# 1NC

## Fwk

#### 6] Extinction outweighs everything – even a small risk of extinction means you vote NEG

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

## DA – Innovation

#### Biotech industry strong now.

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our- insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues. Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6 What about SPACs? The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story. Fundamentals continue strong When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances. In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development. Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries. Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising. For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic. More innovation on the horizon The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science. Looking forward, the combination of advances in biological science and accelerating developments in technology and artificial intelligence has the potential to take innovation to a new level. A recent report from the McKinsey Global Institute analyzed the profound economic and social impact of biological innovation and found that biomolecules, biosystems, biomachines, and biocomputing could collectively produce up to 60 percent of the physical inputs to the global economy. The applications of this “Bio Revolution” range from agriculture (such as the production of nonanimal meat) to energy and materials, and from consumer goods (such as multi-omics tailored diets) to a multitude of health applications.

#### IPR key to innovation.

Bacchus 20 [(James, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida. He was a founding judge and was twice the chairman—the chief judge—of the highest court of world trade, the Appellate Body of the World Trade Organization in Geneva, Switzerland) "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, 12-16-2020, https://www.cato.org/free-trade-bulletin/unnecessary-proposal- wto-waiver-intellectual-property-rights-covid-19-vaccines] TDI

At the heart of this emerging trade debate is a belief by many people worldwide that all medicines should be “global public goods.” There is little room in such a belief for consideration of any rights to IP. As one group of United Nations human rights experts expressed: “There is no room for ... profitability in decision‐making about access to vaccines, essential tests and treatments, and all other medical goods, services and supplies that are at the heart of the right to the highest attainable standard of health for all.”16 This view is myopic. Subordinating IP rights temporarily to pressing public needs during a pandemic or other global health emergency is one thing. Eliminating any consideration of “profitability” in all policymaking relating to “access to vaccines, essential tests and treatments, and all other medical goods, services and supplies” is quite another.17 To be sure, there is a superficial moral appeal in such a view. But does this moral appeal hold up if such a “human rights” approach does not result in meeting those urgent public needs? With the belief that medicines should be “public goods,” there isliterally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rightsin such goods is viewed as a violation of human rights and of the overall public interest. This view, though, does not reflect the practical reality of a world in which many medicines would simply not exist if it were not for the existence of IP rights and the protections they are afforded. Technically, IP rights are exceptions to free trade. A long‐standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rightsis that they are incentives for innovation, which is the main source for long‐term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.”18 The knowledge from innovations inspired by IP rights spills over to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐based and knowledge intensive. Without IP rights as incentives, there would be less new knowledge and thus less innovation. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19 As Stephen Ezell and Nigel Cory of the Information Technology and Innovation Foundation wrote, “A fundamental fault line in the debate over intellectual property pertains to the need to achieve a reasoned balance between access and exclusive rights.”20 This fault line is much on display in the WTO rules on IP rights. These rules recognize that “intellectual property rights are private rights” and that rules and disciplines are necessary for “the provision of effective and appropriate means for the enforcement of trade‐related intellectual property rights.”21 Yet, where social and economic welfare is at stake, WTO members have sought to strike a balance in these rules between upholding IP rights and fulfilling immediate domestic needs.

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

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

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

#### Bioterror causes extinction.

Millett & Snyder-Beattie ‘17 [(Piers Millett: Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford. Andrew Snyder-Beattie: M.S., Director of Research, Future of Humanity Institute, University of Oxford.) " Existential Risk and Cost-Effective Biosecurity," Health Security, 15(4), 08-01-2017, https://www.liebertpub.com/doi/full/10.1089/hs.2017.0028] TDI

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

## Case

1. Theory
   1. Interpretation: The affirmative must specify how much they are going to reduce it by
   2. Standards:
      1. Fairness: Reduce is a broad term and this word is susceptible to change. It forces the Neg to question what DA’s or CP’s to actually read
         1. The Aff can literally just say that the reduction of this is not significant therefore, it is not enough to trigger the negatives DA impacts that’s unfair and bad for the debate round
         2. Topic Education: In order to understand the topic and Data Analysis we need to specify by how much
         3. This does not necessarily need to be in their plan however but not stating the reduction and how much to state the reduction leaves the negative scratching their heads – it’s a must
      2. Judge, if the Aff does not specify in the 1AR, vote neg on presumption and vote neg on solvency deficit we don’t know if a small or large reduction is enough to solve

#### Analytics:

* + - * 1. Their innovation is high now card is outdated – 2019 is 2 years ago

#### Turn – The Aff harms small businesses and reduces Biotech Innovation

“Why Is a Significant Period of Data Exclusivity Necessary in a Pathway for Biosimilars?” *BIO*, archive.bio.org/articles/why-significant-period-data-exclusivity-necessary-pathway-biosimilars.

