## **1**

#### **Despite challenges, pharmaceutical R&D shows signs of growth.**

Terry and Lesser 21. [Colin is a Partner in our Life Sciences practice. He has been with Deloitte since 2011 working in the US firm, until 2014 when he moved to the UK practice. Colin’s client advisory work in the Life Sciences sector ranges across strategy and operations focused on the R&D function including operating model development and implementation as well as post-merger integration (PMI). These engagements have been serving client Boards and their senior leadership teams in R&D, Commercial and Supply Chain. Neil is a principal with Deloitte Consulting LLP in the Life Sciences strategy practice and a leader in the Research & Development strategy practice. He joined Deloitte in 1998 and works with life sciences executives creating and implementing strategies that drive productivity, efficiency, and value. He leads strategy, operating model design, productivity improvement, and large transformation initiatives within R&D and Regulatory Affairs. Neil is a frequent writer and speaker on R&D productivity.] May 2021. Deloitte. “Seeds of Change: Measuring the return from pharmaceutical innovation 2020.” Accessed 19 September 2021. <<https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-measuring-the-return-from-pharmaceutical-innovation-2021.pdf#page=6>> //MHES

IRR – Internal Rate of Return

Breakthrough advances in science and technology continue to fuel innovation in the biopharmaceutical (biopharma) industry and shape health care. However, though biopharma R&D is under mounting pressure, this year's analysis is showing a potential for growth with our cohort seeing small improvements in returns on pharmaceutical innovation. Nevertheless, peak sales remain at much lower levels than in 2013, despite a small uptick this year, and R&D costs continue to increase. Costs are increasing due to the growing complexity of development and longer cycle times. There is a pressing need to optimise processes and fundamentally change the drug development paradigm through use of digital and transformative approaches. COVID-19 has spurred on these changes and the industry is well-positioned to build on the momentum and look optimistically for a future with higher returns on pharmaceutical innovation. Since 2010, our series of reports on Measuring the return from pharmaceutical innovation have provided insights into the state of biopharma R&D, by projecting the internal rate of return (IRR) on investment that 12 large-cap biopharma companies might expect to achieve from their late stage pipelines. In 2015, we added an extension cohort of four more specialised companies and backtracked their R&D investments to 2013. Over time, our analysis has shown that both cohorts have seen large declines in their expected returns, and there has been convergence in the performance of the original and extension cohorts. Moreover, for the first time since our research began, a company in the original cohort acquired an extension cohort company. For these reasons, and for the purpose of this and future reports, we have combined the original and extension cohorts to create a combined cohort of 15 companies. However, since this is a transition report, we also provide a comparative analysis of the performance of the separate cohorts. It should be noted that our analysis period was from May 2019 to April 2020 and, therefore, this report's pipeline of late-stage assets does not fully reflect the COVID-19 vaccines and therapies that have since emerged. Measuring the return from pharmaceutical innovation For the first time since 2014, the average IRR has had an uptick from the previous year, showing signs of a potential reversal in the declining trend. In 2020, the projected internal rate of return (IRR) for the combined cohort was 2.5 per cent, 0.9 percentage points higher than in 2019 but 3.9 percentage points lower than in 2013. The range between top and bottom performers narrowed from 2019 and was the third-lowest since 2013. While ten of the 15 biopharma companies in the combined cohort improved their average IRR from 2019, all but one are below the industry cost of capital. The projected IRR for the original cohort in 2020 was 1.7 per cent - an increase of 1 percentage point from 2019, but a decrease of 3.1 percentage points since 2013. The three company extension cohort, in contrast, had a projected IRR of 6.6 per cent in 2020, up from 5.2 per cent in 2019 but well below the 17.4 per cent achieved in 2013.

#### High risk nature of pharmaceutical R&D means patents are necessary to attract investments.

**Grabowski et al 15.** [Henry G. Grabowski is a professor of economics at Duke University, in Durham, North Carolina.

Joseph A. DiMasi is director of economic analysis at the Tufts Center for the Study of Drug Development, Tufts University, in Boston, Massachusetts. Genia Long is a senior advisor at the Analysis Group, in Boston, Massachusetts.] February 2015. Health Affairs, vol. 34, no. 2. “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation.” Accessed 16 September 2021. <<https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>> //MHES  
The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.  Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. 5 The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. 6 Only approximately one in eight drug candidates survive clinical testing. 6  As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.  Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.  New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.  Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.  Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

Fiscal incentives key to preparedness against emerging threats—bioterror, antimicrobial resistance, and new infectious diseases.

Marjanovic PhD and Feijao PhD 20. [Sonja Marjanovic directs RAND Europe’s portfolio of research in the field of healthcare innovation, industry and policy. Her work provides decisionmakers with evidence and insights to support innovation and improvement in healthcare systems, and to support the translation of innovation into societal benefits for healthcare services and population health. Carolina Feijao is an analyst working in the areas of science and emerging technology at RAND Europe. Previously, she worked for Frontiers, an Open Access scientific publisher, where she led the launch of and managed three peer-reviewed journals: Sustainable Food Systems, Forests and Global Change and Sustainable Cities. She gained experience in policy making through a placement at DEFRA and she has been a research associate for GenPol, a Cambridge-based think tank focusing on gender equality issues. She also participated in the Management of Technology & Innovation Programme at Cambridge Judge Business School and carried out consulting projects ranging from market entry strategies for a plant breeding company to pitching a business proposal on innovative wound dressing products.] 2020. RAND Corporation. “Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement.” Accessed 19 September 2021. <https://www.rand.org/content/dam/rand/pubs/perspectives/PEA400/PEA407-1/RAND\_PEA407-1.pdf> //MHES

