## Indigenous Medicines PIC

#### Indigenous people need strong intellectual property rights to traditional medicines – their unique medicinal knowledge is open to appropriation and theft from larger Western pharmaceutical companies without it – Sinela and Ramcharan ‘05

SINJELA, MPAZI, and ROBIN RAMCHARAN. “Protecting Traditional Knowledge and Traditional Medicines of Indigenous Peoples through Intellectual Property Rights: Issues, Challenges and Strategies.” International Journal on Minority and Group Rights, vol. 12, no. 1, 2005, pp. 1–24. LK

At one stage a desire began to emerge in indigenous circles for a forum in the United Nations that dealt not only with human rights issues but with the broad range of environmental, developmental and cultural issues affecting indigenous populations. This led to calls for the establishment, as a subsidiary body of the ECOSOC, of a permanent forum on indigenous issues. This forum was finally established in 2000 and met for the first time at UN headquarters in New York in the summer of 2002.9 The Permanent Forum has thus far held three sessions. As of the time of writing there is a debate going on whether the buo Commission's Working Group on Indigenous Populations should be continued in the light of the establishment of the Permanent Forum. Some governments have apparently favored the discontinuance of the Working Group while indigenous peoples favor its continuation. At the Summer Session of the ECOSOC in 2004 the Secretary General of the United Nations submitted a report summarizing the views of States and indigenous organizations on this issue, and, as of the time of writing, the issue still remains open. The study by Mr. Martinez Cobo, the Working Group on Indigenous issues, the working group on a draft declaration and the Permanent Forum have thus been the main building blocks within the United Nations in the past four decades to advance the human rights of indigenous peoples. In the course of their work, they have, inter alia, highlighted the need for the protection of the intellectual property rights of indigenous peoples. Following on from the work of Mr. Martinez Cobo, cultural heritage and intellectual property have been issues of interest to the Working Group. In 1992, the Working Group and the World Intellectual Property Organization (WIPO) held a Technical Conference on Indigenous peoples at which participants recommended that the United Nations develop more effective measures to protect the intellectual and cultural property rights of indigenous peoples.10 A 1993 report by Erica Daes, Chairperson of the Working Group, on the protection of cultural and intellectual property, noted that the term "'indigenous' embraces the notion of a distinct and separate culture and way of life, based on long-held traditions and knowledge which are connected, fundamentally, to a specific territory. Indigenous peoples cannot survive, or exercise their fundamental human rights as distinct nations, societies and peoples, without the ability to conserve, revive, develop and teach the wisdom they have inherited from their ancestors."" The Chairperson was "compelled to the conclusion" that the distinction between cultural and intellectual property, from the indigenous viewpoint, was an artificial one. Indeed, "Industrialized societies tend to distinguish between art and science, or between creative inspiration and logical analysis. Indigenous peoples regard all products of the human mind and heart as interrelated, and as flowing from the same source: the relationship between the people and their land, their kinship with other living creatures that share the land, and with the spirit world. Since the ultimate source of knowledge and creativity is the land itself, all of the art and science of a specific people are manifestations of the same underlying relationship, and can be considered as manifestations of the people as a whole."12 It is not a coincidence that Article 8(j) of the 1992 Convention on Biological Diversity (CBD) adopted at the Rio Earth Summit, creates legal obligations for States party to respect, preserve and maintain knowledge, innovations and practices of indigenous people related to the conservation and sustainable use of bio diversity. The protection of cultural and intellectual property "is connected fundamentally with the realization of the territorial rights and self determination of indigenous peoples".13 The Chairpersons' report noted that the Working Group had received news from "indigenous representatives from every continent about the priority and urgency they attach to the protection of their spiritual and cultural life, arts and scientific and medical knowledge".14Consequently, the Draft Declaration prepared by the Sub-Commission, while recognizing in its preamble the "inherent rights and characteristics of indigenous peoples, especially their rights to their lands, territories and resources," provided for the right to fully participate, inter alia, in the cultural life of the State (Article 4), the right to revitalize and practice their cultural traditions (Article 11), the right to revitalize, use, develop and transmit to future generations their language, oral traditions, writing systems and literatures (Article 13) and, more importantly for present purposes, "the right to their traditional medicines and health practices, including the right to the protection of vital medicinal plants, animals and minerals" (Article 22). In this vein, the draft Article 27 provides that "[indigenous peoples have the right to special measures to protect, as intellectual property, their sciences, technologies and cultural manifestations, including genetic resources, seeds, medicines, knowledge of the properties of fauna and flora, oral traditions, literatures, designs and visual performing arts". Moreover, Article 28 provides that States should seek the free and informed consent of indigenous peoples "prior to commencement of any projects on their lands and territories, particularly in connection with natural resource development or exploitation of mineral or other sub-surface resources".15 In December 1995, to give impetus to the Decade for Indigenous People, the UN General Assembly adopted a Program of activities aimed at strengthening international cooperation for the solution of problems faced by indigenous people in such areas as human rights, the environment, development, health, culture and education. Among the specific actions to be taken were: (i) "the promotion and protection of the