## 1NC-Off

#### CP: Member nations of the World Trade Organization should establish a sui generis right for holders of traditional knowledge.

#### That solves the aff by preventing biopiracy while ensuring indigenous communities can use IP as an economic bargaining chip

Garcia 07 [(Javier, attorney at Perkins Coie LLP in Seattle, Washington, J.D. from Gonzaga University School of Law and B.A. from the University of Redlands) “Fighting Biopiracy: The Legislative Protection of Traditional Knowledge,” Berkeley La Raza Law Journal,” 3/2007] JL

The establishment of a sui generis right for holders of traditional knowledge would provide compensation for communities that do not otherwise qualify for patent protection. Under Article 8 of the TRIPS agreement, countries can adopt legislation to protect "sectors of vital importance to their socio-economic and technological development."'' 7 s A sui generis right could therefore be adopted in conjunction with domestic legislation as a catch-all provision pursuant to Article 8. The nature of a traditional knowledge sui generis right is detailed below.

Establishing a sui generis right for traditional knowledge holders could resolve problems stemming from patent law's limited term of protection. 7 6 Foremost among them is that certain forms of traditional knowledge may fall under the realm of public domain, and thus, be exempt from any patent protection. 7 Likewise, some traditional knowledge holders may also seek terms of protection that are incompatible with patent law, seek to prevent any sharing of their knowledge, or seek exclusive rights over their knowledge for an unlimited amount of time. 7 1 Such efforts would prove at odds with current patent law, which only rewards patent . . ... . '79 protection for a limited period of time to enable further innovations. Although a sui generis right could address some of these concerns, traditional knowledge holders will likely have to make sacrifices to avoid the misappropriation of their intellectual property rights. For example, the documentation of traditional knowledge will ultimately submit any documented traditional knowledge to the public domain. This may prove contradictory to the values of some traditional knowledge holders who wish to maintain ownership and control of their knowledge forever; nonetheless, it is an adaptation that must be made to avoid the exploitation of traditional knowledge. A traditional knowledge sui generis right could also overcome patent law's relative incompatibility with communal ownership. Confronting this hurdle is necessary since it may be against communal customs for an individual to own knowledge developed and modified over many generations.' Recognition of a sui generis right could also overcome barriers posed by international patent standards that require that an invention be new and subject to industrial applicability. I5 '

Finally, a sui generis right could modify patent law with respect to traditional knowledge holders to allow benefit sharing among communities not considered inventors under current patent law. For example, in 2004, the University of California, Berkeley, signed an agreement with the Samoan government to isolate from an indigenous tree the gene for a promising anti-AIDS drug and to share any royalties from sale of a gene-derived drug with the people of Samoa. 182 The agreement, signed by the prime minister of Samoa and U.C. Berkeley's Vice Chancellor for research, allocates Samoa's fifty percent share to the government, villages, and the families of healers who first shared the knowledge of how to use the plant. 18 Under the agreement, any commercial developer must "first negotiate an equitable benefit-sharing agreement with Samoa."' 184 This landmark agreement could be duplicated in Mexico under domestic legislation. Agreements like these may pose a problem given the amount of government corruption in Mexico and other 185 developing countries. Nevertheless, it may be the lesser of the two evils. Under domestic legislation or a sui generis right, compensation from patent royalties would be guaranteed at least to the State and would hopefully be spent in Mexico, rather than abroad. Furthermore, local government officials may be more entitled to compensation from profitable traditional knowledge than foreign, corporations.

An effective dispute resolution mechanism is necessary to make domestic legislation successful. First, it allows a country to establish jurisdiction over foreign companies that enter the country to extract resources. The mere existence of a dispute resolution process places foreign companies on notice that they are subject to jurisdiction and criminal or civil liability for violative conduct, such as environmental damage resulting from the excavation of resources, misappropriation of intellectual property rights, and civil rights violations. Currently, foreign companies are entering sovereign territories without permission, but governments do not have the legislation in place to regulate them effectively. 186 A dispute resolution mechanism will force entities to abide by the laws and regulations established by the proposed legislation.

The mechanism should provide a dispute resolution process for domestic conflicts and conflicts involving other sovereign states, thus requiring two levels of dispute-resolution. The first level should be for States to resolve disputes. The second level should provide a dispute-resolution mechanism for private parties who claim ownership of traditional knowledge, such as two tribal communities claiming ownership over the same traditional knowledge. 189 This level of dispute resolution will adjudicate intellectual property rights among all domestic entities, including indigenous communities, local inventors, corporations, or any other patent applicants claiming ownership of traditional knowledge.

The protection of traditional knowledge is vital to underdeveloped countries. Traditional knowledge is one of the few resources and bargaining chips these countries still retain. Accordingly, Mexico and other underdeveloped countries should protect themselves from the misappropriation of traditional knowledge that has already begun. Adopting domestic legislation provides the best means to regulate and control foreign entities seeking to extract and exploit traditional knowledge from vulnerable indigenous communities.