Biotechnology companies must have some certainty that they can protect their investment in the development of new breakthrough therapies for a substantial period of time in order to secure the necessary resources from venture capital firms and other funding sources. Thus, in order to preserve incentives for biomedical innovation, any statutory pathway for follow-on biologics (FOBs) must include a substantial period of data exclusivity. Such non-patent exclusivity is necessary because, due to the very nature of a FOBs regime, the patent system may not provide innovator biologics with effective protection against follow-on manufacturers prematurely entering the market. For biologics to receive the same length of effective market protection as small molecule drugs receive under the Hatch-Waxman Act, the period of data exclusivity in any FOBs framework must be no less than 14 years. Anything less could skew investment away from biologics research and development. The similarity standard for FOBs creates a “protection gap” that may allow for abbreviated regulatory approval while eluding an innovator’s patents. That likelihood exists because of the confluence of two critical factors not present in the Hatch-Waxman Act construct for generic small molecule drugs. First, unlike a generic drug which must be the same as an innovator product, a FOB may be only “similar’ to the corresponding innovator product, and thus the innovator’s patents may not be infringed. Second, because of the nature of biologic products – large molecules produced by living cells and organisms – patent protection is often narrower and easier to “design around” than that of small molecule drugs, and the trend is towards increasingly narrow patents. Strong data exclusivity will preserve the balance that Congress previously found necessary to stimulate innovation in the pharmaceutical industry. In 1984, Congress enacted patent term restoration provisions to provide pharmaceuticals with up to 14 years of patent protection following marketing approval. This time period was selected so that "research intensive companies will have the necessary incentive to increase their research and development activities." H.R. Rep. No. 98-857, at 41 (1984). As a result, the average period of time for marketing a drug product with patent protection now is 11.5 years, and new drugs are, on average, marketed in the U.S. for 13.5 years before the entry of generic competition. Any FOBs pathway should at least guarantee that same degree of effective market protection through data exclusivity. Further, the breakeven point for a biologic occurs after it has been on the market between 12.9 and 16.2 years. Indeed, if the data exclusivity period for biologics is less than the number of years available to drugs under patent term restoration (that is, 14 years), then, because of the patent protection gap and the higher risks of biologics development, it will skew investment away from biomedical innovation. A 14-year period of data exclusivity serves as an insurance policy that provides innovators with some certainty of protection. Data exclusivity would run concurrently with the patent term for the product. It therefore would create actual protection only in those instances where the follow-on manufacturer would be able to work around the patents held by the innovator but still gain abbreviated approval of its FOB. Data exclusivity of 14 years is an essential incentive for biotechnology investment. The majority of biotechnology companies are small, private start-ups, heavily reliant on venture capital investment. Yet these companies hold two-thirds of the industry’s innovative clinical pipeline. Biologics research and development also is a high-risk endeavor, with higher capital costs, higher material costs, greater manufacturing costs and uncertainties, longer development times, and lower late-stage success rates than compared to small molecule drugs. A failure to include substantial data exclusivity as part of a statutory framework for FOBs would undermine incentives to invest in biomedical innovation and thus would slow progress in the development of breakthrough therapies to improve the health and lives of patients suffering from currently untreatable conditions.