rights of indigenous people and their empowerment to make choices which enable them to retain their cultural identity while participating in political, economic and social life, with full respect for their cultural values, languages, traditions and forms of social organization" and (ii) a request for specialized agencies of the UN system and other international and national agencies, as well as communities and private enterprises, "to devote special attention to development activities of benefit to indigenous peoples".16 WIPO has responded accordingly and the report by the Coordinator of the UN Decade for Indigenous Peoples has noted that WIPO's response "has been dramatic" as there is an entire division as part of the regular budget which is now responsible for traditional knowledge and related issues.17 The Permanent Forum has maintained a keen interest in traditional knowledge, soliciting information from all relevant parts of the UN system, notably WIPO.18 The last three sessions of WIPO have focused on its activities in the areas of intellectual property and genetic resources, traditional knowledge and traditional cultural expressions, and are described in greater detail below. Before proceeding to a consideration of the protection of the intellectual property rights of indigenous peoples, we shall in the next section, examine a major heritage of indigenous peoples - traditional medicine. TM, an important part of TK, refers to medicines used by local, tribal and indigenous communities. Such medicine is often herbal and sometimes combined with spiritual elements, such as those practiced by the shaman in tribal communities.19 TM has been refined over centuries of practice by communities who have inherited knowledge from their ancestors. For example, Felix, a member of the Arawak indigenous community of Guyana who works in the Shanklands resort on the banks of Essequibo River, conveyed his impressive knowledge of his community's medicinal uses of various plants and trees in the tropical rainforest. Using the native names of trees, he related the use of the 'yarula' tree for preventing and curing malaria, the use of the 'kakaballi' tree for treating diarrhea and the use of the 'capadulla' tree as a local viagra.20 While relying on textbooks for the Latin names, Felix's knowledge came from his father, the shaman in his community and from inherited knowledge among his people. Thus, often such knowledge is held communally and does not 'belong' to any single person or entity. Equally often, such knowledge cross-cuts communities as well as territorial boundaries. These aspects have implications for intellectual property protection, which we will consider below. The type of TM differs from community to community depending on the type of healing system that is historically prevalent. Until recently non-western healing systems and medicines were disregarded by western health systems, which insist on the development of medicines and healing techniques based on scientific proof and testing. Centuries-old healing systems of the world, such as Chinese traditional medicine and Indian Ayurveda, were given scant attention as the 'scientific' approach was allegedly missing. In Chinese medicine, for example, "disease is viewed as a disharmony of the various elements of the body and the personality of the patient. Chinese therapeutic thought concerns the entire organism's balance, rather than being devoted to clearly localizing and defining the nature of the illness" as in western medicine.21 The argument that non-western medicine is not based on scientific evidence may well ignore the centuries of trial and error, which has actually gone into making a particular medicine or remedy appropriate to a given community. Western science has grudgingly accepted alternative healing systems. However, they have readily sought after TK/IK, which could lead to the production of new drugs, "especially since the cost of putting new drugs on the market is becoming very high".22 Erica Daes noted in her 1993 report, cited above, that studies found that "using traditional knowledge increased the efficiency of screening plants for medical properties by more than 400 percent".23 Already by 1993, estimates of the total world sales of products derived from traditional medicines ran as high as USD 43 billion.24 However, only a tiny fraction of the profits are returned to the indigenous peoples and local communities. For example, it was estimated in the early 1990s, "that less than 0.001 per cent of profits from drugs developed from natural products and traditional knowledge accrue to the traditional people who provided technical leads for research".25 Attempts by Western governments and drug producing companies to harness such TK and TM for their own benefit have led to phenomena such as 'bio piracy' (theft of genetic resources by 'bioprospectors'). Concern has arisen for the preservation of biological diversity and genetic resources. The United States National Cancer Institute had already, by 1960, began a global program to collect and study naturally occurring substances and had tested some 35,000 plant species and a larger number of micro-organisms by 1981. This process intensified with the advent of research to combat AIDS. Pharmaceutical companies, necessarily driven by profit, have become increasingly aware of the potential economic rewards of TK/TM. Among the major US pharmaceutical companies engaged in screening plant species were Merck and Co., Smithkline Beecham, Monsanto, Sterling and Bristol Meyers. But this creates a conflict with the holders of TK/TM. The problem was stated thus by former Filipino President, Fidel Ramos at a ceremony for the signing of a Traditional and Alternative Health Care Law (R.A. 8423) in Manila on 9 December 1998: "We have looked forward to other nations for new technologies and cures, even for ordinary ailments. Indeed, many other nations have been exploiting the potentials of our own resources, claiming them as their own discoveries without giving due credit to us, and in addition to making tremendous profits at our own expense".26 The problem was recognized by Mrs. Daes in her report in 1993, namely that 'collectors' or bio-prospectors, "do not ordinarily have any formal contractual arrangements ... with the indigenous peoples upon whose knowledge of ecology they may rely. Indigenous people have also objected to alleged appropriation of their bodily substances which is taking place in the context of the Human Genome Diversity Project.28

