### 1NC – OFF

#### Strong current IP guarantees causes massive Pharma innovation.

**Stevens and Ezell 20** Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### The most efficacious mainstream drugs come from Indigenous Knowledge – empirics are on our side.

**King 91** Stephen King September 1991 "The Source of Our Cures: A new pharmaceutical company wants to provide reciprocal benefits and recognize the value of indigenous" <https://www.culturalsurvival.org/publications/cultural-survival-quarterly/source-our-cures-new-pharmaceutical-company-wants-provide> //Elmer

**FOR 500 YEARS**, SINCE THE People of South America encountered Europeans on their soil, **the global pharmacopoeia** has been **enriched by a number of important plant-derived medicines discovered and utilized by indigenous people**. The skeletal **muscle relaxant d-tubocurarine** is derived from an Amazonian arrow poison better known as curare, Chonodendron tomentosum. The **antimalarial drug quinine**, obtained from the bark of the several species on Cinchona trees, was first called "Indian fever bark" by the Europeans until the name "Jesuit fever bark" became more popular. Quinidine, also produced from the bark of Cinchona species, is now used as an antiarrhythmic for people with cardiac problems. An important amoebocide and emetic drug **emetine**, obtained from the roots of Cephalis ipecacuana, was utilized by indigenous people in Brazil **to treat dysentery**. One of the world's most important local anesthetics, cocaine is derived from the leaves of Erthroxylum coca and is still used today as medicine by thousands of people in the Andean region of South America. **Pilocarpine**, a drug **used to treat glaucoma**, is derived from the plant Pilocarpups jaborandi and was utilized by indigenous people in Brazil as medicine. These are only a few examples of the mainstream drugs that have been developed based on the - acknowledged - traditional wisdom of indigenous people. Roughly **74 percent of the 121** **plant-derived compounds** currently **used in the global pharmacopoeia** h**ave been discovered through research based on** ethnobotanical information on the **use** of plants **by indigenous people**. It is well known that tropical forest ecosystems contain a tremendous diversity of plant species. Estimates cite a minimum of 250,000 flowering plant species worldwide, at least 90,000 of which are found in the neotropics. Fewer than one percent of these plants have been investigated even superficially for potential pharmacological activity. A surprisingly large proportion of this plant biodiversity is classified, utilized, and actively managed by indigenous and local people of tropical regions. Tropical forest people have a profound knowledge about the utility, of plants found in their environment - an observation confirmed by ethnobotanical and ethnopharmacological research in the past decade (see references). At the same time interdisciplinary research by anthropologists, ecologists, geographers, and tropical agrnomists has shown that indigenous people and rural inhabitants of the neotropics have been - and continue to - actively managing plant genetic resources in their environment (Balee and Posey 1989; Irvine 1987; Denevan and Padoch 1988; Posey 1985); plants used as medicine are often moved and maintained as cultivated or wild/cultivated medical resources.

#### Global pharma is overly reliant on indigenous medicinal knowledge

**Bhattacharya 14** [Sayan Battacharya, Department of Environmental Studies at Rabindra Bharati University in Kolkata, India], “Bioprospecting, biopiracy and food security in India: The emerging sides of neoliberalism”, International Letters of Social and Humanistic Sciences, SciPress Ltd, pg. 49-54, 2014 //SLC PK //re-cut by Elmer

2. BIODIVERSITY, BIOPROSPECTING AND BIOPIRACY Historically there has been prolific scientific interest in the lifestyles, knowledge, cultures, histories, and worldviews of indigenous peoples. Rural communities depend on traditional knowledge for food, health and agriculture. This traditional knowledge forms the basic cultural identity for them, contributing to social cohesiveness and thereby reducing vulnerability and poverty. **80 % of the world’s populations**, mostly the ‘undeveloped’ regions, still **rely on the indigenous medicinal knowledge** of local plants for their medical needs.3 In India, around 70 % of the population directly depends on land-based occupations, forests, wetlands and marine habitats for ecological livelihoods and cultural sustenance.4 Over 7500 species of plants and several hundred animal species and also metals and minerals are utilized by the folk tradition in India. The custodians and carriers of these traditions are tribal as well as non-tribals, including house wives and welders, thousand of herbal healers, bone setter, vishvaidyas, birth attendants, potters, gold-smiths, black smiths, barbers and even wandering monks. According to ASI, there are 4635 ethnic communities in India. In principle each of these communities could be having their own oral medical traditions that have been evolving across time and space.3 Traditional knowledge does not only include only the recorded knowledge of plants for medicinal use but also the oral knowledge that has been passed on from generations to generations. In India there have been a lot of cases where the indigenous knowledge has been tried to be taken away. Due to its easy access, it has been prone to piracy. According to UNDP Human Development Report 1999: “The South is the **source of 90 per cent of the world’s biological wealth** – **India**, for example, **has 81,000 species of fauna and 47,000 of flora**, including 15,000 plant varieties unique to the country – and yet industrial countries hold 97 per cent of all patents worldwide and are driving the rush to patent plant genetic resources.” 5 Today, the **genomics** revolution is **fueling** a **new wave of scientific research in the form of bioprospecting**, and it is impacting the lives of indigenous peoples around the world. Bioprospecting involves searching for, collecting, and deriving genetic materials from biodiversity samples that can be used in commercialized pharmaceutical, agricultural, industrial, or chemical processing end products.6 The **megadiversity** **countries** with 60-70 % of the world`s known biological diversity h**ave significant stake for harnessing the potential of biotechnology** and bioprospecting for achieving sustainable economic development.1 The Convention on Biological Diversity (CBD), the first international treaty provides opportunities to biodiversity rich countries to realize benefits arising out of the utilization of their bioresources. The CBD mentioned that national governments have authority to determine access to their genetic resources, and calls on governments to provide for conservation, sustainable use and equitable sharing of benefits from commercial use of those resources. Between 4 and 40 million biological species are still unknown in the world. New species are being discovered even today. In the last few decades, biotechnology has developed and played a vital role in the development of the agricultural, pharmaceutical and medical industries. As the importance of the biotechnology industry increases, many useful biotechnological inventions can earn their inventors millions of dollars. The real pirates are those developed countries, especially the US, who benefited and prospered from the plundering of natural resources from the developing and less developed countries without paying any royalty to the source countries at all. **Between 25-50 % of current prescription pharmaceuticals come from plants**, either directly or through modifications by biochemical methods, and the value of drugs to the U.S. pharmaceutical industry coming from plant species is estimated at over 30 billion USD per year.2 A multinational company or individual who wishes to develop a new product often makes use of the traditional knowledge of local people in deciding upon a plant, animal or other biological source to study. After the successful production of commercially useful products from those organisms, the company applies for a patent in its own name on those products. In most cases, the inventor not even acknowledges in his patent application that his product was derived from information provided by a local community. Biopiracy therefore can be described as the unjustified extraction of the environmental heritage and traditional knowledge from various regions of the earth for economic exploitation and industrial monopolization.7 Daniel F. Robinson distinguished between three different categories of biopiracy: “Patent-based biopiracy: The patenting of (often spurious) inventions based on biological resources and/or traditional knowledge that are extracted without adequate authorization and benefit-sharing from other (usually developing) countries, indigenous or local communities. Non-patent biopiracy: Other intellectual property control (through plant-variety protection or deceptive trademarks) based on biological resources and/or traditional knowledge that have been extracted without adequate authorization and benefit-sharing from other (usually developing) countries, indigenous or local communities. Misappropriation: The unauthorized extraction of biological resources and/or traditional knowledge from other (usually developing) countries, indigenous or local communities, without adequate benefit-sharing.” 8 2. 1. Global emergence of Biopiracy A recent report of United Nations Development Programme (UNDP) mentioned that “if unpaid royalty payments were being made to developing countries and indigenous peoples for the plant varieties and local knowledge used by multinational food and drug companies, those providers would earn approximately 5.4 billion USD per year”.2 Examples of countries not receiving their full share of these royalties include Tibet, India, Sri Lanka, South Africa, Samoa, Madagascar, Ecuador, Mexico and the Philippines. Since the 1980s, individual inventors or corporations in some countries, such as the United States, Japan, and some European countries, successfully lobbied government to permit exclusive rights to certain biological materials they developed through patenting. They were given exclusive rights to plant and/or reproduce and market them and have the right to prohibit others from planting, reproducing and selling the material provided. 2. 2. Biopiracy in India: few examples In the recent past, there have been several cases of biopiracy of traditional knowledge from India. First it was the patent on wound healing properties of haldi (turmeric).9 Curcuma longa, a type of turmeric, is an Indian herb that has been used as treatment for sprains, inflammatory conditions and wounds. The orange coloured root is native to the subcontinent and South East Asia, and for thousands of years has been a one of the major components of Ayurvedic medicine. In 1995, two US scientists from the University of Mississippi were granted US patent 5,401,504 on the use of turmeric. The scientists claimed that turmeric could heal wounds and claiming this to be novel. They have mentioned in their patent application that turmeric has long been used in India as a traditional medicine for treatment of various sprains and inflammatory conditions. But they claimed that there was no research on the use of turmeric as a healing agent for external wounds. The Indian government vigorously challenged the patent and provided numerous research papers predating the patent, proving that turmeric has long been used in India to heal wounds. As a result, the US Patent and Trademark office rejected all patent claims related to turmeric.10 The Neem tree case is another significant example of biopiracy of Indian medicinal plant. Azadirachtin is one of many active compounds present in bark, leaves, flowers and seeds of the Neem tree or Azadirachta indica. The remarkable properties of this compound have been utilized in India from ancient times in the form of extracts of various kinds produced by Indian farmers and small industrial firms in medicine and agriculture. Use of neem had been described in ancient Indian texts written over 2,000 years ago as an air purifier and effective medicine for almost all types of human and animal diseases because of its insect and pest repellant properties.9,10 A US timber importer studied the curing properties of neem and began importing neem seed to his company headquarter in Wisconsin since 1971. He successfully extracted a pesticidal agent from neem extract called Margosan-O. In 1985, the bio-pesticide derived from neem tree received clearance for the product from the US Environmental Protection Agency (EPA). The patent for the product was sold to the multinational chemical corporation, W.R. Grace after 3 years. Since then, many US and Japanese firms gained patents on formulae for stable neem-based solutions and emulsions and other products. The W.R.Grace approached several Indian manufacturers and industries to purchase their technology. The company ultimately managed to start a joint venture with a firm called P.J. Margo Pvt. Ltd to set up a plant in India. The plant processes up to 20 tonnes of seed a day and also established a network of neem seed suppliers in order to guarantee a constant supply of the seeds at a cheap price. In May 2000, a coalition of groups successfully overturned the patent held by the US company, WR Grace and the US Department of Agriculture over the Indian neem tree.10 Basmati is produced largely in Punjab, Western India and in Pakistan. Basmati rice has been one of the fastest growing export items from India in recent times. It is evident that Basmati has been grown for centuries in the subcontinent. After centuries of observation, experimentation and selection, the Indian farmers have developed numerous varieties of the rice to meet various ecological conditions, cooking needs and taste.9 On 2 September 1997, Texasbased RiceTec Inc. was granted patent number 5663484 for a new plant variety that is a cross between American long-grain rice and Basmati rice. RiceTec claimed that the new varieties have the same or better characteristics as the original Basmati rice and can be successfully grown in specified geographical areas in North America. The patent covers the genetic lines of the basmati and includes genes form the varieties developed by farmers. RiceTec has already been trading rice under brand names such as Kasmati, Texmati and Jasmati. RiceTec’s strain possesses the same qualities and characteristics of the Indian traditional varieties of Basmati. On the question of consumer deception, RiceTec clearly labels its product as ‘American type Basmati rice’.10 No case has been filed in the US so far by any interested party from the Indian subcontinent regarding this serious issue. By mid 2000, however, the Indian government decided to challenge some of the claims of the RiceTec patent. World’s largest importer of Basmati rice, Saudi Arabia and the UK, recognized that Basmati rice is unique to Northern India and Pakistan. Furthermore, the Agricultural and Processed Food Export Development Authority and Trade Mark Watch Agency of India have managed to win the Basmati patent case in at least 15 countries (including UK, Australia, France, Spain, Chile and the UAE). In the Basmati case, RiceTec’s action would really become a threat to the sales of Basmati rice from India, and could affect the economic conditions of the rice farmers in India. Karela (bitter gourd), Jamun (blackberry), Gumar and Brinjal, for instance, are commonly known in India for their anti diabetic characteristics. Their usees are so common in India that there is no novelty involved while using them for curbing diabetes. A patent was, however, obtained in the U.S. by three NRIs for their utilization as a cure for diabetes.11 North East India is very rich in flora especially in cultivation of medicinal plants by the tribes. Resource-rich Nagaland is plagued by bio-piracy with rare medicinal herbs, orchids and other endangered species being smuggled out of the state. These plants are being borne off by pharmaceutical companies for commercial benefits. Ginseng, taxus baccata and cephallu taxus and paris cordifolia have medicinal properties and are often smuggled to Myanmar.12 Some cases have been highlighted with a success story, but there are also numerous stories of deprivation in the context of biopiracy. Corporate patents usually do not recognize or compensate the indigenous people who are the main conservators of those resources. Indigenous communities, over the centuries, have identified and classified plants native to their lands and found their beneficial characteristics. But, the tribes do not have access to legal information that would protect their plants and cultural knowledge nor do they have the finances to obtain them.9 The profit incentive companies often overexploit the beneficial plant resources for commercial use, which ultimately result in the loss of forests and genetic material, crisis of land, plants and cultural knowledge of the indigenous communities. 2. 3. Biopiracy and food security The stealing of biological resources and indigenous knowledge would affect food security, livelihood of indigenous people, and consumers’ choice. More than 70 % of our food supply is dependent on a small number of edible plant resources, mainly wheat, maize, rice, and potato, which are fundamental to food security. Patenting of these plants varieties will definitely pose threat to the consumers. The patenting of biological technology will encourage monopoly control of plant material by Western transnational corporations. Farmers will become dependent of on corporations for their input in agriculture, i.e. seeds, fertilizers, pesticides and herbicides. It has particularly troubling implications for the developing world as the farmers cannot afford to buy seed each year and traditionally set aside a portion of their harvest to plant in the next growing season. Moreover, with the introduction of the genetically modified crops and high yielding varieties, the local crop varieties are being lost and outcompeted.13 The farmer’s rights to choose the desired crops have become difficult to implement. The technology can execute a devastating effect on the economy and food security of the farmers in developing world and can eventually destroy the locally adapted, inexpensive traditional crop varieties.14 The entire process will eventually lead to the monopolization of trade, which is ultimately against the principle of free trade fostered by the World Trade Organization (WTO). India’s agriculture being rich in bio-diversity has been always been an easy prey for big corporations engaging in agribusiness for the purpose of bio-piracy.15 Monsanto, for instance, tried to spread genetically modified brinjals in India in the form of Bt Brinjals in spite of the fact that India itself is a source of over 2500 different unique varieties of brinjals.16 Monsanto’s attempt of taking over the market was opposed by the public forcing the government to ban it for an indefinite period of time.16 But Monsanto is still stealing native crops, including brinjals, and quietly working on GM varieties of them in test fields, which is a clear violation of India's Biological Diversity Act 2002 (BDA). The farmer variety has been used by Monsanto in its breeding programs without taking prior permission from Indian farmers and without entering into any kind of benefit sharing agreement with them. This is not just grossly unethical; it is in violation of international agreements like the Convention on Biological Diversity (CBD) and the International Treaty on Plant Genetic Resources (ITPGR) which recognize the rights of the farming community over the genetic wealth used in agriculture.17

