# 1NC

## Offs

### T

#### Interpretation: The affirmative must specify which provisions of intellectual property law regarding medicines they modify to what degree they do so.

#### Reduce just means make smaller but doesn’t inherently specify, Cambridge:

<https://dictionary.cambridge.org/us/dictionary/english/reduce> //LHP AV

**to** become or to **make** **something** become **smaller** **in** size, amount, **degree**, importance, etc.:

#### TRIPS is wide-reaching in its application, so reducing generally makes no sense, Baker 04

Brook K. Baker; Professor at Northeastern School of Law, member of the Health Global Access Project; 01-03-2004; "View of Arthritic Flexibilities for Accessing Medicines: Analysis of WTO Action Regarding Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health"; https://journals.iupui.edu/index.php/iiclr/article/view/17822/17992, Indiana International and Comparative Law Review; Vol. 14 No. 3, accessed 7-22-2021; JPark

The resulting **TRIPS** Agreement **covers** basic **principles**, **standards**, **and use of patents, enforcement and dispute settlement mechanisms**, **and multiple other subjects**, many of which are tilted in favor of intellectual property owners and against the interests of consumers. Under its key patent provisions, member countries must provide **patent protection for** a minimum of **twenty** **years** from the filing date of a patent application, Article 33, for any invention, including a pharmaceutical product or process, **that** **fulfils** **the** **criteria** of novelty, inventive step and usefulness, Article 27.1. Although preceding patent-rule pluralism in both the developed and undeveloped world had allowed policy-based discrimination between fields of invention, for example by excluding medicines, **Article** **27.1 expressly outlawed** such **discrimination**. **Similarly, it was no longer permissible to discriminate** routinely **against** **imports** in favor of locally produced products, thus allowing major pharmaceutical companies to control the place of production despite illusory promises to undertake technology transfer. 23 Because of **Article** **28,** **the** major pharmaceutical producers **secured** **exclusive rights to exclude others from "making, using, offering for sale, selling, or importing" patented pharmaceutical products** or products made with a patented process. In addition, **Article 39.3 protects undisclosed information** (including clinical test data) **from** "**unfair** commercial **use,"** a provision that may ultimately be interpreted to impede registration of generic drugs even where patent bars are overcome.24

#### Violation: They just defend the resolution as reduce IP instead of specifying what they do to reduce.

#### Vote neg –

#### 1] Topic Lit – all of the literature specifies what aspects of IP law is bad – data exclusivity, minimum protection, trade secrets, compulsory licensing, etc. Absent specification, it’s impossible to engage with core topic questions because they become vague general principle statements that don’t incentivize in-depth research. That outweighs – A] this is the first international trade law topic so we need to maximize our opportunity to learn details B] the medicine IP issue is pressing right now due to the pandemic

#### 2] Shiftiness – absent specification, the aff can always shift the goalposts of what they defend, which A] kills ground because they can strategically choose what to specify in the 1ar to exclude my offense, which outweighs because it moots 100% of my offense so I always lose and B] destroys clash since we can never engage if we’re solely debating about what to debate about C] Irresolvability – there’s no way to resolve the round if we don’t know what we are debating about, which means the judge has to intervene so it’s the worst form of unfairness because skill is irrelevant

#### 3] Presumption – they don’t do anything because reduction only makes sense in context of specific modifications so you can’t know what offense matters and vote neg on presumption

### DA

#### Pharma innovation is strong now – patent incentives are key to maintaining progress, Austin and Hayford 21:

David Austin, [an Analyst in CBO’s Microeconomics Studies Division] and Tamara Hayford, [a principal analyst in the Health, Retirement, and Long-Term Analysis Division, Congressional Budget Office] prepared the report with guidance from Joseph Kile, Lyle Nelson, and Julie Topoleski. Christopher Adams, Pranav Bhandarkar, and David Wylie (formerly of CBO) contributed to the analysis., April 2021, “Research and Development in the Pharmaceutical Industry” <https://www.cbo.gov/publication/57126> //LHP AV DOA: 9/8/21