#### It competes – the CP is anti-topical action

IPTF 04 [(International Intellectual Property Institute, not-for-profit 501 corporation that provides education and training on intellectual property) “Is a Sui Generis System Necessary?” 1/14/2004] JL

WIPO and the WTO are in the process of establishing international rules for the protection of biodiversity. One of the key questions under consideration is whether or not to create a sui generis system to establish the norms and rules for protection. A “sui generis” system simply means “one that is of its own kind1 ”. In this case it refers to the creation of a new national law or the establishment of international norms that would afford protection to intellectual property dealing with genetic resources -or biodiversity - and the biotechnology that might result. It also refers to a law that might protect creations, inventions, models, drawings, designs, innovations contained in images, figures, symbols, petroglyphs, art, music, history and other traditional artistic expressions.

## 1NC-Off

#### Biotech industry strong now.

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

As the pandemic spread across the globe in early 2020, biotech leaders were initially pessimistic, reassessing their cash position and financing constraints. When McKinsey and BioCentury interviewed representatives from 106 biotech companies in May 2020,4 half of those interviewed were expecting delays in financing, and about 80 percent were tight on cash for the next two years and considering trade-offs such as deferring IPOs and acquisitions. Executives feared that valuations would decline because of lower revenue projections and concerns about clinical-trial delays, salesforce-effectiveness gaps, and other operational issues.

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

#### IP protections for traditional knowledge are key to innovation

Ngatcha 20 [(Beatrice T., lawyer and patent agent in Lavery’s intellectual property group, patent agent registered to practice in Canada and the United States,member of the Quebec Bar, doctoral degree in chemistry from *Université Laval* and post-doctoral fellow at the National Research Council in Ottawa) “Natural Products and Pharmaceutical Innovations: What are the Patent Options?” Lavery, 5/29/2020] JL

Natural products play an important role in pharmaceutical innovation. They are active components in many medicines. For example, nearly half of the small molecules used to treat cancer are natural products or directly derived from natural products.[1](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#01) They are also components of vaccines.

The pharmaceutical industry is constantly seeking access to natural products and the traditional knowledge associated with them. These include plants (roots, bark, leaves), micro-organisms (terrestrial and marine), toxins, venoms and other natural biological agents.

In the current race to develop a drug and/or vaccine against COVID-19, natural products or derivatives are surely worth considering as a starting point.

The harvesting of natural resources for use by the pharmaceutical industry is usually carried out by partners such as traditional healers, farmers, academics or businesses. Thus, the process usually involves several stakeholders, including providers and users of natural resources and associated traditional knowledge, which are often located in different parts of the world.

Fair and equitable collaboration in such a context requires well-developed collaboration agreements and access and benefit-sharing agreements. Various instruments of international law encourage the signing of such agreements, including:

The Convention on Biological Diversity (CBD), which recognizes the sovereignty of states over their natural resources. The CBD sets out fundamental principles to regulate access and benefit-sharing, including that access to natural resources, their use and the sharing of benefits arising from them should be based on “mutually agreed terms.”[2](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#02)

The Nagoya Protocol covers the sharing of the results of research and development, the payment of royalties and joint ownership of intellectual property (IP) rights.[3](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#03)

The World Intellectual Property Organization (WIPO) has developed a guide to assist providers and users of natural resources and associated traditional knowledge in the negotiation and establishment of IP clauses in access and benefit-sharing agreements. The guide describes how IP rights can be exploited and managed to achieve the desired objectives, and how the benefits arising from the use can be created and shared in a fair and equitable manner, thereby promoting the conservation and use of biodiversity.[4](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#04)

Furthermore, research and development activities in the pharmaceutical industry are known to be associated with high risk and high investment costs. Indeed, it is widely recognized that the process to develop a drug can take up to 15 years, only about 16% of molecules entering the clinical phase will be approved, and only 1 in 5 marketed drugs generates revenues equal to or greater than the research and development costs involved.[5](https://www.lavery.ca/en/publications/our-publications/3225-natural-products-and-pharmaceutical-innovations-what-are-the-patent-options-ip-intellectual-property.html#05)

In the pharmaceutical industry, intellectual property, especially patents and data protection, is thus considered an essential instrument for securing the economic benefits of an innovation.

Efforts in this intense period of development of a drug/vaccine against COVID-19 are of course focused on the technical aspects directly related to research and development. Nevertheless, those involved should not lose sight of the importance of collaboration agreements and access and benefit-sharing agreements.

#### 50% of medicine comes from IK

Eiland 08 [Dr. Eiland received a doctorate in Oriental Archaeology from Oxford University and an LLM from the Munich Intellectual Property Law Center], “Patenting Traditional Medicine”, Nomos Verlagsgesellschaft mbH & Co. KG, pg. 7-10, 2008 //SLC PK

* TM = traditional medicine

In 1982, it was estimated that about 50 % of all filled prescriptions in the US originated from drugs that were derived – one way or another – from natural substances. This generated US sales of about 20 billion.4 Another estimate found that 3/4 of the plants used in prescription drugs originally came to the attention of drug companies because of their use in TM.5 In 1995, the worldwide market value of TM derived pharmaceuticals was estimated to be $43 billon.6 While one could argue about the precise values, TM has significant pharmaceutical applications. Drug companies are interested in acquiring TM, both natural substances, as well as the knowledge about how to use them.