#### It's the basis of all pharma

**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 //Re-cut by Elmer

**Traditional medicines** (TM)1 can **form the basis of modern pharmaceuticals**. Depend- ing upon national laws, it is possible to protect TM with patents. For instance, a US patent can be issued that derived information or even genetic resources from the TM of another country. This has raised criticism from a number of different perspectives. Most notably there is a perceived conflict between traditional knowledge (TK) struc- tures and patent law. Some question if TM is even an intellectual property (IP) right. There are a number of proposals to protect TM using other forms of IP rights, such as geographical indications and trade secret law. These issues are far from settled, and can have strong political overtones. Before going further, however, TM will be con- sidered in the light of other IP rights. TM has been a source for pharmaceuticals **for a long time**. **Aspirin** is a good example. The ancient Egyptians used willow leaves as an analgesic and anti-inflammatory drug. The Classical world was also familiar with the healing properties of this plant. Hippocrates (460 – 370 BC) recommended the use of extracted juice from the bark of the white willow to suppress pain and fever. It was only in 1828 that the extract of wil- low bark was purified. In 1859 the chemical structure was identified. The drug was mass produced shortly thereafter. Bayer registered the compound on 1 February 1899 under the name of Aspirin. The ‘a’ stood for acetyl, and the ‘spir’ for Spiraea ulmaria, the plant from which the drug had first been isolated. Today it is the most popular analgesic in the world, and new discoveries are ongoing.2 In the case of aspirin, the TK that helped researchers to find the active ingredient was thought at the time to be in the public domain. If aspirin were patented in recent decades, there would no doubt be litigation over who supplied the TK. Other examples of drugs derived from natural substances and that have been incorporated into mainstream medicine are morphine (1806), quinine (1823), atropine (1833) and digitalis.3 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. In the past, such knowledge was regarded as free information. The assumption was that no one had a right to this information, especially because there usually needed to be a long process of development to make TM into a patentable drug. Modern conceptions of the issue leave little doubt that TM can be an IP right. Considering the large profits generated by modern drugs, there has been increasing pressure to pro- tect TM with patents. Several well-known cases of western companies patenting drugs based on TM has also raised concerns. Some advocates who don’t support the patent system but who do wish income to ‘trickle down’ to the communities who developed the TM suggest that an entirely new legal framework be established. Patents are appreciated by this group as unsuitable: First, the invention is not dated, so that it is not possible to determine the critical date. As it would have been used for a long period of time, it would lack novelty. Also, the inventor is not determined, since it is knowledge that belongs to the who community. Patents are granted to individuals, or a small group of them, not to an undetermined group of people.7 The main question that emerges is feasibility. Are patents suitable for protecting TM and, if not, what are the alternatives? The Controversy Bio-piracy is a term minted in the last decades to describe taking biological materials – including TM – and patenting them in the west.8 When this happens TK right holders allege a property right has been violated. The source of the information, as well as the material itself, is not acknowledged. No compensation is paid. When a patent is issued, it is not held by the inventor. The patent will prevent the holder of the TK from taking out a patent themselves. Despite the accusations, however, a patent is granted for an invention that may have little in common with TM as practiced by an indigenous community. Bio-piracy is a very political issue. This highlights the so called north-south divide.9 The accusation is that wealthy nations in the north rely upon colonial era conceptions of property in order to gain access to TK, including TM, for free. TK is not usually protected using a system of written laws in southern countries. It may be controlled as collective property by trained practitioners (such as a Shaman).10 The fact that the legal systems may be different – they may be termed traditional legal systems – does not make them less valid. It does, however, make compliance difficult. This quickly leads into the issue of disclosing the origin of biological materials as a pre-requisite for patent protection. Indeed, without knowing the origin there can be no thought of benefit sharing.11 Yet from a ‘northern perspective’ these proposals could hamper research and lead to higher drug costs. On the other side, some have suggested that protection of medical knowledge, including drugs, with patents is fundamentally incorrect.12 While this subject captures media and public attention, the patent system is unlikely to be replaced any time soon.13 The real questions are how patents can be used to protect TM, and how patents based on the misappropriation of TM can be stopped. Some consideration will also be paid to other legal methods of protecting TM that have been proposed as alternatives to patents. TM involves both the substance itself (assumed here to be botanical) as well as the practices used to prepare it for use. Both India and China14 have ancient medical traditions, but they use very different methods of protecting it. The TM of these two countries will be used as a lens to explore some of the issues involved in patenting. There are then two important divisions in the analysis. The first is the kind of protection provided in national legislation. The second issue is the kind of protection offered to TM of other countries in the west as well as in international agreements. America will receive special attention. Prior use or (unpublished) knowledge of an invention in a foreign country is no bar to obtaining a patent in America.15 This is clearly in order to encourage US business and industry, but according to critics, it has devastating effects on the TK of other nations.

#### Chinese Tribal Medicine proves Compatibility and our Innovation Links.

**Erstling 8**, Jay. "Using patent to protect traditional knowledge." Tex. Wesleyan L. Rev. 15 (2008): 295. https://open.mitchellhamline.edu/cgi/viewcontent.cgi?article=1187&context=facsch (Professor of Law, William Mitchell College of Law, St. Paul, Minnesota.)//Elmer

Advantages of Affirmative Protection Despite the above-mentioned limitations and challenges, **patents have a place in a TK protection system**. A **prime example is** the use of patents to protect **Traditional Chinese Medicine**. The practice of Traditional Chinese Medicine dates back to the beginning of Chinese history. At its most basic, it is "a systematic practice of distinguishing among various illness-causing imbalances of qi. [It] achieves health by restoring a patient's internal yin-yang equilibrium via herbal remedies and physical manipulation."1'69 Traditional Chinese Medicine is of **enormous importance** not only **to** the **Chinese**-**and** the **world's healthcare systems**, but also to the Chinese economy. 170 It is no surprise, therefore, that the Chinese Government has made it a policy to encourage the patenting of innovative Traditional Chinese Medicinal products. Although most developing countries tend to find disfavor with the **TRIPS** Agreement, the Agreement has proven to be a **boon to** the **protection of T**raditional **C**hinese **M**edicine. Prior to the adoption of Article 27.1 of the TRIPS Agreement, which required China to make patents available "for any inventions, whether products or processes, in all fields of technology . . . " the Chinese Patent Law171 did not protect Traditional Chinese Medicine. Since the Law's amendment, there has been a significant **uptake in patent activity**, particularly related to Traditional Chinese Medicine-based pharmaceuticals, and many supporters of Traditional Chinese Medicine believe that **this** activity has **served to incentivize investment in T**raditional **C**hinese **M**edicine, **increase** the **T**raditional **C**hinese **M**edicine **knowledge base**, and transform Traditional Chinese Medicine into a major global export asset. 172 Since 1992, when the Patent Law was amended, applicants have filed patent applications with the State Intellectual Property Office of China (SIPO) at a rate of 1,400 cases a year, 173 but they have not limited their activity to China alone; they have also filed applications in countries such as Germany, Japan, the United Kingdom, and the United States. Moreover, patent holders have begun to enforce the rights they have been granted. For example, in February 2007, China Business News reported that a Chinese patentee Traditional Chinese Medicine manufacturer won the first Traditional Chinese Medicine infringement case against another Chinese company. The patentee was awarded an injunction prohibiting the infringing company from selling the infringing products as well as damages. 174 The **promotion** of Traditional Chinese Medicine has **led to** the establishment of organizations such as the Shanghai Innovative Research Center of Traditional Chinese Medicine (**SIRC**), 75 **which** in turn has further encouraged patent protection for TK. Founded in 2000 with support from the Chinese Ministry of Science and Technology and the Shanghai Municipal Government, SIRC **seeks to modernize T**raditional **C**hinese **M**edicine **and innovate drug discovery** "**by integrating modern life science, chemistry, and information technology** with [Traditional Chinese Medicine]"1 76 -just the right formula to maximize patenting potential. 177 Although the patent system may not be suited to all types of TK, using patents to protect Traditional Chinese Medicine seems to have achieved some success in encouraging new innovation and invention. Communities working to advance other areas of innovative TK may do well to follow China's example.

