**Util**

**The Value is morality because ought in the resolution implies a moral obligation, according to Meriam Webster.**

**Util – Syllogism + Independent Reasons**

**The meta-ethic is moral naturalism – ethics that begin with a priori truth are epistemically inaccessible - Papineau 15:**

David Papineau, <https://plato.stanford.edu/entries/naturalism/>. Stanford Encyclopedia of Philosophy. Sep 15 2015.

Moore took this argument to show that moral facts constitute a distinct species of non-natural fact. However, **any such non-naturalist view of morality faces immediate difficulties, deriving ultimately from the kind of causal closure thesis discussed above. If all physical effects are due to a limited range of physically-grounded natural causes, and if moral facts lie outside this range, then it follow that moral facts can never make any difference to what happens in the physical world** (Harman 1986). At first sight this may seem tolerable (perhaps moral facts indeed don’t have any physical effects). But it has awkward epistemological consequences. **For beings like us, knowledge of the spatiotemporal world is mediated by physical processes involving our sense organs and cognitive systems. If moral facts cannot influence the physical world, then it is hard to see how we can have any knowledge of them.**

**Naturalism means that ethics must start with moral intuitions -**

**[1] Ethical Uncertainty – phil debates have gone on for thousands of years and there hasn’t been a coherent way to explain everything – theres always small dilemmas that are able to be solved via intuitions but not through the extremely broad decision-making processes of different frameworks that [a] means you default to intuitions – if we know something is intuitively wrong there is a higher probability it is [b] means you should use EM to eval the debate**

**[2] Bindingness – [a] agents can’t reject intuitions – that in itself is a conceptual contradiction – in order to not want to act on intuitions you must have some preconception and intuition that intuitions in themselves ought not be used – proving our ethic is inevitable and that means all other ethics collapse [b] inevitability – any strand of reasoning must start with a presumptive claim about the world that begins with assuming moral facts about the world**

**And all justifications of actions rely on value statuses of pain and pleasure – they’re intrinsically valuable – to justify beyond that runs into moral incoherence. Moen 16,**

**Moen 16** [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI // RCT by JPark

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.

**Thus, the standard is maximizing expected well-being. Independently prefer:**

**[1] Actor specificity A] governments must aggregate because their policies benefit some and harm others so the only non-arbitrary way to prioritize is by helping the most amount of people B] No act-omission distinction – governments have to yes/no policies which means that choosing to omit is an act itself so side constraints freeze action C] Actor specificity comes first because different agents have different obligations. Takes out calc indicts because they’re empirically denied.**

**[2] It’s a lexical pre-requisite. Threats to bodily security and life preclude the ability for moral actors to effectively act upon other moral theories since they are in a constant state of crisis that inhibit the ideal moral conditions which other theories presuppose.**

**[3] theory:**

**[A] Topic lit – most articles are written through the lens of util since they’re crafted for policymakers and the general public to understand who take consequences to be important, not philosophy majors. Fairness and education since it’s a lens through which we engage the res.**

**[4] Extinction hijacks and side constrains the framework – it o/w and comes first**

**Pummer 15** [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But **that is a huge mistake.** Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; **it is not the view that the latter don’t matter**. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” **Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good**, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. **We should also take into account moral uncertainty.** What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, **all minimally plausible moral views would converge on the conclusion that we should try to save the world**. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

**Extra 2**

**Consequentialism is the only non-arbitrary way to explain moral intuitions – Sinnott-Armstrong 19**

Sinnott-Armstrong, Walter, "Consequentialism", The Stanford Encyclopedia of Philosophy (Summer 2019 Edition), Edward N. Zalta (ed.), URL = <https://plato.stanford.edu/archives/sum2019/entries/consequentialism/>. // LHP PS

Consequentialism also might be supported by an inference to the best explanation of our moral intuitions. This argument might surprise those who think of consequentialism as counterintuitive, but in fact consequentialists can explain many moral intuitions that trouble deontological theories. Moderate deontologists, for example, often judge that it is morally wrong to kill one person to save five but not morally wrong to kill one person to save a million. They never specify the line between what is morally wrong and what is not morally wrong, and it is hard to imagine any non-arbitrary way for deontologists to justify a cutoff point. In contrast, consequentialists can simply say that the line belongs wherever the benefits outweigh the costs (including any bad side effects). Similarly, when two promises conflict, it often seems clear which one we should keep, and that intuition can often be explained by the amount of harm that would be caused by breaking each promise. In contrast, deontologists are hard pressed to explain which promise is overriding if the reason to keep each promise is simply that it was made (Sinnott-Armstrong 2009). If consequentialists can better explain more common moral intuitions, then consequentialism might have more explanatory coherence overall, despite being counterintuitive in some cases. (Compare Sidgwick 1907, Book IV, Chap. III; and Sverdlik 2011.) And even if act consequentialists cannot argue in this way, it still might work for rule consequentialists (such as Hooker 2000).

**DAs**

## 33SO21 – DA – Innovation (1:05-1:15)

**Pharma innovation is strong now – patent incentives are key to maintaining progress, Austin and Hayford 21:**

David Austin, [an Analyst in CBO’s Microeconomics Studies Division] and Tamara Hayford, [a principal analyst in the Health, Retirement, and Long-Term Analysis Division, Congressional Budget Office] prepared the report with guidance from Joseph Kile, Lyle Nelson, and Julie Topoleski. Christopher Adams, Pranav Bhandarkar, and David Wylie (formerly of CBO) contributed to the analysis., April 2021, “Research and Development in the Pharmaceutical Industry” <https://www.cbo.gov/publication/57126> //LHP AV DOA: 9/8/21

At a Glance This report examines research and development (R&D) by the pharmaceutical industry. Spending on R&D and Its Results. **Spending on R&D and the introduction of new drugs have both increased in the past two decades.** In 2019, the **pharma**ceutical industry **spent $83 billion dollars on R&D.** Adjusted for inflation, **that** **amount is about 10 times what the industry spent per year in the 1980s**. Between 2010 and 2019, the number of **new drugs approved** for **sale increased by 60 percent** compared with the previous decade, with a peak of 59 new drugs approved in 2018. Factors Influencing R&D Spending. **The amount of money that drug companies devote to R&D is determined by** the amount of **revenue** they expect to earn from a new drug, the expected **cost** of developing that drug, **and** **policies** that influence the supply of and demand for drugs. The **expected** **lifetime global revenues of a new drug depends on the prices that companies expect to charge** for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed. **The expected cost** to develop a new drug—**including capital costs and expenditures on drugs that fail to reach the market**—**has been estimated to range from less than $1 billion to more than $2 billion**. The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand. Notes Research and Development in the Pharmaceutical Industry Summary Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered **policies** **that** would **lower** drug **prices** and reduce federal drug expenditures. Such policies would probably **reduce the industry’s incentive to develop new drugs**. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. **The share of revenues that drug companies devote to R&D has also grown**: On **average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000**. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. **Various considerations inform companies’ expectations** about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The **prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments**. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. **Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA**. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and **during that time the company does not receive a financial return on its investment in developing that drug.** The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, **the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, **spending on drug R&D increased by nearly 50 percent between 2015 and 2019**. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, **the trend is broadly representative of R&D spending by the industry as a whole**.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3

**Intellectual property protections are key to pharmaceutical innovation – laundry of list of studies – that solves access better, Ezeli and Cory 19:**

Stephen Ezell, [vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.] and Nigel Cory, [an associate director covering trade policy at the Information Technology and Innovation Foundation. He focuses on cross-border data flows, data governance, intellectual property, and how they each relate to digital trade and the broader digital economy. Cory has provided in-person testimony and written submissions and has published reports and op-eds relating to these issues in the United States, the European Union, Australia, China, India, and New Zealand, among other countries and regions, and he has completed research projects for international bodies such as the Asia Pacific Economic Cooperation and the World Trade Organization.] “The Way Forward for Intellectual Property Internationally” April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> //LHP AV

INTELLECTUAL PROPERTY UNDERPINS INNOVATION AND GROWTH Intellectual property rights arrangements are well recognized, going back to the Middle Ages, as enabling innovators to earn the returns necessary to continue to innovate and promote the availability of leading-edge technologies. **Nobel laureate economist Douglas North**, one of the foremost scholars of economic history, **argues that the introduction of intellectual property rights had one of the most profound impacts on spurring economic growth in human history**. North points out that average global economic growth rates for about one and a half millennia prior to the Industrial Revolution were essentially zero. Eighteenth-century elites in England had practically the same per capita income as their counterparts in third-century Rome.21 North has shown that the inflection point toward greater economic growth was the widespread development of patent systems in the 19th century.22 Gregory Clark, in his seminal book, Farewell to Alms: A Brief Economic History of the World, reached a similar conclusion that the introduction of **IPRs was catalytic to turbo-charging global economic growth**.23 **Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks**. By raising the private rate of return closer to the social rate of return, in**tellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation.** If innovators know that most of the benefits from their innovations would go to others without compensation, **they would be much less likely and capable of engaging in future innovations**. In addition, as they capture a larger portion of the benefits of their innovative activity, **innovating companies obtain the resources to pursue the next generation of innovative activities.** **IP thus produces a number of positive benefits, including: 1) creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring** a country’s **companies can focus on operating productively and innovating**, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; **4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services**.24 Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. The **evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike.** As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that **developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results**, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. The following section details the broad swath of academic literature reviewing the relationships between IPR strengthening and trade, FDI, and technology transfer; IPR reform and innovation and R&D; and IPR reform and exports and industry growth, revealing the benefits of stronger IPR protections for developed and developing countries alike. IPRs Strengthen Trade, FDI, and Technology Transfer A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41 A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45 **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 BOX 1: INNOVATE FOR HEALTH: IP IS NOT THE PROBLEM, BUT PART OF THE SOLUTION **Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services**. Yet the reality is that **stronger IPR rights in developing nations actually unleash the power of developing-country innovators to contribute to solving health challenges both in their own nations and across the global economy**. First, opponents of IP fail to recognize **that intellectual property rights matter for health care innovation in emerging economies.** **A**n Information Technology and Innovation Foundation (ITIF) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market**.57 The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing-country environments where resources and infrastructure are scarce, and that local innovation and **IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** Second, **opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** **While cost is a central factor for policymakers in all countries, given resource scarcity, these trade-offs are not unique to health**. **The greater the resource scarcity, the greater the need for innovation**. One of the biggest challenges policymakers and innovators in developing countries confront again and again is scarcity—in access to trained professionals, in transportation, and in other infrastructure. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.58 A 2014 World Health Organization study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.59 More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens.60 The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens.61 And Ethiopia, a country of some 90 million residents, is served by a single radiation-treatment center located in the capital of Addis Ababa.62 In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.63 Again, **the cost of medicines is far from the most serious problem in the provision of health care services in developing nations**. Indeed, **the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off-patent, and thus potentially available in generic versions**.64 **The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care.** **Stronger IP rights create an environment wherein entrepreneurs can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.** IPRs Strengthen Exports and Industry Growth Academic research has also found that **stronger IPR protections support exports from developing countries and faster growth rates of certain industries.** Yang and Kuo argue that stronger IPR protection improves the export performance of firms benefitting from technology transfer. And in their research, Cavazos Cepeda et al. found that trademark protection has a statistically significant association in relation to the export turnover, sales, and total assets of firms studied. They also found a significant association between copyrights and export turnover. Moreover, they found “a positive influence of patent right protection on export turnover (e.g., sales) under certain specifications with respect to complementary policies.”65 In cross-country studies, researchers have found that stronger patent rights are associated with faster company growth in IP-intensive industries such as pharmaceuticals. In fact, during the early 1990s, a one-standard-deviation increase in patent rights was associated with an increase in firm growth of 0.69 percent (an advantage amounting to nearly one-fifth of the average industry growth rate of 3.7 percent).66 Consequences of Countries Not Enacting Robust IPR Protections and Enforcement **Nations** **that** have not implemented—or **do not enforce**—**robust intellectual property rights protections end up harming their economic development in at least three principle ways. First, they deter future innovative activity. Second, they discourage trade** and foreign direct investment, which only hurts their own consumers and businesses, by both limiting their choices and inhibiting their enterprises’ ability to access best-of-breed technologies that are vital to boosting domestic productivity. **Third, in countries with weak IP protections, firms are forced to invest undue amounts of resources in protection rather than invention**. Ironically, **developing countries’ own economic development opportunities** and intellectual property development potential **are inhibited by their own weak intellectual property protections.** For instance, the lack of effective protection for intellectual property rights in China has limited the introduction of advanced technology and innovation investments by foreign companies, thereby reducing potential benefits to local innovation capacity.67 As Cavazos Cepeda et al. found in a case study of IPR protections in that economy, “China has made progress in strengthening the protection of intellectual property over the past two decades, as attested to by indicators such as the Patent Rights Index…. However, uncertainty around the protection of intellectual property [remains] an important deterrent for foreign as well as domestic firms engaging in R&D-related activities.”68 Ironically, developing countries’ own economic development opportunities and intellectual property development potential are inhibited by their own weak intellectual property protections.