#### CP Text: The member nations of the World Trade Organization ought to do the aff except for with respect to those medicines and data created, discovered, preserved, or primarily used by Indigenous peoples. IP rights for that data should be expanded in a flexible and culturally appropriate context according to principles of IP law including but not limited to repression of unfair competition, recognition of rights, equity and benefit-sharing, prior informed consent, full and effective participation of knowledge holders, and an appropriate framework for access as per the Sinjela and Ramcharan card.

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The question is whether the existing laws, national and international, govern ing intellectual property allow for the effective protection of traditional knowl edge and folklore in particular. If the laws are not appropriate then is there a need for a sui generis system. On the latter point, a sui generis system must be in function of the needs and demands of the TK holders. As Kongolo and Shyllon note, "the fact is that knowledge that is claimed to have been 'invented' and hence 'patented' and converted into intellectual property is often an existing innovation in traditional or indigenous knowledge systems". With respect to the use of traditional medicinal plants, they posit four main issues for consideration: (1) whether the contribution of traditional knowledge to a final product is the sort of contribution that would allow one or more traditional persons to be considered joint inventor; (2) whether publication of information concerning indigenous plant use would bar the availability of a patent, (3) how to address the problems of compensation in the exploitation of herbal knowledge, and (4) whether devel oping countries should recognize through national legislation the rights of tradi tional flows from industrialized countries.61 Any system of protection must recognize the customary laws under which the knowledge evolved. In this connection, WIPO has noted, in the context of the work of the IGC, that, "the use of private property rights for TK protection should thus be carefully balanced with other policy measures to reflect the char acteristics of the protected TK, the stakeholder interests involved, the customary uses, and custodianship patterns. Most countries which have implemented TK protection have therefore supplemented a limited use of private property rights with a combination of other measures."62 Examples of sui generis initiatives include the combination of the grant of exclusive rights with access regulation in Brazil; combination of defensive protection of native insignia with repression of unfair competition in native Indian products in the United States; and combina tion of exclusive property rights, access regulation and unfair competition law to create tailored TK protection measures in Costa Rica and Portugal. "By learning from such national experiences, the combined or comprehensive approach would thus join different legal doctrines and policy tools which have been identified by Member States and have been proven effective in their jurisdictions in order to achieve an appropriate form of protection."63 Thus a 'bundle of rights and methods' may be best suited for the protection of TK. This combined approach "would result in the availability of TK protec tion through a bundle of rights at the national level, which would include the use of existing IP rights, sui generis measures, and non-IP tools, such as access reg ulation and contractual agreements". 61 T. Kongolo and F. Shyllon, 'Panorama of the Most Controversial IP Issues in Developing Countries', 6 European Intellectual Property Review, p. 260. 62 WIPO, Traditional Knowledge: Policy and Legal Options, WIPO/GRTKF/IC/6/4, 12 December 2003, para. 11. The international dimension of protection is addressed in-depth in doc ument WIPO/GRTKF/IC/6/6. Defensive protection of TK is covered only briefly, since documents WIPO/GRTKF/IC/5/6 and WIPO/GRTK.F/IC/6/8 cover this more extensively. 63 6. Key Legal Issues for the Protection of TK/TM What, then, are the core principles and legal doctrines that must underwrite the protection of TK. For this purpose we rely on WIPO studies undertaken for the IGC.64 The principles and doctrines enumerated below have emerged from exten sive discussions within the IGC on national experiences of TK protection. 6.1. Core Principles First, a comprehensive and combined approach is a starting point. It is recog nized that a comprehensive and TK specific approach must be taken using exist ing IP mechanisms, the repression of unfair competition, the grant of exclusive sui generis rights and/or the application of prior informed consent requirements linked to access regimes. It has been noted that a "bundle of rights" and meth ods might be applied for protection. Such a combined approach is not foreign to conventional IP law. For example, ornamental or visually distinctive aspects of products can be protected by a combination of copyright, individual or unfair competition law. Second, the repression of unfair competition, including appropriation and mis take of distinctive traditional characteristics. This may entail the suppression of any false, misleading or culturally offensive references to TK in the commercial arena, and any false or misleading indications or linkage with or endorsement of TK holders. Third, the principle of recognition of rights of TK holders, pertains to con ventional IP rights arising from innovation and intellectual creativity contained in TK elements, as well as to sui generis exclusive rights that may be available for TK. Aggrieved TK holders should be able to seek remedies for misuse of TK and possibly to gain remuneration and benefit-sharing. Fourth, the principle of prior informed consent (PIC) entails confirming that TK, held by a traditional community should not be accessed, recorded, used or commercialized without the prior informed consent of TK holders. Fifth, the principle of equity and benefit-sharing, entails protecting TK in a manner conducive to social and economic welfare, balancing rights and obliga tions, and the equitable sharing of benefits. "A broad principle of equity is cen tral to IP law, and is also implied in non-IP international legal instruments".65 Sixth, the principle of regulatory diversity, including sectoral distinctions, entails that a comprehensive use of TK protection "may need to reflect distinct policy objectives in specific sectors, and may need to be integrated with several regulatory systems at the national level".66 Distinct measures have been taken in some countries to regulate traditional medicine, traditional agricultural practices, TK associated with genetic resources and tradition-based industries.67 64 Ibid., para. 22. 65 Ibid. 66 Ibid., para. 23. 