# NC vs Trips

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#### Innovation high and evergreening is false – postdates your ev and we have stats

Ezell 20. Stephen Ezell, July 2020, “Ensuring U.S. Biopharmaceutical Competitiveness,” Information Technology and Innovation Foundation, <http://www2.itif.org/2020-biopharma-competitiveness.pdf> sean!

Medicines are critical to health. Since 2000, the FDA has approved more than 500 new medicines. 2 As of 2020, biopharmaceutical companies in the United States have more than 3,400 drugs under clinical development, accounting for almost half of the estimated 8,000 medicines under development globally (1,100 of which are being developed to treat various forms of cancers).3 And while some have asserted that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is that most of the drugs currently under development seek to tackle some of the world’s most intractable diseases, including Alzheimer’s, cancer, and communicable diseases. This includes 130 coronavirus vaccines under development globally as well as 144 active trials of coronavirus therapeutic agents, and another 457 development programs for new therapeutic agents, which the FDA is tracking through its Coronavirus Treatment Acceleration Program.4 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA’s Center for Drug Evaluation and Research (CDER) approved 41 new medicines (the most since 1996 at that point), many of which were first-in-class medicines, meaning they represent a possible new pharmacological class for treating a medical condition.5 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases. In 2018, CDER approved a record 59 novel drugs, and in 2019, 48 novel drugs, making 2019 the third-largest approval class in the past 25 years.6 As of 2020, 74 percent of medicines in clinical development in the United States are potentially first-in-class medicines, including 86 percent for Alzheimer’s, 70 percent for various forms of cancer, and 73 percent for cardiovascular diseases

#### IP protections motivate innovators to take risks – that means long term development and prolif

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With the belief that medicines should be “public goods,” there is literally no support in some quarters for the application of the WTO TRIPS Agreement to IP rights in medicines. Any protection of the IP rights in 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 rights is 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

#### Innovation is k2 stopping bioterror

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As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences 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 recognized 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 compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical 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 sec-tor.2 It is therefore unsurprising that we are seeing indus-try-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 com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate 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 rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure 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 com-bination product that is being tested for therapeutic poten-tial 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, bioterror-ism 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 imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious 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 contribu-tions 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 innova-tion conditions.