#### R&D’s key to innovation – otherwise, future pandemics.

**Marjanovic et al. ’20** (Sonja; Ph.D. at the University of Cambridge; May 2020; “How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis”; RAND; <https://www.rand.org/pubs/perspectives/PEA407-1.html>; Accessed: 8-31-2021; AU)

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.**

#### Evolving superbugs trigger extinction.

**Srivatsa ’17** (Kadiyali; specialist in pediatric intensive and critical care medicine in the UK. Invented the bacterial identification tool ‘MAYA’; 1-12-2017; "Superbug Pandemics and How to Prevent Them", American Interest; https://www.the-american-interest.com/2017/01/12/superbug-pandemics-and-how-to-prevent-them/, Accessed: 8-31-2021; AU)

It is by now no secret that the human species is locked in a race of its own making with “superbugs.” Indeed, if popular science fiction is a measure of awareness, the theme has pervaded English-language literature from Michael Crichton’s 1969 Andromeda Strain all the way to Emily St. John Mandel’s 2014 Station Eleven and beyond. By a combination of massive inadvertence and what can only be called stupidity, we must now invent new and effective antibiotics faster than deadly bacteria evolve—and regrettably, they are rapidly doing so with our help. I do not exclude the possibility that bad actors might deliberately engineer deadly superbugs.1 But even if that does not happen, humanity faces an existential threat largely of its own making in the absence of malign intentions. As threats go, this one is entirely predictable. The concept of a “black swan,” Nassim Nicholas Taleb’s term for low-probability but high-impact events, has become widely known in recent years. Taleb did not invent the concept; he only gave it a catchy name to help mainly business executives who know little of statistics or probability. Many have embraced the “black swan” label the way children embrace holiday gifts, which are often bobbles of little value, except to them. But the threat of inadvertent pandemics is not a “black swan” because its probability is not low. If one likes catchy labels, it better fits the term “gray rhino,” which, explains Michele Wucker, is a high-probability, high-impact event that people manage to ignore anyway for a raft of social-psychological reasons.2 A pandemic is a quintessential gray rhino, for it is no longer a matter of if but of when it will challenge us—and of how prepared we are to deal with it when it happens. We have certainly been warned. The curse we have created was understood as a possibility from the very outset, when seventy years ago Sir Alexander Fleming, the discoverer of penicillin, predicted antibiotic resistance. When interviewed for a 2015 article, “The Most Predictable Disaster in the History of the Human Race,” Bill Gates pointed out that one of the costliest disasters of the 20th century, worse even than World War I, was the Spanish Flu pandemic of 1918-19. As the author of the article, Ezra Klein, put it: “No one can say we weren’t warned. And warned. And warned. A pandemic disease is the most predictable catastrophe in the history of the human race, if only because it has happened to the human race so many, many times before.”3 Even with effective new medicines, if we can devise them, we must contain outbreaks of bacterial disease fast, lest they get out of control. In other words, we have a social-organizational challenge before us as well as a strictly medical one. That means getting sufficient amounts of medicine into the right hands and in the right places, but it also means educating people and enabling them to communicate with each other to prevent any outbreak from spreading widely. Responsible governments and cooperative organizations have options in that regard, but even individuals can contribute something. To that end, as a medical doctor I have created a computer app that promises to be useful in that regard—of which more in a moment. But first let us review the situation, for while it has become well known to many people, there is a general resistance to acknowledging the severity and imminence of the danger. What Are the Problems? Bacteria are among the oldest living things on the planet. They are masters of survival and can be found everywhere. Billions of them live on and in every one of us, many of them helping our bodies to run smoothly and stay healthy. Most bacteria that are not helpful to us are at least harmless, but some are not. They invade our cells, spread quickly, and cause havoc that we refer to generically as disease. Millions of people used to die every year as a result of bacterial infections, until we developed antibiotics. These wonder drugs revolutionized medicine, but one can have too much of a good thing. Doctors have used antibiotics recklessly, prescribing them for just about everything, and in the process helped to create strains of bacteria that are resistant to the medicines we have. We even give antibiotics to cattle that are not sick and use them to fatten chickens. Companies large and small still mindlessly market antimicrobial products for hands and home, claiming that they kill bacteria and viruses. They do more harm than good because the low concentrations of antimicrobials that these products contain tend to kill friendly bacteria (not viruses at all), and so clear the way for the mass multiplication of surviving unfriendly bacteria. Perhaps even worse, hospitals have deployed antimicrobial products on an industrial scale for a long time now, the result being a sharp rise in iatrogenic bacterial illnesses. Overuse of antibiotics and commercial products containing them has helped superbugs to evolve. We now increasingly face microorganisms that cannot be killed by antibiotics, antifungals, antivirals, or any other chemical weapon we throw at them. Pandemics are the major risk we run as a result, but it is not the only one. Overuse of antibiotics by doctors, homemakers, and hospital managers could mean that, in the not-too-distant future, something as simple as a minor cut could again become life-threatening if it becomes infected. Few non-medical professionals are aware that antibiotics are the foundation on which nearly all of modern medicine rests. Cancer therapy, organ transplants, surgeries minor and major, and even childbirth all rely on antibiotics to prevent infections. If infections become untreatable we stand to lose most of the medical advances we have made over the past fifty years.

#### Disease perpetuates colonialism – it disproportionately hurts Indigenous people.

**Ostler 20** Jeffrey Ostler 4-29-2020 "Disease Has Never Been Just Disease for Native Americans" <https://www.theatlantic.com/ideas/archive/2020/04/disease-has-never-been-just-disease-native-americans/610852/> (Beekman Professor of Northwest and Pacific History at the University of Oregon.)//Elmer

As the death toll from COVID-19 mounts, **people of color are** clearly **at greater risk** than others. Among **the most vulnerable are Native** Americans. To understand **how dire** the **COVID**-19 situation **is** becoming for these communities, consider the situation unfolding for the **Navajo Nation**, a people with homelands in Arizona, New Mexico, and Utah. As of April 23, **1,360 infections and 52 deaths** had been reported among the Navajo Reservation’s 170,000 people, a **mortality rate of 30 per 100,000**. Only six states have a higher per capita toll. The spread of COVID-19 is **reminiscent of previous disease outbreaks that have ravaged Native American communities**. Many of those outbreaks resulted in catastrophic loss of life, far greater than even the worst-case scenarios for COVID-19. Even the 1918–19 flu pandemic, in which an estimated 650,000 Americans died (0.6 percent of the 1920 population of 106 million), pales in comparison to the losses Native Americans have suffered from disease. Until recently, histories of disease and Native Americans have emphasized “virgin-soil epidemics.” According to this theory, popularized in Jared Diamond’s Guns, Germs, and Steel, when Europeans arrived in the Western Hemisphere, they brought diseases (particularly measles and smallpox) that indigenous people had never experienced. Because they had no immunity to these diseases, so the theory goes, the resulting epidemics took the lives of 70 percent or more of the Native population throughout the Americas. New research, however, provides a much more complicated picture of disease in American Indian history. This research shows that virgin-soil epidemics were not as common as previously believed and shifts the focus to how **diseases repeatedly attacked Native communities** in the decades and **centuries after Europeans first arrived**. Post-contact diseases were **crippling** not so much because indigenous people lacked immunity, but **because** the **conditions** **created by** European and U.S. **colonialism made Native communities vulnerable**. The virgin-soil-epidemic hypothesis was valuable in countering earlier theories that attributed Native American population decline to racial inferiority, but its singular emphasis on biological difference implied that population collapses were nothing more than historical accidents. By stressing the importance of social conditions created by human decisions and actions, the new scholarship provides a far more disturbing picture. It also helps us understand the problems facing Native communities today as they battle the novel coronavirus. Virgin-soil epidemics undoubtedly occurred. In 1633, for example, a smallpox epidemic struck Native communities in New England, reducing the Mohegan and Pequot populations from a combined total of 16,000 to just 3,000. The epidemic spread to the Haudenosaunee in New York, but no farther west than that. Smallpox did not hit communities in the Ohio Valley and Great Lakes until 1756–57, a century or more after initial contact with Europeans. When it did, it was because Native fighters, recruited to fight for the French against the British during the Seven Years’ War, had contracted the virus in the east and infected their communities when they returned home. Lack of immunity mattered, but it was the disruption resulting from war that promoted smallpox’s spread. Smallpox did not arrive in the Southeast until 1696, a century and a half after the Hernando de Soto expedition. It was once thought that de Soto’s men carried smallpox, but this view reflected the flawed assumption that Europeans were always infected with smallpox and always contagious. De Soto’s expedition did cause disease to erupt in Native communities, but the reason was that the expedition’s violent warfare led to outbreaks of pathogens such as dysentery, which was already present in the Americas. When smallpox finally hit the Southeast, it spread rapidly from Virginia to East Texas across networks created by an English trade in Native captives for enslavement in their coastal and West Indies colonies. Raiding, capturing, and transporting human bodies created pathways for the smallpox virus. To make matters worse, those bodies were already weakened by war and its companions—malnutrition, exposure, and lack of palliative care. By the end of the 18th century, most Native communities in what would eventually become the United States had been exposed to smallpox. Nevertheless, as smallpox recurred in the 19th century, its impact correlated not with a lack of prior exposure, but with the presence of adverse social conditions. These same conditions would also make Native communities susceptible to a host of other diseases, including cholera, typhus, malaria, dysentery, tuberculosis, scrofula, and alcoholism. Native vulnerability had—and has—nothing to do with racial inferiority or, since those initial incidents, lack of immunity; rather, it has everything to do with concrete policies pursued by the United States government, its states, and its citizens. Consider the impact of the Indian Removal Act. Formally adopted in 1830, this policy called for the relocation of Native peoples east of the Mississippi River to “Indian Territory” (what would eventually become Oklahoma and Kansas). Most everyone has heard of the Cherokee Trail of Tears, but it is seldom considered a U.S.-caused health crisis. The expulsion of the Cherokee from their homeland in Georgia, North Carolina, and Tennessee had three phases. In the first, the U.S. Army forcibly evicted Cherokees from their homes and held them for several months in concentration camps with inadequate shelter, insufficient food, and no source of clean water. The camps became death traps. Of the 16,000 people held in them, about 2,000 died from dysentery, whooping cough, measles, and “fevers” (probably malaria). In the second phase, the journey west, an additional 1,500 perished, as people, already sick and further weakened by malnutrition, trauma, and exposure, succumbed to multiple pathogens. In the months after reaching Oklahoma—the third phase—an additional 500 died from similar causes. The death toll was 4,000, or 25 percent of the original 16,000 forced from their homes. Although the Cherokee Trail of Tears is the most well known, there were dozens of other such forced removals. Creeks, Seminoles, Chickasaws, Choctaws, Senecas, Wyandots, Potawatomis, Sauks and Mesquakies, Ojibwes, Ottawas, Miamis, Kickapoos, Poncas, Modocs, Kalapuyas, and Takelmas represent only a partial list of nations that suffered trails of tears. Not all experienced the same mortality as the Cherokee, but many did, and for some, the toll was even higher. The allied Sauks and Mesquakies were forced to move four times from their villages in western Illinois—once to central Iowa, once to western Iowa, once to Kansas, and finally to Oklahoma. In 1832, the time of the first expulsion, the Sauks and Mesquakies numbered 6,000. By 1869, when they were finally sent to Oklahoma, their population was only 900, a staggering loss of 85 percent. Year after year, unrelenting diseases, including an outbreak of smallpox in 1851, took many lives. Low fertility and infant mortality, the result of malnutrition, sickness, and trauma, hindered population replacement. The Sauk and Mesquakie catastrophe was not an accident. It was a direct and foreseeable consequence of decisions made by the United States and its citizens to dispossess Native people of desirable lands and shove them someplace else. Navajos (Dinés, as they refer to themselves in their language) were also evicted from their homelands. In the winter of 1863–64, the U.S. Army pursued scorched-earth tactics—destroying their peach trees and cornfields—to drive them to a barren reservation at Bosque Redondo, on the Pecos River in New Mexico. On the 250-mile forced march, known as the Long Walk, several hundred of the 8,000 to 9,000 Dinés died en route. Over the next four years, Dinés lost as many as 2,500 of their people to disease and starvation. In their darkest hour, though, Diné leaders successfully prevailed on government officials to release them from their prison and return home. But even though their population has grown over time, the legacies of the Long Walk remain. The Diné historian Jennifer Denetdale observes that “severe poverty, addiction, suicide and crime on reservations all have their roots in the Long Walk.” As cases of COVID-19 began to appear on the Navajo Reservation in late March, tribal President Jonathan Nez spoke to his people on Facebook. Summoning memories of the Long Walk, he “called on citizens to help one another,” reminding them “that’s when the best came out of many of our ancestors, helping each other out, carrying the load for the elders, carrying the children for our mothers.” “Now it’s our turn,” he said, “to think of our future, our children, our grandchildren.” Ongoing colonialism makes fighting COVID-19 a challenge. Although the Navajo are a sovereign nation with resources of their own, Dinés have a high incidence of conditions—diabetes, hypertension, and lung disease—that increase their susceptibility to becoming severely ill from the coronavirus. Lack of access to clean water makes hand-washing difficult. Many people cannot afford food, hand sanitizer, and other necessities. And there is an acute shortage of hospital beds and medical personnel. Many public officials, health experts, and journalists are drawing attention to the disproportionate impact of COVID-19 on communities of color. Even so, large segments of America are indifferent, if not outright hostile, to recognizing these disparities and the inequities underlying them. Native Americans are visible to the general public far more often as sports mascots than as actual communities. The Trump administration initially resisted providing any relief to tribal nations in the $2 trillion stimulus package passed in early April, and although the legislation ultimately appropriated $10 billion to tribal governments, the Treasury Department, tasked with distributing these funds, has failed to disburse them. According to New Mexico Senator Tom Udall, Treasury Department officials “don’t know how to interact in the appropriate way with tribes and they’re just not getting the job done.” Countering the invisibility of Native peoples, of course, means greater awareness of how COVID-19 is affecting them and enhanced efforts to provide resources to help them combat the current outbreak. It also means creating a deeper understanding of the history of American Indians and disease. Although the virgin-soil-epidemic hypothesis may have been well intentioned, its focus on the brief, if horrific, moment of initial contact consigns disease safely to the distant past and provides colonizers with an alibi. **Indigenous communities are fighting more than a virus**. They are **contending with the ongoing legacy of centuries of violence and dispossession.**

### 1NC – OFF

#### We affirm that the member nations of the World Trade Organization ought to:

#### Modify Intellectual Property Protection of Indigenous Knowledge through implementation of a Sui Generis Intellectual Property Regime that reflects consistent consultation with local communities and traditional communities.

