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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.

#### **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.

#### AT Bagley: a. the counterplan reforms these “current formal systems” that resolves any harm to indigenous peoples b. the terminal impact of disease hurt them even more which outweighs

#### AT Feldman: they’re not discouraged from improving drugs – if they have IK they’ll use it to solve diseases b. it’s not “innovation for who” – it’s innovation for EVERYONE c. they didn’t finish their card and barely had a warrant

### 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 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.

## Case

### Framing

#### Extinction first –

#### 1 – Forecloses future improvement – we can never improve society because our impact is irreversible

#### 2 – Turns suffering – mass death causes suffering because people can’t get access to resources and basic necessities

#### 3 – Moral obligation – allowing people to die is unethical and should be prevented because it creates ethics towards other people

#### 4 – Objectivity – body count is the most objective way to calculate impacts because comparing suffering is unethical

#### 5 – Moral uncertainty – if we’re unsure about which interpretation of the world is true – we ought to preserve the world to keep debating about it

### 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.

#### 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.

#### Developing nations support biopiracy – it’s economic and environmental benefits are key to reduce poverty and stop further environmental degradation.

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)//sid

Stripped of its normative premises layer by layer, the biopiracy narrative loses all appeal. The Convention on Biological Diversity's endorsement of national sovereignty assigns national governments all responsibility for initial access to genetic resources. Access to physical biological specimens is the one aspect of bioprospecting that lies entirely within the control of individual nation- states. Few, if any, national governments have elected to throttle this economic chokepoint for fear of destroying all prospective profits from the commercial development of biological diversity. Within the logical sublayer, the TRIPS accord allows the principal jurisdictions of the North Atlantic alliance-the United States, Canada, and the European Union-to adopt radically diverse solutions to the problem of patenting genetic information. Developing countries such as India, which are the usual complaining parties in instances of alleged biopiracy, enjoy ample discretion under TRIPS to refuse patents on a wide range of biotechnological inventions. Finally, although traditional knowledge is susceptible to protection through a modified form of trade secret law, no convincing economic case for such protection can be made. Within the biopiracy debate, no country strikes a consistent posture toward intellectual property as a legal tool. The southern countries that urge recognition of intellectual property in indigenous knowledge are often proponents of weakening proprietary protection on pharmaceuticals, agricultural chemicals, and educational materials in the name of increased access. 56 A study by the World Intellectual Property Organization (WIPO) found that respondents in 28 less developed countries, despite their misgivings about intellectual property as a legal concept and about aspects of specific intellectual property laws, often "expressed interest in exploring further the actual and potential role" of intellectual property in protecting traditional knowledge. 51 7 Subsequent WIPO publications have committed the organization to the project of developing models for protecting genetic resources, traditional knowledge, and folklore at the international level. " 8 North and south, the local attitude toward intellectual property depends on what is being protected and what degree of protection delivers the greatest benefit to local interests. Global cries for justice demand more ethical starch than this. "[If you go chasing rabbits /.. you know you're going to fall."'5 9 There's no such thing as biopiracy, and it's a good thing too. The real point of the biopiracy narrative is that the global south wants its largest possible share of the world's wealth. As matters stand, it is quite simple: The north is rich, and the south is not. Developing countries will not soon cease clamoring for some compensatory mechanism, whether or not grounded in the law of intellectual property, that would reward their historical contributions to biological knowledge and applications within the global commons. Motivated by "post-colonial theories of obligation to peoples in areas long exploited by the northern hemisphere," much of the international community seeks some way to alleviate "the extreme distress of those living in bio-rich areas of the world." '60Thanks to the "deep antagonism" generated by even the mere perception of illicit international law "that inventors compensate traditional knowledge holders for sharing that knowledge.' 62 The rhetorical consequences of this attack can be quite grim for the developing world. Most obviously, bioprospecting could come to a complete halt. Given the relatively modest profits realized from the first decades of bioprospecting, a comprehensively "instrumental or economic rationale" for protecting the biosphere as a storehouse of commercial value "appears beyond reach.', 163 Paul Heald cogently recognizes, even if the most ardent proponents of the biopiracy narrative do not, that the repeated hurling of "biopiracy!" as a misleading epithets will hardly convince profit-driven multinational corporations to engage the developing world. Moreover, an emphasis on the traditional knowledge of developing countries invites the immediate application of the developed world's standards of environmental protection and performance to vastly poorer countries. Much of the developing world already regards the environmental imperatives of the developed world as imperialism in green drag.'64 The southern campaign to enhance the proprietary status of its germplasm and its ethnobiological knowledge will engage not only the law of property, but also the entire legal apparatus of the industrialized world. Many traditional practices may affirmatively harm the environment, or at least conflict with global values expressed through international environmental law. Asian folk medicine drives global demand for rhinoceros horns and black bear claws. 165 On opposite sides of the Pacific, Japanese appetites66 and Makah rituals clash with the International Convention on Whaling. 68 Consumers in Florida who prize the eggs of endangered sea turtles as aphrodisiacs pay $36 per dozen. 169 The uncomfortable truth is that the developing world enjoys no moral superiority vis-it-vis wealthier countries on matters of environmental ethics. "Small-scale communities are seldom as humane and ecologically sound" as their advocates "portray them to be."'"" "Small firms ... are responsible for a massively disproportionate share of water and air pollution."' 7 ' Agriculture is especially suspect. "One would be hard pressed to identify another industry with as poor an environmental record and as light a regulatory burden."'72 Smaller, family-owned farms routinely underperform their larger, corporate counterparts in core tasks such as soil conservation and erosion control. 