of vaccine IP waiver is political theater." Asia Times, May 9, 2021, asiatimes.com/2021/05/bidens-talk-of-vaccine-ip-waiver-is-political-theater.

On the other hand, Biden, whose political life of half a century was largely spent in the US Congress, is well aware of the **awesome clout** of the pharmaceutical companies in American politics. From that lobby’s perspective, the patent waiver “amounts to the expropriation of the property of the pharmaceutical companies whose innovation and financial investments made the development of Covid-19 vaccines possible in the first place,” as a senior scholar at the Johns Hopkins Center for Health Security puts it. The US pharmaceutical industry and congressional Republicans have already **gone on the offensiv**e blasting Biden’s announcement, saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Senator Richard Burr, the top Republican on the US Senate Health Committee, denounced Biden’s decision. “Intellectual property protections are part of the reason we have these life-saving products,” he said. “Stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather **spend his political capital on getting the necessary legislation through Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry** to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO **dragging on for months, if not years**, without reaching anywhere. The US support for the waiver could even be a tactic to persuade pharmaceutical firms to back less drastic steps like sharing technology and expanding joint ventures to boost global production quickly. So far Covid-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones such as India, and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be **huge opposition** to the TRIPS waiver from the United States’ **European allies as well**. The British press has reported that the UK has been in closed-door talks at the World Trade Organization in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### The Bill quickly secures the vulnerable grid.

Carney 21 [Chris, August 6; Senior Policy Advisor at Nossaman LLC, former US Representative, Former Professor of Political Science at Penn State University; JD Supra, “The US Senate Infrastructure Bill: Securing Our Electrical Grid Through P3s and Grants,” https://www.jdsupra.com/legalnews/the-us-senate-infrastructure-bill-4989100/]

As we begin to better understand the main components of the Infrastructure Investment and Jobs Act that the US Senate is working to pass this week, it is clear that public-private partnerships ("P3s") are a favored funding mechanism of lawmakers to help offset high costs associated with major infrastructure projects in communities. And while past infrastructure bills have used P3s for more conventional projects, the current bill also calls for P3s to help pay for protecting the US electric grid from cyberattacks. Responding to the increasing number of cyberattacks on our nation’s infrastructure, and given the fragile physical condition of our electrical grid, the Senate included provisions to help state, local and tribal entities harden electrical grids for which they are responsible.

Section 40121, Enhancing Grid Security Through Public-Private Partnerships, calls for not only physical protections of electrical grids, but also for enhancing cyber-resilience. This section seeks to encourage the various federal, state and local regulatory authorities, as well as industry participants to engage in a program that audits and assesses the physical security and cybersecurity of utilities, conducts threat assessments to identify and mitigate vulnerabilities, and provides cybersecurity training to utilities. Further, the section calls for strengthening supply chain security, protecting “defense critical” electrical infrastructure and buttressing against a constant barrage of cyberattacks on the grid. In determining the nature of the partnership arrangement, the size of the utility and the area served will be considered, with priority going to utilities with fewer available resources.

Section 40122 compliments the previous section as it seeks to incentivize testing of cybersecurity products meant to be used in the energy sector, including SCADA systems, and to find ways to mitigate any vulnerabilities identified by the testing. Intended as a voluntary program, utilities would be offered technical assistance and databases of vulnerabilities and best practices would be created. Section 40123 incentivizes investment in advanced cybersecurity technology to strengthen the security and resiliency of grid systems through rate adjustments that would be studied and approved by the Secretary of Energy and other relevant Commissions, Councils and Associations.

Lastly, Section 40124, a long sought-after package of cybersecurity grants for state, local and tribal entities is included in the bill. This section adds language that would enable state, local and tribal bodies to apply for funds to upgrade aging computer equipment and software, particularly related to utilities, as they face growing threats of ransomware, denial of service and other cyberattacks. However, under Section 40126, cybersecurity grants may be tied to meeting various security standards established by the Secretary of Homeland Security, and/or submission of a cybersecurity plan by a grant applicant that shows “maturity” in understanding the cyber threat they face and a sophisticated approach to utilizing the grant.

While the final outcome of the Infrastructure Investment and Jobs Act may still be weeks or months away, inclusion of these provisions not only demonstrates a positive step forward for the application of federal P3s and grants generally, they also show that Congress recognizes the seriousness of the cyber threats our electrical grids face. Hopefully, through judicious application of both public-private partnerships and grants, the nation can quickly secure its infrastructure from cyberattacks.