#### Bioterror is the largest medical threat—it o/w’s pandemics on probability

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Taken together, these examples show that this meme no longer serves us well. It is undoubtedly a mistake to underestimate the threats from natural pathogens. At the same time, it is equally unwise to wield this 19-year-old expression like a magic wand, intending to briskly banish concerns about people causing harm with biology. We can’t afford to blind ourselves or others to the uncomfortable truth that, with each passing day, humans grow more capable of outdoing nature and harnessing biotechnology to cause harm on a staggering scale, by either cruelty or carelessness. Nature has no interests, motives, or political goals. To the extent it can be said to “want” anything, it is to perpetually enhance populations’ differential reproductive success, which only rarely aligns with causing greater harm to humans. Notably, the trillions of bacteria living in the average human’s colon appear to have adapted toward a peaceful and often mutually beneficial coexistence with their host. And even deadly pathogens may theoretically evolve toward making humans less sick if doing so opens up more opportunities for transmission between hosts. The process of natural selection, for all its power, is highly constrained in its ability to generate “superbugs” possessing a diabolical suite of traits. Like human bioengineers, natural selection must work around stubborn physiological trade-offs between traits, such as genome replication rate and mutation rate. But natural selection is also handicapped by near-sightedness, driving improvements in traits that enhance a population’s fitness in its current environment with no attention to maintaining or improving traits that enhance fitness in other environments. If creating an especially deadly pathogen were like winning a soccer match against a formidable opponent, natural selection would be competing with all the cunning of an especially persistent horde of 5-year-olds, glued to the ball and only ever capable of playing offense, defense, or goalie at any one time. By contrast, modern biologists are gaining the ability to see the whole field, develop an intuition about where the ball will be next, and play multiple positions simultaneously. Through a combination of rational design, directed evolution, breeding, and brute force trial and error, they can increasingly engineer organisms that excel in multiple desired functions at once, such as the ability to grow quickly in a massive industrial fermenter while churning out commercially valuable biomolecules. This growing capability promises tremendous benefits for agriculture, industry, and human health, but its potential application to the creation of pathogens poses serious concerns. It is worth emphasizing that trained biologists — let alone terrorists — still have difficulty one-upping natural selection’s creative output. Our understanding of biology is very much in its infancy. Yet our knowledge and capabilities are maturing rapidly, as evidenced by Twist’s prolific gene synthesis capabilities, along with recent feats in predicting protein structure, gene editing, and genome assembly. We are much closer to this exciting but frightening horizon today than we were in 2001, and this trend will likely persist. It’s also worth noting that, when it comes to weapons-grade biotechnology, states likely pose a greater risk than non-state terrorists. States have vastly more resources to support the development of biological weapons, and about 23 are known or suspected to have maintained biological weapons programs in the 20th century. Some programs, like North Korea’s, likely persist to this day. As countries jockey for advantage, state biological weapons programs remain an ever-present danger, despite the treaties and export controls designed to rein them in. Covid-19, which has exposed countries’ vulnerability to biological threats, has done little to mitigate this danger. Accidental releases pose an additional source of anthropogenic biorisk. Thanks to the U.S. government’s monitoring program, we know that dozens of agents and toxins with the potential to pose a severe threat to public health and agriculture are reported accidentally lost or released from U.S. labs every year. We also know that accidental releases around the world have already caused significant harm. Such risks increase as biotechnology expands across the world and gains in strength. Biotechnology, with all its promise and peril, is moving fast. It’s irresponsible of us to shrug off current and emerging biotechnological threats by reciting “Nature is the ultimate bioterrorist” like some article of faith. As with global warming, the cost of willful ignorance and inaction is high — and increasing. Our health security requires that we engage cautiously but honestly with the full spectrum of evolving biological risks, striving toward solutions with open eyes and moral courage

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#### Counterplan – add a Health Impact Fund to incentivize Pharmaceuticals to voluntarily lower prices and increase access. This would add a complement to IPP rather than reducing it.

Pogge 10 [Thomas Pogge, Thomas Winfried Menko Pogge is a German philosopher and is the Director of the Global Justice Program and Leitner Professor of Philosophy and International Affairs at Yale University. Cambridge University Press, “Incentives for Global Health: Patent Law and Access to Essential Medicines. The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices,” 2010, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1431180]/ lm

The exclusion of the poor by the existing patent regime requires reform. Given the foregoing discussion, a straightforward and moderate reform would create a supplementary mechanism that, by addressing the needs of the poor, would remedy the injustice now imposed upon them. This reform proposal comprises six elements. First, just as the patent regime provides a general innovation incentive, so its complement encourages pharmaceutical innovation through an incentive that is specified in general terms: as a promise to reward any successful new medicine, in proportion to its success. This kind of mechanism has been described as a comprehensive AMC.14 Second, while the patent regime rewards medicines on the basis of the market demand each generates and then satisfies, thereby effectively excluding the poor, its complement gives equal standing to all by defining success simply in terms of human health. On this complementary track, the success of a medicine is assessed by the reduction in human morbidity and premature mortality it achieves – regardless of whether these harms are averted from rich or poor patients. Third, in order to help overcome the last-mile problem, the rewards available under the complementary mechanism should be tied not to what a medicine can do, but to what it actually achieves in the world. Fourth, when such a general mechanism provides large enough health impact rewards, it will attract sufficient innovation and sufficient efforts to ensure real access to new medicines worldwide. This avoids any need for compulsion. Innovators can be left free to choose between the two tracks, developing on the new track high-impact medicines needed also by many poor patients and on the conventional patent track low-impact medicines desired by the more affluent. Making the health-impact track optional is also crucial for the political success of the proposal. Fifth, in order to reinforce the incentive toward facilitating real access, health impact rewards should be conditional on the medicine being priced no higher than the lowest feasible cost of production and distribution.