#### Mandate widespread ratification, application, and the enforcement of the Swakokpmund Protocol ensuring that local communities and traditional communities are guaranteed continued use of Traditional Medical Knowledge in the traditional context without any legal implication and without licenses and subject to pre-determined sharing of benefits.

#### Implement an opt-in opt-out system where Indigenous Groups are given the right to refuse to relinquish control of Intellectual Property to non-Indigenous Intellectual Property Holders over Traditional Knowledge.

#### Mandate a disclosure of origin requirement as a pre-requisite of Intellectual Property Protection applications.

#### The Swakokpmund Protocol is an Intellectual Property Regime that solves exploitation and protects Traditional Knowledge and People while still allowing usage of Intellectual Property in Medical Innovation – Sua Generis emphasis of collective rights solves IPCB issues with IPRs.

Sinkala 17, Ruth M. "Protection of Traditional Medical Knowledge in the Patent System: Is There Room?." (2017). (Master Programme in Intellectual Property Law at University of Uppselett)//SidK

4.2 The Swakopmund Protocol The **Swakopmund Protocol is a regional legal framework** **designed to address the protection of TK** and folklore and provide a holistic view of African TK holders **for** purposes of **legal certainty and management of** their **inalienable** rights. Evidently, the Swakopmund Protocol is **a sui generis system** for the protection of TK. Therefore, it is **not constrained by** the limitations of patent law or other **mainstream IPR regimes**. It has been described as “**a historic step** **for** ARIPO member states and a significant milestone in the **evolution of i**ntellectual **p**roperty.”130 The protocol begins by stating its purpose as to “**protect** traditional knowledge **holders against** any **unauthorized exploitation** of their rights;131 **misappropriation**, misuse and unlawful exploitation beyond their traditional context”.132 This purpose succinctly addresses the major problems faced by TMK holders. In the analysis to follow, particular aspects of the Swakopmund Protocol relevant to TMK have been selected and will be discussed in detail. The strengths and weaknesses will be explored accordingly. 4.2.1 General Observations 4.2.1.1 Terminology The terminology used in the Swakopmund Protocol such as “local communities and traditional communities” is broad and encompasses a wider variety of groups which may possess TK unlike the use of terms such as “indigenous” which considered in various contexts may have the effect of limiting which groups may qualify as TK holders. This is a commendable feature of the Protocol and reflects a desire to broaden the scope of groups capable of protecting their TK provided the requirements stipulated in section 4 are met. 4.2.1.2 Regional Approach The Swakopmund Protocol adopts a regional approach to protection of TK. Section 24 in capturing the operation of the regional protection approach **mandates** that “**eligible foreign holders of TK shall enjoy** benefits of **protection** **to the same level as holders of t**raditional **k**nowledge and expressions of folklore who are nationals of the country of protection”.133 For TMK, this is commendable because in the African context, migration for various reasons is common place hence foreign groups may exist who hold TMK though not being nationals of the state in which they reside. Enabling such protection may motivate such groups to permit the exploitation of their knowledge without fear of differential or discriminatory treatment. Furthermore, this promotes the principle of non-discrimination and unified regional treatment thus setting the tone for regional cooperation and uniformity in protection awarded to TMK across the region. 4.2.2 Recognition of Peculiarities of TK The Swakopmund Protocol is drafted in a manner which recognises and accommodates accordingly the peculiarities of TK as demonstrated in the aspects below. i. Automatic Protection: Section 5.1 of the Swakopmund Protocol states that protection of **TK** shall not be subject to any formality therefore any knowledge which qualifies as TK134 **is automatically entitled to protection**. This approach is commendable and is in the view of the author entirely correct. The holders of TMK in Africa are in some cases isolated from mainstream society135 thus it is impractical to demand formalities as a prerequisite to granting protection because access to executing the formalities required could prove difficult for such groups. Additionally, formalities would likely involve the payment of various fees and registration paperwork which these traditional communities may not have the capacity to execute unassisted. The Swakopmund Protocol in this regard remedies a flaw found in the patent system by eliminating the need for formalities. Communal Ownership: Section 6 in describing who the holders of TK are recognizes the concept of communal ownership. **Express reference is made to owners being “local and traditional communities”**.136 This **overcomes** a further **shortcoming** of the patent system in that the patent system is **centered on individual ownership and exclusivity**. Continued Use in the Traditional Context: Section 11 **enables continued use of TK in the traditional context without** **any legal implication despite issuances of licenses** or other access agreement with knowledge seekers. This is in sharp contrast with the patent system which entails essentially grants the author a monopoly over the use of the invention. Unauthorized use of a patented pharmaceutical product amounts to an infringement of the rights which accrue to the patent holder. In the traditional medical context, this section is vital because TMK in traditional communities and other parts of the population is widely depended upon as the primary means of treatment137. As a result, the **right to health**, life and self-preservation **remains unaffected** even with the existence of the Swakopmund Protocol. Duration of Protection: The duration of protection for TMK if protection were sought under the patent system would be 20 years138. Once the 20-year period has elapsed, the “invention” falls into the public domain. The provision of a fixed term of protection for TMK is not appropriate for its nature. The Swakopmund Protocol remedies this shortcoming of the patent system by **granting protection to TMK holders in perpetuity** according to section 13. This accommodates the essence of TMK as it is held by the “present owners and their descendants in perpetuity rather than for a limited period.”139 It should be noted however that this does not apply where TMK belongs exclusively to an individual140. 4.2.3 Rights Conferred Upon TK Holders Authorization and Prevention of Exploitation: **Rightsholders have the exclusive right to prevent exploitation of TK without their prior informed consent** and to authorize its use as noted in section 7141.The definition of “prior informed consent” contained in the Swakopmund Protocol142 requires that complete and accurate information be provided to the concerned communities. Although some parties seeking to utilize TMK may come in good faith or bona fide, others may come with bad intentions or mala fide.143 Various local communities have different levels of exposure hence may be vulnerable. This is not to say that local communities lack intellectual capacity nor that they are incapable of representing their own interests. Rather, it is simply to take cognizance of the situation which obtains. Usually, parties who seek to benefit from or utilize TMK are researchers from multinational companies. Thus, there may be a language or other cultural barrier to direct communication with TMK holders. It is therefore submitted that to protect the interests of traditional communities and to enable genuine prior informed consent to be sought, translation services and an “educated” representative must be present to facilitate this communication. Appropriate evidence of the intended use of the TMK and various projections must be presented and fully disclosed during these discussions. Ensuring that such mechanisms are in order and available will empower communities to effectively exercise the right to authorization of use of their TMK. Institution of Legal Proceedings: In the event of unauthorized use of TK, Section 7.4 confers upon local communities the right to institute legal proceedings. In order to do so, some degree of knowledge and representation is necessary. Therefore, the protection of TMK goes beyond mere independent defense by the concerned local communities but requires the involvement of other parties with various levels of expertise to enable traditional communities to fully and effectively assert their rights144. Moral Rights: Moral rights are addressed in section 10 where the Swakopmund Protocol obliges persons to acknowledge the holders, source and origin of TK in a way that respects the cultural values of its holders. This section essentially deals with the right to recognition of the author(s) and is especially important as many aspects of TMK culminate in the development and production of pharmaceutical drugs, herbal products and alternative treatments in the absence of recognition of the role played by TMK in the development process. Such acknowledgement should be given “in a manner that respects the cultural values of its holders.” Therefore, by necessity, parties seeking permission or access to use TMK must to some extent be familiar with the culture of the traditional community from whom they seek knowledge. However, it is unreasonable to expect that all who seek to explore TMK be well versed in the culture of the local community hence a possible practical suggestion may be to insist that such ones gain basic knowledge of respectful cultural practice in the context of the TMK required. Licensing Agreements: The owners of TK have the right to conclude licensing agreements in writing for the use of their knowledge according to section 8 of the Swakopmund Protocol. The written document requirement creates the need to provide support to local communities in the form of knowledgeable neutral individuals capable of representing the interests of traditional communities in such licensing agreements. The issue of compulsory licensing which is a common feature of the patent system is regulated in section 12. It grants the State the mandate to issue a compulsory license where “protected traditional knowledge is not being sufficiently exploited by the rights holder” or where “the rights holder refuses to grant licenses subject to reasonable commercial terms and conditions” only in the interests of public health or public security in order to fulfil national needs. In my view, section 12 by creating a compulsory licensing provision demonstrates balance and a desire for the wider community to benefit from TMK and takes cognizance of the right to healthcare. Notably, the same section does not allow traditional communities to be taken advantage of when these compulsory licenses are issued rather makes provision for appropriate compensation to be given to the traditional communities concerned. At this juncture, a fundamental question arises; does section 12 directly or indirectly create an obligation to exploit TK? In my view, an obligation to exploit TK has been created. Insufficient exploitation (provided the public health or safety requirement is met) constitutes valid grounds for issuance of a compulsory license. Effectively, the Swakopmund Protocol obliges traditional communities to exploit their TMK and this interferes, although for good reason, with their right to decide who may have access to 43 their TMK. However, no description is provided of what would qualify as sufficient or insufficient exploitation. It may then be presumed that an assessment of the prevailing circumstances in each case would have to be undertaken to make this determination. Perhaps, the national authority or a court of competent jurisdiction may be called upon to make such an assessment. It is submitted that although compulsory licensing reduces the extent to which traditional communities may autonomously regulate the use of their TK, this is with good reason particularly in the context of TMK as a greater purpose is served. v. Equitable Benefit Sharing: **The sharing of benefits derived from commercial** or industrial **use** of TK **is to be determined by mutual agreement between the parties** according to section 9 of the Swakopmund Protocol145. The benefit sharing may extend to non- monetary rewards146. The provision for sharing of non-monetary benefits is a practical one as the needs of traditional communities may vary. Particularly in the context of **TMK**, **benefits** derived may **include the development of new drugs or treatments**. The Swakopmund Protocol leaves much room for discussion between traditional communities and access seekers. This “flexibility” may be viewed from two perspectives. On one hand, it may be advantageous in terms of freedom of contract and that non-rigid rules of benefit sharing accommodate various kinds of TK being incorporated into agreements. On the other hand, in the interests of local communities it may have been desirable to include minimum equitable benefit sharing standards.

#### Disclosure of Origin ensures that original TMK owners are able to get compensation and are protected from exploitation.

Sinkala 17, Ruth M. "Protection of Traditional Medical Knowledge in the Patent System: Is There Room?." (2017). (Master Programme in Intellectual Property Law at University of Uppselett)//SidK

3.4.1.2 Disclosure **Disclosure** **is a defensive protection mechanism** which has been pushed forward by the CBD and the IGC92. The introduction of a disclosure requirement **would compel patent applicants to disclose the source or origin of their TK**. This requirement **would** undoubtedly **bring** **forward the true holders of the TMK** thus contribute to **ensuring that patents are not granted erroneously** as often as they would be in the absence of such a requirement. The practical implication of disclosure however would not be merely to mention the origin or source of the TMK, rather it would be **necessary to demand** that the **required procedure in obtaining the TMK has been followed and necessary agreements have been concluded**. The disclosure requirement has been applied in different ways in various jurisdictions in patent law. 3.4.1.2 Disclosure Disclosure is a defensive protection mechanism which has been pushed forward by the CBD and the IGC92. The introduction of a disclosure requirement would compel patent applicants to disclose the source or origin of their TK. This requirement would undoubtedly bring forward the true holders of the TMK thus contribute to ensuring that patents are not granted erroneously as often as they would be in the absence of such a requirement. The practical implication of disclosure however would not be merely to mention the origin or source of the TMK, rather it would be necessary to demand that the required procedure in obtaining the TMK has been followed and necessary agreements have been concluded. The disclosure requirement has been applied in different ways in various jurisdictions in patent law. For example, a full disclosure requirement has been introduced into the national laws of Egypt and India with various degrees of strictness or rigidity. Sweden has adopted a more lenient version of the disclosure requirement stating that patent applicants should disclose the origin of TK but are not required to disclose and that failure to disclose will not affect the patent examination or the validity of the issued patent93. On the other hand, in South Africa the disclosure requirement is strictly enforced and failure to comply will result in invalidity or unenforceability of the patent at issue.94 It is submitted that in order for disclosure to operate effectively as a defensive mechanism, the disclosure required should be mandatory and detailed. Thus, patent applicants would be compelled to disclose and be unable to obtain the desired patent without complying. 3.4.1.3 Advantage of Defensive Protection i. Preservative: The documentation of TMK as a component of defensive protection has a preservative effect. Owing to the volatile nature of TMK, documenting the information to whatever extent serves the purpose of creating a record of its existence thus making it less susceptible to complete loss.