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. The COVID-19 pandemic is a game-changer among global public health threats. The risk to human life (both in terms of morbidity and quality of life), the economic risks, the epidemiology of the disease and speed of escalation have led to a crisis-response by many governments around the world. This has in turn influenced the immediate industry efforts. Many other infectious disease threats may not manifest as crises in the short term and in the same way as COVID-19, but they could nevertheless escalate. They are not considered to be crises from a short term perspective because they are contained to specific regions and affect fewer people at present – or are re-emerging (e.g. Ebola) – or their impacts have not yet materialised at a scale that would qualify as an immediate crisis (e.g. growing risks of antimicrobial resistance to some infectious pathogens). However, such diseases and issues are recognised as global threats that could become crises in the future.13 The emerging threats raise important policy questions about how government and the pharmaceutical industry can work together to ensure that pharmaceutical industry innovation is incentivised sustainably and at scale. This is important to help mitigate against current and emerging threats becoming crises further down the line. At present, there are no clear and specific criteria to determine when a disease can trigger the types of healthcare-innovation-related policy actions that have been deployed in response to the COVID-19 crisis. For example, this applies to criteria for securing financial resources for innovation-related activities, reforming regulation to accelerate trials and regulatory approval processes, and securing reimbursement mechanisms that help enable industry engagement and the search for rapid solutions. The WHO guidance on what constitutes a pandemic phase does provide guidance on national policy response options, but not specifically as they relate to healthcare innovation activity.14 There are also questions as to whether such policy initiatives and incentives should only be applied in crisis situations, or also as part of proactive government and industry efforts to innovate in the areas of public health threats in order to prevent future global calamities. A crisis and ‘emergency mode’ response may be inevitable for some diseases, but more can be done to mitigate against the need for such a response – especially in cases where emerging threats and their consequences can be foreseen and are known to be a risk. We need to anticipate and act now in terms of how we plan and incentivise better for the future, and how we distinguish between different types of infectious disease threats and phases in framing incentives and regulation. Innovative financial instruments must be integral to any sustainable and scalable approach to incentivising pharmaceutical innovation for tackling emerging threats to public health from infectious diseases The pharmaceutical industry has a responsibility to both its shareholders and to society at large. Incentivising the pharmaceutical industry to innovate solely on the grounds of being a socially responsible sector is unlikely to lead to a sustainable and scalable approach for innovating in response to emerging infectious disease threats. There are also potential challenges to the types of innovation (i.e. how radical or incremental) a reliance on incentives rooted solely in a social responsibility argument can lead to. Donating existing compounds for testing is important, but it is different to at-scale, industry-wide intensive investment in R&D geared at developing highly innovative diagnostics, medicines and vaccines. Even in the case of COVID-19, there are significant differences in the scale of innovative activity that focuses on repurposing existing products and technologies – for example, through testing existing antiviral compounds for potential therapeutic value – and more radically innovative R&D efforts aimed at developing something that acts on the COVID-19 virus in fundamentally novel ways.

#### Bioengineered diseases cause extinction.

Millett/Snyder-Beattie 17 [Piers Millet is a Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie previously spent five years at the Future of Humanity Institute (University of Oxford), where he worked as a program manager and later as Director of Research, developing programs across the institute including those in biosecurity and systemic risk. Prior to that, he was a researcher at a personalized medicine startup. He holds a PhD/DPhil in Zoology from the University of Oxford and is an alumnus of the Johns Hopkins Emerging Leaders in Biosecurity Initiative, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out **entirely.** Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population). In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21

## 2

#### Counterplan text: The member nations of the World Trade Organization ought to amend the Agreement on Trade-Related Aspects of Intellectual Property Rights so that it

**- Requires inventors to disclose the geographical source of biotechnological innovations**

**- Requires patent holders to share the benefits of their inventions with the Indigenous communities from which their knowledge came**

**- Recognizes the ability of Indigenous communities to patent their own knowledge and innovations**

#### The counterplan reconciles the TRIPs agreement with the Convention on Biodiversity (CBD) in order to recognize the ability of Indigenous peoples to exercise authority over their own knowledge.

**Fecteau 01.** [Leanne M. Fecteau - \* Managing Editor, BOSTON COLLEGE THIRD WORLD LAW JOURNAL (2000-2001)], The Ayahuasca Patent Revocation: Raising Questions About Current U.S. Patent Policy, 21 B.C. Third World L.J. 69 (2001), <https://lawdigitalcommons.bc.edu/cgi/viewcontent.cgi?article=1150&context=twlj>