**TRIPS Waiver for LDCs was extended until 2033**

**WTO 15**[World Trade Organization, “WTO members agree to extend drug patent exemption for poorest members,” WTO. 2015. <https://www.wto.org/english/news_e/news15_e/trip_06nov15_e.htm> ] /TriumphDebate

**The Council’s decision extends until January 2033 the period during which key provisions of the WTO’s intellectual property agreement, the TRIPS Agreement, do not apply to pharmaceutical products in LDCs.** This means LDCs can choose whether or not to protect pharmaceutical patents and clinical trial data before 2033. The decision also keeps open the option for further extensions beyond that date. The latest extension, the second specifically applied to pharmaceutical products for LDCs, is in line with directions set by WTO ministers in the 2001 Doha Declaration on the TRIPS Agreement and Public Health. It also follows the adoption of the new UN Sustainable Development Goals (SDGs), which affirm the right of developing countries to utilize TRIPS Agreement flexibilities to ensure access to medicines for all. WTO Director-General Roberto Azevêdo hailed the TRIPS Council's decision. **“This decision by the TRIPS Council represents a clear and unambiguous signal that WTO members are committed to addressing the needs of the organization's poorest members**. With the concerns of least developed countries at centre stage next month at our Nairobi Ministerial Conference, now is the time for WTO to build upon this momentum in other areas of our work,” said Director-General Azevêdo. WTO members, speaking in the TRIPS Council, unanimously welcomed the decision. A wide spectrum of members recalled the benefits of this extension for public health outcomes in LDCs, in light of the continuing challenges faced by these countries. Ambassador Shameem Ahsan of Bangladesh, coordinator of the LDC group in the WTO, described the decision as “historic,” adding that it **“will assure the LDCs the necessary legal certainty to procure or to produce generic medicines for those who need it most but do not have any access.”** This step, responding to a request tabled by LDC members of the WTO (IP/C/W/605), comes just a month after the UN General Assembly adopted the SDGs as a framework for global action up to 2030. SDG Goal 3 on ensuring healthy lives and promoting well-being for all at all ages includes the target of providing “access to affordable essential medicines and vaccines”, and in that context recalls the affirmation in the Doha Declaration on the right of developing countries to use to the full the provisions in the TRIPS Agreement regarding flexibilities to protect public health, and, in particular, provide access to medicines for all. The need to take full account of the special needs and circumstances of the LDCs is recognized expressly in the TRIPS Agreement itself, and this recognition runs through many areas of the WTO’s work. LDC members are already exempted from applying all substantive TRIPS standards until 2021, a period that may also be extended. Today’s decision is expected to be followed by a related General Council decision, on the recommendation of the TRIPS Council. The General Council is expected to extend an existing waiver for LDCs concerning exclusive marketing rights for pharmaceuticals, and to agree to a new waiver for LDCs regarding ‘mailbox’ measures for receiving patent applications in this field. These two waivers will complement and buttress the effect of the decision to exclude obligations concerning pharmaceutical patenting, and will also run until 2033. Further information on TRIPS and public health is available here. Information on intellectual property in the WTO, news and official records of the activities of the TRIPS Council, and details of the WTO’s work with other international organizations in the field can be accessed here.

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TRIPS flexibilities can increase access to medicine and have successfully done so under existing patent protections. 

**Quigley, 2015** [Fran Quigley, Clinical Professor at Indiana University McKinney School of Law, November 23rd, 2015, “making Medicines Accessible: Alternatives to the Flawed Patent System”, Health and Human Rights Journal, <https://www.hhrjournal.org/2015/11/making-medicines-accessible-alternatives-to-the-flawed-patent-system-2/> ] /TriumphDebate

The TRIPS agreement represented an historic advancement of the patent paradigm. **Monopoly protection for medicines became the law in many nations that had previously treated medicines as a public good off-limits from private profiteering**.15 But TRIPS did include several substantial exemptions from patent protection, exemptions that came to be known as “flexibilities”. **TRIPS flexibilities allow for a detour around patent-erected barriers that otherwise block access to many critical medicines, yet full embrace of these flexibilities would not change existing international intellectual property law. The central TRIPS flexibility is found in Article 31 of the agreement, which allows governments to issue compulsory licenses for patented drugs**.16 Compulsory licenses permit the manufacture and sale of generic medicines, presumably at prices far lower than the patented versions, with remuneration paid to the patent holder. **TRIPS also allows governments to engage in parallel importation of generic medicine manufactured elsewhere**.17 **The 2001 WTO Doha Declaration underscored the availability and importance of these flexibilities for use in responding to public health needs.18 TRIPS flexibilities have been employed to significantly increase access to medicines in India, Colombia, Indonesia, and over 50 other nations that have produced or procured generic HIV/AIDs medications.**19 **However, since TRIPS and Doha, the US Trade Representative and the pharmaceutical industry have pushed for bilateral and multilateral trade agreements, known as “TRIPS-Plus Agreements,” that narrow the availability of these non-patent options**.20 Many access to medicine advocates consider TRIPS flexibilities to be significantly under-utilized in low and middle-income countries. For example, the Fix the Patent Laws campaign in South Africa urges expanded use of TRIPS flexibilities.21 **Thus, the featured reform in this category would be a significantly broader embrace of the patent exemptions already available under international law.**