173 The propensity to destroy the environment flourishes in any cultural setting. Any environmental advantage along the developmental divide favors countries whose legal systems have adopted the most comprehensive and coherent rules for managing their citizens' contact with the living world in an age of growing scarcity and declining diversity. In industrialized societies, the law has comfortably assimilated the achievements of life scientists and shaped their attitudes. Nations such as the United States routinely confer patents, plant variety certificates, and other intellectual property rights for biological innovations. With equal vigor, however, western nations also subject those scientists to rigorous regulatory schemes in order to preserve the environment and to prevent ethical abuses. 174 It remains unclear whether traditional knowledge will ever qualify for proprietary protection in the world's wealthiest countries. Those practices having taken center stage in an international legal dialogue dominated by accusations of biopiracy, it hardly stretches the imagination to contemplate ways in which wealthier countries may test the developing world's commitment to the complete integration of their traditions into the positive law of the global community. What the global south and its advocates really seek in the struggle over biopiracy is a simple measure of justice. Massive wealth transfers are what they seek later; modest obstacles to patents on biotechnology may appease these advocates while the global community progresses, albeit at a snail's pace, toward some sort of profit-sharing scheme for spreading the rewards of the biotechnological revolution. Resolving disputes over alleged biopiracy does not require significant revision of existing intellectual property laws, let alone the novel and economically senseless solution of proprietary status for traditional knowledge of biological properties and applications. It may be enough simply to ensure that alleged acts of biopiracy do not form the basis for patents under existing intellectual property laws. Cleansing the current patent system of the taint of biopiracy requires little more than a few modifications that would effectively deny intellectual property rights to outsiders who export and exploit knowledge originally developed within a traditional community. American patent law in particular could withstand a modest degree of legislative revision. As the Patent Act of 1935 now reads, "[a] patent may not be obtained ...if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.' 75 Prior art, if found, has a devastating effect on a patent. Prior art that defeats section 102's novelty requirement can also be used to crush a patent for failure to overcome 76 section 103's hurdle of nonobviousness. 1 The trouble lies in the definition of prior art. The Patent Act's definition of prior art embraces patenting or publication in any country, but includes public use or sale solely "in this country.' 77 To be exact: A person shall be entitled to a patent unless ... the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for patent, or ...the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of the application for patent in the United States.' In other words, "while almost all domestic prior knowledge, use, or invention is considered against a later United States patent, almost all similar foreign activity 179 is not.', The United States' policy of limiting prior art to domestic knowledge is out of step with patent law in other developed countries. The European Union considers evidence of foreign public use in assessing the validity of its patents.'80 Indeed, on the basis of foreign public use-specifically, widespread applications of the neem tree in India-the European Patent Office revoked W.R. Grace's patent on "Neemix," a pesticide and insect repellant derived from azadirachtin, a chemical naturally occurring in neem.'' Redefining "prior art" to include traditional knowledge found in other countries would limit the complicity of American patent law in instances of alleged biopiracy. 2 Even under the existing definition of prior art, the Patent and Trademark Office revoked a patent on turmeric after prior art on medicinal uses of the spice was demonstrated through an ancient Sanskrit text and a scientific paper published in 1953 by the Indian Medical Association.'"3 Eliminating American patent law's existing geographical limitation on prior art would, however, still allow "inventions based on traditional knowledge and genetic resources" to be "patentable as long as they are novel and nonobvious in view of [that] prior art. '" At the international level, TRIPS does not require that patent applications state the origin of genetic materials or biological knowledge used to invent a product. Although TRIPS directs members to "require that an applicant for a patent shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art,"'85 the treaty imposes no further disclosure obligations or other mandatory conditions on patent applicants. More comprehensive protection for traditional knowledge lies entirely beyond the scope of TRIPS, and even the most ardent advocates lament that a legal framework for protecting traditional knowledge is "highly unlikely" to "be inserted into TRIPS anytime soon."' What, in the meanwhile, might gainfully warrant the attention of countries both rich and poor? No matter how unprofitable, and no matter how modest in its impact on biodiversity conservation, commercial bioprospecting will persist for years to come. International policymakers should develop a joint framework for its regulation. International coordination on commercial exploitation of biodiversity can improve the very process of collecting rare specimens. Even though the collapse of global fisheries has shaken public confidence in official efforts to achieve "sustainability,"'87 bitter experience teaches that the lack of coordination would be worse. The slash-and-collect approach of Victorian orchid harvesters would probably prevail." Rationalized harvesting would limit instances of "the wonderfully unusual accomplishment of discovering and eradicating in the same instant a new species."'8 9 The international community might also facilitate the professionalization of parataxonomy,'19 especially in the developing world. Millions of species await collection and classification by properly trained field biologists. Transnational cooperation can help translate ethnobiological knowledge into terms understood by the global scientific community. Its economic impact is simple and immediate. "Scientific research," to put it bluntly, "generates jobs."' 9' The science of systematics is so labor-intensive that the task of classifying 10 million species would require 25,000 professional lifetimes.'92 Whether framed as cooperative bioprospecting or north-to-south technology transfer for the enrichment of parataxonomy, commercially oriented initiatives satisfy the Convention on Biological Diversity's exhortation that the international community should adopt "economically and socially sound measures ... as incentives" to conserve biodiversity and to contribute to its sustainable development.' 9' This much binds proponents and enemies of the biopiracy narrative. Bioprospecting represents merely one of many tools needed to stem the ongoing degradation of the global environment. Of this mutually dependent world's numerous environmental problems, "persistent poverty may turn out to be the most aggravating and destructive."' 94 We must remember "above all else" that "human degradation and deprivation.. . constitute the greatest threat not only to national, regional, and world security, but to essential life-supporting ecological systems. In environmental protection, as in any other challenge in international law, "[t]he threat of economic punishment does not deter nations with nothing to lose.' 96 Under the Biodiversity Convention, "economic and social development and eradication of poverty are the first and overriding priorities of' developing countries.'9'