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

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

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

#### Extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

## 1NC-Off

#### WTO is near consensus on fisheries subsidies – success will require continued focus, flexibility, and cooperation among members

WTO 7/15 [(World Trade Organization) “WTO members edge closer to fisheries subsidies agreement,” News and Events, 7/15/2021] JL

During an all-day meeting with 104 ministers and heads of delegation, WTO members pledged to conclude the negotiations soon and certainly before the WTO's Ministerial Conference in early December, and to empower their Geneva-based delegations to do so. Members also confirmed that the negotiating text currently before them can be used as the basis for the talks to strike the final deal.

“I feel new hope this evening. Because ministers and heads of delegation today demonstrated a strong commitment to moving forward and doing the hard work needed to get these negotiations to the finish line. I applaud you for this. In 20 years of negotiations, this is the closest we have ever come towards reaching an outcome — a high-quality outcome that would contribute to building a sustainable blue economy,” said Director-General Ngozi Okonjo-Iweala.

“One fundamental conclusion that I draw from your interventions today is that members are ready to use the text as the basis for future negotiations. A second takeaway from today was that there is universal agreement about the importance of the food and livelihood security of artisanal fishers in developing and least developed countries. The prospect for a deal in the autumn ahead of our Ministerial Conference has clearly improved.”

The UN Food and Agriculture Organization estimates that one-third of global fish stocks are overfished and most of the rest is fully exploited. This is up from 10% in 1970 and 27% in 2000. Depleted stocks threaten the food security of low-income coastal communities, and the livelihoods of poor and vulnerable fishers who must go further and further from shore only to bring back smaller and smaller hauls.

Each year, governments hand out around $35 billion in fisheries subsidies, two-thirds of which go to commercial fishers. These subsidies keep at sea vessels which would otherwise be economically unviable. World leaders in 2015 made a fisheries subsidies agreement by 2020 part of the Sustainable Development Goals and trade ministers reaffirmed this pledge in 2017.

The negotiations on fisheries subsidies disciplines have been ongoing for nearly 20 years. Although there has been recent progress thanks to the intensive work that led to the development of the negotiating text on which members are working, the lack of political impetus in the talks to close the remaining gaps inspired Director-General Okonjo-Iweala to call this meeting of ministers.

Among the thorniest issues to resolve has been how to extend special and differential treatment to developing and least developed country WTO members while preserving the overall objective of enhanced sustainability of the oceans. Ministers said that the livelihoods and food security of poor and vulnerable artisanal fishers in developing and least developed countries were of great importance, as was preserving the sustainability objective of the negotiations.

Amb. Santiago Wills of Colombia, who chairs the Rules Negotiating Group overseeing the fisheries subsidies negotiations, said he had received some valuable inputs from the discussions. He now has greater clarity on the path forward and the next steps that would be required to harvest an agreement. He will be consulting with the Director-General and WTO members about charting the path forward for the next stage of the talks.

“I am very heartened by the responses and messages that we have heard today. What we sought from ministers today was political guidance to help close these negotiations soon. And we did hear that guidance. We have been given the ingredients to reach a successful conclusion; a commitment to finish well ahead of our Ministerial Conference a text that can be the platform for this final stage of the negotiations and fully empowered heads of delegations in Geneva. This represents a real success,” said Amb. Wills.

The Director-General said that delegations needed to prepare for an intensive period of line by line negotiations.

“As we enter this new phase of text-based discussions, the responsibility to conclude these negotiations is truly in the hands of members. To get from here to an agreement, it will be your job to find the necessary trade-offs and flexibilities. A successful outcome by MC12 is ultimately your responsibility,” she said. “The world is watching. The fisheries subsidies negotiations are a test both of the WTO's credibility as a multilateral negotiating forum and of the trading system's ability to respond to problems of the global commons.  If we wait another 20 years, there may be no marine fisheries left to subsidise — or artisanal fishing communities to support.”

#### IP disputes fragment WTO unity and trade off with subsidies negotiation

Patnaik 3/12 [(Priti, journalist in Geneva, Switzerland, master’s in Development Studies from The Graduate Institute in Geneva and a master’s in Business and Economic Reporting from New York University) “Could Vaccine Nationalism Spur Disputes At The WTO?” Geneva Health Files, 3/12/2021] JL

To protect domestic manufacturers and constituencies, countries may resort to filing disputes, if only to send a signal to other members, experts believe. To be sure, this is not only about vaccines. Going forward, export restrictions on raw materials can have implications for therapeutics as well. So the threat of a dispute may be a tool to deal with competition for scarce medical products during the pandemic, experts say.

Although trade restrictive measures are short-sighted and not a preferred policy option, governments see them as powerful instruments to meet political goals, to send a message to domestic stakeholders, sources said.

