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#### Current WTO legislation on IP rights promotes innovation

Ezell et al 4/29 Jaci McDole, Stephen Ezell [Stephen Ezell is 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.] 4/29/21, “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic” Information Technology and Innovation Foundation, <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through> DD AG

Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report.

However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products.

In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17

Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22

Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products.

By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc.

Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27

In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30

#### Reductions in protections kill medical innovation, economic growth, and knowledge building for the future

McDole and Ezell 04/29 – Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at ITIF. She focuses on IP and its correlations to global innovation and trade. Her work includes ITIF’s Innovate4Health Initiatives (2017–2019) and A Covid-19 TRIPS Waiver Makes No More Sense for Copyrights Than It Does for Patents (2021). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she cofounded to study and further robust global IP policies. Stephen J. Ezell is ITIF vice president for Global Innovation Policy. He focuses on science, technology, and innovation policy as well as international competitiveness and trade policy issues. He is the coauthor of Innovating in a Service Driven Economy: Insights Application, and Practice (Palgrave McMillan, 2015) and Innovation Economics: The Race for Global Advantage (Yale 2012). The Information Technology and Innovation Foundation (ITIF) is an independent, nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized by its peers in the think tank community as the global center of excellence for science and technology policy, ITIF’s mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress; April 29, 2021; “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic”; <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through> //advay

Innovation can—and does—happen anywhere and at any time. As society ground to a halt in 2020, innovators around the world worked tirelessly to develop treatments, vaccines, and solutions to COVID-19 pandemic-related challenges. From personal protective equipment (PPE) to treatments and vaccines to autonomous delivery robots to remote and social distancing solutions for the workplace, intellectual property (IP) played an indispensable role in enabling research, development, and commercialization of many of the innovations meeting the challenges of the pandemic. IP enables start-ups to gain access to much-needed capital. IP gives innovators the confidence to invest in research and development (R&D) and provides incentives for commercialization. Indeed, it is difficult to innovate without the protection of ideas.

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some pre-existing innovations, but it would absolutely limit future innovations. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, this time we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.

Moreover, the blame game usually ignores the real, underlying problems. For access to innovations to fight COVID-19, especially biotechnology, vaccines, and therapeutics, the underlying problems are regulatory delays and a lack of adequate and appropriate manufacturing infrastructure.1 The lack of infrastructure has resulted in supply chain bottlenecks in places where few are currently equipped to handle the manufacturing requirements.2 Meanwhile, regulatory delays have prevented vaccines, therapeutics, and diagnostics from entering certain markets.3

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future.

The case studies are:

Bharat Biotech: Covaxin

Gilead: Remdesivir

LumiraDX: SARS-COV-2 Antigen POC Test

Teal Bio: Teal Bio Respirator

XE Ingeniería Médica: CápsulaXE

Surgical Theater: Precision VR

Tombot: Jennie

Starship Technologies: Autonomous Delivery Robots

Triax Technologies: Proximity Trace

Zoom: Video Conferencing

As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future.

THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES

Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5

To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7

In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12

To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13

#### Two Impacts –

#### 1] future pandemics are more likely and more deadly which makes innovation key to stop extinction

Ceballos 5/27 Gerardo Ceballos [PhD, Dr Gerardo Ceballos is an ecologist and conservationist at the Universidad Nacional Autonoma de Mexico. He is particularly recognized for his influential work on global patterns of distribution of diversity, endemism, and extinction risk in vertebrates. He is also well-known for his contribution to understanding the magnitude and impacts of the sixth mass extinction.], 5/27/21, “THE SIXTH MASS EXTINCTION AND THE FUTURE OF HUMANITY”, Population Matters, <https://populationmatters.org/news/2021/05/sixth-mass-extinction-and-future-humanity> DD AG

Somewhere, sometime in late 2019, a coronavirus from a wild species, perhaps a bat or a pangolin, infected a human in China. This could have been an obscure event, lost without trace in the annals of history, as it is very likely this has occurred many times in the last centuries. But this particular event was somehow different. The coronavirus became an epidemic first and a pandemic later. Covid-19 became the worst pandemic since the Spanish flu in 1918. The horrific human suffering it has caused, and its economic, social and political impacts, are still unraveling.

The reason Covid-19 and more than forty other very dangerous viruses, such as Lassa fever, HIV and Ebola, have jumped from wild animals to humans in the last four decades is the destruction of natural environments and the trafficking and consumption of wild animals.

The wildlife trade is to satisfy the insatiable and extravagant demand for these species in the Asian market, in countries such as China, Vietnam and Indonesia. The illegal wildlife trade is a gigantic business. It is as lucrative as the drug trade, but without the legal implications. The immense appetite of China and other Asian societies for exotic animals has promoted exponential growth in trade and profits. Wild and domestic animals sold in “wet markets” are kept in unsanitary and unethical conditions. There, feces, urine and food waste from cages at the top spill into cages at the bottom, creating the perfect conditions for viruses to leap from wild animals to domestic animals and humans. Thousands of wildlife species or their products are traded annually.

Wildlife trade is one of several human impacts, including habitat loss and fragmentation, pollution, toxification and invasive species, that have caused the extinction of thousands of species and threaten many more. Indeed, most people are unaware that the current extinction crisis is unprecedented in human history. Extinction occurs when the last individual of a species dies. The UN recently estimated that one million species, such as the panda, the orangutan and the Sumatran rhino, are at risk of extinction.

The second finding is that population extinctions, which are the prelude to species extinctions, are occurring at very fast rates (Ceballos et al., 2017). Around 32 percent of a sample of 27,000 species have declining populations and have experienced massive geographic range contractions. Population extinctions are a very severe and widespread environmental problem which we have called “Biological Annihilation”.

Finally, our third finding indicates that the magnitude of the extinction crisis is underestimated because there are thousands of species on the brink of extinction (Ceballos et al., 2020). Those species will likely become extinct in the near future unless a massive conservation effort is launched soon.