**Pharma Innovation prevents Extinction – checks new diseases.**

**Engelhardt 8**, H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for **r**esearch and **d**evelopment **spurs innovation** in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of **profit is one of the most effective ways not only to acquire resources but productively to direct human energies** in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such **innovation is** both **necessary to maintain the human species** in an ever-changing and always dangerous environment in which **new microbial** and other threats may at any time emerge to threaten **human well-being, if not survival** (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

## Extensions

#### [1] Extend the uniqueness – IP protections are increasing, and research and development spending is going through the roof – 10x more than the 80s – proves IPR incentivizes drug development & there’s no need to do the aff.

#### [2] Extend the Ezeil and Cory card – IPR makes it so that firms are much more likely to innovate by giving them an incentive – without IPR, firms will have no reason to invest time and millions of dollars into innovative drugs, since generic drug companies will just steal their data and drug and sell it for a lower price. Also OWs in the context of legality – strong IPR protections mean companies won’t be worried about being sued – weakening protections makes it more likely that litigation against patents, even if they’re legitimate, will occur – it also means that companies will be less likely to reveal their trade secrets since they’ll just get stolen. Being able to reveal secrets is important b/c it creates a spillover of knowledge, leading to a chain reaction of innovation.

#### [3] Extend the impact – innovation is both key to solving for known diseases like cancer, and possible unknown diseases like microbial threats or even bioterrorism. The aff destroys incentive for innovation, so if an existential threat comes through humans will be unprepared. Think about it like this – the only reason we have vaccines for COVID now is because of past R&D in mRNA vaccines. If there were no monetary incentive to develop those vaccines before COVID, then we wouldn’t have them right now and the world would be in terrible shape, esp. with mutations.

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**SO21 – DA – Biotech**

**US dominance is secured in biotech now, but China’s closing the gap fast – that allows geopolitical and economic advantages**

Scott **Moore** **2020** [(Director of the Penn Global China Program at the University of Pennsylvania. Previously, Moore was a Young Professional and Water Resources Management Specialist at the World Bank Group, and Environment, Science, Technology, and Health Officer for China at the U.S.) “China’s Role In The Global Biotechnology Sector And Implications For U.S. Policy” <https://www.brookings.edu/wp-content/uploads/2020/04/FP_20200427_china_biotechnology_moore.pdf>] TDI // Recut NChu

EXECUTIVE SUMMARY Even by the standards of emerging technologies, **biotechnology has the potential to utterly transform geopolitics, economics**, and society in the 21st century. Yet while the United States has long been the world leader in most segments of the global biotechnology sector, **China is fast becoming a significant player**. This brief assesses the implications of China’s changing role in biotechnology for the United States, which span national security, data security, and economic competitiveness. On current trends the United States is likely to remain the world leader in most biotechnology areas. **However, the gap between China and the U.S. is narrowing in the biotechnology sector,** and U.S. policymakers must boost public investment, liberalize immigration and foreign student visa policies, and enact regulatory reforms to ensure America remains competitive. At the same time, areas like vaccine development and regulation of emerging technologies like synthetic biology present rich opportunities for Sino-U.S. cooperation. INTRODUCTION Thanks to extensive government funding for biomedical research, an unparalleled ability to translate basic research into commercial products and applications, and strong intellectual property protections, the United States has been the dominant global player in developing and commercializing biotechnology for decades.1 This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.2 However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers. The determination of China’s one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector. Some estimates claim that collectively, **China’s** central, local, and provincial **governments have invested over $100 billion in life sciences** research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.3 The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.4 Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).5 By Western standards, some of these figures are still low. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.6 As these figures suggest, the development of China’s biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector’s rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, **with implications for national security, economic competitiveness, and regulation**. An executive from In-Q-Tel, the U.S. government’s inhouse national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China “intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that.”7 The CEO of European drugmaker AstraZeneca has similarly opined that “Much of [China’s] innovation in the last three to four years has been ‘me too,’ but now on the horizon we can see firstin-class innovation.”8 Yet on the other hand, while China’s biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, there is little reason to believe on current trends that the United States will lose its edge in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security. This brief first examines the key policies and actors in China’s biotechnology sector, then offers an assessment of the sector’s current capabilities and future trends, and finally further explores the implications of developments in Chinese biotechnology for U.S. policy.

**The aff’s waiving of IP doesn’t solve but it does give away sensitive national security information that allows China to lead ahead in biotech**

Josh **Rogin 4-8**. [(Washington Post Columnist covering National Security Issues.) “Opinion: The wrong way to fight vaccine nationalism” https://www.washingtonpost.com/opinions/global-opinions/the-wrong-way-to-fight-vaccine-nationalism/2021/04/08/9a65e15e-98a8-11eb-962b-78c1d8228819\_story.html ] TDI // Recut NChu

Americans will not be safe from covid-19 until the entire world is safe. That basic truth shows why vaccine nationalism is not only immoral but also counterproductive. But the simplest solutions are rarely the correct ones, **and some countries are using the issue to advance their own strategic interests**. The Biden administration must reject the effort by some nations to turn our shared crisis into their opportunity. As the inequities of vaccine distribution worldwide grow, a group of more than 50 developing countries led by India and South Africa is pushing the World Trade Organization to dissolve all international intellectual property protections for pandemic-related products, which would include vaccine research patents, manufacturing designs and technological know-how. The Trump administration rejected the proposal to waive the agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) for the pandemic when it was introduced in October. Now, hundreds of nongovernmental organizations and dozens of Democratic lawmakers are pushing the Biden administration to support the proposal. But many warn **the move would result in the United States handing over a generation of advanced research** — much of it funded by the U.S. taxpayer — **to** our country’s greatest competitors, above all **China**. In Congress, there’s justified frustration with the United States’ failure to respond to China’s robust vaccine diplomacy, in which Beijing has conditioned vaccine offers to pandemic-stricken countries on their ignoring security concerns over Chinese telecom companies or abandoning diplomatic recognition of Taiwan. There’s also a lot of anger at Big Pharma among progressives for profiting from the pandemic. “We are in a race against time, and unfortunately Big Pharma is standing in the way of speedily addressing this problem,” Rep. Jan Schakowsky (D-Ill.), who supports the effort to waive intellectual property protections, told me in an interview. “I think the real security issue is that while the United States balks in making sure that we help ourselves, that these adversaries will just jump right in.” Schakowsky argued that alternative measures for helping poor countries manufacture vaccines are simply not moving fast enough to save lives and that the United States has a duty to respond. House Speaker Nancy Pelosi (D-Calif.) personally conveyed her support for the waiver to President Biden, Schakowsky said. But Big Pharma is just one piece of the puzzle. Countries such as India and South Africa have been trying to weaken WTO intellectual property protections for decades. **The mRNA technology that underpins the Pfizer and Moderna vaccines was funded initially by the Defense Advanced Research Projects Agency and has national security implications.** Inside the Biden administration, the National Security Council has already convened several meetings on the issue. The waiver is supported by many global health officials in the White House and at the U.S. Agency for International Development, who believe the United States’ international reputation is suffering from its perceived “America First” vaccine strategy. On Wednesday, U.S. Trade Representative Katherine Tai spoke with WTO Director General Ngozi Okonjo-Iweala about the waiver issue. USTR is convening its own interagency meetings on the issue, which many see as a move to reassert its jurisdiction over WTO matters. If and when this does get to Biden’s desk, he will also hear from national security officials who believe that waiving TRIPS would result in the forced transfer of national security-sensitive technology to China, **a country that strives to dominate the biotechnology** ***field*** as part of its Made in China 2025 strategy. **Once countries such as China have this technology, they will apply their mercantilist industrial models to ensure their companies dominate these strategically important industries, potentially erasing thousands of U.S. jobs.** “We would be delivering a competitive advantage to countries that are increasingly viewed as our adversaries, at taxpayer expense, when there are other ways of doing this,” said Mark Cohen, senior fellow at the University of California at Berkeley Law School. **A preferable approach would be to build more vaccine-manufacturing capacity** in the United States and then give those vaccines to countries in need, said Cohen. The U.S. pharmaceutical industry would surely benefit, but **that’s preferable to being dependent on other countries when the next pandemic hits.** “If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally,” Cohen said. What’s more, it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licensing agreements are already successfully facilitating cooperation between patent-holding vaccine-makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world. Vaccine equity is a real problem, but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. **That means helping the world and thinking about our strategic interests at the same time.**

**China will convert biotechnology gains to military advantages, undermining US primacy – specifically true in the context of vaccines**

Mercy A. **Kuo 2017** [(Executive Vice President at Pamir Consulting.) “The Great US-China Biotechnology and Artificial Intelligence Race” <https://thediplomat.com/2017/08/the-great-us-china-biotechnology-and-artificial-intelligence-race/>] TDI // Recut NChu

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 tech**nological 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 **is inherently dual-use, therefore a strategic advantage in a nation’s security arsenal.** Using AI systems to understand how the functioning of our genomes impacts our health **is of strategic importance for 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 potential applications 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 to increasingly large U.S. genomic data-sets gives China a knowledge advantage into leading the next steps in 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.**

**Maintenance of the US-led LIO is key to reduce a host of existential threats – establishes great-power peace.**

**Brands 18**. [(Hal Brands is a Henry Kissinger Distinguished Professor at Johns Hopkins University’s School of Advanced International Studies, Scholar at the American Enterprise Institute. “America’s Global Order Is Worth Fighting For, Bloomberg Opinion, Politics & Policy,” August 14, 2018, Bloomberg. <https://www.bloomberg.com/opinion/articles/2018-08-14/america-s-global-order-is-worth-fighting-for>] TDI // Recut NChu