At a Glance This report examines research and development (R&D) by the pharmaceutical industry. Spending on R&D and Its Results. **Spending on R&D and the introduction of new drugs have both increased in the past two decades.** In 2019, the **pharma**ceutical industry **spent $83 billion dollars on R&D.** Adjusted for inflation, **that** **amount is about 10 times what the industry spent per year in the 1980s**. Between 2010 and 2019, the number of **new drugs approved** for **sale increased by 60 percent** compared with the previous decade, with a peak of 59 new drugs approved in 2018. Factors Influencing R&D Spending. **The amount of money that drug companies devote to R&D is determined by** the amount of **revenue** they expect to earn from a new drug, the expected **cost** of developing that drug, **and** **policies** that influence the supply of and demand for drugs. The **expected** **lifetime global revenues of a new drug depends on the prices that companies expect to charge** for the drug in different markets around the world, the volume of sales they anticipate at those prices, and the likelihood the drug-development effort will succeed. **The expected cost** to develop a new drug—**including capital costs and expenditures on drugs that fail to reach the market**—**has been estimated to range from less than $1 billion to more than $2 billion**. The federal government influences the amount of private spending on R&D through programs (such as Medicare) that increase the demand for prescription drugs, through policies (such as spending for basic research and regulations on what must be demonstrated in clinical trials) that affect the supply of new drugs, and through policies (such as recommendations for vaccines) that affect both supply and demand. Notes Research and Development in the Pharmaceutical Industry Summary Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered **policies** **that** would **lower** drug **prices** and reduce federal drug expenditures. Such policies would probably **reduce the industry’s incentive to develop new drugs**. In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? The pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. **The share of revenues that drug companies devote to R&D has also grown**: On **average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses in 2019, which is almost twice as large a share of revenues as they spent in 2000**. That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On average, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), which are costly to develop, hard to imitate, and frequently have high prices. Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. What Factors Influence Spending for R&D? Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, Expected costs to develop a new drug, and Policies and programs that influence the supply of and demand for prescription drugs. **Various considerations inform companies’ expectations** about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The **prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments**. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA.** In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug. **Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA**. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and **during that time the company does not receive a financial return on its investment in developing that drug.** The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatments of uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, **the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D.** Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. In particular, **spending on drug R&D increased by nearly 50 percent between 2015 and 2019**. Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, **the trend is broadly representative of R&D spending by the industry as a whole**.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3

#### Intellectual property protections are key to pharmaceutical innovation – laundry of list of studies – that solves access better, Ezeli and Cory 19:

Stephen Ezell, [vice president, global innovation policy, at the Information Technology and Innovation Foundation (ITIF). He focuses on science and technology policy, international competitiveness, trade, manufacturing, and services issues.] and Nigel Cory, [an associate director covering trade policy at the Information Technology and Innovation Foundation. He focuses on cross-border data flows, data governance, intellectual property, and how they each relate to digital trade and the broader digital economy. Cory has provided in-person testimony and written submissions and has published reports and op-eds relating to these issues in the United States, the European Union, Australia, China, India, and New Zealand, among other countries and regions, and he has completed research projects for international bodies such as the Asia Pacific Economic Cooperation and the World Trade Organization.] “The Way Forward for Intellectual Property Internationally” April 25, 2019, <https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally> //LHP AV