Finally, working to reconcile TRIPS with the goals of the Biodiversity Convention could help to promote a more equal sharing of profits from products developed from indigenous sources of knowledge.236 As discussed above, article 27 of the TRIPS Agreement requires Member States to protect property rights in microorganisms, non-biological and microbiological processes, and plants by either a patent system or a sui generis system.237 In contrast, article 3 of the Biodiversity Convention recognizes that "[s]tates have ... the sovereign right to exploit their own resources pursuant to their own environmental policies .... "238 Despite the differing requirements of the two treaties regarding intellectual property protection, it is possible to reconcile the goals of both. 239 The purpose of the TRIPS Agreement is to reduce distortions and impediments to international trade by protecting intellectual property rights on a globallevel.240 Whereas, the ultimate purpose of the Biodiversity Convention is to prevent the depletion of the Earth's biodiversity and ensure the equitable sharing of the benefits arising out of the use of genetic resources.241 To this end, the Convention recognizes that sovereign nations have the autonomy to enact protective measures to conserve their biodiversity.242 It further provides that nations can protect both the indigenous knowledge of their people and the biological resources within their borders.243 Finally, in contrast to TRIPS, the Biodiversity Convention recognizes that knowledge deserving of intellectual property protection can be held by communities, not just private individuals.244 As India has argued to the WTO, the TRIPS Agreement should be reviewed with an eye to recognizing these points of the Biodiversity Convention.245 First, the WTO should review TRIPS' failure to require that biotechnology patent applications disclose the geographical source of the biological resources and the indigenous knowledge used in the inventive process.246 Presently, TRIPS requires only that the inventor disclose his invention such that a person skilled in the art could utilize it.247 In this way, TRIPS' disclosure requirements are similar to the patent laws of developed countries, which were, for the most part, written with an eye to mechanical and chemical patents.248 TRIPS should be amended to recognize that biotechnological inventions require additional disclosure requirements.249 By including in article 29 a requirement that biotechnological patent applicants disclose the biological source and the indigenous knowledge utilized in the invention, the WTO would take a step toward reconciling TRIPS with the goals of the Biodiversity Convention. 25o Such a disclosure to the public would give countries the opportunity to review patent applications and file any claims before the patent is granted.251 Second, the TRIPS Agreement should be amended to recognize that biological resources and indigenous knowledge are often inseparable.252 To this end, TRIPS should oblige inventors to share the benefits derived from inventions with the communities from whence the biological resources and indigenous knowledge came.253 This could be accomplished through the use of Material Transfer Agreements where the inventor is using biological resources from a developing country and a Transfer of Information Agreement where the invention is based on indigenous knowledge. 254 Thus, recognition of both biological resources gathered and indigenous knowledge used would allow for compensation of the holders of such resources and knowledge. 255 Finally, the WTO should amend TRIPS such that it would recognize the intellectual property rights of both individuals and communities.256 To this end, the WTO should evaluate implementing a system wherein traditional knowledge and contemporary innovations of indigenous communities could be protected under a system of intellectual property rights.257 The ability to patent such knowledge and innovation would provide a concrete means by which to achieve the benefit-sharing objective of the Biodiversity Convention.258 However, under current patent regimes, recognizing an indigenous community's right to patent its cultural knowledge would prove difficult as most patent systems only award patents to individuals.259 One alternative to patenting traditional knowledge would be a system of geographical indications for products derived from traditional knowledge. 260

## 3

#### Counterplan text: The member nations of the World Trade Organization ought to reduce intellectual property protection for medicines except for orphan drugs.

#### Orphan drugs treat rare diseases.

**US Food** and **Drug Administration**. “Rare Diseases at FDA” Accessed 17 September 2021. <https://www.fda.gov/patients/rare-diseases-fda> //MHES

Over 7,000 rare diseases affect more than 30 million people in the United States. Many rare conditions are life-threatening and most do not have treatments. Drug, biologic, and device development in rare diseases is challenging for many reasons, including the complex biology and the lack of understanding of the natural history of many rare diseases. The inherently small population of patients with a rare disease can also make conducting clinical trials difficult. Since the Orphan Drug Act was signed into law in 1983, the FDA has approved hundreds of drugs for rare diseases, but most rare diseases do not have FDA-approved treatments.  The FDA works with many people and groups, such as patients, caregivers, and drug and device manufactures, to support rare disease product development.

#### Orphan drug exclusivity isn’t good enough – patents k2 enforcing IP rights and incentivizing investment.

**Morin** et **al 13**. [Randall Morin is senior director of Intellectual Property at Shire HGT. rmorin@shire.com Kerry Flynn is vice president of Intellectual Property at Shire HGT. kflynn@shire.com Fangli Chen is a partner in the Intellectual Property Group at Choate, Hall & Stewart LLP. fchen@choate.com Eric Marandett is co-chair of the Intellectual Property Litigation Practice Group at Choate, Hall & Stewart LLP. emarandett@choate] September 2013. Association of Corporate Council. “Adopt IP Protections to Ensure Regulatory Exclusivity for Orphan Drugs.” Accessed 14 September 2021. <https://www.choate.com/images/content/1/2/v2/1282/ACC-Docket-Adopt-IP-Protections-to-Ensure-Regulatory-Exclusivity-for-Orphan-Drugs.pdf> //MHES