Many times, people have asked me why we should care about the loss of a species. There are ethical, moral, philosophical, religious and other reasons to be concerned. But perhaps the one that is most tangible for most people is the loss of ecosystem services, which are the benefits that humans derive from the proper function of nature. Ecosystem services include the proper mix of gases in the atmosphere that support life on Earth, the quantity and quality of water, pollination of wild crops and plants, fertilization of the soil, and protection against emerging pests and diseases, among many others. Every time a species is lost, ecosystem services are likely to erode and human well-being is reduced.

The loss of so many ecosystems and species is pushing us towards the point of collapse of civilization. The good news is that there is still time to reduce the current extinction crisis. The species and ecosystems that we manage to save in the next 10 – 15 years will define the future of biodiversity and civilization. What it is at stake is the future of mankind.

#### 2] Anticipated economic results in nuclear war – especially for a post-pandemic world

Tønnesson 15 [Tønnesson is a research professor at the Peace Research Institute Oslo (PRIO) in Norway and the leader of the East Asia Peace program at Uppsala University in Sweden.] “Deterrence, interdependence and Sino–US peace.” International Area Studies Review, volume 18, number 3, pgs. 297-311. 2015 // recut advay

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party. Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

## 2

#### CP: The member nations of the WTO Should Terminate current and ban secondary patents for medicines other than nanomedicine

#### Nanomed is rising and expecting to grow – use and preference for deadly diseases means its here to stay

**Mordor, 21**, “HEALTHCARE NANOTECHNOLOGY (NANOMEDICINE) MARKET - GROWTH, TRENDS, COVID-19 IMPACT, AND FORECASTS (2021 – 2026)”, Group of analysts and researchers that prvoides healthcare based insights to over 1700 companies across the world, URL: [https://www.mordorintelligence.com/industry-reports/healthcare-nanotechnology-nanomedicine-market#](https://www.mordorintelligence.com/industry-reports/healthcare-nanotechnology-nanomedicine-market), KR

The healthcare nanotechnology (nanomedicine) market was valued at USD 219,850 million in 2020, and it is expected to reach USD 461,252 million by 2026, registering a CAGR of nearly 11.9% during the forecast period, 2021-2026.

The use of nanotechnology offers new opportunities for the development of novel strategies in terms of prevention, diagnosis, and treatment of COVID-19 and other viral infections. COVID-19 management was done with the development of nano-based materials, such as disinfectants, personal protective equipment, diagnostic systems, and nanocarrier systems, for treatments and vaccine development. According to a research article by Estefania V. R. Campos, et al., published in the Journal of Nanobiotechnology in 2020, gold nanoparticles were functionalized with probes modified with thiol on the surface, which hybridize with the target and prevent the aggregation of the nanoparticles by salts and, consequently, the color change. This solution can be easily adapted for the diagnosis of COVID-19.

The growth of the healthcare nanotechnology (nanomedicine) market is currently being driven by various factors such as the growing prevalence of cancer and genetic and cardiovascular diseases, increasing advancements in nanoscale technologies for diagnostic procedures, and growing preference for personalized medicines.

Nanomedicine helps improve 0 health and offers solutions for 0 life-threatening diseases, such as cancer, Parkinson’s disease, Alzheimer’s disease, diabetes, orthopedic diseases, and diseases related to blood, lungs, and the cardiovascular system. According to Alzheimer's Disease International, globally, there were around 50 million people with dementia in 2020. This number is expected to double every 20 years, reaching 82 million in 2030 and 152 million in 2050. Therefore, the high burden of dementia is expected to increase the demand for effective therapeutics based on nanomedicine in the management of the disease, which is expected to drive the market growth.

Moreover, the market players are involved in frequent product launches to enhance their market presence. For instance, in October 2020, Medtronic PLC launched its new Adaptix Interbody System, a navigated titanium spinal implant with the Titan nanoLOCK Surface Technology.

However, stringent regulatory issues and the high cost of nanoparticle-assisted medicine, relative to its traditional counterparts, are hindering the growth of the market.

#### Patents are key for phrarma companies to take the risk for developing nanomed

**Bawa, et.al, 05**, Science Direct, “Protecting new ideas and inventions in nanomedicine with patents”, Raj Bawa, MS, PhD, MD '22 is president of Bawa Biotech LLC, a biotech/pharma consultancy and patent law firm based in Ashburn, VA, USA that he founded in 2002. He is an inventor, entrepreneur, professor and registered patent agent licensed to practice before the U.S. Patent & Trademark Office. Currently, he serves as a scientific advisor to Teva Pharmaceutical Industries Ltd. (Israel), is a visiting research scholar at the Pharmaceutical Research Institute of Albany College of Pharmacy (Albany, NY), and is vice president of Guanine, Inc. (Rensselaer, NY). Previously, he was an adjunct professor at Rensselaer Polytechnic Institute (Troy, NY) from 1998-2018, where he received his PhD degree in three years (biophysics/biochemistry), Kapil Bawa, PhD, is Professor of Marketing in the Allen G. Aaronson Department of Marketing and International Business, He has been an invited speaker at industry conferences and forums; has conducted executive development programs in Singapore, Taipei, India, and New York; and has consulted on marketing research projects. He holds a PhD in business from Columbia University, Stephen (Steve) B. Maebius is a partner and intellectual property lawyer with Foley & Lardner LLP. He has led teams within Foley handling a variety of different kinds of IP work, including IP due diligence reviews, infringement and validity opinions, international portfolio management, licensing, litigation with parallel inter partes reviews, reexaminations and interferences, and pharmaceutical patent term extensions. Two IP transactions in which Steve has participated were awarded "Deal of Distinction" status by the Licensing Executives Society. He is a former member of the firm’s Management Committee and former chair of the Intellectual Property Department. Prior to becoming a lawyer, he was a patent examiner in the Biotechnology Group of the U.S. Patent & Trademark Office, and more, URL: [https://www.sciencedirect.com/science/article/abs/pii/S1549963405000675#](https://www.sciencedirect.com/science/article/abs/pii/S1549963405000675)!, KR

As we can see, the time for nanomedicine has come and a classic technologic revolution is unfolding. According to Nanotech Report 2003, venture funds are preferentially going to nanobiotechnology, with 52% of the $900 million in venture capital funding for nanotechnology in 1999 to

2003 going to nanobiotechnology startups [19]. The market for nanobiotechnology has existed for only a few years, but it is expected to exceed $3 billion by 2008, reflecting an annual growth rate of 28% [20].