67 Seventh, a principle of adapting the form of protection to the nature of TK. Whatever law is adopted, that law may be shaped or guided by the particular characteristics of the TK. TK may be disclosed or undisclosed, attributable or unattributable, collectively or individually held, codified or uncodified, and may be defined and bounded by diverse forms of customary laws and protocols."68 Eighth, a principle of effective and appropriate remedies entails "making avail able effective and expeditious remedies such as injunctions and penalties, or mechanisms for payment of use fees or other compensation where there is out right prohibition on third party use".69 Ninth, a principle of safeguarding customary uses entails the encouragement of the use of TK and associated genetic resources, which "should not be restrained by the formal legal protection of TK, nor by other IP rights".70 Tenth, the principle of consistency with access and benefit-sharing frameworks for associated genetic resources entails adopting measures which regulate access to genetic resources and benefit-sharing. Legal protection of TK associated with genetic resources should be coordinated with policy frameworks for associated genetic resources, including conservation, sustainable use and benefit-sharing.71 Related principles governing procedural and consultative process might be con sidered including the principle of full and effective participation of TK holders and the principle of coordination with other relevant fora and processes.72 These principles clearly are geared towards affording maximum flexibility to TK holders, legislators and policy makers. The development of a bundle or menu of legal and policy options, "flexibility can be achieved by drawing selectively on general legal doctrines in order to tailor the form of protection to specific needs, TK subject matter and the legal systems of a given jurisdiction".73 6.2. Legal Doctrines and Policy Tools Various doctrines have been used as policy tools for TK protection in national law. Their selective use "could build a sufficiently versatile doctrinal basis for TK protection". The major doctrines are as follows. The first is the grant of exclusive property rights for TK. Such rights may be communally or collectively held. This is for TK that is distinct and has a clear owner. Existing IP rights have been used to protect TK or TK related subject matter. For example, practitioners of traditional medicine have protected their innovations by using patent rights under patent systems. An example is China, which granted 4479 patents for Traditional Chinese Medicine (TCM) in 2002.74 Where existing exclusive IP rights are deemed to be insufficient to take into 68 Ibid., para. 24. 65 Ibid., para. 25. 70 Ibid., para. 26. 71 Ibid., para. 27. 72 76id., paras. 28-30. 73 76/d., para. 31. 74 The Economist, supra note 43. 21 account the specificities of TK, sui generis rights have been called for. Difficul ties have arisen in this regard: meeting requirements of novelty or originality, and inventive step or non-obviousness; requirements in many IP laws for protected subject-matter to be fixed in material form; and the frequently informal nature of TK and the customary laws and protocols that define ownership; concern that protection systems should correspond to a positive duty to preserve and maintain TK, and not merely provide means to prevent unauthorized use; perceived tension between individualistic notions of IP rights and the sense of collective owner ship of TK; and limitations on the term of protection in IP systems (20 years in the case of patents).75 The second, is the application of the principle of prior informed consent (PIC). This enables a regulatory framework so as to control the use of TK by third par ties and ensure a flow of benefits to the knowledge holders, in ways consistent with the collective nature of TK. The third, is the compensatory liability approach, which would entitle TK holders to compensatory contributions from TK users who borrowed traditional know-how for industrial applications of their own during a specified period of time. This would ensure that TK holders gain a share of the economic and moral rewards resulting from exploitation of such knowledge and at the same time con tribute to ensuring access to such knowledge. The fourth, is repression of unfair competition. The law of unfair competition includes a wide range of remedies, including repression of misleading and decep tive trade practices, unjust enrichment, passing off, and taking of unfair com mercial advantage. The fifth, is recognition of customary laws and protocols, "which functions as a cross-cutting interface with local legal systems in all the above-mentioned tools".76 An African Model Law77 and the sui generis laws of Peru78 and the Philippines79 incorporate customary laws by reference to such laws. 7. Strategies and interim measures These then are the main legal principles and doctrines, which must be consid ered. At the national level, several steps are vital in the search for a functioning and effective TK protection system. 75 Ibid., para. 21. 76 Ibid., para. 45. 77 African Model Law for Protection of the Rights of Local Communities, Farmers and Breeders and the regulation of access to Biological Resources, 2000. 78 See 'Efforts at Protecting Traditional Knowledge: The Experience of Peru', document prepared for WIPO Roundtable on Intellectual Property and Traditional Knowledge, Geneva, 1-2 November 1999. See also WIPO, Intellectual Property Needs and Expectations of Traditional Knowledge Holders. WIPO Report on Fact-finding Missions on Intellectual Property and Traditional Knowledge (1998-1999) Report of Fact Finding missions of the WIPO, Publication No. 768. ™ Philippines Executive Order, No. 247, 1995, Section 2(a). Policy objectives have to be clearly defined for any sui generis system. In the case of TK and TM, for example, the following objectives could be considered: - to create an appropriate system for access to TK - to ensure fair and equitable benefit-sharing for TK - to promote respect, preservation, wider application and development of TK - to provide mechanisms for the enforcement of rights of TK holders; and - to improve the quality of TK-based products and remove low quality tra ditional medicine. (ii) The scope of the subject matter has to be defined and eligible for TK pro tection. The use of appropriate terms and criteria for eligibility has to be clearly spelled out. (iii) Formal requirements for acquisition of rights need to be established. For example, TK protection may be automatic (as in copyright protection which is automatic upon creation of the work) or a formal step may be required, such as registering the TK before protection becomes effective (as in the case of a trademark). (iv) Substantive criteria for eligibility must be established. For example, in Panama's sui generis law, only elements of TK that remain 'traditional', that is intrin sically linked to the community that has originated them, would be pro tected under the sui generis system.80 (v) The nature of rights in TK conferred depends on the legal doctrine or com bination of doctrines used for protection (vi) The scope of rights will determine the degree of control, which the right holder will be able to exercise. Potential rights may include prevention of unauthorized access to protected TK, unauthorized commercial use of such TK, third party claims over protected TK and so on. (vii) Determination of the custodians or beneficiaries. Does an individual or the community own the TK? Is TK understood in the national context to refer to a collective product? This may then dictate the granting of collective rights and not to individuals. On the other hand, distinctive right holders may not be necessary, as collective marks and certification marks may be protected on behalf of a group of beneficiaries. (viii) Expiration and loss of rights. The duration of rights, normally a key issue, may be problematic, as sui generis systems sometimes do not contain expiration and loss of rights provisions. Article 23 of the African Model Law states that community intellectual rights "shall at all times remain inalienable".8' (ix) Sanctions and enforcement. Appropriate mechanisms will need to be devised. Ley de Propiedad Intellectual Indigena, Ley No. 20 (26 June 2000). African Model Law, supra note 77. Defensive protection. This involves, for example, the publication of TK on a digital database, so as to record that a particular community has been using that knowledge. This may avoid the misguided grant of patents men tioned above. (xi) Linkages with benefit sharing schemes. As some TK is closely related to biological and genetic resources, such as when these resources are linked with traditional ways of life, regulation of access to biological resources may serve as a basis for protection of TK. In this regard, related conven tions such as the CBD will have to be closely studied