Sixth, health impact rewards should be funded by governments as a public good. In order to minimise burdens and deadweight losses due to taxes, the cost should be spread as widely as possible. This suggests that the complementary funding mechanism should be global (rather than national) in scope. The reasons that make the reform compelling in any one country or region make it compelling everywhere. Moreover, global scope avoids the problems associated with large price differentials. Global scope also brings huge efficiency gains by diluting the cost of the scheme without diluting its benefits: no matter how many beneficiaries we may add, the cost of achieving an innovation remains the same even while its aggregate benefit increases with the number of beneficiaries.15 Finally, an international agreement would also reinforce the commitment of individual countries to the scheme. Pharmaceutical innovation is therefore best encouraged by promising to reward any safe and effective new medicine in proportion to its global health impact. Such a promise constitutes an AMC that is fully comprehensive: by including not merely all diseases but also all patients.

The proposal is then for the creation of a new international agency that offers to reward any new medicine based on its health impact during its first decade or so.16 This Health Impact Fund („HIF‟) would provide ample rewards for the development of new high-impact medicines without excluding the poor from its use.

#### That solves the aff by including the poor and increasing access but doesn’t trigger the disad because it’s voluntary, IPP remains unchanged, and increases innovation.

Pogge 10 [Thomas Pogge, Thomas Winfried Menko Pogge is a German philosopher and is the Director of the Global Justice Program and Leitner Professor of Philosophy and International Affairs at Yale University. Cambridge University Press, “Incentives for Global Health: Patent Law and Access to Essential Medicines. The Health Impact Fund: Better Pharmaceutical Innovations at Much Lower Prices,” 2010, https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=1431180]/ lm

Let us recapitulate how the HIF would provide a full systemic solution to the seven problems described earlier: High Prices would not exist for HIF-registered medicines. Innovators would typically not even want a higher price as this would reduce their health impact rewards by impeding access to their product by most of the world‟s population. The HIF counts health benefits to the poorest of patients equally with health benefits to the richest. Diseases Concentrated among the Poor, insofar as they substantially aggravate the GBD, would no longer be neglected. In fact, the more destructive ones among them would come to present some of the most lucrative R&D opportunities for biotechnology and pharmaceutical companies. This would happen without undermining the profit opportunities such companies now enjoy by developing remedies for the ailments of the affluent. Bias toward Maintenance Drugs would be absent from HIF-encouraged R&D. The HIF assesses each registered medicine‟s health impact in terms of how its use reduces mortality and morbidity worldwide – without regard to whether it achieves this reduction through cure, symptom relief, or prevention. This would guide firms to deliberate about potential research projects in a way that is also optimal for global public health: namely in terms of the expected global health impact of the new medicine relative to the cost of developing it. The profitability of research projects would be aligned with their cost-effectiveness in terms of global public health. Wastefulness would be dramatically lower for HIF-registered products. There would be no deadweight losses from large mark-ups. There would be little costly litigation as generic competitors would lack incentives to compete and innovators would have no incentive to suppress generic products (because they enhance the innovator‟s health impact reward). Innovators might therefore often not even bother to obtain, police, and defend patents in many national jurisdictions. To register a medicine with the HIF, innovators need show only once that they have an effective and innovative product. Counterfeiting of HIF-registered products would be unattractive. With the genuine item widely available near or even below the marginal cost of production, there is little to be gained from producing and selling fakes. Excessive Marketing would also be much reduced for HIF-registered medicines. Because each innovator is rewarded for the health impact of its addition to the medical arsenal, incentives to develop me-too drugs to compete with an existing HIF-registered medicine would be weak. And innovators would have incentives to urge a HIF-registered drug upon doctors and patients only insofar as such marketing results in measurable therapeutic benefits for which the innovator would then be rewarded. The Last-Mile Problem would be mitigated because each HIF-registered innovator would have strong incentives to ensure that patients are fully instructed and properly provisioned so that they make optimal use (dosage, compliance, etc) of its medicines, which will then, through wide and effective deployment, have their optimal publichealth impact. Rather than ignore poor countries as unprofitable markets, pharmaceutical companies would, moreover, have incentives to work with one another and with national health ministries, international agencies and NGOs toward improving the health systems of these countries in order to enhance the impact of their HIFregistered medicines there.

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