Commercial nanomedicine, however, is at a nascent stage. Large-scale production challenges, high production costs, the public’s general reluctance to embrace innovative technology without real safety guidelines or products, and a well-established micrometer-scale industry are just a few of the bottlenecks facing early-stage nanotechnology (and nanomedicine) commercialization [5]. However, two major factors that will drive commercialization in nanomedicine in the near future will be federal funding and the expiration of drug patents [9]. Other drivers may include an aging population’s desire for novel drugs and therapies and the impact of bioinformatics on elucidation of the Human Genome Project genetic data. According to Merrill Lynch, 23 of the top global pharmaceutical patents will expire by 2008, accounting for an annual revenue loss of more than $46 billion [21]. Big pharmaceutical companies, currently reluctant to commit major resources to nanotechnology R&D, may well look to nanomedicine research and nano- medicine-related patents to eventually replace some of these lost revenues.

Patents are already shaping the rapidly evolving field of nanoscience generally and nanomedicine in particular. In fact, for the past decade a swarm of nanoscale inventions of biologic or medical relevance has been arriving at the US Patent and Trademark Office (PTO) [2,5,7,12 - 16]. Similar to their importance to the development of the biotechnology and information technology industries, patents will also play a critical role in the success of the global nanomedicine revolution. In the future, nanomedicine will mimic what the biotechnology start-ups of the early 1980s faced, namely, corporate partnerships, licensing, and venture opportunities. Patents are central to all these activities. As we enter this golden era of nanomedicine in the next decade, with the field maturing and the promised breakthroughs accruing, patents will generate licensing revenue, provide leverage in deals and mergers, and reduce the likelihood of infringe- ment. We believe that nanomedicine will almost certainly develop as biotechnology has, through intensive research that produces novel products and processes. We predict that the Bayh-Dole Act of 1980 will also assist nanomedicine- related companies in the way it helped biotechnology startups: by liberalizing the transfer of university-owned patents funded by government grants.

#### Advances in nanomed directly correlate to new medicine innovation and techniques

**Al-Ahmady, Ali-Boucetta, 20**, , 12/9/20, Zahraa, Hanene, Pharmacology Department, Center for Health, Aging, and Understanding Disease (CHAUD), School of Science and Technology, Nottingham Trent University, Nottingham, United Kingdom, School of Pharmacy and Optometry, University of Manchester, Manchester, United Kingdom, Nanomedicine, Drug Delivery & Nanotoxicology Laboratory, The School of Pharmacy, College of Medical & Dental Sciences, University of Birmingham, Birmingham, United Kingdom “Nanomedicine & Nanotoxicology Future Could Be Reshaped Post-COVID-19 Pandemic”, Frontiers in Nanotechnology, URL: <https://www.frontiersin.org/articles/10.3389/fnano.2020.610465/full>, KR

* All parts mentioning that “this will lead to…” etc.. are in reference to people acknowledging the importance of nanomedicine for viruses like covid -- imo

In an attempt to reduce animal testing, new in vitro models are evolving and will hopefully allow us to better understand the potential and toxicological effects of NPs (Stueckle and Roberts, 2019). With the severity of the COVID-19 disease, scientists around the globe quickly started developing COVID-19 animal models (Imai et al., 2020; Singh et al., 2020) but more interestingly relevant 3D models known as organoids to be able to understand the drastic effects of SARS-CoV-2 in vitro (Allison, 2020; Clevers, 2020; Dickson, 2020; Elbadawi and Efferth, 2020; Yang et al., 2020). The joint research efforts in understanding SARS-CoV-2 gives hope that similar efforts will be put together to combat other illnesses such as cancer and neurodegenerative disorders. It has also allowed us to realize that what is seen with SARS-CoV-2 is a form of nanotoxicity and that several new tools such as artificial intelligence have been deployed to understand the disease and develop therapies to combat it (Ahuja et al., 2020; Shaker et al., 2020). Therefore, similar tools should be used in the design of future nanotoxicology studies but also in the development of bioinspired drug delivery systems like viruses (Aulicino et al., 2020).

The Future of Nanomedicine & Nanotoxicology and Conclusive Remarks

Advances in nanotechnology design and fabrication set the foundation for several innovative solutions many of those have been repurposed in response to SARS-CoV-2 which highlights the potential that nanotechnology hold for several applications (Kaushik, 2019; Shin et al., 2020). Accelerated translation of those technologies into the clinic and breaking barriers of regulatory authorities indicates a build of trust in this growing field. The use of lipid nanoparticle, viral based vaccines, viral-like nanoparticles and other hard nanomaterials for vital detection and fabrication of personal protection equipment has been at the forefront in the COVID-19 pandemic. While these technologies are all very promising, it is understandable that some may take many months before proving their potential and may not realize their true impact for COVID- 19 pandemic. However, this will lay the basis for these platform technologies to adapt to other currently existing health challenges and future health crises. We believe that this will be a big push for nanomedical applications and become an incentive for the scientific and industrial communities, stakeholders, funding and regulatory bodies to invest more effort in this ever-growing field.

An interesting feature of nanomedicine is the ability to provide a generic platform that can be easily adapted to suit the application in need. This has been extensively demonstrated during this short period since the start of the pandemic. For example, just by changing the therapeutic molecule encapsulated inside natural or synthetic nanoparticles different examples of COVID-19 vaccine have been developed. As of 29th of October 2020, there are already 13 vaccine candidates in clinical trials that are based on nanotechnology, many are in Phase III and already showing promising results. This is indeed not the case for small drug molecules that must be fully modified and undergo retesting for each new application. Despite such clear differences, specific regulations for nanomedicine approval is still lacking and any new nanomedicine product still has to go through the full clinical approval process (Germain et al., 2020). A recent comparison of the approval rates of nanomedicine products compared to small drug molecules has shown that nanomedicine outperformed traditional drugs 4 times in oncology. Not many differences have been observed in other medical conditions which have been an area of debate recently, questioning whether nanomedicines are still delivering to their potential and whether they have any applicability outside oncology (Park, 2019). We believe that during the coronavirus pandemic the nanomedicine field has shined building up on excising platforms and knowledge and provided innovative excellent therapeutic modalities for COVID-19. Therefore, there is a need to build on existing power and enable the clinical development of nanoproducts to solve unmet clinical needs outside oncology. It is also crucial to address the gaps facing nanomedicine development such as; clinical and business engagement, nanotoxicological aspect of new classes of nanomaterials, mass production to GMP standards and global clarification on regulatory approval both on the physicochemical characterization and biological activity particularly when it comes to multifunctional products. In addition the design of nanotoxicological studies should be expanded to include relevant models (including co-morbidities) and exploit modern tools to understand nanomaterials toxicity. History had shown that crises can create new potential for innovative technology, and this pandemic could be the time to re-shape the future of the nanomedicine and nanotoxicology fields.