The first argument is **easily disposed** of. Yes, the postwar world has been **thoroughly imperfect**, featuring nuclear arms races, genocides, widespread poverty and other scourges. But the world has **always been** imperfect, and by **any** meaningful **comparison**, the last **seven decades** have been a **veritable golden age**. The **liberal international** economic order has led to an **explosion** of **domestic** and **global prosperity**: According to World Bank data, both U.S. and global **per capita** income have increased **roughly three-fold** (in inflation-adjusted terms) since 1960, with U.S. gross domestic product increasing nearly six-fold. The U.S. **system** of alliances and forward military deployments has **contributed critically** to the **longest period** of **great-power peace** in modern history, and **the incidence of war** and conquest **more broadly** have dropped **dramatically**. The number of **democracies** in the world has **increased** from perhaps a dozen during World War II to well over 100 today; **respect for basic** human rights has also reached **impressive levels**. As a **bevy of scholarship** has shown, the policies that the U.S. has **pursued** and the **international order** it has built have contributed **enormously** and **directly** to these **outcomes**. If the **liberal international order** can’t be considered a **smashing success**, no **international order** could be. The second critique is also overstated. It is true that Washington, like all great powers throughout history, has been willing to bend the rules to get its way. It is hard to reconcile Cold War-era interventions in Guatemala, Chile and other countries with a professed solicitude for human rights and democracy; the Iraq War of 2003 is only one instance in which the U.S. brushed aside the concerns of international organizations such as the U.N. Security Council. Likewise, when the U.S. government determined that the Bretton Woods system of monetary relations no longer suited its interests in the 1970s, it terminated that scheme and insisted on creating a more favorable one. But again, the proper standard here is not sainthood but reality. And the U.S. has **generally** enlisted its power in the **service** of **universal values** such as **democracy** and **human rights**; it has, more often than not, promoted **a positive-sum** international system in which **like-minded** nations can be **secure** and **wealthy**. This goes back to the very beginning of the liberal order: Washington did not seek to hold its defeated adversaries in subjugation after World War II; it rebuilt Japan and western Germany into thriving, democratic allies that became fierce economic competitors to the U.S. The U.S. has taken this approach not simply because it wanted to do good in the world — powerful as this motivation is — but because of a hard-headed desire to do good for itself. In an interdependent global environment, American officials have long calculated, the U.S. cannot divorce its own well-being from that of the wider world. And in contrast to how other great powers — Imperial Japan, for instance, or the Soviet Union — ruled their spheres of influence, American behavior has been positively enlightened. It is this relatively benign behavior that has convinced so many countries to tolerate American leadership — and it is the emergence of a darker form of U.S. hegemony under the Trump administration that so profoundly worries them today. As for the third critique, the premise is right, but the **conclusion** can easily **go too far**. It is always **dangerous** to become **so enraptured** by past **achievements** that one **loses sight** of the **need for adaptation** in **the future**. This is particularly true today, because the strength of the liberal order is being tested from within and without, by issues ranging from unequal burden-sharing among American allies to the ambivalence of the American people themselves. There is **little evidence** to suggest, however, that either American power or **the liberal order** it supports have **eroded** so **dramatically** that **Washington**’s postwar project cannot be **sustained**. Quite the contrary — the U.S. is likely to remain the **world’s strongest power** for **decades to come**.

**Extensions:**

**First, “incremental” innovations are a key aspect of R&D, Jones 6**

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

As already mentioned, **the costs and time necessary to bring a drug to the market are considerable**. While the initial patents covering the basic chemical or protein entity are important to encourage the further investment to bring the drug to the market, **the length of time afforded protection** by such patents ‐ due to the considerable amount of time necessary to develop a suitable formulation and presentation of the drug, and the time to conduct clinical trials ‐ **usually does not provide sufficient protection to balance the overall financial investment.** Further, **many inventions** made during the develop‐ ment of the drug formulation or presentation, while possibly **viewed as ’incremental inventions’ by some, are actually critical to bringing the drug to the market**. Indeed, as a proportion of all patents granted worldwide, very few relate to what may be termed “breakthroughs”. **The vast majority cover innovations which build on inventions of others, with the benefit of full disclosure of those inventions in patent specifications**. That is what the patent system was designed to encourage. **By its very nature**, there‐ fore**, it encourages inventors to adapt and modify the developments** patented by others **incrementally** or in any other way. It would therefore, in ICC’s view, be wholly in‐ appropriate not to allow patents for such forms of innovation; and any such change would adversely affect the ability to finance future drug research. **The innovation process in the pharmaceutical sector, as for all other scientific sectors, is one of evolution**. The criteria for patentability are clear. Patents are available for any invention, whether product or process, in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. **If an invention meets these criteria, it is entitled to patent protection. If it does not, it is not patentable. Of these criteria, the most relevant here is inventive step**. The invention must not have been obvious to a person skilled in the relevant art at the time the application for a patent was first filed, taking into account the state of the art at that time. There is no common understand‐ 192 7 Negative Evidence ing around the world on how this criterion should be applied and TRIPS provides no guidance. The precise manner in which it is applied differs from country to country. It even differs over time within the same country. Significant progress has, however, been made in harmonizing the standard, particularly in the US, Japan and Europe. This harmonized standard should, in ICC’s view, in time become the “gold standard” for patents globally. In the meantime, it may be necessary and appropriate, to encourage investment in local research and manufacturing, for developing countries to adopt a lower threshold to provide easy access to patents for local entrepreneurs. But in ICC’s view, it cannot be right to require such countries to adopt a higher standard of inventive step. In any event, neither the inventive step requirement, nor the other basic criteria, make any distinction between different types of innovation œ for example between “in‐ cremental” and “discrete”, or between “me too” and “breakthrough” innovations. As with any innovation, all of these have to be judged against the same basic rules, and that, in ICC’s view, is entirely appropriate. To the extent that genuine concerns about patent quality exist, they relate to the whole range of patents**. They are not specific to patents for healthcare products, nor to patents for so‐called incremental innovations. If such inventions fail to meet the fundamental criteria set out above, patents should not be granted for them; and where patents have wrongly been granted, courts should (and have) corrected those errors** œ all as part of the international efforts referred to above to ensure that an appropriate balance is achieved between all entities affected by patents. **However, the fact that there have been some examples of patent‐granting authorities ap‐ plying the criteria incorrectly does not justify fundamental change to those underlying principles.**

**Second, evergreening only proves flaws in the application process, not the legitimacy of patents themselves, Jones 6**

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

**In the context of pharmaceuticals, it has been suggested** that **patent protection should not be given to inventions comprising different salts, esters or other derivatives of known drugs,** different dosage forms or means of administration of existing products, combinations of known products (including fixed dose combinations), nor “mere” new uses of known compounds, (all of which might qualify for the misnomer “incrementally modified drugs”); nor for modifications to medical devices (such as a single‐, rather than multiple‐dose, syringe). **These suggestions are, in ICC’s view, misconceived. As stated above, if any such inventions do not satisfy the basic patentability criteria, patents should not be granted for them**; and if patents are found wrongly to have been granted, courts and patents offices should correct those errors, just as they should for patents in any field and for any category of innovation. This approach should address, and is addressing, concerns about illegitimate extension of patent term, or “evergreening”. **There is no need for separate, or new, legislation to deal with this issue. Further, the suggestion that such inventions do not benefit society is wrong. These types of so‐called “incremental” innovation generally result in better health outcomes2, for example by increasing efficacy, reducing side effects and/or making administration easier, resulting in improved compliance and greater effectiveness**

**Extinction hijacks and side constrains the framework – it o/w and comes first**

**Pummer 15** [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But **that is a huge mistake.** Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; **it is not the view that the latter don’t matter**. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” **Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good**, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. **We should also take into account moral uncertainty.** What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, **all minimally plausible moral views would converge on the conclusion that we should try to save the world**. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

**[1] Extend the uniqueness – The aff’s plan causes the US to give away super important national information about advances due to the reduction of IP. China then uses this information for military advantages against the US and democratic countries..**

**[2] Extend Kuo 17 – Genomics has a great strategic advantage for China which will be used for military enhancement etc. It gives China a huge knowledge increase that could be used in very bad ways and takes the US away from the leading.**

**[3] Extend the impact – Only maintaining US power reduces existential threats and promotes peace. Global prosperity contributed to the longest power-peace and the US has enlisted its power in democracy and human rights. All these would go away, wwe would have terror, no rights, war, etc. if China gains power.**

**ROB**

**The role of the ballot is to vote for the debater who best proves the truth or falsity of the Resolution; the aff must prove it true and the neg must prove it false. Prefer: [A] Constitutivism: The ballot asks you to either vote aff or neg based on the given resolution a) Five dictionariesdefine to negate as to deny the truth of and affirmas to prove true which means its intrinsic to the nature of the activity b) the purpose of debate is the acquisition of knowledge in pursuit of truth – a resolutional focus is key to depth of exploration which o/w on specificity. It’s a jurisdictional issue since it questions whether the judge should go outside the scope of the game – that’s a meta constraint on anything else since the judge voting aff if they affirm better and neg the contrary proves that it’s an independent voter and otherwise they could just hack against or for you which means it also controls the internal link to fairness since that’s definitionally unfair and a practice can only make sense based on intrinsic rules. [B] Logic: Any counter role of the ballot collapses to truth testing because every property assumes truth of the property i.e. if I say, “I am awake” it is the same as “it is true that I am awake” which means they are also a question of truth claims because it’s inherent. It also means their ROB warrants aren’t mutually exclusive with mine. [C] Inclusion: a) other ROBs open the door for personal lives of debaters to factor into decisions and compare who is more oppressed which causes violence in a space where some people go to escape. b) Anything can function under truth testing insofar as it proves the resolution either true or false. Specific role of the ballots exclude all offense besides those that follow from their framework which shuts out people without the technical skill or resources to prep for it.**

**Extensions**

**Extend my ROB**

* **Vote for the debater who best proves the truth or falsity of the Resolution**
* **Constitutivism; the ballot asks you to vote aff or neg**
  + **Negate means to deny truth**
  + **Affirm means to provoke truth**
  + **Resolutional focus outweighs on education on specificity**
  + **And it outweighs on fairness, resolution is the rules, anything else is outside of them**
* **Logic; Any counter rob collapses**
  + **Every property assumes truth of property, I am awake is the same as it is true that I am awake**
  + **This means their Rob warrants aren’t mutually exclusive with mine**
* **Inclusion; other rob factor in person lifes**
  + **This causes violence, who is more oppressed?**
  + **Debate is a place to escape**
  + **Other rob collapses because they still prove the resolution true or false,**
  + **Specific rob moot all offense, killing fairness**

**paradigm**

**Reject 1ar theory on face – [A] 1ar theory time skews the rest of the round since they have the 1ar and 2ar, which is 7 minutes compared to my 2nr, which is 6 minutes. This gives them a whole minute advantage on the theory debate, that’s a lot in such a time crunched event and outweighs their strat args since I need time to execute strat and get ground. [B] I lose the flex of being able to indict practices of the aff without going new in the 2nr, which gives them the ability to effectively weigh on the theory debate. Also outweighs on spikes because you have the ability to weigh an entirely conceded theory spike while I have to weigh my theory interp against all possible interps of the aff. [C] 1ar theory is a no risk issue because the aff can go hard for no rvi in the 2ar, which skews my strat because either I either lose on substance or theory, screws the 2nr because I can’t respond to the initial spike, only the violation. [D] I only have once chance to respond after it is introduced while they have two chances [E] they get to speak before and after me which means they get to frame the debate and end the debate, which is abusive in the 2n I have to go for a counterinterp and respond to their shell while they can choose either in the 2ar. [F] Even if you win that you should have 1ar theory, it shouldn’t be drop the debater because of those reasons.**

**Extensions**

**Extend my paradigm**

* **Reject 1ar theory**
  + **Time skews round; they have two speeches and 7 minutes, I have one speech and 6 minutes**
  + **I lose flex to weigh theory against spikes and interps**
  + **1ar theory is no risk for aff, they can go for no rvi in 2ar**
  + **I only have one chance to respond; they have two**
  + **They get to speak before and after me, they can frame and end debate**
  + **Even if you win 1ar theory, you lose dtd cus of these reasons**

**A/T**

**Weak protections lead 2 trade secrets**

**1] With weaker IP protections, pharmaceutical companies will resort to trade secrets over patents---that undermines the public scientific collaboration that informs global public health response.**

Gewertz, Nevin. "Intellectual Property And The Pharmaceutical Industry: A Moral Crossroads Between Health And Propert." Journal of Business Ethics 55:3. December, 2004. Web. August 18, 2021. <https://www.jstor.org/stable/25123392?seq=1#metadata\_info\_tab\_contents>.