#### AT – Bagley – counterplan solves but preventing innovation from being exploitive

#### AT – Feldman – a] this is super cherry picked – just gives examples of a few drugs being exploited but not a general trend b] if a drug hurts you then people wont buy it which would kill pharma profits – means there isn’t an incentive for negative innovation

### 1NC – OFF

#### Counterplan Text – Member states of the World Trade Organization ought to consult the World Health Organization on whether or not the member nations of the World Trade Organization ought to do the plan. The World Health Organization ought to publicly declare that their decision will represent their future decisions on all intellectual property protections on medicines.

#### The Plan’s unilateral action by the WTO on medical IP undermines WHO legitimacy – forcing a perception of WHO action against Patents is key to re-assert it

Rimmer 4, Matthew. "The race to patent the SARS virus: the TRIPS agreement and access to essential medicines." Melbourne Journal of International Law 5.2 (2004): 335-374.

<https://law.unimelb.edu.au/__data/assets/pdf_file/0007/1681117/Rimmer.pdf> (BA (Hons), LLB (Hons) (Australian National University), PhD (New South Wales); Lecturer at ACIPA, the Faculty of Law, The Australian National University)//SidK + Elmer

The WHO has been instrumental in coordinating the international network of research on the SARS virus. It has emphasised the need for collaboration between the network participants. The WHO presented the containment of the SARS virus as ‘one of the biggest success stories in public health in recent years’.206 However, it **was less active in the debate over patent law** and public health epidemics. The 56th World Health Assembly considered the relationship between intellectual property, innovation and public health. It stressed that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.207 However, there was much disagreement amongst the member states as to what measures would be appropriate. The WHO has made a number of aspirational statements about patent law and access to essential medicines. Arguably, though, the organisation could be a much more informed and vocal advocate. Initially, the WHO did not view the patent issues related to SARS as being within its field of activities. The agency didnoteven seem aware of the patent proceedings, leaving individual research institutions without guidance. Spokesman Dick Thompson said: ‘What we care about is [that] the international collaboration continues to function. Patents, they don’t really concern us’.208 The director of WHO’s Global Influenza project, Klaus Stöhr, expressed his opinion that the patent filings would not interfere with the international cooperation on the SARS research: ‘I don’t think this will undermine the collaborative spirit of the network of labs’.209 However, he believed that, after the international network of researchers had identified the coronavirus, it was necessary to rely upon companies to commercialise such research. Klaus Stöhr conceded: ‘At a certain point of time you have to give way for competitive pharmaceutical companies’.210 On a policy front, the WHO remained deferential to the WTO over the debate over patent law and access to essential medicines, observing: Owing to the inconclusive nature of the studies conducted to date, and because of the effect that potentially significant price increases could have on access to drugs in poor countries, WHO is currently monitoring and evaluating the effects of TRIPS on the prices of medicines. It is also monitoring the TRIPS impact on other important issues such as transfer of technology, levels of research and development for drugs for neglected diseases, and the evolution of generic drug markets.211 In such a statement, the WHO appears diffident, unwilling to take on more than a spectator role. Such a position is arguably too timid, given the gravity of national emergencies, such as the SARS virus. The organisation could take a much stronger stance on the impact of the **TRIPS** Agreement on public health concerns. The WHO has since enunciated a position statement on the patenting of the SARS virus. A number of high ranking officials from the organisation have commented on the need to ensure that international research into the SARS virus is not impeded by competition over patents. Arguably though, the WHO **should not be limited to a mere spectator role in such policy discussions. It** needstoplay an active advocacy role in the debate over patent law and access to essential medicines. The WHO released a position statement on ‘Patent Applications for the SARS Virus and Genes’ on 29 May 2003.212 The organisation stressed that it had no per se objection to the patenting of the SARS virus: Some people have objected to the SARS patent applications on the ground that the virus and its genes should not be patentable because they are mere discoveries, not inventions. This distinction no longer prevents the granting of patents; the novel claim rests not with the virus itself but with its isolation, and likewise with the identification of the genetic sequence not its mere occurrence. Many patents have been issued on viruses and genetic sequences, though the appropriate policies to follow in such cases — particularly as genomic sequencing becomes more routine and less ‘inventive’ — remain matters of dispute.213 Furthermore, it recognised that public institutions could legitimately use patents as a defensive means to prevent undue commercial exploitation of the research: The “defensive” use of patents can be a legitimate part of researchers’ efforts to make their discoveries (and further discoveries derived therefrom) widely available to other researchers, in the best collaborative traditions of biomedical science.214 The WHO affirmed the need for further cooperation between research organisations in respect of the SARS virus: ‘For continued progress against SARS, it is essential that we nurture the spirit of the unprecedented, global collaboration that rapidly discovered the novel virus and sequenced its genome’.215 The WHO announced its intention to monitor the effects of patents (and patent applications) on the speed with which SARS diagnostic tests, treatments, and vaccines are developed and made available for use, and on the manner in which prices are set for these technologies. It observed: In the longer term, the manner in which SARS patent rights are pursued could have a profound effect on the willingness of researchers and public health officials to collaborate regarding future outbreaks of new infectious diseases. WHO will therefore examine whether the terms of reference for such collaborations need to be modified to ensure that the credit for any intellectual property developed is appropriately attributed, that revenues derived from licensing such property are devoted to suitable uses, and that legitimate rewards for innovative efforts do not impose undue burdens on efforts to make tests, therapies, and preventive measure available to all.216 It maintained that in order to tackle new public health problems with international impact, such as the emergence of severe acute respiratory syndrome (SARS), access to new medicines with potential therapeutic effect, and health innovations and discoveries should be universally available without discrimination.219 The Assembly requested that the Director-General continue to support Member States in the exchange and transfer of technology and research findings, according high priority to access to antiretroviral drugs to combat HIV/AIDS and medicines to control tuberculosis, malaria and other major health problems, in the context of paragraph 7 of the Doha Declaration which promotes and encourages technology transfer.220 The WHO also considered a report on the emergence of the SARS virus and the international response to the infectious disease.221 It was ‘deeply concerned that SARS ... poses a serious threat to global health security, the livelihood of populations, the functioning of health systems, and the stability and growth of economies’.222 The Committee on Infectious Diseases requested that the Director-General ‘mobilize global scientific research to improve understanding of the disease and to develop control tools such as diagnostic tests, drugs and vaccines that are accessible to and affordable by Member States’.223 The Director-General of the WHO, Dr Gro Harlem Brundtland, **told the World Health** Assembly that there was a need to build trust and forge solidarity in the face of public health epidemics: ‘**Ensuring that patent regimes stimulate research and do not hinder international scientific cooperation** is a critical challenge — whether the target is SARS or any other threat to human health’.224 Similarly, Dr Marie-Paule Kieny, Director of the WHO Initiative for Vaccine Research, said: If we are to develop a SARS vaccine more quickly than usual, we have to continue to work together on many fronts at once, on scientific research, intellectual property and patents issues, and accessibility. It is a very complicated process, involving an unprecedented level of international cooperation, which is changing the way we work.225 She emphasised that patents and intellectual property issues and their safeguards can help rather than hinder the rapid development of SARS vaccines and ensure that, once developed, they are available in both industrialised and developing countries.226 C Summary The WHO should play a much more active role in the policy debate over patent law and access to essential medicines. James Love, the director of the Consumer Project on Technology, run by Ralph Nader, is critical of the WHO statement on ‘Intellectual Property Rights, Innovation, and Public Health’.227 He maintains that the Assembly could have addressed ‘practical examples, like SARS’ and cites the report in The Washington Post that notes that a number of commercial companies are investing in SARS research.228 The non-government organisation Médecins Sans Frontières has been critical in the past of the passive role played by the WHO in the debate over access to essential medicines: ‘As the world’s leading health agency, and armed with the clear mandate of recent World Health Assembly resolutions, the WHO can and should **do much more’**.229 The WHO should become a vocal advocate for public health concerns at the WTO and its TRIPS Council — especially in relation to patent law and the SARS virus. It must staunchly defend the rights of member states to incorporate measures in their legislation that protect access to medicines — such as compulsory licensing, parallel imports, and measures to accelerate the introduction of generic pharmaceutical drugs. It needs to develop a clearer vision on global equity pricing for essential medicines. The race to patent the SARS virus seems to be an inefficient means of allocating resources. A number of public research organisations — including the BCCA, the CDC and HKU — were compelled to file patents in respect of the genetic coding of the SARS virus. Such measures were promoted as ‘defensive patenting’ — a means to ensure that public research and communication were not jeopardised by commercial parties seeking exclusive private control. However, there are important drawbacks to such a strategy. The filing of patents by public research organisations may be prohibitively expensive. It will also be difficult to resolve the competing claims between the various parties — especially given that they were involved in an international research network together. Seth Shulman argues that there is a need for international cooperation and communication in dealing with public health emergencies such as the SARS virus: The success of a global research network in identifying the pathogen is an example of the huge payoff that can result when researchers put aside visions of patents and glory for their individual laboratories and let their work behave more like, well, a virus. After all, the hallmark of an opportunistic virus like the one that causes SARS is its ability to spread quickly. Those mounting a response need to disseminate their information and innovation just as rapidly.230 There is a danger that such competition for patent rights may undermine trust and cooperation within the research network. Hopefully, however, such concerns could be resolved through patent pooling or joint ownership of patents. Furthermore, a number of commercial companies have filed patent applications in respect of research and development into the SARS virus. There will be a need for cooperation between the public and private sectors in developing genetic tests, vaccines, and pharmaceutical drugs that deal with the SARS virus. There is also a need to reform the patent system to deal with international collaborative research networks — such as that created to combat the SARS virus. Several proposals have been put forward. There has been a renewed debate over whether patents should be granted in respect of genes and gene sequences. Some commentators have maintained that the SARS virus should fall within the scope of patentable subject matter — to promote research and development in the field. However, a number of critics of genetic technology have argued that the SARS virus should not be patentable because it is a discovery of nature, and a commercialisation of life. There has been a discussion over the lack of harmonisation over the criteria of novelty and inventive step between patent regimes. As Peter Yu comments, ‘[w]hile [the] US system awards patents to those who are the first to invent, the European system awards patents to those who are the first to file an application’.231 There have been calls for the requirement of utility to be raised. There have also been concerns about prior art, secret use and public disclosure. Representative Lamar Smith of Texas has put forward the CREATE Act, which recognises the collaborative nature of research across multiple institutions. Such reforms are intended to ensure that the patent system is better adapted to deal with the global nature of scientific inquiry. The race to patent the SARS virus also raises important questions about international treaties dealing with access to essential medicines. The public health epidemic raises similar issues to other infectious diseases — such as AIDS, malaria, tuberculosis, influenza, and so forth. The WHO made a public statement about its position on the patenting of the SARS virus. It has stated that it will continue to monitor developments in this field. Arguably, there is a need for the WHO to play a larger role in the debate over patent law and access to essential medicines. Not only could it mediate legal disputes over patents in respect of essential medicines, it could be a vocal advocate in policy discussions. The WTO has also played an important role in the debate over patent law and access to essential medicines. A number of public interest measures could be utilised to secure access to patents relating to the SARS virus including compulsory licensing, parallel importation and research exceptions. The appearance of the SARS virus shows that there should be an open-ended interpretation of the scope of diseases covered by the Doha Declaration on the TRIPS Agreement and Public Health. Important lessons should be learned from the emergence of the SARS virus, and the threat posed to global health. As the World Health Report 2003 notes: SARS will not be the last new disease to take advantage of modern global conditions. In the last two decades of the 20th century, new diseases emerged at the rate of one per year, and this trend is certain to continue. Not all of these emerging infections will transmit easily from person to person as does SARS. Some will emerge, cause illness in humans and then disappear, perhaps to recur at some time in the future. Others will emerge, cause human illness and transmit for a few generations, become attenuated, and likewise disappear. And still others will emerge, become endemic, and remain important parts of our human infectious disease ecology.232 Already, in 2004, there have been worries that pharmaceutical drug companies and patent rights are impeding efforts to prevent an outbreak of bird flu — avian influenza.233 There is a need to ensure that the patent system is sufficiently flexible and adaptable to cope with the appearance of new infectious diseases.234

#### WHO says yes

Kimball 21 [(Spencer, news editor with CNBC.com) “WHO chief urges world to follow U.S. lead and support waiving Covid vaccine patent protections,” CNBC, 5/7/2021] JL

World Health Organization Director General-Tedros Adhanom Ghebreyesus on Friday urged other countries, particularly the Group of Seven industrialized nations, to follow the U.S. example and support a World Trade Organization motion to temporarily waive Covid-19 vaccine patent protections. “Wednesday’s announcement by the U.S. that it will support a temporary waiver of intellectual property protections for Covid-19 vaccines is a significant statement of solidarity and support for vaccine equity,” Tedros said at a press briefing. “I know that this is not a politically easy thing to do, so I very much appreciate the leadership of the U.S. and we urge other countries to follow their example.”