## Innovation DA

#### The pharma industry is strong now but patents are key for continued economic growth. Batell and PhRMA 14:

Batell and PhRMA {Battelle is the world’s largest nonprofit independent research and development organization, providing innovative solutions to the world’s most pressing needs through its four global businesses: Laboratory Management, National Security, Energy, Environment and Material Sciences, and Health and Life Sciences. The Pharmaceutical Research and Manufacturers of America (PhRMA) represents the country’s leading pharmaceutical research and biotechnology companies, which are devoted to inventing medicines that allow patients to live longer, healthier, and more productive lives.}, 14 – “The U.S. Biopharmaceutical Industry: Perspectives on Future Growth and The Factors That Will Drive It,” http://phrma-docs.phrma.org/sites/default/files/pdf/2014-economic-futures-report.pdf//marlborough-wr//

Compared to other capital-intensive, advanced manufacturing industries in the U.S., the biopharmaceutical industry is a leader in R&D investment, IP generation, venture capital investment, and R&D employment. Policies and infrastructure that helped foster these innovative activities have allowed the U.S. to seize global leadership in biopharmaceutical R&D over the past 30 years. However, as this report details, other countries are seeking to compete with the U.S. by borrowing and building upon some of these pro-innovation policies to improve their own operating environment and become more favorable to biopharmaceutical companies making decisions about where to locate their R&D and manufacturing activities. A unique contribution of this report was the inclusion of the perspective of senior-level strategic planning executives of biopharmaceutical companies regarding what policy areas they see as most likely to impact the favorability of the U.S. business operating environment. The executives cited the following factors as having the most impact on the favorability of the operating environment and hence, potential growth of the innovative biopharmaceutical industry in the U.S.: • Coverage and payment policies that support and encourage medical innovation • A well-functioning, science-based regulatory system • Strong IP protection and enforcement in the U.S. and abroad The top sub-attribute identified as driving future biopharmaceutical industry growth in the U.S. cited by executives was a domestic IP system that provides adequate patent rights and data protection. Collectively, these factors underscore the need to reduce uncertainties and ensure adequate incentives for the lengthy, costly, and risky R&D investments necessary to develop new treatments needed by patients and society to address our most costly and challenging diseases. With more than 300,000 jobs at stake between the two scenarios, the continued growth and leadership of the U.S. innovative biopharmaceutical industry cannot be taken for granted. Continued innovation is fundamental to U.S. economic well-being and the nation’s ability to compete effectively in a globalized economy and to take advantage of the expected growth in demand for new medicines around the world. Just as other countries have drawn lessons from the growth of the U.S. biopharmaceutical sector, the U.S. needs to assess how it can improve the environment for innovation and continue to boost job creation by increasing R&D investment, fostering a robust talent pool, enhancing economic growth and sustainability, and continuing to bring new medicines to patients.

#### COVID has kept patents and innovation strong, but continued protection is key to innovation by incentivizing biomedical research – it’s also crucial to preventing counterfeit medicines, economic collapse, and fatal diseases, which independently turns case. Even with renumeration costs it wont compare to the astronomical costs of drug r&d – the only reason pharma companies have innovation incentive is their ability to set the price, massive influx of generics will undercut that. Macdole and Ezell 4-29:

Jaci Mcdole and Stephen Ezell {Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). She focuses on IP and its correlations to global innovation and trade. McDole holds a double BA in Music Business and Radio-Television with a minor in Marketing, an MS in Education, and a JD with a specialization in intellectual property (Southern Illinois University Carbondale). McDole comes to ITIF from the Institute for Intellectual Property Research, an organization she co-founded to study and further robust global IP policies. Stephen Ezell is vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He comes to ITIF from Peer Insight, an innovation research and consulting firm he cofounded in 2003 to study the practice of innovation in service industries. At Peer Insight, Ezell led the Global Service Innovation Consortium, published multiple research papers on service innovation, and researched national service innovation policies being implemented by governments worldwide. Prior to forming Peer Insight, Ezell worked in the New Service Development group at the NASDAQ Stock Market, where he spearheaded the creation of the NASDAQ Market Intelligence Desk and the NASDAQ Corporate Services Network, services for NASDAQ-listed corporations. Previously, Ezell cofounded two successful innovation ventures, the high-tech services firm Brivo Systems and Lynx Capital, a boutique investment bank. Ezell holds a B.S. from the School of Foreign Service at Georgetown University, with an honors certificate from Georgetown’s Landegger International Business Diplomacy program.}, 21 - ("Ten Ways Ip Has Enabled Innovations That Have Helped Sustain The World Through The Pandemic," Information Technology & Innovation Foundation, 4-29-2021, https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through)//marlborough-wr/