The granting of a United States patent establishes a form of monopoly rights to specific creative works. The granting of exclusive monopoly rights prevents others from enjoying any positive externalities de rived from the idea itself. Yet, does the right to intellectual property include the right to exclude and limit the actions of others? A simple utilitarian analysis of the potential consequences of non exclusive intellectual property elucidates the need for patent rights to incorporate exclusive monopoly rights. **Without exclusive monopoly rights granted to their products, pharma**ceutical **companies would be forced to keep product information a secret**. **The usage of public forums for intellectual dialogue such as academic journals and conferences would give way to trade secrets** (Mansfield, 1993). **This type of secretive behavior would have nefarious effects both the scientific community and the collaborative principles upon which it thrives**. The exclusive monopoly rights rewarded by the state in the form of a patent are necessary to promote intellectual dialogue and to avoid the usage of trade secrets.

**A/T Counterfeits**

**Unpatented medicine cause counterfeits—**

**Lynbecker 16** [(Kristina M. L. Acri née, an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker’s research analyzes the difficulties of strengthening intellectual property rights protection in developing countries, specifically special problems facing the pharmaceutical industry.) “Counterfeit Medicines and the Role of IP in Patient Safety,” IPWatchDog, 7/27/16. <https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/>] RR

**The threat of counterfeit goods took center stage** on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). **Focusing on trade opportunities and challenges for American businesses in the digital age,** Senator Hatch stated: “The Organization for Economic Co-Operation and Development (**OECD) recently released a study that shows that counterfeit products accounted for up to 2.5 percent of world trade,** or $461 billion, in 2013. This is a dramatic increase from a 2008 estimate that showed that **fake products accounted for less than half that amount.** **Counterfeits are a worldwide problem**, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1] As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that **global policymakers** **may be working against each other when it** **comes to battling counterfeit drugs**, **especially in the context of intellectual property rights**. While the Senate Hearing and the OECD report highlight **the importance of strong IP protection in combating the growing threat of counterfeit goods**, **their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals**. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines. **While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation,** **they also serve to inhibit counterfeiting**. The World Health Organization has determined that **counterfeiting is facilitated where “there is weak drug regulatory control and enforcemen**t; **there is** a scarcity and/or erratic supply of basic medicines; there are extended, **relatively unregulated markets and distribution chains**, both in developing and developed country systems; **price differentials create an incentive for drug diversion** within and between established channels; **there is lack of effective intellectual property protection**; due regard is not paid to quality assurance”.[3] [Kristina] According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that **more than one million people die each year from counterfeit drugs**.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated **700,000 deaths from malaria and tuberculosis are attributable to fake drugs.** [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] Given the devastating impact of counterfeit medicines on patients and **the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access.** **Without the assurance of quality medicines**, **access is meaningless**. Moreover, **while falsely presenting intellectual property rights as the primary obstacle to global health care**, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need: inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives.

**AT Generic Drug Manufacturers Solve**

**Generic medicine is dangerous—contamination and unsanitary manufacturing conditions.**

**White 19** [(C. Micheal, Professor and Head of the Department of Pharmacy Practice, University of Connecticut) “Why your generic drugs may not be safe and the FDA may be too lax” The Conversation, 12/4/19. <https://theconversation.com/why-your-generic-drugs-may-not-be-safe-and-the-fda-may-be-too-lax-125529>] RR

This leads to a vital question: **Are generics safe? If drug manufacturers followed the FDA’s strict regulations, the answer would be a resounding yes**. Unfortunately for those who turn to generics to save money, **the FDA relies heavily on the honor system** **with foreign manufacturers**, **and U.S. consumers get burned**. **Eighty percent of the active ingredients** **and 40% of the finished generic drugs used in the U.S. are** **manufactured overseas**. As a pharmacist, I know that the safety of prescription medications is vital. My research, recently published in the “Annals of Pharmacotherapy,” raises alarming concerns about our vulnerabilities. Do experts have something to add to public debate? Where are your drugs being made? A pharmacist at a drug plant outside Mumbai in 2012, shortly after a change in patent law allowed production of a generic cancer drug. Rafiq Mugbool/AP Photo **Generic drug manufacturers either make bulk powders** **with the active ingredient in them** **or buy those active ingredients from other companies** **and turn them into pills,** ointments or injectable products. In 2010, **64% of foreign manufacturing plants**, predominantly in India and China, **had never been inspected by the FDA**. By 2015, 33% remained uninspected. In addition, **companies in other countries are informed before an inspection**, **giving them time to clean up a mess.** Domestic inspections are unannounced. Faking results The FDA informs manufacturing plants in other countries when it plans to inspect their plants. Andrew Harnik/AP Photo As I detail in my paper, when announced foreign FDA inspections began to occur in earnest between 2010 and 2015, numerous manufacturing plants were subsequently barred from shipping drugs to the U.S. after the inspections uncovered shady activities or serious quality defects. **Unscrupulous foreign producers shredded documents** shortly **before FDA visits**, hid documents offsite**, altered** or manipulated **safety** or quality **data** or **utilized unsanitary manufacturing conditions**. Ranbaxy Corporation pleaded guilty in 2013 to shipping substandard drugs to the U.S. **and making intentionally false statements**. The company had to withdraw 73 million pills from circulation, and the company paid a $500 million fine. **These quality and safety issues can be deadly**. In 2008, **100 patients in the U.S. died after receiving generic heparin products** from foreign manufacturers. Heparin is an anticoagulant used to prevent or treat blood clots in about 10 million hospitalized patients a year and is extracted from pig intestines. Some of the heparin was fraudulently replaced with chondroitin, a dietary supplement for joint aches, that had sulphur groups added to the molecule to make it look like heparin. One of the **heparin manufacturers** inspected by the FDA **received a warning letter after it was found to have used raw material from uncertified farm**s, used storage equipment with unidentified material adhering to it and had insufficient testing for impurities. **These issues continue to this day**. **Dozens of blood-pressure and anti-ulcer drugs were recalled in 2018 and 2019 due to contamination with the potentially carcinogenic compounds** N-nitrosodimethylamine or N-nitrosodiethylamine. One of the major producers of these active ingredient powders used by multiple generic manufacturers was inspected in 2017. The FDA found that the company fraudulently omitted failing test results and replaced them with passing scores. This raises a critical question: **How many more violations would occur with inspections occurring as frequently as they do in the U.S., and more importantly, if they were unannounced?** Relatively speaking, the number of drugs proved to be tainted or substandard has been small, and the FDA has made some progress since 2010. But **the potential for harm is still great.**

**AT Evergreening Aff**

**First, “incremental” innovations are a key aspect of R&D, Jones 6**

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

As already mentioned, **the costs and time necessary to bring a drug to the market are considerable**. While the initial patents covering the basic chemical or protein entity are important to encourage the further investment to bring the drug to the market, **the length of time afforded protection** by such patents ‐ due to the considerable amount of time necessary to develop a suitable formulation and presentation of the drug, and the time to conduct clinical trials ‐ **usually does not provide sufficient protection to balance the overall financial investment.** Further, **many inventions** made during the develop‐ ment of the drug formulation or presentation, while possibly **viewed as ’incremental inventions’ by some, are actually critical to bringing the drug to the market**. Indeed, as a proportion of all patents granted worldwide, very few relate to what may be termed “breakthroughs”. **The vast majority cover innovations which build on inventions of others, with the benefit of full disclosure of those inventions in patent specifications**. That is what the patent system was designed to encourage. **By its very nature**, there‐ fore**, it encourages inventors to adapt and modify the developments** patented by others **incrementally** or in any other way. It would therefore, in ICC’s view, be wholly in‐ appropriate not to allow patents for such forms of innovation; and any such change would adversely affect the ability to finance future drug research. **The innovation process in the pharmaceutical sector, as for all other scientific sectors, is one of evolution**. The criteria for patentability are clear. Patents are available for any invention, whether product or process, in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. **If an invention meets these criteria, it is entitled to patent protection. If it does not, it is not patentable. Of these criteria, the most relevant here is inventive step**. The invention must not have been obvious to a person skilled in the relevant art at the time the application for a patent was first filed, taking into account the state of the art at that time. There is no common understand‐ 192 7 Negative Evidence ing around the world on how this criterion should be applied and TRIPS provides no guidance. The precise manner in which it is applied differs from country to country. It even differs over time within the same country. Significant progress has, however, been made in harmonizing the standard, particularly in the US, Japan and Europe. This harmonized standard should, in ICC’s view, in time become the “gold standard” for patents globally. In the meantime, it may be necessary and appropriate, to encourage investment in local research and manufacturing, for developing countries to adopt a lower threshold to provide easy access to patents for local entrepreneurs. But in ICC’s view, it cannot be right to require such countries to adopt a higher standard of inventive step. In any event, neither the inventive step requirement, nor the other basic criteria, make any distinction between different types of innovation œ for example between “in‐ cremental” and “discrete”, or between “me too” and “breakthrough” innovations. As with any innovation, all of these have to be judged against the same basic rules, and that, in ICC’s view, is entirely appropriate. To the extent that genuine concerns about patent quality exist, they relate to the whole range of patents**. They are not specific to patents for healthcare products, nor to patents for so‐called incremental innovations. If such inventions fail to meet the fundamental criteria set out above, patents should not be granted for them; and where patents have wrongly been granted, courts should (and have) corrected those errors** œ all as part of the international efforts referred to above to ensure that an appropriate balance is achieved between all entities affected by patents. **However, the fact that there have been some examples of patent‐granting authorities ap‐ plying the criteria incorrectly does not justify fundamental change to those underlying principles.**