#### The Aff is wrong about Data Exlusivity

“Data Exclusivity Is Not the Same as Market Exclusivity.” *GaBi Online*, www.gabionline.net/policies-legislation/Data-exclusivity-is-not-the-same-as-market-exclusivity.

According to him, data exclusivity is not the same as market exclusivity. “During a period of data exclusivity, a competitor would be unable to piggyback on the massive investment in R & D made by an innovator to receive approval from the FDA for their ‘copy-cat’ product. Simply put, during the period of exclusivity the FDA may not rely on an innovator’s safety and efficacy data to approve a competitor’s product. Market exclusivity is an altogether different thing – it is the inability of any competitor to enter a specific market. Market exclusivity for biological products would mean that there could be, for example, just one drug to treat leukaemia, one drug to treat diabetes, one drug to treat MS. “This is not the case”, he stresses. “At any moment, hundreds of biotech companies are racing to develop the next wonder drug for any one of these diseases. That situation will not change because of data exclusivity periods. There will continue to be competition among innovative biological products regardless of a data exclusivity period enacted as part of biosimilars legislation”. According to Mr Quinn, providing innovators with data exclusivity enables them to recoup the investments they made into developing new products and testing product safety and efficacy. “This allows them to continue to invest in new breakthrough medicines, therapies and cures for diseases such as cancer, HIV/Aids and ALS. Competitors are free at any time to conduct their own costly research and development, including clinical trials, and create their own biologicals”, he argues. Furthermore, Mr Quinn states that it is fiction that 12 years of data exclusivity would extend innovators’ monopoly power. “Data exclusivity does not give it any sort of monopoly”, he writes. “You would be hard pressed to find a term that is used more and understood less than the term ‘monopoly’. “Patents don’t give monopolies, and neither would data exclusivity. If patents gave monopolies then how is it possible that anyone other than Apple could sell a portable MP3 player? Apple has the iPod and iPhone locked up tight, but not so tight that other companies are prohibited from selling similar products. Look at all the iPhone wanna-bes that are on the market now. Seriously! You have to stop thinking that patents grant monopolies. What they do is make it difficult for others to copy an innovation, but if you can make something that does the same thing that isn’t a copy, then patent law does not prevent that”. He explains that similarly, products that compete with innovative biologicals can still be introduced during the period of data exclusivity. A period of data exclusivity merely means that those who do not innovate cannot piggyback off the hard work of innovators and rely on the research conducted by the innovator company. They must conduct their own safety and efficacy research and testing to obtain FDA approval and, obviously, not infringe the patents owned by the innovator. “So can we please stop using the world ‘monopoly’? No matter how many times it is used it will never accurately describe the protections provided. If you doubt that do a patent search and you will see in every industry numerous patents that all purport to cover similar things. How else, for example, could Microsoft and Apple both have patent portfolios? How else could Motorola and Nokia have patent portfolios? How else could AMD and IBM have patent portfolios? And so on” Mr Quinn states. (see also [Minimal 12 years of biologicals data exclusivity required](http://www.gabionline.net/Biosimilars/News/Minimal-12-years-of-biologicals-data-exclusivity-required), [12 years exclusivity workable for patients; not anticompetitive](http://www.gabionline.net/Generics/General/12-years-exclusivity-workable-for-patients-not-anticompetitive) and [Innovative biologicals development must be preserved](http://www.gabionline.net/Pharma-News/Innovative-biologicals-development-must-be-preserved))