#### Grid vulnerabilities spark nuclear war – extinction.

Klare 19 [Michael; November; Professor Emeritus of Peace and World Security Studies at Hampshire College; Arms Control Association, “Cyber Battles, Nuclear Outcomes? Dangerous New Pathways to Escalation,” https://www.armscontrol.org/act/2019-11/features/cyber-battles-nuclear-outcomes-dangerous-new-pathways-escalation]

Yet another pathway to escalation could arise from a cascading series of cyberstrikes and counterstrikes against vital national infrastructure rather than on military targets. All major powers, along with Iran and North Korea, have developed and deployed cyberweapons designed to disrupt and destroy major elements of an adversary’s key economic systems, such as power grids, financial systems, and transportation networks. As noted, Russia has infiltrated the U.S. electrical grid, and it is widely believed that the United States has done the same in Russia.12 The Pentagon has also devised a plan known as “Nitro Zeus,” intended to immobilize the entire Iranian economy and so force it to capitulate to U.S. demands or, if that approach failed, to pave the way for a crippling air and missile attack.13

The danger here is that economic attacks of this sort, if undertaken during a period of tension and crisis, could lead to an escalating series of tit-for-tat attacks against ever more vital elements of an adversary’s critical infrastructure, producing widespread chaos and harm and eventually leading one side to initiate kinetic attacks on critical military targets, risking the slippery slope to nuclear conflict. For example, a Russian cyberattack on the U.S. power grid could trigger U.S. attacks on Russian energy and financial systems, causing widespread disorder in both countries and generating an impulse for even more devastating attacks. At some point, such attacks “could lead to major conflict and possibly nuclear war.”14

# Case

### ADV

#### Aff gets circumvented- powerful countries use bilateral agreements to force other countries to accept their IPR protections- its empirically proven

DC = developing country

NIT = Net Importers of Technology (this references developing countries)

NET = Net Exporters of Technology (countries with advanced economies)

Marcellin 16 Marcellin, Sherry (Professor, London School of Economics). The political economy of pharmaceutical patents: US sectional interests and the African Group at the WTO. Routledge, 2016./SJKS

In July 1988, prior to the Montreal Mid-Term Review, DCs had sensed that the approach being proposed by industrialised countries was desirable on the grounds that the alternative would be a proliferation of unilateral or bilateral actions (MTN.GNG/NG11/8: 31). These NITs maintained that acceptance of such an approach would be tantamount to creating a licence to force, in the name of trade, modifications in standards for the protection of IP in a way that had not been found acceptable or possible so far in WIPO (ibid). Brazil subsequently informed the Group that on October 20, 1988, unilateral restrictions had been applied by the US to Brazilian exports as a retaliatory measure in connection with an IP issue; that this type of action seriously inhibited Brazil’s participation in the work of the Group, since ‘no country could be expected to participate in negotiations while experiencing pressures on the substance of its position’ (MTN.GNG/NG11/10: 27). The Brazilian delegate maintained that such action by the US constituted a blatant infringement of GATT rules and was contrary to the Standstill commitment of the Punta del Este Declaration. ‘The United States action was an attempt to coerce Brazil to change its intellectual property legislation, and furthermore represented an attempt by the United States to improve its negotiating position in the Uruguay Round’ (ibid). A US delegate countered that the measures had been taken with regret and as a last resort after all alternative ways of defending legitimate US interests had been exhausted, and that the US further believed that the adoption of effective patent protection was in Brazil’s own interest (ibid: 28). The US had therefore applied its strategy of coercive unilateralism against one of the two most important players championing the cause of the South in the TRIPS negotiations, the other being India. Apprehensive about the resistance of this dominant Southern duo, the United States sought to utilise its market size as a bargaining tool to secure changes to national IP regimes. It therefore decided to impact the more powerful of the two at the time, thereby indirectly admonishing India and the entire coalition against strengthened IP rules, as well as their domestic export constituencies who would be affected by US decisions to restrict imports. Moreover, because Brazil and India appeared to be collaborating extensively in maintaining a united front, a resulting strain on Brazil’s economy would likely affect their co-operation. However, since market opening and closure have been treated as the currency of trade negotiations in the post-war period (Steinberg 2002: 347), the move to place restrictions on Brazilian exports by the largest consumer market in the GPE should not have been entirely unanticipated. Brazil was also the regional leader in South America and disciplining it would send an unequivocal warning to other South American countries (Drahos and Braithwaite 2002: 136), including Argentina, Chile and Peru who were also active participants in the negotiations. This would mark the start of a series of coercive strategies aimed at compliance with the US private-sector envisioned GATT IPP.