#### WHO Cred key to Global Right to Health – medicine access is critical.

* Note the Bottom Paragraph is at the bottom of the PDF – I put a paragraph break to indicate it as such – no words are missing.

Bluestone 3, Ken. "Strengthening WHO's position should be a priority for the new Director-General." The Lancet 361.9351 (2003): 2. (Senior Policy Adviser, Voluntary Service Overseas (VSO))//Elmer

To meet these challenges, WHO must strengthen its resolve to maintain its **independence and lead its member states**, **even at the risk of causing controversy**. A meaningful example is the role that WHO can have in **ensuring access to medicines** for the world’s poorest people. WHO is the only global institution that has the **remit to drive this agenda forward**, yet has failed to do so convincingly. The new Director-General must support and reinvigorate the advocacy efforts of the organisation and provide a proper counterbalance to the interests of the pharmaceutical industry and wealthy member states. As the new Director-General takes office, they will face the dual challenge of **seeing that** the broadest possible public health interpretation of the World Trade Organization’s Doha Agreement on Trade Related Aspects on Intellectual Property Rights (TRIPS) **is not lost, and** of seizing an opportunity to bring about an international framework for sustainable and predictable tiered pricing of medicines. Without the active intervention of a public health advocate at the level of WHO, there is a risk that both of these initiatives **could founder.** Some people in positions of power still do not have high expectations of WHO or its new Director-General. But for the world’s poorest people, the overwhelming majority of whom live in developing countries, this person’s legacy could literally make the difference between life and death. Ken Bluestone Senior Policy Adviser, Voluntary Service Overseas (VSO)

New leader should re-establish WHO’s credibility The credibility of WHO’s advocacy of the right to health for all has been eroded in recent years. A large reason is WHO’s **failure to challenge the pharmaceutical** industry on access to medicines for people with HIV/AIDS and other diseases. WHO’s collaboration with the industry in the “Accelerated Access” programme on antiretroviral medicines sounds good. In fact, the programme has served as a cover for the organisation’s frequent acceptance of industry arguments for restricting treatment access. To re-establish WHO’s credibility, the new Director-General must lead the organisation to stand consistently with those most deprived of health services. Kenneth Roth, Executive Director, Human Rights Watch.

#### Right to Health solves Nationalist Populism.

Friedman 17 Eric Friedman March 2017 “New WHO Leader Will Need Human Rights to Counter Nationalistic Populism” <https://www.hhrjournal.org/2017/03/new-who-leader-will-need-human-rights-to-counter-populism/> (JD, Project Leader of the Platform for a Framework Convention on Global Health at the O’Neill Institute for National and Global Health Law at the Georgetown University Law Center in Washington, DC)//Elmer

The need for WHO leadership on human rights—and for global leadership on health and human rights beyond WHO—has always been present, yet has become ever more pressing. A reactionary, nationalist populism has been gaining momentum, particularly in the United States and parts of Europe, and some of its most disturbing features, such as xenophobia and disregard for international law and institutions, are surfacing elsewhere. Persisting health challenges—such as immense national and global health inequities, with universal health coverage and the Sustainable Development Goals offering some hope of lessening them—and growing threats such as outbreaks of infectious disease, worsening antimicrobial resistance, and climate change demand the type of leadership that the right to health entails. In this immensely challenging environment, WHO needs to become a 21st century institution that has the gravitas and credibility to carve a path through these obstacles towards global health justice. The next WHO Director-General, to be elected in May, must lead the organization there. The right to health can light the way ahead, with reforms to, and driven by, WHO. These reforms must develop an internal governance that is far more welcoming of civil society, with WHO member states significantly increasing contributions so work on the social determinants of health can expand, and with enhanced transparency and accountability. Furthermore, reforms are needed so that WHO leads on global health equity and human rights, including through national health equity strategies and, above all, the Framework Convention on Global Health (FCGH). The FCGH could help bring the right to health to the next level by capturing core aspects of the right to health, such as: 1) participation and accountability, setting clear standards for people’s participation in health policy-making at all levels, and establishing multi-layered health accountability frameworks with standards to which all nations would be held; 2) equity, including by catalyzing national health equity strategies—which must be developed through broad participation, itself a potentially empowering process—and advancing data disaggregation and more equitable financing; 3) financial resources, with global norms on national and international health financing responsibilities; and 4) respecting and promoting the right to health in all policies, from setting standards on health impact assessments—including participatory processes in developing them, human rights standards, an equity focus, and follow-up processes—to firmly ensuring the primacy of the right to health in other legal regimes that may undermine. From an earlier WHO treaty, the Framework Convention on Tobacco Control, we know the power of international law to significantly advance health, with the transformative power of legally binding global health norms. As a treaty, the FCGH would increase political accountability and accountability through the courts, while helping protect health other treaty-based international regimes, such as trade. It would also be a bold assertion of global solidarity for global justice, as so urgently needed, “demonstrating that the community of nations are indeed stronger together.” One candidate for the WHO Director-General election, David Nabarro, has recognized the value and civil society support that FCGH has already received, and the need to further explore the treaty (mentioned at 1:46:38 mark). A good first step would be establishing a WHO working group on the FCGH, with broad participation, particularly from states, civil society, and representatives of communities most affected by health inequities, along with relevant international agencies. We see signs of resistance of the dangerous nationalist populism, from protests that persist and judicial checks on one of the administration’s vilest acts (an immigration and refugee travel ban, with its effects falling heaviest on Muslims) in the United States to the rejection of the far-right candidate in the elections in the Netherland. Such resistance can prevent some of the worst impacts on the right to health, from discrimination against migrants to cuts to programs vital for health. Meanwhile, let’s construct an edifice for the future of health and human rights, even as we stand against its destruction. WHO, right to health, and FCGH leadership ought to be a core part of that endeavor.

#### Populism is an existential threat.

de Waal 16 Alex de Waal 12-5-2016 “Garrison America and the Threat of Global War” <http://bostonreview.net/war-security-politics-global-justice/alex-de-waal-garrison-america-and-threat-global-war> (Executive Director of the World Peace Foundation at the Fletcher School at Tufts University)//Elmer

Polanyi recounts how economic and financial crisis led to global calamity. Something similar could happen today. In fact we are already in a steady unpicking of the liberal peace that glowed at the turn of the millennium. Since approximately 2008, the historic decline in the number and lethality of wars appears to have been reversed. Today’s wars are not like World War I, with formal declarations of war, clear war zones, rules of engagement, and definite endings. But they are wars nonetheless. What does a world in global, generalized war look like? We have an unwinnable “war on terror” that is metastasizing with every escalation, and which has blurred the boundaries between war and everything else. We have deep states—built on a new oligarchy of generals, spies, and private-sector suppliers—that are strangling liberalism. We have emboldened middle powers (such as Saudi Arabia) and revanchist powers (such as Russia) rearming and taking unilateral military action across borders (Ukraine and Syria). We have massive profiteering from conflicts by the arms industry, as well as through the corruption and organized crime that follow in their wake (Afghanistan). We have impoverishment and starvation through economic warfare, the worst case being Yemen. We have “peacekeeping” forces fighting wars (Somalia). We have regional rivals threatening one another, some with nuclear weapons (India and Pakistan) and others with possibilities of acquiring them (Saudi Arabia and Iran). Above all, today’s generalized war is a conflict of destabilization, with big powers intervening in the domestic politics of others, buying influence in their security establishments, bribing their way to big commercial contracts and thereby corroding respect for government, and manipulating public opinion through the media. Washington, D.C., and Moscow each does this in its own way. Put the pieces together and a global political market of rival plutocracies comes into view. Add virulent reactionary populism to the mix and it resembles a war on democracy. What more might we see? Economic liberalism is a creed of optimism and abundance; reactionary protectionism feeds on pessimistic scarcity. If we see punitive trade wars and national leaders taking preemptive action to secure strategic resources within the walls of their garrison states, then old-fashioned territorial disputes along with accelerated state-commercial grabbing of land and minerals are in prospect. We could see mobilization against immigrants and minorities as a way of enflaming and rewarding a constituency that can police borders, enforce the new political rightness, and even become electoral vigilantes. Liberal multilateralism is a system of seeking common wins through peaceful negotiation; case-by-case power dealing is a zero-sum calculus. We may see regional arms races, nuclear proliferation, and opportunistic power coalitions to exploit the weak. In such a global political marketplace, we would see middle-ranking and junior states rewarded for the toughness of their bargaining, and foreign policy and security strategy delegated to the CEOs of oil companies, defense contractors, bankers, and real estate magnates. The United Nations system appeals to leaders to live up to the highest standards. The fact that they so often conceal their transgressions is the tribute that vice pays to virtue. A cabal of plutocratic populists would revel in the opposite: applauding one another’s readiness to tear up cosmopolitan liberalism and pursue a latter-day mercantilist naked self-interest. Garrison America could opportunistically collude with similarly constituted political-military business regimes in Russia, China, Turkey, and elsewhere for a new realpolitik global concert, redolent of the early nineteenth-century era of the Congress of Vienna, bringing a façade of stability for as long as they collude—and war when they fall out. And there is a danger that, in response to a terrorist outrage or an international political crisis, President Trump will do something stupid, just as Europe’s leaders so unthinkingly strolled into World War I. The multilateral security system is in poor health and may not be able to cope. Underpinning this is a simple truth: the plutocratic populist order is a future that does not work. If illustration were needed of the logic of hiding under the blanket rather than facing difficult realities, look no further than Trump’s readiness to deny climate change. We have been here before, more or less, and from history we can gather important lessons about what we must do now. The importance of defending civility with democratic deliberation, respecting human rights and values, and maintaining a commitment to public goods and the global commons—including the future of the planet—remain evergreen. We need to find our way to a new 1945—and the global political settlement for a tamed and humane capitalism—without having to suffer the catastrophic traumas of trying everything else first.

#### Reject 1AR theory- A] 7-6 time skew means it’s endlessly aff biased B] I don’t have a 3nr which allows for endless extrapolation C] 1AR theory is skewed to the aff because they have a 2ar judge psychology warrant.

#### Infinite abuse claims are wrong- A] Spikes solve-you can just preempt paradigms in the 1AC B] Functional limits- 1nc is only 7 minutes long

## Case

### 1NC – AT: Framing

#### Reducing existential risks is the top priority in any coherent moral theory

Plummer 15 (Theron, Philosophy @St. Andrews http://blog.practicalethics.ox.ac.uk/2015/05/moral-agreement-on-saving-the-world/)

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

#### Weigh magnitude times probability---“probability first” framing is rooted in psychological biases and leads to mass death

Clarke 08 [Lee, member of a National Academy of Science committee that considered decision-making models, Anschutz Distinguished Scholar at Princeton University, Fellow of AAAS, Professor Sociology (Rutgers), Ph.D. (SUNY), “Possibilistic Thinking: A New Conceptual Tool for Thinking about Extreme Events,” Fall, Social Research 75.3, JSTOR]