For example, as discussed above, during the seven-year period of orphan exclusivity, the FDA cannot approve the same drug for the same orphan indication, but can approve the same drug for another disease or condition. However, once a drug is approved for sale, physicians may prescribe the drug “off-label” for disorders other than the specific conditions for which the products are approved. Orphan drug exclusivity does not extend to other uses for the same drug, but a valid and enforceable patent can. In this way, patent protection helps address the competitive risk associated with off-label use. For example, a sponsor of an orphan drug can seek patent protection for the drug substance itself, for various therapeutic uses of the drug substance, including, but not limited to, the relevant orphan indication, and for various processes of making the drug substance, assuming such aspects are novel, useful and nonobvious in accordance with patent law. Such patents can effectively foreclose competition with an orphan product through the back door of off-label use. ■ Can patent protection extend the actual market exclusivity for a drug, thereby enhancing the incentive for investment? For a typical drug, market exclusivity of 11 to 13 years may be necessary to secure sufficient incentives for the expensive and risky investment in drug development. In view of the small market for an orphan drug and the need to maintain sufficiently high prices to recoup the upfront R&D investment, obtaining an adequate period of market exclusivity is critical to justify the equally expensive and complex investment in orphan drug development. Thus, patents can play an important role in extending the actual market exclusivity period to create the necessary incentive for investment. ■ What is an effective patent strategy? To seek patent protection, an invention must be new, useful and nonobvious. An applicant for patent must also provide written description of the invention and enable a person skilled in the art to make and use it. As for any other drugs, patent claims that most effectively secure exclusivity for orphan drugs are those that cover the drug substance as a new composition of matter. But the discovery of a new compound typically occurs at an early stage in the course of drug development, long before therapeutic value is validated in clinical trials. This is especially true for orphan indications, because the therapeutic efficacy in an orphan indication sometimes is discovered later in the course of study, and it can take longer to complete clinical trials due to the small patient populations. Generally, it takes an average of about 10 years to bring a regular drug candidate to market. For orphan drugs, it can take even longer. Patent law, on the other hand, promotes early filing. By the time an orphan drug gets to market, some early-filed patents may have little remaining life. Although some of the lost time during clinical trials and regulatory review may be restored through patent term extension,2  this time lag poses particular challenges for patent protection for orphan drugs, and requires more thoughtful and strategic patent filing and life cycle management. The most important step in using patent protection to supplement orphan exclusivity is to patent the drug product composition of matter. However, because of the long development timelines associated with orphan development, maximizing exclusivity often will require additional filings covering advances made during the development process. Such subsequent patent filings can be directed to dosage forms, formulations, administration mode, drug metabolites, a particular polymorph, a single enantiomer isolated from a racemic mixture, or combination therapy. Prior art, sometimes created by the drug developer’s own earlier filings, can present a significant obstacle to subsequent patent filings. Therefore, to develop an effective patent portfolio to maximize exclusivity, companies need to strategically plan each filing. For example, to leave room for subsequent patent filings, companies should avoid disclosing, explicitly or inherently, the therapeutic uses, dosages and formulations in the earlier new compound composition filings, in order to avoid generating novelty-destroying prior art. To address potential obviousness issues, a company may need to show why such new therapeutic use, dosages and formulations are not obvious to a person working in the field, coupled with unexpected properties provided by such new therapeutic use, dosages and formulations. ■ Has your company struck the right balance between patent rights and orphan exclusivity rights in order to protect your drug around the world? Companies have greater control and flexibility in enforcing patent rights as compared with orphan exclusivity rights. The FDA (or its regulatory counterparts in other countries) primarily enforces orphan exclusivity, without the need for drug sponsors to bring costly and risky infringement actions. This may be particularly advantageous in countries that do not have well established and functioning patent enforcement systems, or in situations in which patent protection is not an option. On the other hand, a company itself controls when and how to assert its patents, without needing to rely on action by an outside authority like the FDA. The recent KV v. FDA case (discussed below) illustrates the risk associated with relying on government action to maintain exclusivity. The limitations of orphan exclusivity The recent lawsuit brought by KV Pharmaceuticals Company (KV) against the FDA over its orphan drug product Makena provides a stark example of the potential shortcomings of orphan protection. KV and its wholly owned subsidiary TherRX Corporation (Ther-RX) own and market a drug called Makena, which is a hydroxyprogestoerone caproate injection (also known as “17P”). On Jan. 25, 2007, the FDA designated Makena as an “orphan drug” to be used for the prevention of preterm birth in women who have a singleton pregnancy and a history of prior preterm delivery. Makena was approved on Feb. 3, 2011, thereby commencing its seven-year orphan exclusivity period. However, for a number of years before the FDA approved Makena, women were treated for risk of preterm birth with versions of hydroxyprogesterone caproate that were compounded by entities known as “compounding pharmacies” or “compounders.” When Makena was released, there was some controversy over its high listed price. In a surprising move, the FDA issued a statement in March 2011 stating, in relevant part, that “[i]n order to support access to this important drug, at this time and under this unique situation, the FDA does not intend to take enforcement action against pharmacies that compound hydroxyprogesterone caproate based on a valid prescription for an individually identified patient unless the compounded products are unsafe, of substandard quality, or are not being compounded in accordance with appropriate standards for compounding sterile products.” The FDA issued further public statements on Makena on Nov. 8, 2011 and June 15, 2012, and none of these statements have announced an intent to take enforcement action against compounded 17P. Patent protection complements orphan exclusivity ■ It protects against gaps in orphan protection; ■ Extends exclusivity to adequately incentivize the investment; and ■ Offers more robust enforcement rights. The most important step in using patent protection to supplement orphan exclusivity is to patent the drug product composition of matter. However, because of the long development timelines associated with orphan development, maximizing exclusivity often will require additional filings covering advances made during the development process. On July 5, 2012, KV sued the FDA. In its complaint, KV asserted that “FDA’s statement and inaction have undermined the exclusivity conferred with the orphan drug designation and devalued their substantial investment in the drug.” The complaint asked the court to issue an injunction that would proactively require the FDA to enforce Makena’s orphan designation by taking action against the compounders. The judge dismissed the lawsuit, citing the Supreme Court directive that “an agency’s decision not to prosecute or enforce, whether through civil or criminal process, is a decision generally committed to an agency’s absolute discretion” and is therefore presumed to be unreviewable by the court. Moreover, it is uncertain whether the FDA would have had the authority to take action against the compounders. Drug products made by compounders typically are not subject to the FDA approval process and, instead, are regulated by the states. Congress presently is considering proposed legislation that, if enacted, would expand FDA authority over compounders. KV’s business model was built on the presumption that sales of Makena would be sufficient to at least recoup its substantial investment in development of the product. The compounded version of 17P displaced Makena in the market and substantially undercut its sales. It does not appear that KV obtained sufficient patent protection for Makena. Indeed, no infringement action has been brought against the compounding pharmacies. KV Pharmaceuticals eventually filed a voluntary Chapter 11 petition in the US Bankruptcy Court. The facts and circumstances surrounding the Makena litigation were quite unique. Nevertheless, the case illustrates the vulnerability of orphan exclusivity protection and how little control a drug sponsor may have over enforcing the exclusivity for its product. By contrast, despite the costs and uncertainty associated with patent litigation, the patent system does provide a robust avenue for enforcing patent rights. Indeed, patent protection historically has been a critical value driver necessary to encourage the extraordinary expense and risk of drug development, even for drugs that serve large patient populations and, therefore, carry the potential for substantial economic reward even over a short period of exclusivity. For orphan products with small and sometimes diffuse patient populations, the risk is particularly acute. The development costs are just as substantial, the development timeline often is longer, and the development risks associated with treating a smaller patient population often are greater. The somewhat longer (seven-year) and more robust regulatory protection alone often is not enough to justify the expense. A comprehensive patent strategy provides a key complement to orphan exclusivity by providing a buffer against the exceptions to orphan protection (e.g., the enforcement problem encountered in the Makena situation). An IP strategy that is closely coordinated with clinical development is key to success. As explained above, companies should rigorously seek protection for novel compounds, formulations, manufacturing processes and any other innovations discovered as the development process progresses, to ensure maximum protection for the resulting orphan treatment and to supplement the exclusivity provided by orphan drug statutes. The best way to ensure sufficient return on the investment in orphan drug development is to combine the benefits of regulatory exclusivity and patent protection.

