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#### 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.

#### Our Link is overwhelming – here’s the 1AC Evidence –

#### 1] 1AC Bhattacharya 14

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

#### 2] 1AC Eisland 18

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.**

### 2 – CP

#### 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.

### Case

#### 1] Indigenous peoples don’t meet IP requirements.

DeGeer 02 [Marcia Ellen DeGeer (Juris Doctor candidate, New England School of Law). “Biopiracy: The Appropriation of Indigenous Peoples’ Cultural Knowledge”. NEW ENG. J. INT’L & COMP. L. 2002. Accessed 8/27/21. <https://ipmall.law.unh.edu/sites/default/files/hosted_resources/PLANT_PATENT_ARTICLES/biopiracy_and_indigenous_knowledges.pdf> //Xu]

Indigenous Peoples have a difficult time meeting the requirements of patent law. First, they fail the novelty requirement because of the difficulty in identifying an original inventor because the whole tribe possesses the knowledge.51 Second, the tribes fail the non-obviousness test because traditional cultivation practices are considered unscientific due to their process of exchanging information that has an oral tradition and is often undocumented while the scientific extraction of genes is patentable.52 When a pharmaceutical company “scientifically” identifies components of a plant, the company becomes the inventor even though the Indigenous tribe may have shown the company where the plant grows, how they have cultivated it and their purpose for using it. The Western scientific research is valued over the Indigenous Peoples’ knowledge. Third, the Indigenous Peoples fail the useful requirement as it is defined in international law because they do not make a profit from the use of the plants and knowledge. Additionally, Indigenous Peoples often lack the legal and financial resources to protect themselves from biopiracy. “In the United States, filing fees cost $380.00 for a ‘small entity,’ as well as $605.00 for issuing a patent.”53 The application process involves a myriad of deadlines with a particular order to each step; any misstep comes with a financial penalty.54

#### The role of the judge is to vote for the better debater anything else is self serving arbitrary and triggers innovation

#### No resistant praxis

#### Drop them for reading this aff as a prefiat impact as a non Indigenous person

#### they have never experienced how it feels to be an indigenous person which means the aff is functionally only a way for the aff to win and commodifies indigenous suffering

#### 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.