“My hunch is that all countries are sort of sitting on both sides of the fence. On the one hand, governments would like to maintain the discretion and the ability to impose export restrictions if they need to or if they think they need to. Whether that is medical products or personal protective equipment. On the other hand, everybody dislikes it when other countries impose export restrictions. So I think there is enough of an incentive for countries to sit down and negotiate,” one legal expert noted.

Sources also pointed to political declarations last year where WTO members came together and said that they would not impose restrictive trade measures. “In order to be constructive, countries decided that they were going to signal to members that will not introduce exports restrictive measures even though it may be expedient to do so,” one trade expert said. The way out, some feel, is to find solution to placing limits on export restrictions.

It is not just trade restrictive measures that could result in trade disputes. The heated political discussions on the TRIPS waiver at WTO is also aggravating the potential for disputes, according to experts involved in litigations in international trade in Geneva. Therefore these ostensibly independent processes, can catalyse disputes.

“The waiver discussion is very heated and it is aggravating the discussion on the EU's export restrictions. If the waiver succeeds, then the opposing members cannot do anything about it. So they will be looking at other ways to beat up on behavior they do not like on the COVID-19 front,” one trade law expert said.  Do not rule out disputes against supporters of the TRIPS waiver proposal, in case the waiver is adopted, the source added.

In their statement at the WTO General Council meeting last week, the EU said, “In order to ensure that vaccines and their ingredients are not directed to export destinations in unjustified volumes, the European Union had no choice but to introduce a transparency mechanism on Covid-19 vaccine export transactions.” The EU has said that the measures are WTO-consistent.

It added “Since the entry into force of the scheme on the 1 February, we have received 150 requests for export authorisation. All of them have been accepted. I repeat, all of them.” This week, the European Commission extended transparency and authorisation mechanism for exports of COVID-19 vaccines.

The EU is also a part of the Ottawa Group proposal on Trade and Health that also spells out commitments towards export restrictions. (See also *E.U. Exports Millions of Covid Vaccine Doses Despite Supply Crunch at Home*)

“Members bring disputes all the time, even when they know that it's going to take a long time to get a result and often they bring a dispute as leverage for negotiations. Filing a dispute does not mean they are looking for a solution. It does not mean the dispute will be litigated all the way to the end,” a trade lawyer said.

It could also result in a negotiated arrangement, like it was in 2001 in the U.S.-Brazil case. “Why did the U.S. bring a case against Brazil? It gave them leverage in negotiations, and to satisfy domestic stakeholders,” the lawyer added.

The impasse at the Appellate Body may not be a deterrent for countries to dissuade countries from bringing a dispute, some believe.

“The Appellate Body not being functional is not a problem. Countries have recourse to Article 25 under the Dispute Settlement Understanding (DSU) that provides for ‘expeditious arbitration as a alternate means to dispute settlement’,” a source involved in the WTO litigation process said. (The EU, for example, is a signatory to the Multi-party interim appeal arbitration arrangement, MPIA.)

While disputes may take up precious energy and resources of members already stretched in fighting to address the pandemic, it may likely be a strategy to address trade protectionism. Not all agree.

“I think the law is not really an answer here, I hate to say that because I'm a lawyer. But I really don't think the law is an answer because the law is so generically drafted right that and it's politically so sensitive. Which WTO panel will tell a member that restricting vaccines is not legitimate? It will ultimately harm the legitimacy of the trading system,” the person added.

#### Overfishing collapses biodiversity

DUJS 12 [(Dartmouth Undergraduate Journal of Science, official open access science journal of Dartmouth College, publishing original scientific research, multidisciplinary review articles, and science news) “The Threats of Overfishing: Consequences at the Commercial Level,” 3/11/2012] JL

According to marine ecologists, overfishing is the greatest threat to ocean ecosystems today (1). Overfishing occurs because fish are captured at a faster rate than they can reproduce (2). Advanced fishing technology and an increased demand for fish have led to overfishing, causing several marine species to become extinct or endangered as a result (3, 4). In the long-term, overfishing can have a devastating impact on ocean communities as it destabilizes the food chain and destroys the natural habitats of many aquatic species (2).

In the past, fishing was more sustainable because fishermen could not access every location and because they had a limited capacity for fish aboard their vessels. Today, however, small trawlers and fishing boats have been replaced by giant factory ships that can capture and process extremely large amounts of prey at a given time (2). These ships use sonar instruments and global positioning systems (GPS) to rapidly locate large schools of fish (1). Fishing lines are deployed with thousands of large hooks that can reach areas up to 120 kilometers deep. The trawling vessels and machines can even reach depths of 170 kilometers and can store an extraordinarily large volume of fish. Each year, these huge trawling ships comb an area twice the size of the United States. They use massive nets 50 meters wide with the capacity to pull the weight of a medium-sized plane (2). They also have several plants for processing and packing fish, large freezing systems, fishmeal processing plants, and powerful engines that can carry this enormous fishing gear around the ocean. Because these ships have all the equipment necessary to freeze and tin fish, they only need to return to their base once they are full. Even when the ships are filled, however, the fish are often transferred to refrigerated vessels in the middle of the ocean and are processed for consumption later (4). As such, industrial fishing has expanded considerably and fishermen can now explore new shores and deeper waters to keep up with the increased demand for seafood. In fact, it has been reported by the United Nations Food and Agricultural Organization (FAO) that over 70 percent of the world’s fisheries are either ‘fully exploited’, ‘over exploited’ or ‘significantly depleted’ (5). The annual total global catch of fish is 124 million metric tons, which is equivalent in weight to 378 Empire State Buildings (2).