#### Squo solves—rich nations are already donating

Inskeep 9-22 Steve Inskeep, 9-22-2021, "U.S. Officials Are Buying More Vaccine Doses To Donate To Other Countries," NPR.org, [https://www.npr.org/2021/09/22/1039565460/u-s-officials-are-buying-more-vaccine-doses-to-donate-to-other-countries //](https://www.npr.org/2021/09/22/1039565460/u-s-officials-are-buying-more-vaccine-doses-to-donate-to-other-countries%20//) EH

President Biden will announce the U.S. is buying 500 million more doses of the Pfizer-BioNTech COVID-19 vaccine. That would bring the total promised U.S. vaccine donations to more than 1.1 billion. Today, the United States answers a criticism from some parts of the world. It's a criticism that rich countries have taken a larger share of available COVID vaccines than poorer nations, which also need the vaccine. Even as a minority of Americans rejects the widely available medication, people in other countries are desperate for more. And today, President Biden will announce the United States is nearly doubling the amount of vaccine it is promising to donate to poorer countries. NPR White House correspondent Tamara Keith is covering this story. Tam, good morning. TAMARA KEITH, BYLINE: Good morning. INSKEEP: What is the president going to say exactly? KEITH: The president is going to announce 500 million additional doses of the Pfizer vaccine will be purchased. He'll make that announcement at a virtual COVID-19 summit that he's hosting. The summit is aimed at getting other wealthy countries, NGOs and others, to commit to vaccinating the world. This big bunch of doses is on top of another 500 million doses he announced that the U.S. would be purchasing earlier this year, all aimed at low- and lower-middle-income countries. This will bring the total U.S. contribution to 1.1 billion doses. That's a lot more than any other country by a lot. President Biden gave a preview in his speech at the U.N. yesterday. (SOUNDBITE OF ARCHIVED RECORDING) PRESIDENT JOE BIDEN: To fight this pandemic, we need a collective act of science and political will. We need to act now to get shots in arms as fast as possible and expand access to oxygen, tests, treatments, to save lives around the world. KEITH: Biden will also, at this conference, get behind an ambitious goal of having 70% of the world's population vaccinated by this time next year. INSKEEP: OK, you said 1.1 billion doses in total on the way, which is a lot, but there are 7 billion people in the world. How big a deal is this? KEITH: Yeah, it is a significant contribution, but there are a lot of questions, including whether this announcement will be a catalyst for other rich countries to donate more doses. I asked Carolyn Reynolds at the Pandemic Action Network to do some of that math for us, and she said that, to meet that 70% goal, about 5 billion more doses will be needed for low- and middle-income countries. So this U.S. contribution would be about a fifth of that. The challenge now, she said, is timing and delivery. She and other global health advocates are pressing to get shots in arms much faster. The majority of the doses the U.S. is donating won't be delivered until next year - so put that another way, most of the vaccines going to poor countries will be delivered in the third year of this deadly pandemic.

### Covid

#### IPR hasn’t harmed access – manufacturing capacity alt cause

Mercurio 2/12 (Bryan Mercurio, [Simon F.S. Li Professor of Law at the Chinese University of Hong Kong (CUHK), having served as Associate Dean (Research) from 2010-14 and again from 2017-19. Professor Mercurio specialises in international economic law (IEL), with particular expertise in the intersection between trade law and intellectual property rights, free trade agreements, trade in services, dispute settlement and increasingly international investment law.], 2-12-2021, “WTO Waiver from Intellectual Property Protection for COVID-19 Vaccines and Treatments: A Critical Review“, No Publication, accessed: 8-8-2021, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3789820) ajs

2. Intellectual property rights have not hampered access to COVID-19 vaccines

A WTO waiver is an extreme measure which should only be used when existing WTO obligations prove inadequate. This was the case in relation to the compulsory licencing provisions under Article 31 of the TRIPS Agreement, which essentially precluded Members with no or inadequate manufacturing capabilities from making use of the flexibility granted in the TRIPS Agreement. 25 This was also the case with the Kimberley Process, which attempts to eliminate trade in “conflict diamonds”. 26

Although the IP waiver proposal states that “there are several reports about intellectual property rights hindering or potentially hindering timely provisioning of affordable medical products to the patients”, 27 the sponsors did not provide further elaboration or evidence to support their declaration that “many countries especially developing countries may face institutional and legal difficulties when using flexibilities available [under the TRIPS Agreement]”. 28 Instead, many of the examples used by India and South Africa point to problems not with the TRIPS Agreement but rather to failures at the domestic level. As mentioned above, the WTO allowed for the importation of medicines under a compulsory licence in 2003, and yet many developing countries have yet to put in place any framework to allow their country to make use of the flexibility. 29 This is not an institutional problem of the international system but rather a problem at the country level.