#### Nanomed key to prevent massive disease spread and pandemic

Singh et.al, 21, “Insights from nanotechnology in COVID-19: prevention, detection, therapy and immunomodulation”, Future Medicine, Institute of Life Sciences, Priya Singh, Deepika Singh‡ Pratikshya Sa, Priyanka Mohapatra, Auromira Khuntia & Sanjeeb K Sahoo Bhubaneswar, Odisha, 751023, India, Regional Center for Biotechnology, Pali, Haryana, 121001, India (all from the first institute and all in second except for Deppika and Sahoo) URL: <https://www.futuremedicine.com/doi/10.2217/nnm-2021-0004>, KR

As COVID-19 is a highly contagious disease and presently there is a lack of effective treatment and vaccination for the same, preventing the spread of infection is of the utmost importance. Efforts have been made to prevent the transmission of the virus through social distancing, use of masks and PPE and reinforcement of hygiene methods [30]. In this context, several companies are investing in nanotechnology-based products for the development of effective cleaning products and PPE. Research evidence suggests that silver nanoparticles have potent antimicrobial effects and are one of the most useful metal disinfectants against viruses, bacteria and other micro-organisms [30,34]. Silver has been used to control infections since ancient times. The reported mechanisms for its antimicrobial activity are: inhibiting cellular respiration and disrupting metabolic pathways, leading to enhanced production of reactive oxygen species; forming pores and punctures on a bacterial cell wall by interacting with peptidoglycan molecules; and disrupting microbial DNA, thereby inhibiting viral replication [35]. Silver nanoparticles are better antimicrobial agents than their macro counterparts due to the larger surface-to-volume ratio that results from their nano size, which increases the area of reactivity with microbes and enhances cellular uptake and infiltration into biological membranes. Further, the toxicity of silver nanoparticles is size- and shape-dependent. It has been found that the smaller the size, the higher is the toxicity due to higher reactivity and ion release in cells [36].

Working in this direction SHEPROS, a Malaysian company, has developed Nano Silver sanitizer containing a suspension of silver nanoparticles of size 25 nm that kills a broad spectrum of micro-organisms, including viruses, by adversely affecting cellular metabolism and inhibiting cell growth through suppression of the basal metabolism of the electron transport system. This product is available on the market and can be used as a sanitizer against SARS-CoV-2 [37,38]. Similarly, Weinnovate Biosolutions, a startup supported jointly by the Indian Department of Science and Technology and Department of Biotechnology, has developed a nonalcoholic aqueous-based colloidal silver solution which shows its antiviral effect by preventing the synthesis of viral negative-strand RNA and viral budding [39]. Other silver-based nanoformulations marketed as sanitizers and disinfectants are listed in Table 1. NanoTouch Materials, LLC, a USA-based company, has developed NanoSeptic® Surface, which helps in disinfection of public touchpoints, such as door handles, elevator buttons and even the rear of phones, protecting them against SARS-CoV-2. This disinfectant is composed of mineral nanocrystals, which act as a catalyst in the presence of light to create a powerful oxidation reaction that oxidizes organic contaminants [40].

\*table ommited\*

Studies suggest that surface contamination plays a significant role in the transmission of viruses. Several nanomaterials (e.g., titanium dioxide, copper oxide and silver nanoparticles), when associated with polymers and textiles, can reduce the viability of viruses on surfaces, especially in conditions of light exposure [41]. Working in this direction a Chilean/USA-based company, Copper 3D, has developed a nanocomposite face mask named NanoHack in which 5% copper oxide nanoparticles are impregnated in three layers of nonwoven polypropylene filters, bestowing them with excellent antiviral activity against SARS-COV-2. This mask is popular throughout the globe [42]. Promethean Particles Ltd, a UK-based company, is developing copper nanoparticle-embedded polymer fibers in collaboration with leading research facilities and textile companies for use in PPE kits [43]. Further, the development of protective materials that can not only capture the viruses but also kill them would havea far-reaching effect in preventing the spread of COVID-19. For this, nanomaterials that have an inherent antiviral activity, such as silver nanoparticles, graphene oxide (GO), copper oxide nanoparticles, two-dimensional carbides and nitrides can be employed. It was found that coating these nanomaterials on masks and PPE enhances their ability to capture and inactivate viruses [18]. In this context, RESPILON Group, a Czech Republic-based company, has developed ReSpimask® VK, which is available on the market and has 99.9 % filtration efficiency for viruses and bacteria. The filter of the mask is enriched with accelerated copper oxide nanoparticles, due to which it not only intercepts the viruses but also actively kills them [44]. Further, a reusable and recyclable mask can also be developed by depositing a few layers of graphene on a low-melting-temperature unwoven mask. The excellent hydrophobic and photothermal properties of graphene help to repel the incoming aqueous droplets and allow for sunlight sterilization, respectively [45]. This product is still under development and is not yet available on the market. Apart from its usage in cleaning products and PPE, nanotechnology has also been employed in the development of air purifiers to prevent airborne transmission of the SARS-CoV-2 virus. In this context, the TeqAir 200 air ionizer developed by TEQOYA, a France-based company, is already on the market. As the size of SARS-CoV-2 is close to the median of the particle sizes for which TEQOYA air purifiers are efficient, they would be expected to reduce the concentration of SARS-CoV-2 in the air [46]. Apart from those mentioned above, we have summarized other examples of nanotechnology-based products to prevent COVID-19 spread in Table 1.