Fishing gear is often non-selective in the fish it targets. For example, any fish that are too big to get through the mesh of a net are captured. Therefore, overfishing does not only threaten the species of fish that is targeted for food, but also many non-target species. As a result, these other species, including marine mammals and seabirds, are accidentally caught in the fishing gear and killed (6). For example, for every ton of prawn caught, three tons of other fish are killed and thrown away. Those in the trade refer to this practice of inadvertent catching of other species as bycatch (4). The FAO has pointed out that about 25 percent of the world’s captured fish end up thrown overboard because they are caught unintentionally, are illegal market species, or are of inferior quality and size. Many of the fish caught this way include endangered and over exploited species, 95 percent of which are eventually thrown away (2). Bycatch is not just limited to just unwanted fish, but rather affects all types of marine life, including whales, dolphins, porpoises, fur seals, albatrosses, and turtles. For example, tuna fisheries are indirectly responsible for the deaths of an estimated one million sharks annually due to bycatch. Small cetaceans, such as dolphins and porpoises, are also targets of bycatch as they are often caught in fishing nets. In fact, hundreds of dolphin corpses are washed up on the beaches of Europe every year, bringing attention to the growing scale of this problem (6).

Many modern fishing methods are also irreversibly destructive. For example, bottom trawling, a technique that uses extremely wide nets armed with heavy metal rollers, can crush everything in the path of the gear, destroying fragile corals, smashing rock formations, and killing several tons of fish and animals as bycatch (7). As such, these practices can wreak havoc on delicate marine ecosystems.

Not surprisingly, it has been reported that industrial fishing takes between only 10 and 15 years to wipe out a tenth of whichever species it targets (2). In fact, several marine species have already been fished to commercial extinction, and this number is rapidly increasing (1). One of the reasons for this is that the regulation of fishing vessels and the fishing industry is universally inadequate. Roughly two-thirds of the ocean is free of laws and fishing vessels only follow the laws ratified by their country of origin. However, most fishing countries have not ratified any international convention to protect the sea or marine life (2). Moreover, fishing factory ships and companies are given access to fisheries before the long–term impact of their fishing practices is understood (1).

Today, the number of fish caught worldwide is actually shrinking as the fishing industry is in decline from many years of overfishing (2). The year 1988 was the first time in human history that global wild fish catches dropped and they have continued to fall ever since. In European waters, four out of every five known fish stocks are already beyond safe biological limits (7). Illegal and unreported fishing have also contributed a great deal to the depletion of the oceans and continues to be a serious problem.

A new study conducted by the International Union for Conservation of Nature (IUCN) found that 5 out of the 8 tuna species are at risk of extinction (8). All three species of bluefin tuna, for example, are threatened with extinction and are at a population that makes their recovery practically irreversible (2). The IUCN has also reported that freshwater fish are among the most endangered species, with more than a third facing extinction. Not surprisingly, among those at the greatest risk are species like the Mekong giant catfish, the freshwater stingray, and the European eel, which are used to make some of the most expensive caviars. The Mekong giant catfish is the closest to extinction, with as few as 250 left. Overfishing has reduced the numbers of Mekong freshwater stingray by over 50 percent in Southeast Asia and has reduced the giant Mekong salmon carp population by over 90 percent (9).

As previously mentioned, shark populations have also been greatly affected by overfishing. There are already more than 135 species of shark on the IUCN’s list of endangered animals and more are being added each year. For example, the number of scalloped hammerhead shark has decreased by 99% over the past 30 years. Other species recently added to the endangered list include the smooth hammerhead, shortfin mako, common thresher, big-eye thresher, silky, tiger, bull, and dusky (10). Besides being caught as bycatch, sharks are now also being targeted by commercial fishermen for their fins which can fetch a substantial price on the Asian food market. Sharks are particularly vulnerable to exploitation because they have long life spans, are exceptionally slow to mature (taking as long as 16 years in some cases), and are relatively unprolific breeders (11). Recent reports suggest that over fishing has caused a 90% decline in shark populations across the world’s oceans and up to 99% along the US east coast, which are some of the best managed waters in the world. Because sharks are at the top of the food chain, a decline in their numbers has devastating consequences on marine ecosystems (10).