**Second, evergreening only proves flaws in the application process, not the legitimacy of patents themselves, Jones 6**

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

**In the context of pharmaceuticals, it has been suggested** that **patent protection should not be given to inventions comprising different salts, esters or other derivatives of known drugs,** different dosage forms or means of administration of existing products, combinations of known products (including fixed dose combinations), nor “mere” new uses of known compounds, (all of which might qualify for the misnomer “incrementally modified drugs”); nor for modifications to medical devices (such as a single‐, rather than multiple‐dose, syringe). **These suggestions are, in ICC’s view, misconceived. As stated above, if any such inventions do not satisfy the basic patentability criteria, patents should not be granted for them**; and if patents are found wrongly to have been granted, courts and patents offices should correct those errors, just as they should for patents in any field and for any category of innovation. This approach should address, and is addressing, concerns about illegitimate extension of patent term, or “evergreening”. **There is no need for separate, or new, legislation to deal with this issue. Further, the suggestion that such inventions do not benefit society is wrong. These types of so‐called “incremental” innovation generally result in better health outcomes2, for example by increasing efficacy, reducing side effects and/or making administration easier, resulting in improved compliance and greater effectiveness**

**AT WTO Credibility**

**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**

**AT Innovation Aff**

**Uniqueness**

**Innovation is back up – COVID and empirics prove – The Economist 20**

“Drug Innovation Is Back in Fashion.” The Economist, The Economist Newspaper, 23 May 2020, [www.economist.com/leaders/2020/05/23/drug-innovation-is-back-in-fashion](http://www.economist.com/leaders/2020/05/23/drug-innovation-is-back-in-fashion). // LHP

The **pandemic has reminded** the **world of the industry’s** strengths—its **capacity to innovate** and provide drugs on a vast scale. Many of the **big firms**, such as Johnson & Johnson and Sanofi, are **working on covid-**19 **vaccines and therapies**. **Scores of smaller companies are at work**, too. On May 18th **Moderna**, an American biotech firm, said that its much-anticipated vaccine has shown positive early results (although some analysts questioned the validity of its tests). **AstraZeneca**, a big British firm that invests heavily in research and development (r&d), is working on a vaccine with scientists at Oxford University, helped by $1bn of new funding from America’s government. **Even before the virus, the industry had started to invest more heavily**. In the **most recent quarter America’s 30 biggest firms boosted their r&d by a median of 6% year on year**. Now **medical innovation is back in fashion.**

**Link Turns**

**A/T Covid aff**

**Uniqueness/Solvency**

**[1] The Plan can’t solve COVID - Lack of key supplies  – conceded in cx that they don’t have the resources**

**Tepper 21** James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

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

**[2] The affirmative can’t solve the root cause of the problems developing nations face – WTO News Briefing 20**

WTO News Briefing; ; 10‐16‐2020; ”Members discuss intellectual property response to the COVID‐19 pandemic”; https://www.wto.org/english/news\_e/news20\_e/trip\_20 oct20\_e.htm, World Trade Organization News, accessed 7‐21‐2021; JPark

While a number of developing and least developed country members welcomed the proposal as a contribution to the discussion, many were still studying it in their capitals and asked for clarification on certain points, particularly regarding its practical imple‐ mentation and the possible economic and legal impact of the waiver at national level. **A number of developing and developed country members opposed the waiver proposal, noting that there is no indication that intellectual property rights (IPRs) have been a gen‐ uine barrier to accessing COVID‐19 related medicines and technologies. While acknowl‐ edging that the sustained and continued supply of such medicines and technologies is a difficult task, they observed that non‐efficient and underfunded health care and pro‐ curement systems, spiking demand and lack of manufacturing capacity are much more likely to impede access to these material**s. In the view of these members, solutions can be legitimately sought within the existing IP system as the TRIPS Agreement provides enough tools and sufficient policy space for members to take measures to protect public health. **The suspension of IPRs, even for a limited period of time, was not only unnec‐ essary but it would also undermine the collaborative efforts to fight the pandemic that are already under way.**

**[3] Investing in manufacturing and distribution is a better anti‐COVID strategy than breaking patents – Rogin 21**

Josh Rogin (political analyst for CNN; foreign policy columnist at the Washington Post; B.A. in international affairs from the George Washington University’s Elliott School of International Affairs). “The wrong way to fight vaccine nationalism.” Wash‐ ington Post. 8 April 2021. JDN. https://www.washingtonpost.com/opinions/global‐ opinions/the‐wrong‐way‐to‐fight‐vaccine‐nationalism/2021/04/08/9a65e15e‐98a8‐11eb‐ 962b‐78c1d8228819\_story.html

**A preferable approach would be to build more vaccine‐manufacturing capacity in the United States and then give those vaccines to countries in need**, said Cohen. The U.S. pharmaceutical industry would surely benefit, but that’s preferable to being dependent on other countries when the next pandemic hits.  “**If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally**,” Cohen said.  What’s more, **it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place**. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licens‐ ing agreements are already successfully facilitating cooperation between patent‐holding vaccine‐makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world.  **Vaccine equity is a real problem but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. That means helping the world and thinking about our strategic interests at the same time.**

**Link Turns**

**[1] Turn- Waiving patents can’t resolve drug access issues but instead create a more dangerous scenario for developing countries – Garde 21**

Damian Garde (national biotech reporter for STAT), Helen Branswell (senior writer at STAT covering infectious diseases and global health; former CDC Knight Fellow and Nieman Global Health Fellow at Harvard; recipient of the 2020 George Polk Award for coverage of the Covid pandemic), and Matthew Herper (senior writer at STAT covering medicine). “Waiver of patent rights on Covid‐19 vaccines, in near term, may be more symbolic than substantive.” Stat News. 6 May 2021. JDN. https://www.statnews.com/2021/05/06/waiver‐of‐patent‐rights‐on‐covid‐19‐vaccines‐ in‐near‐term‐may‐be‐more‐symbolic‐than‐substantive/

In October, **Moderna vowed not to enforce its Covid‐19‐related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines**. “There are currently no generic vaccines primarily because there are hundreds of pro‐ cess steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, **but the transfer of skills is not that simple,” said Norman Baylor,** who formerly **headed the F**ood and **D**rug **A**dministration**’s Office of Vaccines Research and Review**, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — **using messenger RNA technology** — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. **There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instanc**e, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in‐demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry‐wide ... looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly **all of the peo‐ ple who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing**.”  As Michelle McMurry‐Heath, CEO of the trade group BIO, put it in a statement, “**hand‐ ing needy countries a recipe book without the ingredients, safeguards, and sizable work‐ force needed will not help people waiting for the vaccine.”**

**A vaccine waiver greenlights counterfeit medicine – independently turns Case.**

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

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

**The** [**World Health Organization(link is external)**](http://www.who.int/about/definition/en/print.html) **defines the right to health as “a complete state of physical, mental and social well-being, and not merely the absence of disease or infirmity.” States should ensure both freedoms and entitlements**. The former include the right to control one’s health and body, including sexual and reproductive freedom, and the freedom from interference such as torture, non-consensual medical treatment and experimentation. Entitlements include access to adequate health care facilities and services, as well as appropriate State measures in relation to the socio-economic determinants of health, such as food, water and sanitation, safe and health working conditions, housing, and poverty. The right to health is closely interconnected with numerous other human rights, including the rights to food, water, housing, work, education, life, non-discrimination, privacy, access to information, the prohibition against torture, among others. In its [General Comment 14(link is external)](http://tbinternet.ohchr.org/_layouts/treatybodyexternal/Download.aspx?symbolno=E%2fC.12%2f2000%2f4&Lang=en), the UN [Committee on Economic, Social, and Cultural Rights(link is external)](http://www.ohchr.org/en/hrbodies/cescr/pages/cescrindex.aspx) (CESCR) provided detailed guidance to States regarding their obligations to respect, protect and fulfil the right to health. The Committee also noted that the right includes the following interrelated and essential features: **Availability. States should ensure the provision of enough functioning public health and individual health care facilities throughout their territory, as well as safe water and sanitation facilities, trained and fairly-paid medical professionals, and essential medicines. Accessibility. Access to health involves four key elements: non-discrimination, physical accessibility, economic accessibility, and information accessibility. Health facilities and services should be accessible to everyone, especially the most vulnerable, without discrimination on any prohibited ground. The facilities and services, as well as underlying determinants of health such as water and sanitation amenities, must be within safe physical reach. Health care facilities, goods and services must be affordable for all, with any payment based on the principle of equity so that poorer households are not disproportionately burdened with health-related expenses. States must ensure that every person has the right to seek, receive and impart information on health, in balance with the confidentiality of medical information. Acceptability. Health facilities should be respectful of medical ethics and the culture of individuals and communities, as well as attentive to gender and life-cycle requirements. Quality. Health facilities should be scientifically and medically appropriate and of good quality. Among other things, this requires the provision of necessary medicines and equipment, skilled medical professionals, and adequate water and sanitation.**

**Right to Health CP**

**CP Text – Member nations of the world trade organization ought to participate in infrastructure building strategies in LDCs.**

**This solves access. Current IP provisions are not the issue, rather the lack of infrastructure. Pharmaceutical funded government programs provide the means to do this. Cutting profits indirectly prevents corporations from attaining the funds to do this. Alton**

Alton, Gregg. “The Global Challenge of Access to Medicines.” STAT, www.statnews.com/sponsor/2017/02/17/global-challenge-access-medicines-2/.

In developing countries, **generic licensing** — where patent holders grant licenses that allow another drug company to manufacture a generic version of their drug — **has helped transform treatment access, providing high-quality, low-cost drugs to resource-poor countries and communities.** **Of the 15 million people living with HIV in developing countries receiving treatment today, 10 million receive therapies developed by Gilead;** the vast majority of these are in generic form, supplied as a result of Gilead’s licensing agreements. The company’s breakthrough hepatitis C medicines, first approved just three years ago, are already available generically in many developing countries too. The [2016 Access to Medicine Index](http://accesstomedicineindex.org/) recently recognized Gilead’s approach to patents and licensing as the best in the industry. **Yet generic licensing is only one part of the solution to a highly complex challenge**. Tiered or differential pricing is used regularly in the pharmaceutical industry. The idea is simple enough: setting prices for countries according to their economic situation, as determined by their varying level of national income. However, **Gilead looks not only at the purchasing power, but also considers other factors such as disease burden, treatment needs, and health-care infrastructure to help shape the company’s thinking. Some of the prices Gilead has set result in little or no profit to the company. For example, the company’s HIV medicines are available at not-for-profit pricing in 124 developing countries, and Gilead offers its hepatitis C medicines at a flat price to governments in 105 countries.** This gives countries the ability to plan programmatically and financially, to encourage treatment scale-up. Even though the approaches just described may address the cost of medicines, multiple additional factors are barriers to access. **In many middle- and low-income countries, health systems have suffered from decades of under-investment, a high proportion of people having to pay for health-care out of their own pocket, leaving the most vulnerable populations unable to access life-saving treatments even when those medicines are available at low cost**. In fact, figures from the World Health Organization show that in 47 low-income countries, out-of-pocket payments represent more than half of total health expenditures. **Some countries also do not have enough trained health workers, or lack robust regulatory systems to quickly approve and regulate the use of new drugs**. That’s why companies like Gilead must work with governments, non-profit organizations, and communities to build the programs, capacity, and expertise needed to overcome the complex barriers to access. A **comprehensive access approach must embrace a diverse range of strategies: pilot projects to validate innovative delivery models; dedicated and transparent drug registration policies; training for nurses, doctors, and community health workers; supply chain management; and partnerships to reach vulnerable populations most in need or at risk, are all needed. For example, Gilead supports the U.S. government’s DREAMS (Determined, Resilient, Empowered, AIDS-free, Mentored, and Safe women) initiative to give adolescent girls and young women in Africa access to medication to reduce their risk of HIV infection.** No one who works in this field is naïve about the scope of the challenge — after all, despite enormous progress 20 million people living with HIV still don’t receive life-saving medicines. Access to medicine is not an exact science, and while there is no single or simple answer to the global access question, progress is possible. Innovator pharmaceutical companies, ministries of health and finance, health-care professionals, non-profits, generic manufacturers, researchers, and community organizations all have important roles to play. **With greater collaboration and a focus on the real-world barriers that prevent people from receiving care, the full potential of biomedical innovation can be unlocked for all those in need.**