Past global experiences of viral outbreaks suggest that immunizing individuals is the only prevention from the future influence of viral infections, hence biomedical intervention toward vaccination is the prime focus of research. Vaccination has served as the most effective public health program that can prevent or control the spread of contagious disease and it seems to be the only hope to combat COVID-19. The uncontrolled increase in the number of SARS-CoV-2 infected cases and the emergence of new strains of SARS-CoV-2 has emphasized the urgent global need for vaccine development. Vaccination is the process of immunization whereby the host immune system is activated to induce long-term immune memory, which protects against future infection by a pathogen. It prevents infectious diseases by inducing a controlled immune response against the pathogen by mimicking its natural interaction with the host immune system. Vaccines consist of two major components: an antigen, which targets the immune system to activate it, and an adjuvant, which is coadministered with vaccines to potentiate or modulate the immune system against the antigen [47].

Conventional vaccines include either live attenuated pathogens which have a risk of reversion to virulent strains, or inactivated pathogens which generally display weak immunogenicity. This has led to the development of next-generation subunit vaccines like RNA or DNA encoding viral antigens, which could overcome these limitations; however, they suffer from low immunogenicity [48]. Because all of these are proteins which are easily degraded in the body, successful vaccines are still difficult to achieve for various infectious diseases. Nanotechnology-based platforms have been used for specific delivery and sustainable release of antigens, adjuvants and immunoregulatory agents [49] as they can control improper immune stimulation, loss of bioactivity of immunoactive agents during circulation, and off-target side effects. Pharmaceutical companies are using nanoparticles for vaccine development and delivery (Table 2). Companies like BioNTech/Pfizer and Moderna have encapsulated their mRNA vaccines in lipid nanoparticles [50,51], whereas Oxford/AstraZeneca and CanSino [52] have incorporated the antigen-encoding sequence into the DNA of adenovirus [53]. On the other hand, Novavax, Inc., a nanotechnology-based company, has conjugated the S protein of SARS-CoV-2 onto the surface of nano-sized virus-like particles [54] for effective delivery of vaccines to the host body [55]. The next-generation vaccines like subunit vaccines rely on adjuvants that can enhance the vaccine’s potency in elevating the immune response against specific antigens. In this regard, the nano-scale adjuvant can be of great potential in encapsulating and presenting these antigens to the immune cells to improve the immunogenicity in groups that respond poorly to vaccines [56]. Clinically relevant vaccine adjuvants like aluminum-based nanoparticles have been studied for their dendritic cell (DC) cross-presentation efficiency and subsequent induction of cellular immunity. Aluminum adjuvants are known to promote strong default T helper 2 cell differentiation and antibody production through DCs but lack the ability to induce a T helper 1 cell immune response. This can be improved by the use of alum nanoparticles in combination with Toll-like receptor ligands to enhance the cross presentations by DCs [57]. Knudesen et al. compared and categorized different clinical-grade nanoparticle-based adjuvants like alum, MF59 (R), GLA-SE, IC31 (R) and CAF01 based on their immune profiles and protective efficacy to give insights for the rational development of next-generation vaccines for humans [58]. Recently, Novavax marked the entry of its coronavirus vaccine candidate NVX-CoV2373, which includes the company’s proprietary Matrix-M™ adjuvant, to clinical trials [59]. Thus, owing to the flexible nature of nanotechnology, nanoparticles can be engineered to strengthen immune stimulation with desired adjuvant activities.

#### XA Disease cause extinction

## 3

#### Existential threats outweigh – all life has infinite value and extinction eliminates the possibility for future generations – err neg, because of innate cognitive biases

GPP 17 (Global Priorities Project, Future of Humanity Institute at the University of Oxford, Ministry for Foreign Affairs of Finland, “Existential Risk: Diplomacy and Governance,” Global Priorities Project, 2017, <https://www.fhi.ox.ac.uk/wp-content/uploads/Existential-Risks-2017-01-23.pdf>,