Overfishing impacts not just the particular species that is exploited, but also damages other species of fish and disrupts local ecosystems. The stability of ecological communities depends largely on the interactions between predators and prey (12). Thereby, the balance of the food chain is disturbed when certain species are removed. As a result, many ocean species are disappearing and losing their habitats. The evolutionary process of marine species is also being altered, causing cycles of premature reproduction and relative decreases in the size of fish across generations. As predators diminish, the populations of smaller fish escalate because they were previously the food source of the bigger fish. In addition, the disappearance of these species affects many other species, like seabirds and sea mammals, which are vulnerable to the lack of food (2).

A recent study found that overfishing is also decreasing the genetic diversity of fish worldwide. Diversity is projected to be reduced further if overfishing continues at the same rate (13). This has serious effects on nutrient recycling in marine ecosystems because fish species vary widely in their rates of nitrogen and phosphorus excretion. As such, altering fish communities creates divergent nutrient recycling patterns and disrupts the functioning of the ecosystem. Recently conducted studies in lakes affected by overfishing show that loss of species contributes to a decline in nutrient recycling and destabilizes the ecosystem (14).

While it is often overlooked for other environmental issues, overfishing has historically caused more ecological extinction than any other human influence on coastal ecosystems, including water pollution (5). Unfortunately, due to a lack of data, the extent of this damage has only recently been recognized (15).

#### Continued biodiversity loss causes extinction

Carrington 18 [(Damian, the Guardian's Environment editor) "Humanity has wiped out 60% of a animal populations since 1970, report finds," The Guardian, 10/29/18] TDI

Humanity has wiped out 60% of mammals, birds, fish and reptiles since 1970, leading the world’s foremost experts to warn that the annihilation of wildlife is now an emergency that threatens civilisation.

The new estimate of the massacre of wildlife is made in a major report produced by WWF and involving 59 scientists from across the globe. It finds that the vast and growing consumption of food and resources by the global population is destroying the web of life, billions of years in the making, upon which human society ultimately depends for clean air, water and everything else.

“We are sleepwalking towards the edge of a cliff” said Mike Barrett, executive director of science and conservation at WWF. “If there was a 60% decline in the human population, that would be equivalent to emptying North America, South America, Africa, Europe, China and Oceania. That is the scale of what we have done.”

“This is far more than just being about losing the wonders of nature, desperately sad though that is,” he said. “T**his is** actually now jeopardising the future of people. Nature is not a ‘nice to have’ – it is our life-support system.”

“We are rapidly running out of time,” said Prof Johan Rockström, a global sustainability expert at the Potsdam Institute for Climate Impact Research in Germany. “Only by addressing both ecosystems and climate do we stand a chance of safeguarding a stable planet for humanity’s future on Earth.”

Many scientists believe the world has begun a sixth mass extinction, the first to be caused by a species – Homo sapiens. Other recent analyses have revealed that humankind has destroyed 83% of all mammals and half of plants since the dawn of civilisation and that, even if the destruction were to end now, it would take 5-7 million years for the natural world to recover.

The Living Planet Index, produced for WWF by the Zoological Society of London, uses data on 16,704 populations of mammals, birds, fish, reptiles and amphibians, representing more than 4,000 species, to track the decline of wildlife. Between 1970 and 2014, the latest data available, populations fell by an average of 60%. Four years ago, the decline was 52%. The “shocking truth”, said Barrett, is that the wildlife crash is continuing unabated.

Wildlife and the ecosystems are vital to human life, said Prof Bob Watson, one of the world’s most eminent environmental scientists and currently chair of an intergovernmental panel on biodiversity that said in March that the destruction of nature is as dangerous as climate change.

“Nature contributes to human wellbeing culturally and spiritually, as well as through the critical production of food, clean water, and energy, and through regulating the Earth’s climate, pollution, pollination and floods,” he said. “The Living Planet report clearly demonstrates that human activities are destroying nature at an unacceptable rate, threatening the wellbeing of current and future generations.”

The biggest cause of wildlife losses is the destruction of natural habitats, much of it to create farmland. Three-quarters of all land on Earth is now significantly affected by human activities. Killing for food is the next biggest cause – 300 mammal species are being eaten into extinction – while the oceans are massively overfished, with more than half now being industrially fished.

Chemical pollution is also significant: half the world’s killer whale populations are now doomed to die from PCB contamination. Global trade introduces invasive species and disease, with amphibians decimated by a fungal disease thought to be spread by the pet trade.

The worst affected region is South and Central America, which has seen an 89% drop in vertebrate populations, largely driven by the felling of vast areas of wildlife-rich forest. In the tropical savannah called cerrado, an area the size of Greater London is cleared every two months, said Barrett.

“It is a classic example of where the disappearance is the result of our own consumption, because the deforestation is being driven by ever expanding agriculture producing soy, which is being exported to countries including the UK to feed pigs and chickens,” he said. The UK itself has lost much of its wildlife, ranking 189th for biodiversity loss out of 218 nations in 2016.

The habitats suffering the greatest damage are rivers and lakes, where wildlife populations have fallen 83%, due to the enormous thirst of agriculture and the large number of dams. “Again there is this direct link between the food system and the depletion of wildlife,” said Barrett. Eating less meat is an essential part of reversing losses, he said.