To better understand the role of IP in enabling solutions related to COVID-19 challenges, this report relies on 10 case studies drawn from a variety of nations, technical fields, and firm sizes. This is but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. From a paramedic in Mexico to a veteran vaccine manufacturing company in India and a tech start-up in Estonia to a U.S.-based company offering workplace Internet of Things (IoT) services, small and large organizations alike are working to combat the pandemic. Some have adapted existing innovations, while others have developed novel solutions. All are working to take the world out of the pandemic and into the future. The case studies are: Bharat Biotech: Covaxin Gilead: Remdesivir LumiraDX: SARS-COV-2 Antigen POC Test Teal Bio: Teal Bio Respirator XE Ingeniería Médica: CápsulaXE Surgical Theater: Precision VR Tombot: Jennie Starship Technologies: Autonomous Delivery Robots Triax Technologies: Proximity Trace Zoom: Video Conferencing As the case studies show, IP is critical to enabling innovation. Policymakers around the world need to ensure robust IP protections are—and remain—in place if they wish their citizens to have safe and innovative solutions to health care, workplace, and societal challenges in the future. THE ROLE OF INTELLECTUAL PROPERTY IN R&D-INTENSIVE INDUSTRIES Intangible assets, such as IP rights, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.4 For start-ups, this means much of the capital needed to operate is directly related to IP (see Teal Bio case study for more on this). IP also plays an especially important role for R&D-intensive industries.5 To take the example of the biopharmaceutical industry, it is characterized by high-risk, time-consuming, and expensive processes including basic research, drug discovery, pre-clinical trials, three stages of human clinical trials, regulatory review, and post-approval research and safety monitoring. The drug development process spans an average of 11.5 to 15 years.6 For every 5,000 to 10,000 compounds screened on average during the basic research and drug discovery phases, approximately 250 molecular compounds, or 2.5 to 5 percent, make it to preclinical testing. Out of those 250 molecular compounds, approximately 5 make it to clinical testing. That is, 0.05 to 0.1 percent of drugs make it from basic research into clinical trials. Of those rare few which make it to clinical testing, less than 12 percent are ultimately approved for use by the U.S. Food and Drug Administration (FDA).7 In addition to high risks, drug development is costly, and the expenses associated with it are increasing. A 2019 report by the Deloitte Center for Health Solutions concluded that since 2010 the average cost of bringing a new drug to market increased by 67 percent.8 Numerous studies have examined the substantial cost of biopharmaceutical R&D, and most confirm investing in new drug development requires $1.7 billion to $3.2 billion up front on average.9 A 2018 study by the Coalition for Epidemic Preparedness found similar risks and figures for vaccines, stating, “In general, vaccine development from discovery to licensure can cost billions of dollars, can take over 10 years to complete, and has an average 94 percent chance of failure.”10 Yet, a 2010 study found that 80 percent of new drugs—that is, the less than 12 percent ultimately approved by the FDA—made less than their capitalized R&D costs.11 Another study found that only 1 percent (maybe three new drugs each year) of the most successful 10 percent of FDA approved drugs generate half of the profits of the entire drug industry.12 To say the least, biopharmaceutical R&D represents a high-stakes, long-term endeavor with precarious returns. Without IP protection, biopharmaceutical manufacturers have little incentive to take the risks necessary to engage in the R&D process because they would be unable to recoup even a fraction of the costs incurred. Diminished revenues also result in reduced investments in R&D which means less research into cancer drugs, Alzheimer cures, vaccines, and more. IP rights give life-sciences enterprises the confidence needed to undertake the difficult, risky, and expensive process of life-sciences innovation secure in the knowledge they can capture a share of the gains from their innovations, which is indispensable not only to recouping the up-front R&D costs of a given drug, but which can generate sufficient profits to enable investment in future generations of biomedical innovation and thus perpetuate the enterprises into the future.13 THE IMPORTANCE OF INTELLECTUAL PROPERTY TO INNOVATION Although anti-IP proponents have attacked biopharmaceutical manufacturers particularly hard, the reality is all IP-protected innovations are at risk if these rights are ignored, or vitiated. Certain arguments have shown a desire for the term “COVID-19 innovations” to include everything from vaccines, therapeutics, diagnostics, and PPE to biotechnology, AI-related data, and educational materials.14 This could potentially open the floodgates to invalidate IP protection on many of the innovations highlighted in this report. However, much of the current discussion concerning IP focuses almost entirely on litigation fears or R&D incentives. Although R&D is an important aspect of IP, as previously mentioned, these discussions ignore the fact that IP protection can be—and often is—used for other purposes, including generating initial capital to create a company and begin manufacturing and, more importantly, using licensing agreements and IP to track the supply chain and ensure quality control of products. This report highlights but a handful of the thousands of IP-enabled innovations that have sprung forth over the past year in an effort to meet the tremendous challenges brought on by COVID-19 globally. In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world.15 The global struggle against counterfeit and non-regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains.16 Some communities already ravaged by COVID-19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products.17 Polish authorities discovered vials of antiwrinkle treatment labeled as COVID-19 vaccines. 18 In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants.20 Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down.21 But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products.22 Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower. This is largely because counterfeiting tends to be an IP-related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products. Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth.23 This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance.24 It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion).25 The study also shows 38.9 percent of employment is directly or indirectly attributed to IP-intensive industries, and IP generates higher wages and greater revenue per employee, especially for small-to-medium-sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP-intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst the pandemic, growing 4 percent from 2019.28 The top-four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID-19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation. There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike.31 First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives.32 Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.33 There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines.34 And fifth, strong IP boosts exports, including in developing countries.35 Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.36 The following case studies illustrate these benefits of IP and how they’ve enabled innovative solutions to help global society navigate the COVID-19 pandemic.

#### This sets a precedent that spills over to all future diseases – Hopkins 21:

Jared S. Hopkins {Jared S. Hopkins is a New York-based reporter for The Wall Street Journal covering the pharmaceutical industry, including companies such as Pfizer Inc. and Merck & Co. He previously was a health-care reporter at Bloomberg News and an investigative reporter at the Chicago Tribune. Jared started his career at The Times-News in Twin Falls, Idaho covering politics. In 2014, he was a finalist for the Livingston Award For Young Journalists for an investigation into charities founded by professional athletes. In 2011, he was a finalist for the Pulitzer Prize in Investigative Reporting for a series about neglect at a residential facility for disabled kids. Jared graduated from the Merrill College of Journalism at the University of Maryland-College Park with a bachelor's degree in journalism}, 21 - ("U.S. Support for Patent Waiver Unlikely to Cost Covid-19 Vaccine Makers in Short Term ," WSJ, 5-7-2021, https://www.wsj.com/articles/u-s-support-for-patent-waiver-unlikely-to-cost-covid-19-vaccine-makers-in-short-term-11620414260)//marlborough-wr/