1.2. THE ETHICS OF EXISTENTIAL RISK In his book Reasons and Persons, Oxford philosopher Derek Parfit advanced an influential argument about the importance of avoiding extinction: I believe that if we destroy mankind, as we now can, this outcome will be much worse than most people think. Compare three outcomes: (1) Peace. (2) A nuclear war that kills 99% of the world’s existing population. (3) A nuclear war that kills 100%. (2) would be worse than (1), and (3) would be worse than (2). Which is the greater of these two differences? Most people believe that the greater difference is between (1) and (2). I believe that the difference between (2) and (3) is very much greater. ... The Earth will remain habitable for at least another billion years. Civilization began only a few thousand years ago. If we do not destroy mankind, these few thousand years may be only a tiny fraction of the whole of civilized human history. The difference between (2) and (3) may thus be the difference between this tiny fraction and all of the rest of this history. If we compare this possible history to a day, what has occurred so far is only a fraction of a second.65 In this argument, it seems that Parfit is assuming that the survivors of a nuclear war that kills 99% of the population would eventually be able to recover civilisation without long-term effect. As we have seen, this may not be a safe assumption – but for the purposes of this thought experiment, the point stands. What makes existential catastrophes especially bad is that they would “destroy the future,” as another Oxford philosopher, Nick Bostrom, puts it.66 This future could potentially be extremely long and full of flourishing, and would therefore have extremely large value. In standard risk analysis, when working out how to respond to risk, we work out the expected value of risk reduction, by weighing the probability that an action will prevent an adverse event against the severity of the event. Because the value of preventing existential catastrophe is so vast, even a tiny probability of prevention has huge expected value.67 Of course, there is persisting reasonable disagreement about ethics and there are a number of ways one might resist this conclusion.68 Therefore, it would be unjustified to be overconfident in Parfit and Bostrom’s argument. In some areas, government policy does give significant weight to future generations. For example, in assessing the risks of nuclear waste storage, governments have considered timeframes of thousands, hundreds of thousands, and even a million years.69 Justifications for this policy usually appeal to principles of intergenerational equity according to which future generations ought to get as much protection as current generations.70 Similarly, widely accepted norms of sustainable development require development that meets the needs of the current generation without compromising the ability of future generations to meet their own needs.71 However, when it comes to existential risk, it would seem that we fail to live up to principles of intergenerational equity. Existential catastrophe would not only give future generations less than the current generations; it would give them nothing. Indeed, reducing existential risk plausibly has a quite low cost for us in comparison with the huge expected value it has for future generations. In spite of this, relatively little is done to reduce existential risk. Unless we give up on norms of intergenerational equity, they give us a strong case for significantly increasing our efforts to reduce existential risks. 1.3. WHY EXISTENTIAL RISKS MAY BE SYSTEMATICALLY UNDERINVESTED IN, AND THE ROLE OF THE INTERNATIONAL COMMUNITY In spite of the importance of existential risk reduction, it probably receives less attention than is warranted. As a result, concerted international cooperation is required if we are to receive adequate protection from existential risks. 1.3.1. Why existential risks are likely to be underinvested in There are several reasons why existential risk reduction is likely to be underinvested in. Firstly, it is a global public good. Economic theory predicts that such goods tend to be underprovided. The benefits of existential risk reduction are widely and indivisibly dispersed around the globe from the countries responsible for taking action. Consequently, a country which reduces existential risk gains only a small portion of the benefits but bears the full brunt of the costs. Countries thus have strong incentives to free ride, receiving the benefits of risk reduction without contributing. As a result, too few do what is in the common interest. Secondly, as already suggested above, existential risk reduction is an intergenerational public good: most of the benefits are enjoyed by future generations who have no say in the political process. For these goods, the problem is temporal free riding: the current generation enjoys the benefits of inaction while future generations bear the costs. Thirdly, many existential risks, such as machine superintelligence, engineered pandemics, and solar geoengineering, pose an unprecedented and uncertain future threat. Consequently, it is hard to develop a satisfactory governance regime for them: there are few existing governance instruments which can be applied to these risks, and it is unclear what shape new instruments should take. In this way, our position with regard to these emerging risks is comparable to the one we faced when nuclear weapons first became available. Cognitive biases also lead people to underestimate existential risks. Since there have not been any catastrophes of this magnitude, these risks are not salient to politicians and the public.72 This is an example of the misapplication of the availability heuristic, a mental shortcut which assumes that something is important only if it can be readily recalled. Another cognitive bias affecting perceptions of existential risk is scope neglect. In a seminal 1992 study, three groups were asked how much they would be willing to pay to save 2,000, 20,000 or 200,000 birds from drowning in uncovered oil ponds. The groups answered $80, $78, and $88, respectively.73 In this case, the size of the benefits had little effect on the scale of the preferred response. People become numbed to the effect of saving lives when the numbers get too large. 74 Scope neglect is a particularly acute problem for existential risk because the numbers at stake are so large. Due to scope neglect, decision-makers are prone to treat existential risks in a similar way to problems which are less severe by many orders of magnitude. A wide range of other cognitive biases are likely to affect the evaluation of existential risks.75

#### Math --- prioritize avoiding existential risk

Bostrom 11

Nick Bostrom, Professor in the Faculty of Philosophy & Oxford Martin School, Director of the Future of Humanity Institute, and Director of the Programme on the Impacts of Future Technology at the University of Oxford, recipient of the 2009 Eugene R. Gannon Award for the Continued Pursuit of Human Advancement, holds a Ph.D. in Philosophy from the London School of Economics, 2011 (“Existential Risk: The most important task for all humanity” Draft of a Paper published on ExistentialRisk.com, <http://www.existential-risk.org/concept.html>)AS

But even this reflection fails to bring out the seriousness of existential risk. What makes existential catastrophes especially bad is not that they would show up robustly on a plot like the one in figure 3, causing a precipitous drop in world population or average quality of life. Instead, their significance lies primarily in the fact that they would destroy the future. The philosopher Derek Parfit made a similar point with the following thought experiment: I believe that if we destroy mankind, as we now can, this outcome will be *much* worse than most people think. Compare three outcomes: (1) **Peace.** (2) **A nuclear** **war that kills 99%** of the world’s existing population. (3) **A nuclear war that kills 100%.** (2) would be worse than (1), and (3) would be worse than (2). Which is the greater of these two differences? Most people believe that the greater difference is between (1) and (2). **I believe that the difference between (2) and (3) is *very much* greater.** … The Earth will remain habitable for at least another billion years. Civilization began only a few thousand years ago. If we do not destroy mankind, these few thousand years may be only a tiny fraction of the whole of civilized human history. The difference between (2) and (3) may thus be the difference between this tiny fraction and all of the rest of this history. If we compare this possible history to a day, what has occurred so far is only a fraction of a second. (10: 453-454) To calculate the loss associated with an existential catastrophe, we must consider how much value would come to exist in its absence. **It turns out that the ultimate potential for Earth-originating intelligent life is literally astronomical**. One gets a large number even if one confines one’s consideration to the potential for biological human beings living on Earth. If we suppose with Parfit that our planet will remain habitable for at least another billion years, and we assume that at least one billion people could live on it sustainably, then the potential exist for at least 1018 human lives. These lives could also be considerably better than the average contemporary human life, which is so often marred by disease, poverty, injustice, and various biological limitations that could be partly overcome through continuing technological and moral progress. However, the relevant figure is not how many people could live on Earth but how many descendants we could have in total. One lower bound of the number of biological human life-years in the future accessible universe (based on current cosmological estimates) is 1034 years.[[7]](http://www.existential-risk.org/concept.html#_ftn7) Another estimate, which assumes that future minds will be mainly implemented in computational hardware instead of biological neuronal wetware, produces a lower bound of 1054 human-brain-emulation subjective life-years (or 1071 basic computational operations).(4)[[8]](http://www.existential-risk.org/concept.html#_ftn8) If we make the less conservative assumption that future civilizations could eventually press close to the absolute bounds of known physics (using some as yet unimagined technology), we get radically higher estimates of the amount of computation and memory storage that is achievable and thus of the number of years of subjective experience that could be realized.[[9]](http://www.existential-risk.org/concept.html#_ftn9) Even if we use the most conservative of these estimates, which entirely ignores the possibility of space colonization and software minds, we find that the expected loss of an existential catastrophe is greater than the value of 1018 human lives. This implies that the expected value of reducing existential risk by a mere *one millionth of one percentage point* is at least ten times the value of a billion human lives. The more technologically comprehensive estimate of 1054 human-brain-emulation subjective life-years (or 1052 lives of ordinary length) makes the same point even more starkly. **Even if we give this allegedly lower bound on the cumulative output potential of a technologically mature civilization a mere 1% chance of being correct, we find that the expected value of reducing existential risk by a mere *one billionth of one billionth of one percentage point* is worth a hundred billion times as much as a billion human lives**. One might consequently argue that even the tiniest reduction of existential risk has an expected value greater than that of the definite provision of any “ordinary” good, such as the direct benefit of saving 1 billion lives. And, further, that the absolute value of the *indirect* effect of saving 1 billion lives on the total cumulative amount of existential risk—positive or negative—is almost certainly larger than the positive value of the direct benefit of such an action.[[10]](http://www.existential-risk.org/concept.html#_ftn10)