#### Rare diseases disproportionately affect people of color.

**Rare Disease Diversity** Coalition **n.d.** (RDDC, No Date, accessed on 9-6-2021, Rare Disease Diversity Coalition, "Charting thePath Forwardfor Equity inRare Diseases",<https://3hqwxl1mqiah5r73r2q7zll1-wpengine.netdna-ssl.com/wp-content/uploads/2021/03/RDDC_Path_Forward_Final.pdf>)//sid

While the rare disease community continues to face hurdles generally, people of color face additional hurdles in their quest for care . Barriers to diagnosis and treatment for people of color often have deadly consequences . Flaws across the entire system have a compounding effect on the care that Black, Native American, Hispanic, Asian, and Pacific Islander Americans with rare diseases receive . **Americans of color** **continue to be underrepresented** **in** genome-wide association studies and **clinical research** **trials**, **leading to a lack of understanding about effective treatments**, particularly in diverse populations . Despite making up more than 38 percent of the U .S . population, people of color comprise only 16 percent of research study participants .20 On the patient side, people of color are less likely to have affordable access to health care and rare disease experts .21 To make matters worse, some **rare diseases disproportionately** **impact people of color** . **For instance**, sarcoidosis, **sickle cell anemia**, thalassemia, **and** some **forms of lupus** are known to **affect minority populations at higher rates** **than the general** **population** .22 And implicit bias particularly harms people of color with rare diseases .23

## Case

### UV

#### Yes on 1ar theory not DTD – evaluate punishment after abuse.

They didn’t read no RVIs

### Framing

#### **The standard is maximizing expected well-being.**

#### [1] Moral uncertainty means preventing extinction should be our highest priority. **Bostrom** **12** [Nick Bostrom. Faculty of Philosophy & Oxford Martin School University of Oxford. “Existential Risk Prevention as Global Priority.” Global Policy (2012)] <https://www.existential-risk.org/concept.html#:~:text=Existential%20Risk%20Prevention%20as%20Global%20Priority%20ABSTRACT%3A%20Existential,in%20net%20existential%20risk%20have%20enormous%20expected%20value.> These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ Our present understanding of axiology might well be confused. We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity; we might not even yet be able to imagine the best ends of our journey. If we are indeed profoundly uncertain about our ultimate aims, then we should recognize that there is a great option value in preserving — and ideally improving — our ability to recognize value and to steer the future accordingly. Ensuring that there will be a future version of humanity with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value. To do this, we must prevent any existential catastrophe.

#### [2] They’re wrong about cognitive biases – we’re naturally prone to underestimate existential risks.

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

1.3. WHY EXISTENTIAL RISKS MAY BE SYSTEMATICALLY UNDERINVESTED IN, AND THE ROLE OF THE INTERNATIONAL COMMUNITY In spite of the importance of existential risk reduction, it probably receives less attention than is warranted. As a result, concerted international cooperation is required if we are to receive adequate protection from existential risks. 1.3.1. Why existential risks are likely to be underinvested in There are several reasons why existential risk reduction is likely to be underinvested in. Firstly, it is a global public good. Economic theory predicts that such goods tend to be underprovided. The benefits of existential risk reduction are widely and indivisibly dispersed around the globe from the countries responsible for taking action. Consequently, a country which reduces existential risk gains only a small portion of the benefits but bears the full brunt of the costs. Countries thus have strong incentives to free ride, receiving the benefits of risk reduction without contributing. As a result, too few do what is in the common interest. Secondly, as already suggested above, existential risk reduction is an intergenerational public good: most of the benefits are enjoyed by future generations who have no say in the political process. For these goods, the problem is temporal free riding: the current generation enjoys the benefits of inaction while future generations bear the costs. Thirdly, many existential risks, such as machine superintelligence, engineered pandemics, and solar geoengineering, pose an unprecedented and uncertain future threat. Consequently, it is hard to develop a satisfactory governance regime for them: there are few existing governance instruments which can be applied to these risks, and it is unclear what shape new instruments should take. In this way, our position with regard to these emerging risks is comparable to the one we faced when nuclear weapons first became available. Cognitive biases also lead people to underestimate existential risks. Since there have not been any catastrophes of this magnitude, these risks are not salient to politicians and the public.72 This is an example of the misapplication of the availability heuristic, a mental shortcut which assumes that something is important only if it can be readily recalled. Another cognitive bias affecting perceptions of existential risk is scope neglect. In a seminal 1992 study, three groups were asked how much they would be willing to pay to save 2,000, 20,000 or 200,000 birds from drowning in uncovered oil ponds. The groups answered $80, $78, and $88, respectively.73 In this case, the size of the benefits had little effect on the scale of the preferred response. People become numbed to the effect of saving lives when the numbers get too large. 74 Scope neglect is a particularly acute problem for existential risk because the numbers at stake are so large. Due to scope neglect, decision-makers are prone to treat existential risks in a similar way to problems which are less severe by many orders of magnitude. A wide range of other cognitive biases are likely to affect the evaluation of existential risks.75