Two additional factors which make the proposed waiver unnecessary and potentially harmful. First, pharmaceutical companies are selling the vaccine at extremely reasonable rates and several announced plans for extensive not-for-profit sales.30 Although agreements between the pharmaceutical companies and governments are not publicly disclosed, the Belgian Secretary of State Eva De Bleeker temporarily made publicly available in a tweet the prices the EU is being charged by each manufacturer. The De Bleeker tweet indicated the European Commission negotiated price arrangements with six companies, with the range of spending between €1.78 and €18 per coronavirus vaccine dosage. Specific price per dose listed for each of the six vaccines was as follows: Oxford/AstraZeneca: (€1.78), Johnson & Johnson (€8.50), Sanofi/GSK (€7.56), CureVac (€10), BioNTech/Pfizer (€12) and Moderna (€18).31

While much as been made of the fact that South Africa agreed to purchase 1.5 million doses of the Oxford/AstraZeneca from the Serum Institute of India (SII) at a cost of €4.321 per dose,32 these criticisms are directed at the lack of transparency in pharmaceutical licenses and production contracts – an issue which would be wholly unaddressed by a waiver of IPRs.

Moreover, while the disparity in pricing is concerning the overall per dosage rate South Africa is paying nevertheless represents value for money given the expected health and economic returns on investment. Despite the disparity in pricing between nations, the larger point remains that the industry has not only rapidly produced vaccines for the novel coronavirus but is making them available at unquestionably reasonable prices.

Second, the proposed waiver will do nothing to address the problem of lack of capacity or the transfer of technology and goodwill. Pharmaceutical companies have not applied for patents in the majority of developing countries – in such countries, any manufacturer is free to produce and market the vaccine inside the territory of that country or to export the vaccine to other countries where patents have not been filed.33 Patents cannot be the problem in the countries where no patent applications have been filed, but the lack of production in such countries points to the real problem – these countries lack manufacturing capacity and capability.

While advanced pharmaceutical companies will have the technology, know-how and readiness to manufacture, store and transport complex vaccine formulations, such factories and logistics exist in only a handful of countries.34 Regardless of whether an IP waiver is granted, the remaining countries will be left without enhanced vaccine access and still reliant on imported supplies. With prices for the vaccine already very low, it is doubtful that generic suppliers will be able to provide the vaccine at significantly lower prices. Under such a scenario, the benefit of the waiver would go not to the countries in need but to the generic supplier who would not need to pay the licence fee or royalty to the innovator. Thus, the waiver would simply serve to benefit advanced generic manufacturers, most of which are located in a handful of countries, including China and Brazil as well as (unsurprisingly) India and South Africa. Countries would perhaps be better off obtaining the vaccine from suppliers that have negotiated a voluntary licence from the patent holder, as such licences include provisions for the transfer of technology, know-how and ongoing quality assurance support.

### Innovation

#### Big pharma just steal smaller innovations and then market it better, no incentive cuz they cant sell

#### Strong IPR is key to innovation – empirics and FDI

Ezell and Cory 19 [Stephen Ezell, BS from School of Foreign Service at Georgetown, VP of global innovation policy at Information Technology and Innovation Foundation. Nigel Cory, MA in public policy from Georgetown, BA in international business from Griffith University, Associate Director of trade policy at Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies.] “The Way Forward for Intellectual Property Internationally,” Information Technology and Innovation Foundation, April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> TG

* FDI – foreign direct investment

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 countries 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.

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

#### Feldman is a joke.

Risch 17 [Michael; “Data for the Evergreening Debate,” Written Description; 11/21/17; <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] Justin

**Feldman and Wang** argue that the Orange Book has been used by companies to "evergreen" their drugs - that is, to extend exclusivity beyond patent expiration. The paper is on SSRN and the abstract is here:

Why do drug prices remain so high? Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, just how pervasive is such behavior? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry?

This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. Every year, at least 74% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.

I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs.

My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0.

Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue.

Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided

### Insulin

#### C/A iinnovation

#### Extinction ow