In scholarly work, the subfield of disasters is often seen as narrow. One reason for this is that a lot of scholarship on disasters is practically oriented, for obvious reasons, and the social sciences have a deep-seated suspicion of practical work. This is especially true in sociology. Tierney (2007b) has treated this topic at length, so there is no reason to repeat the point here. There is another, somewhat unappreciated reason that work on disaster is seen as narrow, a reason that holds some irony for the main thrust of my argument here: disasters are unusual and the social sciences are generally biased toward phenomena that are frequent. Methods textbooks caution against using case stud- ies as representative of anything, and articles in mainstreams journals that are not based on probability samples must issue similar obligatory caveats. The premise, itself narrow, is that the only way to be certain that we know something about the social world, and the only way to control for subjective influences in data acquisition, is to follow the tenets of probabilistic sampling. This view is a correlate of the central way of defining rational action and rational policy in academic work of all varieties and also in much practical work, which is to say in terms of probabilities. The irony is that probabilistic thinking has its own biases, which, if unacknowledged and uncorrected for, lead to a conceptual neglect of extreme events. This leaves us, as scholars, paying attention to disasters only when they happen and doing that makes the accumulation of good ideas about disaster vulnerable to issue-attention cycles (Birkland, 2007). These conceptual blinders lead to a neglect of disasters as "strategic research sites" (Merton, 1987), which results in learning less about disaster than we could and in missing opportunities to use disaster to learn about society (cf. Sorokin, 1942). We need new conceptual tools because of an upward trend in frequency and severity of disaster since 1970 (Perrow, 2007), and because of a growing intellectual attention to the idea of worst cases (Clarke, 2006b; Clarke, in press). For instance, the chief scientist in charge of studying earthquakes for the US Geological Service, Lucile Jones, has worked on the combination of events that could happen in California that would constitute a "give up scenario": a very long-shaking earthquake in southern California just when the Santa Anna winds are making everything dry and likely to burn. In such conditions, meaningful response to the fires would be impossible and recovery would take an extraordinarily long time. There are other similar pockets of scholarly interest in extreme events, some spurred by September 11 and many catalyzed by Katrina. The consequences of disasters are also becoming more severe, both in terms of lives lost and property damaged. People and their places are becoming more vulnerable. The most important reason that vulnerabilities are increasing is population concentration (Clarke, 2006b). This is a general phenomenon and includes, for example, flying in jumbo jets, working in tall buildings, and attending events in large capacity sports arenas. Considering disasters whose origin is a natural hazard, the specific cause of increased vulnerability is that people are moving to where hazards originate, and most especially to where the water is. In some places, this makes them vulnerable to hurricanes that can create devastating storm surges; in others it makes them vulnerable to earthquakes that can create tsunamis. In any case, the general problem is that people concentrate themselves in dangerous places, so when the hazard comes disasters are intensified. More than one-half of Florida's population lives within 20 miles of the sea. Additionally, Florida's population grows every year, along with increasing development along the coasts. The risk of exposure to a devastating hurricane is obviously high in Florida. No one should be surprised if during the next hurricane season Florida becomes the scene of great tragedy. The demographic pressures and attendant development are wide- spread. People are concentrating along the coasts of the United States, and, like Florida, this puts people at risk of water-related hazards. Or consider the Pacific Rim, the coastline down the west coasts of North and South America, south to Oceania, and then up the eastern coast- line of Asia. There the hazards are particularly threatening. Maps of population concentration around the Pacific Rim should be seen as target maps, because along those shorelines are some of the most active tectonic plates in the world. The 2004 Indonesian earthquake and tsunami, which killed at least 250,000 people, demonstrated the kind of damage that issues from the movement of tectonic plates. (Few in the United States recognize that there is a subduction zone just off the coast of Oregon and Washington that is quite similar to the one in Indonesia.) Additionally, volcanoes reside atop the meeting of tectonic plates; the typhoons that originate in the Pacific Ocean generate furiously fatal winds. Perrow (2007) has generalized the point about concentration, arguing not only that we increase vulnerabilities by increasing the breadth and depth of exposure to hazards but also by concentrating industrial facilities with catastrophic potential. Some of Perrow's most important examples concern chemical production facilities. These are facilities that bring together in a single place multiple stages of production used in the production of toxic substances. Key to Perrow's argument is that there is no technically necessary reason for such concentration, although there may be good economic reasons for it. The general point is that we can expect more disasters, whether their origins are "natural" or "technological." We can also expect more death and destruction from them. I predict we will continue to be poorly prepared to deal with disaster. People around the world were appalled with the incompetence of America's leaders and orga- nizations in the wake of Hurricanes Katrina and Rita. Day after day we watched people suffering unnecessarily. Leaders were slow to grasp the importance of the event. With a few notable exceptions, organi- zations lumbered to a late rescue. Setting aside our moral reaction to the official neglect, perhaps we ought to ask why we should have expected a competent response at all? Are US leaders and organiza- tions particularly attuned to the suffering of people in disasters? Is the political economy of the United States organized so that people, espe- cially poor people, are attended to quickly and effectively in noncri- sis situations? The answers to these questions are obvious. If social systems are not arranged to ensure people's well-being in normal times, there is no good reason to expect them to be so inclined in disastrous times. Still, if we are ever going to be reasonably well prepared to avoid or respond to the next Katrina-like event, we need to identify the barriers to effective thinking about, and effective response to, disas- ters. One of those barriers is that we do not have a set of concepts that would help us think rigorously about out-sized events. The chief toolkit of concepts that we have for thinking about important social events comes from probability theory. There are good reasons for this, as probability theory has obviously served social research well. Still, the toolkit is incomplete when it comes to extreme events, especially when it is used as a base whence to make normative judgments about what people, organizations, and governments should and should not do. As a complement to probabilistic thinking I propose that we need possibilistic thinking. In this paper I explicate the notion of possibilistic thinking. I first discuss the equation of probabilism with rationality in scholarly thought, followed by a section that shows the ubiquity of possibilis- tic thinking in everyday life. Demonstrating the latter will provide an opportunity to explore the limits of the probabilistic approach: that possibilistic thinking is widespread suggests it could be used more rigorously in social research. I will then address the most vexing prob- lem with advancing and employing possibilistic thinking: the prob- lem of infinite imagination. I argue that possibilism can be used with discipline, and that we can be smarter about responding to disasters by doing so.

#### AT – McGonigle 2

#### A] epistemology is non verifiable and prevents effective weighing which kills debatability – only frameworks grounded in materialism work in the context of debate B] This barely warrants epistemics just explains that laws have been harmful towards natives people – only our framework is descriptive of debate

#### AT – Barker 19

#### A] Requires winning a tradeoff between their framing and ours solving ongoing/racially discriminatory harms which is false---disease makes all their harms worse OR we solve all the colonialism offense B] way too overarching force them to indict specific solvency C] Existential fears need not be settler projections of demise but can be contingently appropriated to reverse indigenous erasure

Weiss 15—Ph.D. candidate, Anthropology, University of Chicago (Joseph, “UNSETTLING FUTURES: HAIDA FUTURE-MAKING, POLITICS AND MOBILITY IN THE SETTLER COLONIAL PRESENT,” Dissertation submitted to the Faculty of the Division of Social Sciences, Department of Anthropology, University of Chicago, December 2015, 223-232, dml)

And yet, something has changed in this landscape from the initial erasures of Native futurity we drew out in the first chapter. In the narratives of colonial actors like Duncan Campbell Scott, it was absolutely clear that “Indians” were disappearing because their social worlds were being superseded by more “civilized” ways of living and being, ones that these Native subjects would also, inevitably, in the end, adopt (or failing that, perish outright). There was a future. It was simply a settler one. But the nightmare futures of that my Haida interlocutors ward against in their own future-making reach beyond Haida life alone. Environmental collapse, most dramatically, threatens the sustainability of all life; toxins in the land and the waters threaten human lives regardless of their relative indigeneity, race, or gender (e.g. Choy 2011; Crate 2011). Put another way, the impetus for non-Haida (and non-First Nations subjects more generally) to be “united against Enbridge” with their indigenous neighbours comes in no small part because an oil spill also profoundly threatens the lives and livelihoods of non-Aboriginal coastal residents, a fact which Masa Takei, among others, made clear in Chapter 3. Nor is the anxiety that young people might abandon their small town to pursue economic and educational advantage in an urban context limited to reserve communities. Instead, the compulsions of capitalist economic life compel such migrations throughout the globe. The nightmare futures that Haida people constitute alternative futures to ward against are not just future of indigenous erasure under settler colonialism. They are erasures of settler society itself.

There is thus an extraordinary political claim embedded in Haida future-making, a claim which gains its power precisely because Haida future-making as we have seen it does not (perhaps cannot) escape from the larger field of settler-colonial determination. Instead, in Haida future-making we find the implicit assertion that Haida people can make futures that address the dilemmas of Haida and settler life alike, ones that can at least “navigate,” to borrow Appadurai’s phrasing, towards possible futures that do not end in absolute erasure. If Povinelli and Byrd are correct and settler liberal governance makes itself possible and legitimate through a perpetual deferral of the problems of the present, then part of the power of Haida future-making is to expose the threatening non-futures that might emerge out of this bracketed present, to expose as lie the liberal promise of a good life always yet to come and to attempt to constitute alternatives.

#### ROB is to vote for the better debater. Only evaluating the consequences of the plan allows us to determine the practical impacts of politics and preserves the predictability that fosters engagement. Rigorous contestation and third and fourth-line testing are key to generate the self-reflexivity that creates ethical subjects arbitrarily excluding offense is bad and prevents in depth clash and engagement that allows for education which is the unique purpose of debate.

### 1NC – AT: Advantage

#### Top-Level – the Aff solves none of the Case – card zero has a medicine key warrant – ask yourself which evidence is medicine-specific - this zaps the Aff solvency to zero – the amount of biopiracy stays the same since they’ll either just 1] continue bioprospecting with the same intensity, but for agriculture and food, not medicine or 2] patent food, then claim its medicinal properties which circumvents the plan.

#### Multiple Alt causes to the Aff – crops, cosmetics, food.

Silva 20 [Daniella Silva (reporter for NBC News focusing on the economic recovery and its effect on families, as well as immigration). “Biopiracy: the largely lawless plundering of Earth’s genetic wealth”. Landscape News. 15 December 2020. Accessed 8/26/21. <https://news.globallandscapesforum.org/48905/biopiracy-the-largely-lawless-plundering-of-earths-genetic-wealth/> //Xu+Elmer]