#### 3] Ground - a] Both debaters have accessible ground under util (DAs, Advantages, etc) b] all impacts can function under util - k2 fairness since we both need some sort of offense to win

#### 4] Predictability - most authors assume utilitarianism when writing articles—they’re tailored to the general public - k2 fairness and education since we need research in order to engage in the round

### Adv 1

#### COVAX and licensing agreements ensure vaccine access now, but patent waiver causes unsafe vaccines and decks innovation.

Crosby et al. 21 (Daniel Crosby [Lawyer specializing in international trade/law], Evan Diamond [Lawyer specializing in pharmaceutical and biotechnology patent litigation], Isabel Fernandez de la Cuesta [Lawyer specializing in international treaty arbitration], Jamieson Greer [Lawyer specializing in international trade], Jeffrey Telep [Lawyer specializing in international trade litigation], Brian White [Lawyer specializing in international arbitration], Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products, JD Supra, 3/5/2021, <https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/>) hwof

Efforts to develop, produce, and equitably distribute medical products. WTO Members recognize that unprecedented demand for medical products used in the fight against COVID-19 has far outstripped supply of required supplies. Several WTO Members have pointed out that intellectual property protections have not limited production of vaccines and other medical products. Rather, these Members have argued that intellectual property protection has incentivized the research, development and production of the necessary vaccines, treatments and products. Moreover, the international community is coordinating and funding equitable COVID-19 vaccine distribution globally through COVAX, which is organized by Gavi, the Vaccine Alliance, the World Health Organization and the Coalition for Epidemic Preparedness Innovations. Despite these facts, less developed countries continue to push for a waiver of all intellectual property protection for medical products related to the pandemic. Waiver risks uncontrolled use of patented technologies, without improving vaccine access. Pharmaceutical companies can provide, and have provided, licenses to distribute or scale-up production of COVID-19 vaccines and therapies at reduced cost. Such license agreements allow for expanded access in low- and middle-income countries, while also setting reasonable parameters so that patents and other IP rights are used to address the specific medical needs of the COVID-19 pandemic at hand, and not for other purposes. License agreements also allow for orderly technology transfer, including of unpatented “trade secret” information and other critical “know-how,” that may be essential to efficiently producing and scaling-up safe and effective versions of technologically complex vaccines and biologic drug products. Under the present TRIPS waiver proposal, however, member countries could try to exploit an extraordinarily broad scope of IP and copy patented technologies so long as they are “in relation to prevention, containment or treatment of COVID-19.” For example, under an expansive reading of the proposed waiver language, a member country could try to produce patented pharmaceutical compounds that have other indicated uses predating COVID-19, if such compounds had later been studied or experimentally used for potential symptomatic relief or antiviral activity in COVID-19 patients. The same risks may be faced by manufacturers of patented materials or devices that have multiple uses predating COVID-19, but also may be used as “personal protective equipment” or components thereof, or in other measures arguably relating to COVID-19 “prevention” or “containment.” At the same time, it is unclear how the proposed TRIPS waiver could provide the technology transfer and know-how critical for making the complex molecules and formulations constituting the various COVID-19 vaccines. Vaccine manufacture undertaken by an unauthorized party without the proper processes and controls could result in a different product that is potentially ineffective or results in unwanted health consequences. And even if an unauthorized manufacturer could overcome those substantial hurdles to reverse-engineer and scale up a safe and effective vaccine copy, it would likely take substantial time and a series of failures to do so. Notably, several of the original COVID-19 vaccine developers have recently faced low product yield and other manufacturing challenges during pre-commercial scale-up efforts and the initial months of commercial production.

#### Waiver won’t solve vaccine inequity – numerous alt causes.

**Acharya et al 4/14.** [Krishna Prasad Acharya @ Animal Quarantine Office, Budhanilkantha, Kathmandu, Nepal. Tirth Raj Ghimire @ Animal Research Laboratory, Faculty of Science, Nepal Academy of Science and Technology (NAST), Khumaltar, Lalitpur, Nepal and Supram Hosuru Subramanya @ Manipal College of Medical Sciences, Pokhara, Nepal] 14 April 2021. NPJ Vaccines, vol. 54, no. 6. “Access to and equitable distribution of COVID-19 vaccine in low-income countries.” Accessed 7 October 2021. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8047027/>> //MHES