#### Anticipating extinction breeds empathy and entangled care. Turns moral reasoning

Offord, 17—Faculty of Humanities, School of Humanities Research and Graduate Studies, Bentley Campus (Baden, “BEYOND OUR NUCLEAR ENTANGLEMENT,” Angelaki, 22:3, 17-25, dml) [ableist language modifications denoted by brackets]

You are steered towards overwhelming and inexplicable pain when you consider the nuclear entanglement that the species Homo sapiens finds itself in. This is because the fact of living in the nuclear age presents an existential, aesthetic, ethical and psychological challenge that defines human consciousness. Although an immanent threat and ever-present danger to the very existence of the human species, living with the possibility of nuclear war has infiltrated the matrix of modernity so profoundly as to paralyse [shut down] our mind-set to respond adequately. We have chosen to ignore the facts at the heart of the nuclear program with its dangerous algorithm; we have chosen to live with the capacity and possibility of a collective, pervasive and even planetary-scale suicide; and the techno-industrial-national powers that claim there is “no immediate danger” ad infinitum.8

This has led to one of the key logics of modernity's insanity. As Harari writes: “Nuclear weapons have turned war between superpowers into a mad act of collective suicide, and therefore forced the most powerful nations on earth to find alternative and peaceful ways to resolve conflicts.”9 This is the nuclear algorithm at work, a methodology of madness. In revisiting Jacques Derrida in “No Apocalypse, Not Now (Full Speed Ahead, Seven Missiles, Seven Missives),”10 who described nuclear war as a “non-event,” it is clear that the pathology of the “non-event” remains as active as ever even in the time of Donald Trump and Kim Jong-un with their stichomythic nuclear posturing.

The question of our times is whether we have an equal or more compelling capacity and willingness to end this impoverished but ever-present logic of pain and uncertainty. How not simply to bring about disarmament, but to go beyond this politically charged, as well as mythological and psychological nuclear algorithm? How to find love amidst the nuclear entanglement; the antidote to this entanglement? Is it possible to end the pathology of power that exists with nuclear capacity? Sadly, the last lines of Nitin Sawhney's “Broken Skin” underscore this entanglement:

Just 5 miles from India's nuclear test site

Children play in the shade of the village water tank

Here in the Rajasthan desert people say

They're proud their country showed their nuclear capability.11

As an activist scholar working in the fields of human rights and cultural studies, responding to the nuclear algorithm is an imperative. Your politics, ethics and scholarship are indivisible in this cause. An acute sense of care for the world, informed by pacifist and non-violent, de-colonialist approaches to knowledge and practice, pervades your concern. You are aware that there are other ways of knowing than those you are familiar and credentialed with. You are aware that you are complicit in the prisons that you choose to live inside,12 and that there is no such thing as an innocent bystander. You use your scholarship to shake up the world from its paralysis, abjection and amnesia; to unsettle the epistemic and structural violence that is ubiquitous to neoliberalism and its machinery; to create dialogic and learning spaces for the work of critical human rights and critical justice to take place. All this, and to enable an ethics of intervention through understanding what is at the very heart of the critical human rights impulse, creating a “dialogue for being, because I am not without the other.”13

Furthermore, as a critical human rights advocate living in a nuclear armed world, your challenge is to reconceptualise the human community as Ashis Nandy has argued, to see how we can learn to co-exist with others in conviviality and also learn to co-survive with the non-human, even to flourish. A dialogue for being requires a leap into a human rights frame that includes a deep ecological dimension, where the planet itself is inherently involved as a participant in its future. This requires scholarship that “thinks like a mountain.”14 A critical human rights approach understands that it cannot be simply human-centric. It requires a nuanced and arresting clarity to present perspectives on co-existence and co-survival that are from human and non-human viewpoints.15

Ultimately, you realise that your struggle is not confined to declarations, treaties, legislation, and law, though they have their role. It must go further to produce “creative intellectual exchange that might release new ethical energies for mutually assured survival.”16 Taking an anti-nuclear stance and enabling a post-nuclear activism demands a revolution within the field of human rights work. Recognising the entanglement of nuclearism with the Anthropocene, for one thing, requires a profound shift in focus from the human-centric to a more-than-human co-survival. It also requires a fundamental shift in understanding our human culture, in which the very epistemic and rational acts of sundering from co-survival with the planet and environment takes place. In the end, you realise, as Raimon Panikkar has articulated, “it is not realistic to toil for peace if we do not proceed to a disarmament of the bellicose culture in which we live.”17 Or, as Geshe Lhakdor suggests, there must be “inner disarmament for external disarmament.”18 In this sense, it is within the cultural arena, our human society, where the entanglement of subjective meaning making, nature and politics occurs, that we need to disarm.