The Living Planet Index has been criticised as being too broad a measure of wildlife losses and smoothing over crucial details. But all indicators, from extinction rates to intactness of ecosystems, show colossal losses. “They all tell you the same story,” said Barrett.

Conservation efforts can work, with tiger numbers having risen 20% in India in six years as habitat is protected. Giant pandas in China and otters in the UK have also been doing well.

But Marco Lambertini, director general of WWF International, said the fundamental issue was consumption: “We can no longer ignore the impact of current unsustainable production models and wasteful lifestyles.”

## Case

### Framing

1. **Moral uncertainty means preventing extinction should be our highest priority.  
   Bostrom 12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)]  
   These reflections on **moral uncertainty suggest** an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might** well **be confused. We may not** nowknow — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet **be able to imagine the best ends** of our journey. **If we are** indeedprofoundly **uncertain** about our ultimate aims,then we should recognize that **there is a great** option **value in preserving** — and ideally improving — **our ability to recognize value and** to **steer the future accordingly. Ensuring** that **there will be a future** version of **humanity** with great powers and a propensity to use them wisely **is** plausibly **the best way** available to us **to increase the probability that the future will contain** a lot of **value.** To do this, we must prevent any existential catastrophe.
2. **Reducing the risk of extinction is always priority number one.   
   Bostrom 12** [Faculty of Philosophy and Oxford Martin School, University of Oxford.], Existential Risk Prevention as Global Priority.  Forthcoming book (Global Policy). MP. [http://www.existenti...org/concept.pdf](http://www.existential-risk.org/concept.pdf)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 10^16 human lives**.  **This implies that the expected value of   reducing existential risk by a mere one millionth of one percentage point is at least a hundred times the   value of a million human lives.**  The more technologically comprehensive estimate of 10  54 humanbrain-emulation subjective life-years (or 10  52  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 riskâ€”positive or negativeâ€”is almost   certainly larger than the positive value of the direct benefit of such an action.

### Advantage

#### ROB is to vote for the better debater – anything else is arbitrary, self–serving, and impact justified – they haven’t justified how debate shapes subject formation – it doesn’t – the role of individual debate rounds is white noise – *can you remember what happened round 5 of Meadows your sophomore year?*

#### They can only leverage the amount of settler colonialism solved by the aff – alt causes – Chinese oppression of Uighurs, Turkey’s involvement in Syria, and Native Americans making $.60 to the dollar

#### The aff doesn’t solve- it doesn’t prevent inequitable military presence of countries in vulnerable populations, it doesn’t give indigenous people their land back or solve for greater instances of economic coercion, and it doesn’t solve for inequality in every other sector of society irrespective of medicine – all of which are massive alt causes to the aff’s impact

#### Their impact card is from 1984 and details a nuclear/great power war scenario that hasn’t happened – the only impact they have access to is fairness and inequality

#### Patents prevent biopiracy

Erstling 09 [(Jay, Emeritus Professor of Law at Mitchell Hamline School of Law, J.D., Cornell University Law School, 1974) “Using Patents to Protect Traditional Knowledge,” Texas Wesleyan Law Review, 2009] JL

Finally, while the patent system has been accused of facilitating biopiracy by tolerating third-party patenting of TK, using the patent system appropriately to protect TK can serve more to prevent biopiracy than to permit it. Biopiracy generally refers to the exploitation of traditional knowledge or genetic resources-typically by multinational companies-without the authorization of the holders of that knowledge, and/or the patenting of inventions based on traditional knowledge without the consent of the knowledge holders or payment of compensation.24 Several cases of alleged biopiracy, including patents granted for neem, turmeric, the enola bean, and quinoa, have aroused controversy and focused attention on how patenting can lead to unjust results.25 Although it is extremely difficult to estimate the extent to which biopiracy actually takes place in any particular country, protecting TK could provide some assurance against misappropriation by clarifying the duty that third parties owe to the holders of the knowledge when the knowledge has contributed to an invention that is the subject of a patent application.

#### TRIPs waiver is a symbolic gesture that prevents vaccine production and distribution

Ikenson 6/25 [(Dan, former director of the Cato Institute's Herbert A. Stiefel Center for Trade Policy Studies, MA in economics from George Washington University) “Stop Blaming Patents For The World’s Low Vaccination Rates,” Forbes, 6/25/2021] JL

The premise of the need for a TRIPS waiver is simply absurd. It serves to divert attention from the failures of governments to protect their citizens with smart public health policies and, importantly, to demonize intellectual property protections more broadly. Governments are already free to waive IP protections and to engage in compulsory licensing in times of health crises but have not done so because patents are not the bottleneck. The bottlenecks result from limited global expertise in the highly technical process of producing the vaccine, the dearth of production facilities and capacity to ramp up production at existing facilities, the tight supply of crucial pharmaceutical ingredients (including vials, bags, and other components), and the limited distribution channels through which the proper handling of vaccines at proper temperatures can be assured.