# AT Aff

## AT Covid 19 Aff

### Uniqueness/Solvency

#### [1] The Plan can’t solve COVID - Lack of key supplies  – conceded in cx that they don’t have the resources

**Tepper 21** James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

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

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WTO News Briefing; ; 10‐16‐2020; ”Members discuss intellectual property response to the COVID‐19 pandemic”; https://www.wto.org/english/news\_e/news20\_e/trip\_20 oct20\_e.htm, World Trade Organization News, accessed 7‐21‐2021; JPark

While a number of developing and least developed country members welcomed the proposal as a contribution to the discussion, many were still studying it in their capitals and asked for clarification on certain points, particularly regarding its practical imple‐ mentation and the possible economic and legal impact of the waiver at national level. **A number of developing and developed country members opposed the waiver proposal, noting that there is no indication that intellectual property rights (IPRs) have been a gen‐ uine barrier to accessing COVID‐19 related medicines and technologies. While acknowl‐ edging that the sustained and continued supply of such medicines and technologies is a difficult task, they observed that non‐efficient and underfunded health care and pro‐ curement systems, spiking demand and lack of manufacturing capacity are much more likely to impede access to these material**s. In the view of these members, solutions can be legitimately sought within the existing IP system as the TRIPS Agreement provides enough tools and sufficient policy space for members to take measures to protect public health. **The suspension of IPRs, even for a limited period of time, was not only unnec‐ essary but it would also undermine the collaborative efforts to fight the pandemic that are already under way.**

#### [3] Investing in manufacturing and distribution is a better anti‐COVID strategy than breaking patents – Rogin 21

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**A preferable approach would be to build more vaccine‐manufacturing capacity in the United States and then give those vaccines to countries in need**, said Cohen. The U.S. pharmaceutical industry would surely benefit, but that’s preferable to being dependent on other countries when the next pandemic hits.  “**If there’s anything that the pandemic has taught us, it’s that we need to have a robust supply chain, for ourselves and for the world generally**,” Cohen said.  What’s more, **it’s not clear that waiving the TRIPS agreement for the pandemic would work in the first place**. Bill Gates and others involved in the current vaccine distribution scheme have argued that it would not result in more vaccines, pointing out that licens‐ ing agreements are already successfully facilitating cooperation between patent‐holding vaccine‐makers and foreign manufacturers. Critics respond that such cooperation is still failing to meet the urgent needs in the developing world.  **Vaccine equity is a real problem but waiving intellectual property rights is not the solution. If the current system is not getting shots into the arms of people in poor countries, we must fix that for their sake and ours. But the pandemic and our responses to it have geopolitical implications, whether we like it or not. That means helping the world and thinking about our strategic interests at the same time.**

#### [4] Hesitancy high worldwide – means no solvency

Andrea **Taylor, 2/6** [Andrea Taylor, (Andrea leads a portfolio of global innovation programs focused on evaluation, scaling, and adaptation of healthcare innovations to address critical access and quality challenges. Her work with the Duke Global Health Innovation Center and Innovations in Healthcare drive evidence-based recommendations for scaling transformative models of care, adapting models into new contexts, and facilitating system change. She is the research lead for the Launch and Scale project’s COVID-19 workstream, analyzing global data on vaccines, partnerships, and therapeutics to combat the pandemic. She led design and research for the USAID-funded Social Entrepreneurship Accelerator at Duke (SEAD) and the development of several publications for the recent evaluation of the Saving Lives at Birth program, with USAID and GCC.)]. "VACCINE HESITANCY WILL SOON BECOME THE PRIMARY OBSTACLE TO GLOBAL IMMUNITY – Global Health Innovation Center." 2-16-2021, Accessed 8-5-2021. https://dukeghic.org/2021/02/16/vaccine-hesitancy-will-soon-become-the-primary-obstacle-to-global-immunity/ // duongie

Vaccine hesitancy will soon become the primary obstacle to global immunity Global manufacturing capacity has been the primary rate limiter for Covid-19 vaccinations. Our vaccine manufacturing infrastructure was not designed to produce enough doses to cover 70% of the world’s population within a year (in addition to regular and routine vaccines) and, as expected, demand is outstripping supply. There has been good news on the manufacturing front, however, with several large pharma companies recently joining with rivals to ramp up production. At the same time, data on vaccine hesitancy suggest that it may soon overtake manufacturing capacity as the primary obstacle to global coverage and reaching herd immunity. If this is the case, we will soon find that producing enough vaccines does not translate to enough vaccinations. Covid-19 vaccine hesitancy is growing around the world. A survey of 15 countries found that willingness to get a Covid-19 vaccine dropped in nearly all of the countries between October and December 2020. France and Russia had the lowest rates of vaccine intent in the survey, below 50%. Another survey of 32 countries found that fewer than half of the population in Lebanon, France, Croatia, and Serbia intend to get vaccinated. In Peru, vaccine hesitancy grew by 26 percentage points (from 22% to 48%) between August and December and the population is now evenly split between those willing and those not willing to receive the vaccine. Other data indicate some countries fall much lower: in the Philippines, fewer than a third are willing to have a Covid-19 vaccine. Even in China, a country with historically high rates of vaccine take-up, intent to get a Covid-19 vaccine dropped in late 2020 (though at 80% China was still at the top of the chart). Negative coverage of western-developed vaccines in Chinese state media appears to be fueling mistrust of even Chinese-developed Covid-19 vaccines and slowing vaccination rates. In both the US and UK, recent studies found that hesitancy rates are highest among younger adults, racial minorities, and people with lower education and income. A similar trend was noted this week in Israel, where vaccine take-up has slowed and is particularly low among minority communities and younger populations. There was improvement in vaccine intent among Black and LatinX populations in the US between December and January; however, these groups are still most likely to say that they will “wait and see” rather than get the vaccine as soon as possible. Experts suggest that supply may outstrip demand in the US as early as April. Public health leaders in countries around the world have pulled every lever they can to secure vaccine doses to protect their populations. Each dose is the result of unprecedented scientific and industry cooperation, complex negotiations, and a flat-out global effort. But the race to develop, manufacture, and distribute vaccines must result in vaccinations. We need to get ahead of vaccine hesitancy now, with strong outreach campaigns, before it becomes the rate limiter.

### Link Turns

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Damian Garde (national biotech reporter for STAT), Helen Branswell (senior writer at STAT covering infectious diseases and global health; former CDC Knight Fellow and Nieman Global Health Fellow at Harvard; recipient of the 2020 George Polk Award for coverage of the Covid pandemic), and Matthew Herper (senior writer at STAT covering medicine). “Waiver of patent rights on Covid‐19 vaccines, in near term, may be more symbolic than substantive.” Stat News. 6 May 2021. JDN. https://www.statnews.com/2021/05/06/waiver‐of‐patent‐rights‐on‐covid‐19‐vaccines‐ in‐near‐term‐may‐be‐more‐symbolic‐than‐substantive/

In October, **Moderna vowed not to enforce its Covid‐19‐related patents for the duration of the pandemic, opening the door for manufacturers that might want to copy its vaccine. But to date, it’s unclear whether anyone has, despite the vaccine’s demonstrated efficacy and the worldwide demand for doses. That underscores the drug industry’s case that patents are just one facet of the complex process of producing vaccines**. “There are currently no generic vaccines primarily because there are hundreds of pro‐ cess steps involved in the manufacturing of vaccines, and thousands of check points for testing to assure the quality and consistency of manufacturing. One may transfer the IP, **but the transfer of skills is not that simple,” said Norman Baylor,** who formerly **headed the F**ood and **D**rug **A**dministration**’s Office of Vaccines Research and Review**, and who is now president of Biologics Consulting. While there are factories around the world that can reliably produce generic Lipitor, vaccines like the ones from Pfizer and Moderna — **using messenger RNA technology** — require skilled expertise that even existing manufacturers are having trouble sourcing. “In such a setting, imagining that someone will have staff who can create a new site or refurbish or reconfigure an existing site to make mRNA [vaccine] is highly, highly unlikely,” Yadav said. **There are already huge constraints on some of the raw materials and equipment used to make vaccines. Pfizer, for instanc**e, had to appeal to the Biden administration to use the Defense Production Act to help it cut the line for in‐demand materials necessary for manufacturing. Rajeev Venkayya, head of Takeda Vaccines — which is not producing its own Covid vaccine but is helping to make vaccine for Novavax — said supply shortages are impacting not just Covid vaccine production but the manufacture of other vaccines and biological products as well. “This is an industry‐wide ... looming crisis that will not at all be solved by more tech transfers,” Venkayya said. He suggested many of the people advocating for this move are viewing the issue through the prism of drug development, where lifting intellectual property restrictions can lead to an influx of successful generic manufacturing. “I think in this area there is an unrecognized gap in understanding of the complexities of vaccine manufacturing by many of the ‘experts’ that are discussing it,” said Venkayya, who stressed that while he believes they have good intentions, “nearly **all of the peo‐ ple who are providing views on the value of removing patent protections have zero experience in vaccine development and manufacturing**.”  As Michelle McMurry‐Heath, CEO of the trade group BIO, put it in a statement, “**hand‐ ing needy countries a recipe book without the ingredients, safeguards, and sizable work‐ force needed will not help people waiting for the vaccine.”**

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

#### 3] Lack of access is not a result of IP – rather IP is key to ensure high quality vaccines that pass regulatory hurdles, which means the plan actually reduces access

**Stevens**, Philip, **and** Mark **Schultz 1/14**. “Why Intellectual Property Rights Matter for COVID-19 - Geneva Network - Intellectual Property Rights and Covid-19.” Geneva Network, 14 Jan. 2021, geneva-network.com/research/why-intellectual-property-rights-matter-for-covid-19/. Philip Stevens in the Founder and Executive Director of Geneva Network. He is also a Senior Fellow at the Institute for Democracy and Economic Affairs, Malaysia.; Professor Mark F. Schultz is the Goodyear Tire & Rubber Company Endowed Chair in Intellectual Property Law, the Director of the Intellectual Property and Technology Law Program at the University of Akron School of Law. He was a professor at Southern Illinois University School of Law for 16 years and was co-founder and a leader of the Center for Protection of Intellectual Property (CPIP) at George Mason University in Washington, D.C., where he remains a non-resident Senior Scholar. He also serves as a Senior Fellow of the Geneva Network. //sid

IP has underpinned the research and development that has led to the arrival of several game-changing vaccines. But the challenge does not end there. Perhaps the biggest hurdle is manufacturing billions of doses or new antibody treatments while maintaining the highest quality standards.