#### Ext impacts turn structural violence

## Case

### Top Level

#### Generic companies are horrible and results in counterfeits

Fox 17, Erin. "How pharma companies game the system to keep drugs expensive." Harvard Business Review (April 6, 2017), https://hbr. org/2017/04/how-pharma-companies-game-the-system-to-keep-drugs-expensive (last visited on November 22, 2019) (2017). (director of Drug Information at University of Utah Health)//Elmer // recut MNHS NL

Problems with generic drug makers Although makers of a branded drug are using a variety of tactics to create barriers to healthy competition, generic drug companies are often not helping their own case. In 2015, there were 267 recalls of generic drug products—more than one every other day. These recalls are for quality issues such as products not dissolving properly, becoming contaminated, or even being outright counterfeits. A few high-profile recalls have shaken the belief that generic drugs are truly the same. In 2014, the FDA withdrew approval of Budeprion XL 300 — Teva’s generic version of GlaxoSmithKline’s Wellbutrin XL. Testing showed the drug did not properly release its key ingredient, substantiating consumers’ claims that the generic was not equivalent. In addition, concerns about contaminated generic Lipitor caused the FDA to launch a $20 million initiative to test generic products to ensure they are truly therapeutically equivalent. In some cases, patent law also collides with the FDA’s manufacturing rules. For example, the Novartis patent for Diovan expired in 2012. Ranbaxy received exclusivity for 180 days for the first generic product. However, due to poor quality manufacturing, Ranbaxy couldn’t obtain final FDA approval for its generic version. The FDA banned shipments of Ranbaxy products to the United States. Ranbaxy ended up paying a $500 million fine, the largest penalty paid by a generic firm for violations. Due to these protracted problems with the company that had won exclusivity, a generic product did not become available until 2014. The two-year delay cost Medicare and Medicaid at least $900 million. Ranbaxy’s poor-quality manufacturing also delayed other key generic products like Valcyte and Nexium. Ironically, it was Mylan—involved in its own drug pricing scandal over its EpiPen allergy-reaction injector—that filed the first lawsuit to have the FDA strip Ranbaxy of its exclusivity. Mylan made multiple attempts to produce generic products but was overruled in the courts.

#### Nope! The market is flooded already and the profit incentive is for prescription so the plan by definition cant solve the existing opioid crisis. Uniqueness overwhelms aff solvency.

Mineta 10 [David Mineta, Decriminalization would increase the use and the economic and social costs of drugs.,America’s Quarterly,2010,https://www.americasquarterly.org/node/1915,3-1-2019 amrita]

Legal drugs are cheap and easy to obtain. High profits make the addiction business lucrative. Consider the Dutch experiment with commercialized marijuana: after “coffee shops” were widely promoted in the Netherlands, the rate of regular marijuana use among 18-to-20-year-olds more than doubled.3 Because of crime, drug tourism and public nuisance problems, the Dutch have severely restricted the number of coffee shops where marijuana is sold commercially. The U.S. does not need another vice industry dedicated to promoting and supporting addiction. Think about the tobacco industry, dominated by lobbyists, glorified by advertisements, promoted by global marketing designed to skirt domestic regulation, and defended by “scientific” institutes determined to present the drug in the softest possible light. Do we want the same for marijuana and cocaine? Why not legalize and tax drugs to gain much-needed revenue? Our experience with alcohol and tobacco shows that tax revenue from these substances does not even begin to cover the costs associated with them. Federal excise taxes collected on alcohol in 2002 totaled $8.3 billion, which is only 4.5 percent of the $184 billion in alcohol-related costs, such as lost productivity and increased health care spending. With tobacco, we spend more than $200 billion annually on social costs, but collect only about $25 billion in taxes. Illegal drugs represented about $181 billion in social costs in 2002—a figure that would increase, because of increased use, under legalization.4 A central tenet of legalization is that it would eliminate underground drug markets, since drugs would be available openly. But there is no reason to believe legalization would bring about this result. Instead, government would have to regulate a new, legal market while continuing to pay for the negative effects of an underground market whose suppliers have little economic incentive to disappear. When the Canadians instituted a cigarette tax creating a mere $2-per-pack differential versus the U.S. price, it created such a huge smuggling problem that Canada was forced to repeal the tax increase.5 The enthusiasm of advocates for decriminalized and regulated drugs should be tempered by our experience with prescription drugs like OxyContin© and other analgesic opioids. These are legal, highly regulated drugs, dispensed under supervision; yet unintentional U.S. drug overdose death rates have increased roughly five-fold between 1990 and 2006, due primarily to deaths attributed to narcotic pain relievers. The idea that legalizing drugs will lessen drug abuse contradicts research showing that misperceptions of prescription drugs as less harmful actually contribute to their abuse.6

#### Medicaid is a huge alt cause, Current Medicare only provides full coverage for Opioids.

**Their author Hemel & Ouellette 20**[Daniel J Hemel, Assistant professor of law and Ronald H.Coase Research scholar@ university of Chicago law school. Lisa Larrimore Ouellette, Associate professor of law and Justin M. January-June 2020, “Innovation institutions and the opioid crisis” Journal of Law and the Biosciences, Volume 7, Issue 1, <https://doi.org/10.1093/jlb/lsaa001> | DD JH

Demand-side subsidies are another set of institutions that perhaps could have but did not correct IP’s flaws as the opioid crisis sprung up and spread. The largest government programs providing subsidies for prescription drugs are Medicare Part D and Medicaid, which are administered at the federal level by the Centers for Medicare & Medicaid Services (CMS). Medicare Part D is an opt-in federal benefit for people over 65 or with certain disabilities.165 The formula for benefits is complex, but in 2019, Medicare Part D covers 75 per cent of brand-name costs up to an initial coverage limit of $3820, after a $415 deductible.166 Medicaid is a joint federal-state program that provides healthcare coverage for low-income individuals. Medicaid beneficiaries receive full coverage for prescription drugs, with some states requiring a small co-pay.167 Within these limits, Medicare and Medicaid have generally reimbursed the costs of prescription opioids such as OxyContin. Indeed, in 2016, opioids were provided to one-third of Medicare Part D beneficiaries (14.4 million individuals).168 The nearly 80 million opioid prescriptions cost taxpayers $4.1 billion.169 From 2011 to 2016, Medicaid reimbursed an average of 30 million opioid prescriptions per year.170 In contrast, even though almost half of nonelderly adults with opioid use disorder are Medicaid beneficiaries, many states deny or limit coverage for medication-assisted treatments such as Suboxone, including by imposing barriers such as prior authorization requirements.171 Part of the blame for the proliferation of opioids and the more limited spread of opioid addiction treatments may thus lie with the institutional design choices that led to subsidies for opioids and not for addiction treatments.