INTELLECTUAL PROPERTY UNDERPINS INNOVATION AND GROWTH Intellectual property rights arrangements are well recognized, going back to the Middle Ages, as enabling innovators to earn the returns necessary to continue to innovate and promote the availability of leading-edge technologies. **Nobel laureate economist Douglas North**, one of the foremost scholars of economic history, **argues that the introduction of intellectual property rights had one of the most profound impacts on spurring economic growth in human history**. North points out that average global economic growth rates for about one and a half millennia prior to the Industrial Revolution were essentially zero. Eighteenth-century elites in England had practically the same per capita income as their counterparts in third-century Rome.21 North has shown that the inflection point toward greater economic growth was the widespread development of patent systems in the 19th century.22 Gregory Clark, in his seminal book, Farewell to Alms: A Brief Economic History of the World, reached a similar conclusion that the introduction of **IPRs was catalytic to turbo-charging global economic growth**.23 **Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks**. By raising the private rate of return closer to the social rate of return, in**tellectual property rights address the knowledge-asset incentive problem, allowing inventors to realize economic gain from their inventions, thereby catalyzing investment in knowledge creation.** If innovators know that most of the benefits from their innovations would go to others without compensation, **they would be much less likely and capable of engaging in future innovations**. In addition, as they capture a larger portion of the benefits of their innovative activity, **innovating companies obtain the resources to pursue the next generation of innovative activities.** **IP thus produces a number of positive benefits, including: 1) creating powerful incentives for domestic innovation; 2) inducing knowledge spillovers that help others to innovate; 3) ensuring** a country’s **companies can focus on operating productively and innovating**, instead of having to devote an undue amount of their time and resources to protecting their IP in an environment where it’s at risk; **4) promoting the international diffusion of technology, innovation, and knowhow; and 5) boosting a country’s levels of research and development, inbound foreign direct investment (FDI), and exports of goods and services**.24 Robust intellectual property rights spur innovative activity by increasing the appropriability of the returns to innovation, enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks. The **evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike.** As the definitive 2010 OECD review of the effects of intellectual property rights protections on developing countries, “Policy Complements to the Strengthening of IPRs in Developing Countries” found, “The results point to a tendency for IPR reform to deliver positive economic results.”25 The OECD study found that **developing-country IPR reforms concerning patent protection have tended to deliver the most substantial results**, although the results for copyright reform and trademark reform are also positive and significant. But to have the greatest impact on economic growth, IPR reforms must occur concomitantly with other positive complements, particularly ones regarding inputs for innovative and productive processes and the ability to conduct business. These include policies that influence the macro-environment for firms as well as the availability of resources (e.g., related to education), a country’s legal and institutional conditions, and fiscal incentives.26 The evidence shows that strong intellectual property rights protections are vitally important for both developed and developing countries alike. The following section details the broad swath of academic literature reviewing the relationships between IPR strengthening and trade, FDI, and technology transfer; IPR reform and innovation and R&D; and IPR reform and exports and industry growth, revealing the benefits of stronger IPR protections for developed and developing countries alike. IPRs Strengthen Trade, FDI, and Technology Transfer A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Strengthening IPR protection has been shown to correlate with increased trade.27 For instance, Fink and Primo Braga found that IPR protection is positively associated with international trade flows, in particular of manufactured, non-fuel imports.28 Other studies have found a positive association between IPR protection and trade flows in high-technology products.29 Likewise, strengthening of IPR protection has also been connected with increased inflows of FDI. Cavazos Cepeda et al. found that a 1 percent increase in the protection of IPRs as measured by the Patent Rights Index (a measure of the strength of countries’ IPR regimes) is associated with a 2.8 percent increase in the inflow of FDI.30 Similarly, a 1 percent increase in trademark protection levels is associated with a 3.8 percent increase in incoming FDI; and a 1 percent increase in copyright protection yields a 6.8 percent increase in FDI.31 Moreover, the researchers identified a virtuous cycle between FDI and protection of IP, whereby improvements in the IPR environment are associated with improved economic performance—in particular with respect to FDI—and, in turn, further improvements in the IPR environment. Park and Lippoldt showed that stronger IPRs in developing countries are associated with an increase of technology-intensive FDI, while Awokuse and Yin provided a concrete example concerning the relationship of IPR protection in China to FDI inflows, concluding that IPR reforms in China have had a positive and significant effect on inbound FDI.32 There is also evidence that countries with similar levels of intellectual property protection trade more with one another.33 Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41 A wealth of academic research has documented the relationship between the strength of a country’s intellectual property protections and the extent of trade, foreign direct investment, and technology transfer it enjoys. Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45 **IPRs Strengthen Innovation** Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that **counties with stronger IP protection have more creative outputs** (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), **even at varying levels of development**.46 **IPR reforms also introduce strong incentives for domestic innovation**. **Sherwood**, using case studies from 18 developing countries, **concluded that poor provision of intellectual property rights deters local innovation and risk-taking**.47 In contrast, **IPR reform has been associated with increased innovative activity, as measured by domestic patent filings**, albeit with some variation across countries and sectors.48 For example, **Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets**.49 **Park** **and Lippoldt also observed that** the provision of adequate protection for **IPRs can help to stimulate local innovation**, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, **local innovators are introduced to technologies** first **through** the technology transfer that takes place in an environment wherein **protection** of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D activity in an economy. Studies by Varsakelis and by Kanwar and Evenson found that **R&D to GDP ratios are positively related to the strength of patent rights**, and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56 BOX 1: INNOVATE FOR HEALTH: IP IS NOT THE PROBLEM, BUT PART OF THE SOLUTION **Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services**. Yet the reality is that **stronger IPR rights in developing nations actually unleash the power of developing-country innovators to contribute to solving health challenges**