To be sure, global health officials and biopharmaceutical companies have been working to resolve these real bottlenecks—a process that has benefited significantly from the fact that U.S. officials have more bandwidth to devote more attention and other resources to these matters precisely because U.S. vaccination efforts have been successful. And why have they been successful? In large measure, they have been successful because intellectual property protections have bred expectations of future intellectual property protections, which has invited and enabled an accumulation of R&D investment, infrastructure, and expertise in the United States.

The effort to surmount these real impediments to producing, distributing, and injecting vaccines is not made any easier by a symbolic waiver of IP protections—and may be made more difficult. The volume of vaccines necessary to ending the pandemic requires governments and public health officials to coordinate and focus on ramping up the capacity to produce and distribute, and to safeguard against the squandering of pharmaceutical ingredients by ensuring those inputs are channeled to producers with expertise in manufacturing and distribution. On the contrary, suspending IP protection might encourage novice firms with no expertise to end up wasting limited, essential ingredients.

#### Unpatented medicine cause counterfeits—

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

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated:

“The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that counterfeit products accounted for up to 2.5 percent of world trade, or $461 billion, in 2013. This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount. Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1]

As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines.

While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3]

[Kristina]

According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5]

While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report,

“INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11]

Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless. Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need: inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives.

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

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

This leads to a vital question: Are generics safe? If drug manufacturers followed the FDA’s strict regulations, the answer would be a resounding yes. Unfortunately for those who turn to generics to save money, the FDA relies heavily on the honor system with foreign manufacturers, and U.S. consumers get burned. Eighty percent of the active ingredients and 40% of the finished generic drugs used in the U.S. are manufactured overseas.

As a pharmacist, I know that the safety of prescription medications is vital. My research, recently published in the “Annals of Pharmacotherapy,” raises alarming concerns about our vulnerabilities.

Do experts have something to add to public debate?

Where are your drugs being made?

A pharmacist at a drug plant outside Mumbai in 2012, shortly after a change in patent law allowed production of a generic cancer drug. Rafiq Mugbool/AP Photo

Generic drug manufacturers either make bulk powders with the active ingredient in them or buy those active ingredients from other companies and turn them into pills, ointments or injectable products.

In 2010, 64% of foreign manufacturing plants, predominantly in India and China, had never been inspected by the FDA. By 2015, 33% remained uninspected.

In addition, companies in other countries are informed before an inspection, giving them time to clean up a mess. Domestic inspections are unannounced.

Faking results

The FDA informs manufacturing plants in other countries when it plans to inspect their plants. Andrew Harnik/AP Photo

As I detail in my paper, when announced foreign FDA inspections began to occur in earnest between 2010 and 2015, numerous manufacturing plants were subsequently barred from shipping drugs to the U.S. after the inspections uncovered shady activities or serious quality defects.

Unscrupulous foreign producers shredded documents shortly before FDA visits, hid documents offsite, altered or manipulated safety or quality data or utilized unsanitary manufacturing conditions. Ranbaxy Corporation pleaded guilty in 2013 to shipping substandard drugs to the U.S. and making intentionally false statements. The company had to withdraw 73 million pills from circulation, and the company paid a $500 million fine.

These quality and safety issues can be deadly. In 2008, 100 patients in the U.S. died after receiving generic heparin products

from foreign manufacturers. Heparin is an anticoagulant used to prevent or treat blood clots in about 10 million hospitalized patients a year and is extracted from pig intestines.

Some of the heparin was fraudulently replaced with chondroitin, a dietary supplement for joint aches, that had sulphur groups added to the molecule to make it look like heparin.

One of the heparin manufacturers inspected by the FDA received a warning letter after it was found to have used raw material from uncertified farms, used storage equipment with unidentified material adhering to it and had insufficient testing for impurities.

These issues continue to this day. Dozens of blood-pressure and anti-ulcer drugs were recalled in 2018 and 2019 due to contamination with the potentially carcinogenic compounds N-nitrosodimethylamine or N-nitrosodiethylamine.

One of the major producers of these active ingredient powders used by multiple generic manufacturers was inspected in 2017. The FDA found that the company fraudulently omitted failing test results and replaced them with passing scores.

This raises a critical question: How many more violations would occur with inspections occurring as frequently as they do in the U.S., and more importantly, if they were unannounced? Relatively speaking, the number of drugs proved to be tainted or substandard has been small, and the FDA has made some progress since 2010. But the potential for harm is still great.

#### TRIPs waivers is a symbolic gesture that prevents vaccine production and distribution

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To be sure, global health officials and biopharmaceutical companies have been working to resolve these real bottlenecks—a process that has benefited significantly from the fact that U.S. officials have more bandwidth to devote more attention and other resources to these matters precisely because U.S. vaccination efforts have been successful. And why have they been successful? In large measure, they have been successful because intellectual property protections have bred expectations of future intellectual property protections, which has invited and enabled an accumulation of R&D investment, infrastructure, and expertise in the United States.

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