LIC = low-income country

The COVID-19 pandemic has resulted in the deaths and severe illness of many people and the disruption of normal lives, a loss of jobs, a loss of trade, and has dwindled the already weak national economies in the LICs. In this situation, equitable access to a suitable and effective vaccine, especially for the front-line workers, is critical for mitigating and maintaining public health systems and economic growth. That is why the demand for COVID-19 vaccines has been soaring, although supply has been limited. Many underlying causes of vaccine inequity exist in the LICs, which we now discuss in turn. First, many LICs have low socio-economic status with low levels of education, income, and occupation. These factors may directly affect the vaccine-purchasing and accepting processes of their people. Second, the geographical landscape of many LICs poses a significant challenge to vaccine distribution. Many high altitudinal landscapes within Hindu-Kush Himalayan regions, such as Nepal, Bhutan, Pakistan, and Afghanistan, make it very difficult for the vaccine campaigners and staff to distribute vaccines. The difficult situation might be worsened in the desert and remote areas engulfed in war, instability, and conflict. In this context, more than 160 million people have been estimated to be at risk of inaccessibility of the COVID-19 vaccine in Yemen, Syria, South Sudan, and Ethiopia11. Third, people from urban slums and marginalized and migratory populations have poor access to immunization facilities. Vaccine distribution is challenging in urban and peri-urban slums that are overgrowing in developing countries. Fourth, most of the available COVID-19 vaccines need to be transported and stored at refrigerating to freezing temperatures, for example, the Oxford-AstraZeneca COVID-19 vaccine at 2–8 °C and the Pfizer vaccine at −70 °C, although new stability data submitted by the companies to the US regulator show that the latter vaccine can be stored at temperatures of −15 to −25 °C for up to 2 weeks12. Even to protect their quality, care is still needed after transferring these vaccines to the refrigerator or following thawing. Strict regulations for temperature are critical for the maintenance of efficacy, potency, and stability of vaccines. These are significant challenges in LICs due to a shortage of cold chain infrastructures and a lack of advanced technology to monitor the cold chain for storage, distribution, and transportation of vaccines, especially in the rural regions13–15. It could result in low immunization coverage in these areas and, subsequently, the probable endemicity of COVID-19 infections. Fifth, levels of vaccine hesitancy, fear, and confusion have been raised in many countries because of the range of data from efficacy trials for the same product. For example, the Sinovac, a Chinese company, showed 50–91% efficacy16,17. Also, there is the apparent doubt whether the vaccines that have been designed and developed by the researchers following one year of the experiment will work against new variants of the virus. In this context, it is not easy for a developing nation to decide to spend a considerable amount of money to purchase the old vaccines or wait for other future products that would work against new variants. Finally, obtaining intellectual property (IP) of COVID-19 vaccines by the developing countries from vaccine developers has not been entirely successful yet18. Although competitions may exist between many pharmaceutical companies, they are welcoming any interested company and country to license their intellectual property for COVID-19 vaccines. It has assured that vaccines should be global public innovations. Based on this principle, Moderna announced that it allows open access to the relevant IP for the pandemic period and is planning to out-license the IP during the post-pandemic period19. Notably, unrestricted access to IP of COVID-19 vaccine has been a boon for few countries like India, the Republic of Korea, Brazil, Indonesia, and South Africa, which have already started producing vaccines. However, LICs cannot easily take advantage of this due to their lack of domestic vaccine manufacturing capacity and thus rely on rich countries or their vaccine-developing companies. Most LICs lack vaccine-producing resources like policy, planning, programs, vaccinologists, organized laboratories, industries, Research & Developments, and government funding. Thus, even if a license is given to these countries, it will not solve vaccine production problems. Currently, rich countries have been blamed for the underlying unequal distribution of COVID-19 vaccines around the globe. That may not be entirely true. These countries have contributed their efforts in resources and funding, and partnership with other countries. For example, the activities of the US toward the COVID-19 Vaccine Global Access (COVAX) facility, co-led by the Global Alliance for Vaccines and Immunisation (GAVI), the Coalition for Epidemic Preparedness Innovations (CEPI), and WHO are crucial. Although Trump’s government withdrew from WHO in July 2020, accusing it of being a puppet of China during the COVID-19 pandemic, the Biden Government is currently planning to join COVAX and rejoin the WHO. COVAX is working for quick, fair, safe, and global equitable access to COVID-19 vaccines, and thus, it is one of the best options for LICs to combat the pandemic. COVAX aims to vaccinate at least 20% of the people in 92 LICs of Africa, Asia, and Latin America by the end of 2021 as a first step20. Although affluent COVAX participants are criticized for stockpiling vaccines for themselves, COVAX might be proved a boon for the LICs if such confusion and criticism are removed.

### Adv 2

#### No solvency – they just push Indigenous Knowledge into the public domain.

#### Bioprospecting key to drug discovery – it’s much easier than synthesizing new chemicals.

Cooke 18. [Justin Cooke is a medical herbalist, and the founder of The Sunlight Experiment. He has a passion for scientific research and discovery is what motivates him to produce content like this everyday. He earned a Bachelor of health sciences (BHSc) degree in 2018, and currently writes for a number of prominent health and medical blogs.] 14 June 2018. The Sunlight Experiment. “What is Bioprospecting? Why is it Important?” Accessed 6 October 2021. < <https://thesunlightexperiment.com/blog/2018/6/7/what-is-bioprospecting-why-is-it-important>> //MHES