There’s more to it than starting a global manufacturing free for all by overriding or ignoring patents. A spokesperson for Regeneron, a manufacturer of a novel COVID-19 antibody treatment explained to [The Lancet](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext): “Manufacturing antibody medicines is incredibly complex and transferring the technology takes many months, as well as significant resources and skill. Unfortunately, it is not as simple as putting a recipe on the internet and committing to not sue other companies during the pandemic”.

[John-Arne Røttingen](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext), chair of the WHO COVID-19 Solidarity trial, explains that technology transfer will be crucial to scaling up production, but voluntary mechanisms are better: “If you want to establish a biological production line, you need a lot of additional information, expertise, processes, and biological samples, cell lines, or bacteria” to be able to document to regulatory agencies that you have an identical product, he explains.

#### 4] Can’t make enough vaccines vital components are too scarce

**Tepper 4-10** James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

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

#### 5] The plan only hurts manufacturing moving bottlenecks to less efficient manufacturers

Alex **Knapp, 5/7** [Alex Knapp, (senior editor at Forbes covering healthcare, science, and cutting edge technology.)]. "Patent Waivers Won’t Impact Big Pharma’s Bottom Line—But Could Slow Covid Vaccine Rollouts." Forbes, 5-7-2021, Accessed 8-5-2021. https://www.forbes.com/sites/alexknapp/2021/05/07/patent-waivers-wont-impact-big-pharmas-bottom-line-but-could-slow-covid-vaccine-rollouts/?sh=78866f727862 // duongie

On Wednesday, the Biden Administration stated that it would support a proposal to temporarily waive protection of intellectual property (IP) rights for Covid vaccines during the pandemic, in a bid to boost production and accelerate vaccine distribution throughout the world. Industry trade groups immediately criticized the move, and investors reacted simultaneously—share prices plummeted, though they’ve been slowly recovering Thursday and Friday. Wall Street analysts at Morgan Stanley, Jefferies and Brookline Capital Markets, however, said in reports this week that waiving vaccine IP was unlikely to impact the financials of major vaccine makers, noting that current bottlenecks in vaccine production are related to supply chain, technical knowledge and difficulty in scaling up production. However, they caution that for the same reason, waivers could slow down current production by disrupting the market for raw materials. “Manufacturing supplies, raw materials, vials, stoppers and other key materials are in limited supply for 2021, and certainly for the 2021 calendar year,” wrote analysts from Jeffries, meaning that waivers can’t solve immediate vaccination needs in India and South Africa, where Covid-19 cases are surging. That report also notes that the mRNA vaccines from Pfizer and Moderna have yet to be authorized for use in India, as regulators desired local clinical trial data, which is another hurdle to overcome. Morgan Stanley commented that U.S. support alone doesn’t necessarily mean that a World Trade Organization agreement on the waiver would happen, especially since Germany has expressed opposition. The firm additionally notes that “manufacturing vaccines is a much more complicated process than making chemical drugs, and a patent waiver by itself would not enable other entities to manufacture their own copies of complex vaccines.” Jefferies analysts also remarked that another barrier to increased vaccine production is “ensuring the quality of the product, which is also not trivial.” Contractors for vaccine makers Pfizer, AstraZeneca and Johnson & Johnson have all run into quality-control issues that have led to millions of vaccine doses being discarded. On a company earnings call yesterday, Moderna CEO Stéphane Bancel said he doubted that waiving IP rights would impact his company much, because it would take months or even years for other companies to scale up manufacturing. Meanwhile, the biotech company has recently committed to expanding its own manufacturing capacity and expects to be able to make up to 3 billion doses of vaccine in 2022. Morgan Stanley analysts noted that in October 2020, Moderna “stated it would not enforce its patents during the pandemic, but to our knowledge, no one else has started manufacturing a vaccine that would violate Moderna’s patents.” The team at Brookline Capital markets noted that if a company did begin manufacturing vaccines based on Moderna’s patents, the upside would be an additional licensing revenue stream for the company. On Friday, vaccine manufacturer Novavax, which has reached an agreement with the private-public global health partnership Gavi to provide 1.1 billion vaccine doses to low income countries, stated its opposition to the WTO waiving patents, arguing that it “could further constrain resources by diverting them to entities incapable of manufacturing safe and effective vaccines in the near term.” Jeffries analysts note that a waiver wouldn’t put Novavax at immediate risk, as a key component of the company’s vaccine “is in limited supply and a majority of the raw material has already been locked up” by the company. That said, Morgan Stanley struck a similar point to Novavax about the risk involved in waiving patents. The analysts point out waivers could be counterproductive and actually slow down vaccine manufacturing. “An IP waiver now may exacerbate supply issues,” they write, “if some countries start to try to secure raw materials ahead of being able to produce a vaccine and cause shortages and disruptions in the supply chain.”

### Impact Turn

## AT Innovation Aff

### Uniqueness

#### [1] Innovation is back up – COVID and empirics prove – The Economist 20

“Drug Innovation Is Back in Fashion.” The Economist, The Economist Newspaper, 23 May 2020, [www.economist.com/leaders/2020/05/23/drug-innovation-is-back-in-fashion](http://www.economist.com/leaders/2020/05/23/drug-innovation-is-back-in-fashion). // LHP

The **pandemic has reminded** the **world of the industry’s** strengths—its **capacity to innovate** and provide drugs on a vast scale. Many of the **big firms**, such as Johnson & Johnson and Sanofi, are **working on covid-**19 **vaccines and therapies**. **Scores of smaller companies are at work**, too. On May 18th **Moderna**, an American biotech firm, said that its much-anticipated vaccine has shown positive early results (although some analysts questioned the validity of its tests). **AstraZeneca**, a big British firm that invests heavily in research and development (r&d), is working on a vaccine with scientists at Oxford University, helped by $1bn of new funding from America’s government. **Even before the virus, the industry had started to invest more heavily**. In the **most recent quarter America’s 30 biggest firms boosted their r&d by a median of 6% year on year**. Now **medical innovation is back in fashion.**

**[2] Pharma innovation is doing great now – answers all your warrants. 2020**

Lisa Jarvis, 1-17-2020, (Based in Chicago, Lisa has been covering the biotech and pharmaceutical industries at C&EN since 2006. She writes feature articles that weave together the business and science of developing drugs, while also serving as pharmaceuticals editor for the magazine. She has a particular interest in rare diseases, innovative models for drug discovery, and emerging technologies.) "The new drugs of 2019," Chemical &amp; Engineering News, <https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2019/98/i3> //Jay

Although pharmaceutical companies last year were unable to top the record-shattering [59 new drugs approved in the US in 2018](https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2018/97/i3), they were still on a roll. In 2019, the Food and Drug Administration green-lighted 48 medicines, a crop that includes myriad modalities and many new treatments for long-neglected diseases. Taken together, the **past 3 years of approvals represent drug companies’ most productive period in more than 2 decades.** Still, some analysts caution that the steady flow of new medicines could mask troubling indications about the health of the industry. The year brought several notable trends. The first was an uptick in the number of novel mechanisms on display in the new drugs. Roughly 42% of the medicines were first in class, meaning they had new mechanisms of action; this is a jump over the prior 4 years, when that portion ranged between 32 and 36%. Another trend was the influx of newer modalities. While small molecules continue to account for the lion’s share of **new molecular entities (NMEs), making up 67% of overall approvals in 2019,** the list also includes several antibody-drug conjugates, an antisense **oligonucleotide therapy, and a therapy based on RNA interference (RNAi**). Yet another encouraging trend was the influx of innovative therapies for underserved diseases. Standout approvals include two new drugs for sickle cell anemia (Global Blood Therapeutics’ Oxbryta and Novartis’s Adakveo), an antibiotic for treatment-resistant tuberculosis (Global Alliance for TB Drug Development’s pretomanid), and a therapy for women experiencing postpartum depression (Sage Therapeutics’ Zulresso). “The quality of the drugs over the last decade or so has steadily improved since the depths of the innovation crisis 10–12 years ago,” says Bernard Munos, a senior fellow at FasterCures, a drug research think tank. “We’re seeing stuff that frankly would have looked like science fiction back then.” Those futuristic new therapies include [Novartis’s Zolgensma](https://cen.acs.org/articles/97/i22/FDA-approves-second-gene-therapy.html), a gene therapy for spinal muscular atrophy; Alnylam Pharmaceuticals’ Givlaari, the company’s second marketed RNAi-based therapy; and several critical vaccines for infectious diseases, including Ebola, smallpox, and dengue fever. Not all those edgy therapies appear in C&EN’s list. We track approvals granted through the FDA’s main drug approval arm, the Center for Drug Evaluation and Research; drugs like vaccines and gene therapies are generally reviewed through the agency’s Center for Biologics Evaluation and Research. The new-approvals list also doesn’t include several therapies that made their way to patients for the first time, even though the FDA doesn’t consider them new drugs. For example, the agency gave its green light to Johnson & Johnson’s Spravato, making it the first new treatment option for people with major depressive disorder in more than 50 years. The drug is the S enantiomer of ketamine, an N-methyl-D-aspartate receptor antagonist that had been long approved as an anesthetic, gained notoriety as a club drug, and was used for years off label to treat severe depression ([see page 18](https://cen.acs.org/biological-chemistry/neuroscience/Ketamine-revolutionizing-antidepressant-research-still/98/i3)). Also notable in 2019 was a slight dip in the number of cancer drugs, which in recent years typically made up more than a quarter of all new medicines. Last year’s 11 cancer treatments accounted for roughly 23% of approvals.

### Link Turns

### Impact

#### [1] Only some new medications are truly innovative – nonuniques the DA impact – P4AD 21

“Big Pharma's Big Lie: The Truth About Innovation & Drug Prices.” *P4AD*, Patients For Affordable Drugs, Feb. 2021, patientsforaffordabledrugs.org/wp-content/uploads/2021/02/P4AD-Report-Innovation.V33.pdf. // LHP AB

[Only bipartisan national organization dedicated to research on and lowering of drug prices. Does not take money from big pharma.]