The Biden administration’s unexpected support for [temporarily waiving Covid-19 vaccine patents](https://www.wsj.com/articles/u-s-backs-waiver-of-intellectual-property-protection-for-covid-19-vaccines-11620243518?mod=article_inline) won’t have an immediate financial impact on the companies making the shots, industry officials and analysts said. Yet the decision could mark a shift in Washington’s longstanding support of the industry’s valuable intellectual property, patent-law experts said. A waiver, if it does go into effect, may pose long-term risks to the vaccine makers, analysts said. [Moderna](https://www.wsj.com/market-data/quotes/MRNA) Inc., [MRNA -4.12%](https://www.wsj.com/market-data/quotes/MRNA?mod=chiclets) [Pfizer](https://www.wsj.com/market-data/quotes/PFE) Inc. [PFE -3.10%](https://www.wsj.com/market-data/quotes/PFE?mod=chiclets) and other vaccine makers weren’t counting on sales from the developing countries that would gain access to the vaccine technology, analysts said. If patents and other crucial product information behind the technology is made available, it would take at least several months before shots were produced, industry officials said. Yet long-term Covid-19 sales could take a hit if other companies and countries gained access to the technologies and figured out how to use it. Western drugmakers could also confront competition sooner for other medicines they are hoping to make using the technologies. A World Trade Organization waiver could also set a precedent for waiving patents for other medicines, a long-sought goal of some developing countries, patient groups and others to try to reduce the costs of prescription drugs. “It sets a tremendous precedent of waiving IP rights that’s likely going to come up in future pandemics or in other serious diseases,” said David Silverstein, a patent lawyer at Axinn, Veltrop & Harkrider LLP who advises drugmakers. “Other than that, this is largely symbolic.”

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20 Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** 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 imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious 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 contribu-tions 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 innova-tion conditions.

#### Bioterror causes extinction---early response key

Farmer 17 (“Bioterrorism could kill more people than nuclear war, Bill Gates to warn world leaders” http://www.telegraph.co.uk/news/2017/02/17/biological-terrorism-could-kill-people-nuclear-attacks-bill/)

Bioterrorists could one day kill hundreds of millions of people in an attack more deadly than nuclear war, Bill Gates will warn world leaders. Rapid advances in genetic engineering have opened the door for small terrorism groups to tailor and easily turn biological viruses into weapons. A resulting disease pandemic is currently one of the most deadly threats faced by the world, he believes, yet governments are complacent about the scale of the risk. Speaking ahead of an address to the Munich Security Conference, the richest man in the world said that while governments are concerned with the proliferation of nuclear and chemical weapons, they are overlooking the threat of biological warfare. Mr Gates, whose charitable foundationis funding research into quickly spotting outbreaks and speeding up vaccine production, said the defence and security establishment “have not been following biology and I’m here to bring them a little bit of bad news”. Mr Gates will today (Saturday) tell an audience of international leaders and senior officers that the world’s next deadly pandemic “could originate on the computer screen of a terrorist”. He told the Telegraph: “Natural epidemics can be extremely large. Intentionally caused epidemics, bioterrorism, would be the largest of all. “With nuclear weapons, you’d think you would probably stop after killing 100million. Smallpox won’t stop. Because the population is naïve, and there are no real preparations. That, if it got out and spread, would be a larger number.” He said developments in genetic engineering were proceeding at a “mind-blowing rate”. Biological warfare ambitions once limited to a handful of nation states are now open to small groups with limited resources and skills. He said: “They make it much easier for a non-state person. It doesn’t take much biology expertise nowadays to assemble a smallpox virus. Biology is making it way easier to create these things.” The increasingly common use of gene editing technology would make it difficult to spot any potential terrorist conspiracy. Technologies which have made it easy to read DNA sequences and tinker with them to rewrite or tweak genes have many legitimate uses. He said: “It’s not like when someone says, ‘Hey I’d like some Plutonium’ and you start saying ‘Hmmm.. I wonder why he wants Plutonium?’” Mr Gates said the potential death toll from a disease outbreak could be higher than other threats such as climate change or nuclear war. He said: “This is like earthquakes, you should think in order of magnitudes. If you can kill 10 people that’s a one, 100 people that’s a two... Bioterrorism is the thing that can give you not just sixes, but sevens, eights and nines. “With nuclear war, once you have got a six, or a seven, or eight, you’d think it would probably stop. [With bioterrorism] it’s just unbounded if you are not there to stop the spread of it.” By tailoring the genes of a virus, it would be possible to manipulate its ability to spread and its ability to harm people. Mr Gates said one of the most potentially deadly outbreaks could involve the humble flu virus. It would be relatively easy to engineer a new flu strain combining qualities from varieties that spread like wildfire with varieties that were deadly. The last time that happened naturally was the 1918 Spanish Influenza pandemic, which went on to kill more than 50 million people – or nearly three times the death toll from the First World War. By comparison, the recent Ebola outbreak in West Africa which killed just over 11,000 was “a Richter Scale three, it’s a nothing,” he said. But despite the potential, the founder of Microsoft said that world leaders and their militaries could not see beyond the more recognised risks. He said: “Should the world be serious about this? It is somewhat serious about normal classic warfare and nuclear warfare, but today it is not very serious about bio-defence or natural epidemics.” He went on: “They do tend to say ‘How easy is it to get fissile material and how accurate are the plans out on the internet for dirty bombs, plutonium bombs and hydrogen bombs?’ “They have some people that do that. What I am suggesting is that the number of people that look at bio-defence is worth increasing.” Whether naturally occurring, or deliberately started, it is almost certain that a highly lethal global pandemic will occur within our lifetimes, he believes. But the good news for those contemplating the potential damage is that the same biotechnology can prevent epidemics spreading out of control. Mr Gates will say in his speech that most of the things needed to protect against a naturally occurring pandemic are the same things needed to prepare for an intentional biological attack. Nations must amass an arsenal of new weapons to fight such a disease outbreak, including vaccines, drugs and diagnostic techniques. Being able to develop a vaccine as soon as possible against a new outbreak is particularly important and could save huge numbers of lives, scientists working at his foundation believe.