Prior to the early 1940’s, death from infection was common. Catch a bug like Pneumonia or Strep throat and you may very well have died from it. Enter Alexander Fleming, the scientist who discovered the first antibiotic, penicillin. He didn’t create this compound however, he merely isolated it from a common mould, the type that you may find on old orange peels or bread. Thanks to this medical advancement, death from infectious disease is no longer an issue for most people. This development came to us through a process known as bioprospecting. There are many other examples of medicines that were sourced through the concept of bioprospecting, including chemotherapy drugs, pain medications, antidepressants, and even psychedelic drugs like LSD. Bioprospecting remains today an essential element of new drug discovery. The Search For New Drugs The human body is incredibly complex. This means that there are an unfathomable number of things that can go wrong with the human body. We’re constantly trying to search for new solutions to old problems, like our age-old war with cancer, as well as improvements to old medicines that have limited efficacy (like antidepressants, and seizure medications). Additionally, drugs that were effective in the past, may no longer be effective today. A great example of this is antibiotics. These medications are essential for public health, but are losing their effectiveness as bacteria becomes resistant to their effects. This places a heavy burden on researchers to develop new drugs to replace them before it's too late and global outbreak occurs. Finding new drug candidates is no easy task. The majority of drug research falls flat on its back despite years of hard work and rigorous testing. Additionally, searching for new chemicals from scratch is like trying to find a needle in a haystack... while blindfolded with your hands tied behind your back. There are simply too many chemical combinations possible to brute force effective medicines. This is why many scientists look for prospective new drugs from plants and fungi. With a long history of use, and incredible chemical diversity, plants offer us a boost in drug discovery. Based on traditional uses, scientists can take a closer look at the active constituents of plants used for a certain condition. Based on these findings, these chemicals can then be isolated or synthesised to create new drugs. Drug Development Is Driven By Patent Law The pharmaceutical industry is notoriously cut-throat. The high cost of drug discovery and new drug development makes it important that the final profits produced from the drug remains in the hands of those who worked hard to create it. This is controlled by patent laws. Patent laws are important. Let’s put ourselves in the shoes of these drug companies for just a moment. Imagine you spend 10 years and 100 million dollars developing a treatment for multiple sclerosis. The drug is completed and released… you can finally begin off-setting the insane development costs you spent making it. Once the drug is released, however, other companies realise the usefulness of this medication, and begin manufacturing and selling it at a cheaper price. The reason they can sell it cheaper than you is because they didn’t dump 100 million dollars into its development like you did. People begin to buy your competitors version of the drug over yours because it’s cheaper. All your hard work and investment of both time and money was for nothing. This example is exactly what would happen without patent laws, and would be enough to completely halt future drug development. It wouldn’t be a sustainable business practice to spend all your money paving the way for all your competitors to profit from. Patent laws ensure that the companies spending the time and money developing new, innovative drugs are entitled to the profits for the first 10 years following discovery. Due to the high cost required to produce these drugs, it’s necessary for these companies to justify spending this money to do it. Tangent Warning: Many people will argue that developing new drugs to cure disease should be done regardless of cost and that locking in profits through patent laws is unethical. It’s important to remember that drug companies need to turn a profit in order to avoid bankruptcy. Profits are used for paying back the cost of drug discovery, as well as funding the development of new drugs. I’m not arguing that medicines shouldn’t be free for any inhabitant of earth, because I believe they should. However, the only way to achieve this is to transition from market driven drug development (pharmaceutical companies in the private sector) to government-funded development (aka higher taxes and less efficiency). We can weigh out the options of both but I don’t see how either one is much better than the other. Searching For New Chemicals From Natural Sources Plants, fungi, and animals are master chemists. In fact, life itself could be isolated down to a chemical reaction. Whenever we add chemicals into our body, either from plants, animals, or man-made compounds, it’s going to have an effect in some way on our bodies natural chemical processes. The trick is to figure out which ones cause positive changes, and what the best way to use it is. Plants offer a headstart in this search through traditional medical practices. We can identify a long list of herbal medicines for nearly any condition, in nearly any part of the world. From here we can begin the long and tedious process of sifting through it using the scientific method and high-tech chemical analysis to push this understanding even further.

#### Several alt causes to biopiracy that the aff can’t solve.

Beattie et al 11. [Andrew J. Beattie @ Department of Biological Sciences, Macquarie University, North Ryde, NSW 2109, Mark Hay @ School of Biology, Georgia Institute of Technology, Atlanta, Georgia, USA, Bill Magnusson @ Instituto Nacional de Pesquisas da Amazonia, Manaus, Brazil, Rocky de Nys @ School of Marine and Tropical Biology, James Cook University, Townsville, James Smeathers @ School of Human Movement Studies, Faculty of Health, Queensland University of Technology, Kelvin grove, Queensland, Australia, Julian F. V. Vincent @ Department of Mechanical Engineering, The University, Bath, UK] 1 May 2011. Austral. Ecol, vol. 36, no. 3. “Ecology and bioprospecting” Accessed 9 October 2021. <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3380369/>> //MHES

Bioprospecting is the exploration of biodiversity for new resources of social and commercial value. It is carried out by a wide range of established industries such as pharmaceuticals, manufacturing and agriculture as well as a wide range of comparatively new ones such as aquaculture, bioremediation, biomining, biomimetic engineering and nanotechnology. The benefits of bioprospecting have emerged from such a wide range of organisms and environments worldwide that it is not possible to predict what species or habitats will be critical to society, or industry, in the future. The benefits include an unexpected variety of products that include chemicals, genes, metabolic pathways, structures, materials and behaviours. These may provide physical blueprints or inspiration for new designs. Criticism aimed at bioprospecting has been addressed, in part, by international treaties and legal agreements aimed at stopping biopiracy and many activities are now funded by agencies that require capacity-building and economic benefits in host countries. Thus, much contemporary bioprospecting has multiple goals, including the conservation of biodiversity, the sustainable management of natural resources and economic development. Ecologists are involved in three vital ways: first, applying ecological principles to the discovery of new resources. In this context, natural history becomes a vast economic database. Second, carrying out field studies, most of them demographic, to help regulate the harvest of wild species. Third, emphasizing the profound importance of millions of mostly microscopic species to the global economy.

#### Alt causes mean the aff creates a false consciousness: settlers act under the belief that they’re doing something helpful so they’re less likely to take steps towards decolonization etc.

#### 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 wealt

h. 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'