The drug industry talks a lot about how reforms to lower prices threaten cutting-edge breakthroughs, but in reality, **only a fraction of new medications are truly innovative. Since 1975, only 10 to 15 percent of drugs entering the market represented therapeutic advances**; instead, **drug companies prioritized the development of existing drugs with minor variations that lack clinical significance**.21 Drug patents offer a stark illustration of this point. Between 2005 and 2015, **78 percent of drug patents were related to drugs already on the market**.22 Instead of investing in R&D that could lead to new breakthrough therapies, drug **companies** **spend resources obtaining patents on old drugs** — not to improve user experience — but **to extend patent protection, prolong monopoly pricing periods, and keep generic competitors off the market**. 21 Light, D. W., & Lexchin, J. R. (2012). Pharmaceutical research and development: what do we get for all that money?. BMJ, 345. https://doi.org/10.1136/ bmj.e4348 22 Feldman, R. (2018). May Your Drug Price Be Evergreen. Oxford Journal of Law and the Biosciences, 5(3),590-647. http://dx.doi.org/10.2139/ssrn.3061567 23 Frank, R. G. (2019, November 13). **Drug companies exaggerate — controlling drug prices won’t threaten innovation**. The Hill. https://thehill.com/opinion/ healthcare/470266-drug-companies-exaggerate-controlling-drug-prices-wont-threaten-innovation So if we understand that **new drugs are not the same as new cures, a small reduction in new drugs doesn’t pose a threat to innovation**. **Harvard economist** Richard Frank summed it up this way: “**If drug companies claim lowering drug prices means somewhat fewer new drug launches, remember that there are numerous new products sold every year whose elimination would have little to no impact on the health of Americans**.”23

## AT WTO Credibility

#### 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**

## AT Biodiversity

### No Impact

#### No tipping point

* Permian-Triassic extinction proves resiliency
* No data on tipping points
* Ecosystems never outright collapse
* 600 models prove no ecosystem collapse

**Hance 18** [Jeremy Hance, wildlife blogger for the Guardian and a journalist with Mongabay focusing on forests, indigenous people, climate change and more. He is also the author of Life is Good: Conservation in an Age of Mass Extinction. Could biodiversity destruction lead to a global tipping point? Jan 16, 2018. https://www.theguardian.com/environment/radical-conservation/2018/jan/16/biodiversity-extinction-tipping-point-planetary-boundary]

Just over 250 million years ago, the planet suffered what may be described as its greatest holocaust: ninety-six percent of marine genera (plural of genus) and seventy percent of land vertebrate vanished for good. Even insects suffered a mass extinction – the only time before or since. Entire classes of animals – like trilobites – went out like a match in the wind.

But what’s arguably most fascinating about this event – known as the Permian-Triassic extinction or more poetically, the Great Dying – is the fact that anything survived at all. Life, it seems, **is so ridiculously adaptable** that not only did thousands of species make it through whatever killed off nearly everything (no one knows for certain though theories abound) but, somehow, after millions of years life even recovered and went on to write new tales.

Even as the Permian-Triassic extinction event shows the fragility of life, it also proves its **resilience** in the long-term. The lessons of such mass extinctions – five to date and arguably a sixth happening as I write – inform science today. Given that extinction levels are currently 1,000 (some even say 10,000) times the background rate, researchers have long worried about our current destruction of biodiversity – and what that may mean for our future Earth and ourselves.

In 2009, a group of researchers identified nine global boundaries for the planet that if passed could theoretically push the Earth into an uninhabitable state for our species. These global boundaries include climate change, freshwater use, ocean acidification and, yes, biodiversity loss (among others). The group has since updated the terminology surrounding biodiversity, now calling it “biosphere integrity,” but that hasn’t spared it from critique.

A paper last year in Trends in Ecology & Evolution scathingly attacked the idea of any global biodiversity boundary.

“It makes **no sense** that there exists a tipping point of biodiversity loss beyond which the Earth will collapse,” said co-author and ecologist, José Montoya, with Paul Sabatier Univeristy in France. “There is **no rationale** for this.”

Montoya wrote the paper along with Ian Donohue, an ecologist at Trinity College in Ireland and Stuart Pimm, one of the world’s leading experts on extinctions, with Duke University in the US.

Montoya, Donohue and Pimm argue that there isn’t evidence of a point at which loss of species leads to ecosystem collapse, **globally** or even **locally**. If the planet didn’t collapse after the Permian-Triassic extinction event, **it won’t collapse now** – though our descendants may well curse us for the damage we’ve done.

Instead, according to the researchers, every loss of species counts. But the damage is gradual and incremental, not a sudden plunge. Ecosystems, according to them, slowly degrade but **never fail outright.**

“Of more than 600 experiments of biodiversity effects on various functions, **none showed a collapse**,” Montoya said. “In general, the loss of species has a detrimental effect on ecosystem functions...We progressively lose pollination services, water quality, plant biomass, and many other important functions as we lose species. But we never observe a critical level of biodiversity over which functions collapse.”

#### Tech & adaptation solve

**Child 9** [Matthew Child, Conservation Biologist. Putting ‘Ecosystem Services’ in Their Place! January 2009. <http://www.conservationtoday.org/index.php?/Editorials/Matt-Child/Putting-the-ecosystem-services-argument-in-its-place.html>]

**Society can get along just fine without biodiversity**.  “What?! Are you high? What’s the matter with you?!” I hear you think to yourselves reservedly.  But ponder it for a second: even if we were to live in a world in which there was no longer biodiversity but some minimum level of ‘biodeficiency’ (perhaps a few plants and a few sparrows and whatever), technology and human industriousness could plausibly **allow us to exist on this Earth for posterity**. The advent of scenario planning has helped elucidate this possibility by imagining landscapes covered by ‘technogardens’, complete with control towers that mimic the necessities of the seasons1. In this kind of scenario, ecosystem services are created and controlled by the human endeavour. And ecosystems would be human products, subject to the same industrialisation as the panoply of our packaged lives. Such ‘efficiencies’ of land use would theoretically allow society the luxury of setting aside the remaining land for nature reserves and parks. But would we actually do that? Having finally been convinced that nature is merely utilitarian, ironically by those conservationists whose original intention was to demonstrate the opposite, it’s doubtful whether the public would put up much resistance if the remaining land were annexed by Technogarden Inc. (Whose slogan would probably be: Why leave nature to chance?)  There is also no real precedent to believe that governments and industry leaders would stick to a ‘land sparing’ arrangement even if some people did decide that Wilderness (I capitalised to give it a mystical pronoun sort of feel) is invaluable. Take the contemporary example of developing-world agricultural systems: the question is whether to promote ‘wildlife friendly’ farming (a kind of integrated eco-agriculture) or ‘land sparing’ techniques (here: farm; there: nature). Research is beginning to show that land sparing is probably better for biodiversity (Ben Phalan, unpublished data), especially species sensitive to disturbance (which are most of the cool ones). So cordon off pieces of land, farm the living daylights out of it, and then leave the rest for wildlife. Well, yes. However, developing world citizens and their governments probably won’t see it that way. Just ‘leaving’ land alone for nature is anathema to anyone who doesn’t own an iPod.  The truth of the matter is that, no matter how we spin it or how many justifications we give for land to be left alone to produce ‘services’, optimisation will only ever lead to optimisation. It’s the eerie way in which we’re wired: the evolutionary residue of our hoarding Pleistocene past interacting with the neon-emblazoned signs and symbols of society urge us to consume ever greater amounts. Such blatant obsession with material wealth only promulgates Thoreau’s dread observation that “fruit is not ripe until turned to dollars”. Inadvertently, the value-laden ecosystem service argument for conservation will only lead to a more impoverished world. Search your feelings: you know this to be true.  By reducing nature to dollar signs destined for the cold quarantine of appraisal, we slick the conveyer belts of industrial progress. There is no way we can create a paradigm shift in the consumer conscious if we concede that ecosystems and economics exist on the same scale. The problem is twofold: firstly, if we agree that species can be valued then it can be deduced that most species are not valuable. (That’s pretty catchy, right? Maybe it’ll become a marketing campaign for Technogarden Inc.). The majority of ecosystem services are provided by a core group of species that fulfil basic functional criteria2. And there’s no real naming of names when it comes to species and ‘services’. In practical terms, this means that most species can be **substituted** and the ‘services’ we so cherish will still be delivered. It also means that rare and endangered species are probably not worth the ‘cost’ of protecting because they fail to effectively (and consistently) produce an anthropocentric service. “But what about keystone species?!” I hear you cry in anguish, “They’re pretty cool and can’t really be substituted!”  No, they can’t really. It’d be tricky at the very least. But I’m going to say something controversial right now, brace yourselves: the consequences of losing keystone species exists on a scale below the potential of the human endeavour to engineer solutions. Most species losses have severe ecological repercussions, this much is definitely true. But it’s probably a safe bet that, in reality, **very few** of these cases would translate into **tangible disadvantages for humans**. Don’t get me wrong, services like flood abatement, water purification, fibre production and so on are important. But their resilience and quality is mostly determined by sound land management (burning regimes, erosion control, stocking rates), and has little or nothing to do with what most people think of when they hear the word ‘biodiversity’: birds and animals. (The ‘charismatic megafauna’, to give it a buzz phrase spin). Ecosystems services are real and important but most of them can be produced and managed at the producer trophic level. Bird and animal diversity is far more important for sustaining and creating biodiversity (in terms of ensuring ecological relationships and maintaining evolutionary connections). This is an important argument if we recognise and want to convince others of our role as stewards of life. But it is dishonest and ultimately destructive to the conservation movement to try and shove the ‘biodiversity’ concept into what is already a pretty shallow economic framework.  Unless we are, of course, speaking about (drum-roll) the greatest hoax of all: “Existence Value”!

#### No impact to biod

**Hance 13** [Jeremy Hance, senior writer at Mongabay citing Barry Brook, Sir Hubert Wilkins Chair of Climate Change at the School of Earth and Environmental Sciences at the University of Adelaide, and Director of Climate Science at the University of Adelaide’s Environment Institute. Warnings of Global Ecological Tipping Points May Be Overstated. 3-5-2013. http://news.mongabay.com/2013/0305-hance-tipping-points.html#r2IbUBDMyux2eU7i.99]

There's little evidence that the Earth is nearing a global ecological tipping point, according to a new Trends in Ecology and Evolution paper that is bound to be controversial. The authors argue that despite numerous warnings that the Earth is headed toward an ecological tipping point due to environmental stressors, such as habitat loss or climate change, it's unlikely this will occur anytime soon—at least not on land. The paper comes with a number of caveats, including that a global tipping point could occur in marine ecosystems due to ocean acidification from burning fossil fuels. In addition, regional tipping points, such as the Arctic ice melt or the Amazon rainforest drying out, are still of great concern.

"When others have said that a planetary critical transition is possible/likely, they've done so without any underlying model (or past/present examples, apart from catastrophic drivers like asteroid strikes)," lead author Barry Brook and Director of Climate Science at the University of Adelaide told mongabay.com. "**It’s just speculation** and we’ve argued [...] that this conjecture is not logically grounded. No one has found the opposite of what we suggested—they’ve just proposed it."

According to Brook and his team, a truly global tipping point must include an impact large enough to spread across the entire world, hitting various continents, in addition to causing some uniform response.

"These criteria, however, are very unlikely to be met in the real world," says Brook.

The idea of such a tipping point comes from ecological research, which has shown that some ecosystems will flip to a new state after becoming heavily degraded. But Brook and his team say that tipping points in individual ecosystems should not be conflated with impacts across the Earth as a whole.

Even climate change, which some scientists might consider the ultimate tipping point, does not fit the bill, according to the paper. Impacts from climate change, while global, will not be uniform and hence not a "tipping point" as such.

"Local and regional ecosystems **vary considerably** in their responses to climate change, and their regime shifts are therefore likely to vary considerably across the terrestrial biosphere," the authors write.

Barry adds that, "from a planetary perspective, this diversity in ecosystem responses creates an essentially **gradual** pattern of change, **without** any identifiable **tipping points**."

The paper further argues that biodiversity loss on land may not have the large-scale impacts that some ecologists argue, since invasive species could potentially take the role of vanishing ones.

"So we can lose the unique evolutionary history (bad, from an intrinsic viewpoint) but not necessarily the role they impart in terms of ecosystem stability or provision of services," explains Brook. The controversial argument goes against many scientists' view that decreased biodiversity will ultimately lessen ecological services, such as pollination, water purification, and carbon sequestration.