## Case:

#### Patents are good---key to innovation.

Laxminarayan 1, Ramanan Laxminarayan directs the Center for Disease Dynamics, Economics & Policy. He is also a Senior Research Scholar and Lecturer at Princeton University. - See more at: http://www.cddep.org/profile/ramanan\_laxminarayan#sthash.YqaghohJ.dpuf Spring 2001 http://www.rff.org/files/sharepoint/WorkImages/Download/RFF-Resources-143-antibiotic.pdf

The Role of Patents Firms that manufacture antibiotics face conflicting incentives with respect to resistance. On the one hand, bacterial resistance to a product can reduce the demand for that product. On the other hand, the resistance makes old drugs obsolete and can therefore encourage investment in new antibiotics. Pharmaceutical firms are driven to maximize profits during the course of the drug’s effective patent life—the period of time between obtaining regulatory approval for the antibiotic and the expiration of product and process patents to manufacture the drug. Given the paucity of tools at the policymaker’s disposal, the use of **patents** to influence antibiotic use may be worth considering. A longer effective patent life could increase incentives for a company to **minimize** **resistance**, since the company would enjoy a longer period of monopoly benefits from its antibiotic’s effectiveness. Patent breadth is another critical consideration. When resistance is significant, other things being equal, it may be prudent to assign **broad patents** that cover an entire class of antibiotics rather than a single antibiotic. In such a situation, the benefits of preserving effectiveness could outweigh the cost to society of greater monopoly power associated with broader patents. Broad patents may prevent many firms from competing inefficiently for the same pool of effectiveness embodied in a class of antibiotics, while providing an incentive to develop new antibiotics.

#### Even if data sharing is productive, it still eliminates the financial incentive for companies to operate. Data sharing cannot be divorced from patent infringement. Things like patent thickets exist in the squo that mean even if data is shared, companies have too many patents for it to be useful, companies would fear retaliation.

Stiglitz & Wallach 4/26 - Joseph E. Stiglitz and Lori Wallach [Joseph E. Stiglitz, co-recipient of the 2001 Nobel Memorial Prize in Economics Sciences, teaches at Columbia University. Lori Wallach is the director of Public Citizen’s Global Trade Watch.], “Opinion: Preserving intellectual property barriers to covid-19 vaccines is morally wrong and foolish,” *Washington Post* (Web). April 26, 2021. Accessed Aug. 10, 2021. <https://www.washingtonpost.com/opinions/2021/04/26/preserving-intellectual-property-barriers-covid-19-vaccines-is-morally-wrong-foolish/> AT

Unfortunately, the drug companies have consistently done whatever they can to preserve their monopoly control. Even today, as they battle the waiver and argue that existing compulsory licensing rights are sufficient, they lobby the U.S. government to sanction countries that use that tool.¶ These corporations have also undermined this option by building “thickets” of intellectual property barriers. They fortify their monopolies by registering exclusive rights to industrial designs and undisclosed data, such as trade secrets and test data, in addition to numerous patents and copyrights for each medicine. Each element would require a license, and the WTO’s flexibilities might not even encompass all of them.¶ Making matters more difficult, “product-by-product” and “country-by-country” compulsory licensing is nigh impossible to coordinate across countries for medicines with complex global supply chains, such as covid-19 vaccines.

**IPR is key to stopping counterfeits.**

**Kilbride 2020** [Patrick, vice president of International Intellectual Property for the Global Intellectual Property Center at the U.S. Chamber of Commerce, IP Watchdog, "Calls for WTO to Suspend IP Rights for Vaccine Innovation Would Jeopardize Incredible Progress" December 9, https://www.ipwatchdog.com/2020/12/09/calls-wto-suspend-ip-rights-vaccine-innovation-jeopardize-incredible-progress/id=128085/

Finally: A safe, legitimate marketplace. Patents facilitate a market for innovative medicines, throughout the development stage, as well as in commercialization. Licensing arrangements facilitate the types of collaborations that have proven so successful in 2020; they also ensure that third-party manufacturers are making, using, and selling COVID-19 solutions safely and ethically. Without it, counterfeiters and other bad actors could put shoddy, unreliable, and downright dangerous dupes on the market, all the while marketing them as legitimate products. It’s literally a matter of life and death: Thousands, if not millions, of people die each year at the hands of counterfeit drugs.

**Turns case – increased vaccine hesitancy means you’ll never solve current or future pandemics.**

**Baschuk 2021** [Bryce, reporter for Bloomberg News, "Covid-19 pandemic: WTO holiday from vaccine talks draws calls for action" July 26, https://www.business-standard.com/article/current-affairs/covid-19-pandemic-wto-holiday-from-vaccine-talks-draws-calls-for-action-121072601721\_1.html

Specifically, opponents to the waiver say it would create a chaotic patchwork of laws, unravel existing industry partnerships, lead to a supply crunch for scarce vaccine inputs and inject even more uncertainty into already complex arrangements.¶ There’s also the possibility that an IP waiver could result in the production of counterfeit and substandard medicines, which could increase vaccine hesitancy that’s already pervasive in even the world’s wealthiest nations.

#### Turn: Reductions in IPR could result in unsafe or ineffective medicines. Turns solvency because too many people will be afraid of the vaccine to achieve herd immunity.

Crosby et al. 21Daniel Crosby, Evan Diamond, Isabel Fernandez De La Cuesta, Jamieson Greer, Jeffrey Telep, Brian White; Crosby specializes in international trade, investment and matters related to public international law. Diamond is a partner on our Intellectual Property, Patent, Trademark and Copyright Litigation team.; 3-5-2021; "Group of Nearly 60 WTO Members Seek Unprecedented Waiver from WTO Intellectual Property Protection for COVID-related Medical Products"; https://www.jdsupra.com/legalnews/group-of-nearly-60-wto-members-seek-2523821/, JD Supra, accessed 7-21-2021; JPark

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.