**Commercialization of genetic resources** is a booming business. **From** drugs and **cosmetics to teas and genetically modified crops,** **plant and animal materials are ubiquitous in consumer markets**. Many of these products are **aggressively protected** **by patents** that profess the products’ “novelty” and “innovativeness.” But these products are arguably neither new nor innovative, as their use of genetic resources has been developed based on existent traditional knowledge of the natural world, often held among Indigenous groups and rural farmers. Yet, these traditional knowledge holders are rarely compensated for their role in producing and safeguarding the biodiversity from which the patent-holders profit. This phenomenon is known as biopiracy. The term biopiracy was coined in the early 1990s by Pat Mooney, founder of ETC Group – an organization which works to protect the world’s most vulnerable people from socioeconomic and environmental impacts of new technologies – to describe the theft or misappropriation of genetic resources and traditional knowledge through the intellectual property system. It also encompasses unauthorized and uncompensated collection of genetic resources for commercial purposes. One of the most widely cited examples of biopiracy is that of U.S. multinational corporation W.R. Grace’s 1994 patent for a neem tree seed extract used in their antifungal spray, Neemex. Although the company claimed its patent was the product of a unique invention, neem extracts had been used by rural farmers in India for more than 2,000 years in insect repellants, soaps and contraceptives. After years of activists and farmers fighting the patent, it was overturned by the Environmental Protection Organization (EPO) in 2000 due to “lack of novelty and innovative step.” While the neem patent was overturned, it is often difficult to legislate against biopiracy as the term has no single legal definition, and regulations around it differ by region. This ambiguity leaves plenty of room for countless cases of companies patenting everything from gene sequences to crop varieties to human cell lines without fairly compensating the countries and communities of origin. It’s not that the intellectual property system is invalid, notes Susan Bragdon, director of Seeds For All and policy advisor at Oxfam Novib. But when it comes to traditional knowledge holders and Indigenous rights, “the patent and intellectual property system wasn’t designed to provide benefits to communities,” she says. Critics of the current patent system, including Mooney, believe that current intellectual property regimes threaten Indigenous rights, favor monopolies over biodiversity and increase social inequities because they allow powerful people and groups to own the most basic building blocks of life. The specter of colonialism Biopiracy is historically rooted in colonialism. Top commodities like sugar, pepper, quinine and coffee were all taken from formerly colonized countries via Western trading companies that plundered local ecologies for profit. Today, environmental activists like the prolific Indian author and researcher Vandana Shiva have argued that patenting genetic material or other components of living organisms is comparable to “the second coming of Columbus” because of how it has reinforced colonial power dynamics between the Global North and South. “90 percent of genetic resources are in the South and 90 percent of patents are in the North,” noted Green Member of European Parliament Sandrine Bélier in an interview with EurActive. Another parallel Shiva draws between biopiracy and colonialism is in the way that pirated seed resources are used to create forced crop monopolies. In her book, “Biopiracy: the plunder of nature and knowledge,” Shiva cites how Monsanto took steps to flood the Indian marketplace with patented cotton seeds in the early 2000s, which resulted in a cotton monopoly that sent many farmers into debt because of the steep price increases and royalties Monsanto charged for their special seeds. Such categorical rules over a market also prevent local farmers from saving and sharing seeds to propagate diverse crops that are well adapted to microclimates and specific conditions, as they have often done for centuries. “There is a fundamental clash between the idea of (Western) technological progress and the idea that no one group or individual has a ‘right’ to monopolize genetic resources,” says Manuel Ruiz Muller, director and principal researcher of the Peruvian Society for Environmental Law (SPDA). “Cultural and human rights often collide with economic rights and intellectual rights.” Toward fair access and benefit sharing The key question is: how can humans share in the use of the Earth’s genetic resources while protecting the rights of smaller actors like developing governments, local communities and Indigenous people? While there are many pieces of legislation dealing with biopiracy and intellectual property rights, the U.N. Convention on Biological Diversity (CBD) and its Nagoya Protocol on access and benefit sharing have been especially influential. The Nagoya Protocol is an international legal framework under the CBD that aims for fair benefit sharing of profits associated with use of genetic resources. It obliges governments and the private sector to establish transparent, mutually agreed-upon terms for how benefits from the use of genetic resources will be shared. But the current framework is riddled with pitfalls. In 25 years, few access and benefits contracts – which legally dictate fair and equitable sharing of benefits from genetic resources – have come about as a result of the Nagoya Protocol, and those that have often result in trivial profits flowing back to traditional knowledge holders, according to an article from Intellectual Property Watch. Access and benefits contracts for genetic materials do not always result in a direct commercial application, and even when they do, the percentage of benefits that flow back to communities can be as low as 0.1 percent of total corporate profits, according to an article from Trade for Development News. “You’ve noticed the piles of money pouring into the coffers of Indigenous peoples and peasants around the world because of access and benefits agreements, right?” Mooney asks with sarcasm. “Of course not. It’s virtually nothing.” Some experts including professor of international governance at the University of Leeds, Graham Dutfield, argue that ending biopiracy would require ceding political space to Indigenous and marginalized groups so that they are on more equal footing to negotiate benefit sharing. But even when political goodwill is present, there are many practical barriers to successful access and benefits regimes. It is possible to have multiple traditional knowledge holders across different countries for the same herbal medicine, for example. In such situations, it is not clear with whom pharmaceutical companies hoping to develop a drug should negotiate benefits or how those benefits will be shared with diverse cultural groups. “I think access and benefit sharing hasn’t proven to be a good mechanism to reward and incentivize communities that are shepherding and managing biodiversity,” says Bragdon. “There haven’t been sufficient benefits to halt the erosion of biodiversity. I think it’s been highly problematic.” Digital Dilemma Additionally, access and benefits agreements often interpret genetic resources as physical matter, which ignores the modern reality of digital DNA and cloud storage. Researchers can freely access many gene banks without agreeing to disclose potential commercial applications or share benefits resulting from their work. “The issue [with biopiracy] today is that companies and private actors can take out patents on digital sequences of DNA – it’s not just about the physical seeds,” says Mooney. “We see companies sucking up all the genetic information they can and storing it on their proprietary clouds.” There are talks of including digital sequencing information (DSI) – disembodied pieces of genetic code – in the CBD, meaning researchers and companies would have to pay to use and copy gene bank information. But the move has been met with resistance. A 2018 article in Science magazine argues that including DSI in an international agreement against biopiracy could “stifle research, hamper the fight against disease outbreaks, and even jeopardize food safety.” Both Mooney and Ruiz Muller are skeptical of these claims. “The critique is misplaced and has to be nuanced substantially,” says Ruiz Muller. The current CBD and Nagoya Protocol have a transactional approach to access and benefit sharing in which two parties negotiate a contract for the use of a particular genetic resource. Under such a system, he argues that including “natural information” – a better term for DSI – in a new framework could negatively impact research; it could lead to countries racing to claim sole jurisdiction over certain pieces of widespread genetic resources and actively competing against one another for contracts.

#### Alt Causes is offense – it’s a guise for the Settler State to continue violence under the guise of benevolence drawing Indigenous movements into a trick of time by false reforms.

#### Biopiracy thesis is wrong and misunderstands IP law.

Chen 6, Jim. "There's no such thing as biopiracy... and it's a good thing too." McGeorge L. Rev. 37 (2006): 1. (Associate Dean for Faculty and James L. Krusemark Professor of Law, University of Minnesota Law School)//Elmer

This Article begins, as do so many other works of legal scholarship, with a story.' Imagine a wonder plant teeming with extraordinary chemical properties. Like most living organisms in a diverse but fragile biosphere, it is native to one of the many poor countries of the global south. The local population and professional botanists agree that the wonder plant deserves the title of "village pharmacy."2 The developing country where this wonder plant is native supplies both the genetic material and the ethnobiological knowledge that an American life sciences company uses to develop pesticides, antiseptics, and even contraceptives. One product in particular, a pesticide and insect repellant, is markedly more stable and effective than traditional formulations known to and used by farmers in the source country. The American company proceeds to patent the new pesticide. The company not only fails to compensate the source country; it also asserts patent rights in this pesticide and other products developed from that wonder plant and traditional knowledge of its uses. In other words, the company stands in position to collect a patent-driven premium from the very villagers who informed it of the wonder plant's properties and who helped harvest the company's first samples of the plant. Writers of fiction are repeatedly told to draw the elements of their craft from real life. So too with this slightly more fact-driven version of storytelling. W.R. Grace's encounter with India's neem tree (Azadirachta indica) neatly fits this narrative.3 Approaching this story in notoriety is that of Eli Lilly & Company's derivation of vinblastine and vincristine, two cancer-fighting alkaloids, from the rosy periwinkle (Catharanthus roseus, formerly classified as Vinca rosea)." Vinblastine is used in treating Hodgkin's disease,5 while vincristine has become the drug of choice for treating childhood leukemia.6 Though neem and the periwinkle deserve more airspace, I shall offer a third story as the paradigmatic tale of alleged northern greed and southern victimhood in the global debate over biodiversity, biotechnology, and the proper relationship between the environmental protection, technological innovation, and social justice. The United States has literally gotten fat. In this Malthusian world,7 references to food security as an apology for American agricultural policies that constrict production and raise producer prices are nothing short of obscene.' "Only a nation that is obscenely rich by the West's historical standards and the larger world's contemporary standards can indulge in food aid either as a means of suppressing domestic supplies or as a tool for shaping foreign relations, much less both."9 The real public health crisis in America and other wealthy nations is not starvation, but obesity.'1 The prescription for this societal pathology is actually quite simple." Americans should eat less and exercise more. Having experienced a shocking increase of 26 years in life expectancy over the course of a mere 75 years of comprehensive food and drug regulation, however, American society as a whole evidently expects to continue the twentieth century's unprecedented and probably unrepeatable actuarial leap forward through pharmaceutical wizardry. 12 In other words, we would sooner take diet pills than limit portions or work out. What we want is a slick pharmaceutical solution: "One pill makes you small."' 3 As is **true of roughly four-fifths of all known drugs,** **an effective pharmaceutical remedy** for obesity **is** likely to be **derived from a natural source.**14 One plausible pharmacological candidate, the cactus Hoodia gordoniis, is prized for its appetite-suppressing, thirst-quenching, and awareness-heightening qualities. What the San people of South Africa have known for thousands of years about the plant they call "Xhoba" languished for three decades in the laboratories of the Council for Scientific and Industrial Research (CSIR). 6 Pfizer Corporation eventually acquired the rights to a hoodia-derived compound called P57 (so named because it was the 57th chemical tested) and at one time planned to market a diet drug that would compete against currently available concoctions that rely on the troubled combination of ephedra and caffeine. 7 A safe, effective substitute, if successfully tested and marketed, would earn massive profits. "Purchasers of diet products are often 'pathetically eager' to obtain a more slender figure."' 8 In July 2003, however, Pfizer withdrew from the project and discontinued clinical development of P57.' 9 The failure to exploit hoodia commercially mooted the immediate question of whether P57's developers owed the San people any compensation. As the stories of neem and the rosy periwinkle illustrate, however, demands for global justice hound almost every effort to extract agricultural or pharmaceutical value from the biological bounty of the developing world. So frequent, so familiar, and so uniform are **tales of biological exploitation** that they now **follow a predictable script**: <Large northern corporation> <seeks I is developing> a highly sophisticated <plant variety / pharmaceutical product> and sends researchers to <exotic place>. After interviewing local <farmers / foragers>, the company's researchers identify a <species / variety / breed> of <life form> that seems responsible for <desirable trait>. The researchers collect a few speciments and collate their interviews. The samples and the local lore inspire a successful program of <crossbreeding / genetic engineering / pharmaceutical development>, which saves the company thousands of hours and enables it to eclipse its competition. The company never shares its profits, however, with the local community from which it derived genetic resources and traditional knowledge. 20 **This is the paradigmatic biopiracy narrative.** That unmistakably accusatory word has set the rhetorical baseline in many debates within the international law of environmental protection and intellectual property for years to come. Many critics condemn the northern "[c]orporations [that] are surveying remote areas of the world for medicinal plants, indigenous relatives of common food crops, exotic sweeteners, sources of naturally occurring pesticides, and even the genetic material of once-isolated indigenous peoples."'" The epithets "biological colonialism, '22 "genetic imperialism, '23 and even plain "plunder"24 dominate many instances of the biopiracy narrative. I come not to praise the biopiracy narrative, but to bury it. Most **allegations of biopiracy** are so thoroughly **riddled with inconsistencies** and outright lies that the entire genre, pending further clarification, must be consigned to the realm of "rural" legend. **Grace has no patent on neem-derived products in India**,25 **and it is "not clear that the Grace patent**," **granted under American law,**26 "**will have any [negative] economic or social effect in India**., 27 The European Patent Office's decision to revoke the Grace patent further weakens its impact on India." **The fear that** the Grace **patent would deprive** **Indian villagers of the right to continue traditional uses of neem** (including the use of the tree's branches as toothbrushes) **is purely scurrilous**. **Neem in its natural form is unpatentable**.29 As for the rosy periwinkle, Madagascar has an even weaker claim of unjust treatment. 0 The rosy periwinkle is native to Madagascar but grows throughout the tropics. In 1952, Robert Laing Noble, a member of the medical faculty at the University of Western Ontario, received 25 rosy periwinkle leaves from his brother, Clark Noble, who in turn reported that the leaves were used in Jamaica for diabetes treatment when insulin was unavailable. The leaves had little effect on blood sugar but strongly inhibited white blood cells. By 1958, Robert Noble's research team at Western Ontario successfully isolated and purified the potent alkaloid extract now known as vinblastine. Working independently, Eli Lilly & Co. found that a crude extract of the whole periwinkle plant prolonged the lives of mice with leukemia. Eli Lilly eventually synthesized vincristine. Insofar as Jamaica has a much stronger claim as the source of traditional knowledge that facilitated the development of vinblastine and vincristine, even advocates of benefit-sharing find it difficult, if not altogether impossible, to fashion a convincing case that Eli Lilly should compensate Madagascar.3 1 Despite its implausibility, the **biopiracy narrative** now **dominates legal scholarship** on the commercialization of products whose development can be traced to a developing country. Advocates for the global south have been clamoring for proprietary protection against northern, industrial uses of ethnobiological knowledge, and that demand shows no sign of abating.32 Against this tide, piecemeal rebuttal of the biopiracy narrative seems futile. In any event, "[i]t would be a very easy and cheap display of commonplace learning" to pierce the "glowing and emphatic language" of the biopiracy narrative,33 as conveyed in individual stories about neem, rosy periwinkle, or hoodia. The time has come, in short, to dismantle the myth of biopiracy root and branch. This Article takes a modest first step toward deconstructing the biopiracy narrative. It will assess claims of biopiracy according to the layered model of information platforms. Every information platform consists of three distinct layers-physical, logical, and content-and biological information is no exception. Layer by layer, I will strip the biopiracy narrative of its plausibility. The conventional biological distinction between phenotypes and genotypes separates the physical from the logical layer of information in individual biological specimens and in species at large. Ethnobiological knowledge is best characterized as the inventive transformation of genetic information into commercially valuable applications. An appropriately utilitarian view of property and its relationship to each layer of biological information thus dissolves any allegation of biopiracy. Having drained the biopiracy narrative of its rhetorical power, this Article will conclude by briefly considering what the proponents of this narrative have been seeking and how the global community might give the global south what it needs (if not necessarily what it wants). Most of all, advocates for the global south seek some way of compensating traditional communities for their contribution to the global storehouse of biological knowledge. Although that goal remains out of reach, more modest-and in many ways more beneficial intermediate objectives are quite feasible. **Simple** and salutary **reforms of existing patent law can prevent outsiders from securing i**ntellectual **p**roperty **in knowledge already developed by traditional communities**. To the extent that bioprospecting will remain part of the global community's portfolio of tools for protecting the biosphere, countries rich and poor should develop a framework for regulating this practice and cooperate in encouraging the professionalization of parataxonomy.