**both in their own nations and across the global economy**. First, opponents of IP fail to recognize **that intellectual property rights matter for health care innovation in emerging economies.** **A**n Information Technology and Innovation Foundation (ITIF) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market**.57 The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing-country environments where resources and infrastructure are scarce, and that local innovation and **IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** Second, **opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** **While cost is a central factor for policymakers in all countries, given resource scarcity, these trade-offs are not unique to health**. **The greater the resource scarcity, the greater the need for innovation**. One of the biggest challenges policymakers and innovators in developing countries confront again and again is scarcity—in access to trained professionals, in transportation, and in other infrastructure. For example, reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals.58 A 2014 World Health Organization study estimated a shortage of 7 million public health care workers, with that number expected to rise to 13 million by 2035.59 More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens.60 The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens.61 And Ethiopia, a country of some 90 million residents, is served by a single radiation-treatment center located in the capital of Addis Ababa.62 In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, on average, essential medicines are available in public-sector facilities in developing countries only 40 percent of the time.63 Again, **the cost of medicines is far from the most serious problem in the provision of health care services in developing nations**. Indeed, **the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off-patent, and thus potentially available in generic versions**.64 **The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care.** **Stronger IP rights create an environment wherein entrepreneurs can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.** IPRs Strengthen Exports and Industry Growth Academic research has also found that **stronger IPR protections support exports from developing countries and faster growth rates of certain industries.** Yang and Kuo argue that stronger IPR protection improves the export performance of firms benefitting from technology transfer. And in their research, Cavazos Cepeda et al. found that trademark protection has a statistically significant association in relation to the export turnover, sales, and total assets of firms studied. They also found a significant association between copyrights and export turnover. Moreover, they found “a positive influence of patent right protection on export turnover (e.g., sales) under certain specifications with respect to complementary policies.”65 In cross-country studies, researchers have found that stronger patent rights are associated with faster company growth in IP-intensive industries such as pharmaceuticals. In fact, during the early 1990s, a one-standard-deviation increase in patent rights was associated with an increase in firm growth of 0.69 percent (an advantage amounting to nearly one-fifth of the average industry growth rate of 3.7 percent).66 Consequences of Countries Not Enacting Robust IPR Protections and Enforcement **Nations** **that** have not implemented—or **do not enforce**—**robust intellectual property rights protections end up harming their economic development in at least three principle ways. First, they deter future innovative activity. Second, they discourage trade** and foreign direct investment, which only hurts their own consumers and businesses, by both limiting their choices and inhibiting their enterprises’ ability to access best-of-breed technologies that are vital to boosting domestic productivity. **Third, in countries with weak IP protections, firms are forced to invest undue amounts of resources in protection rather than invention**. Ironically, **developing countries’ own economic development opportunities** and intellectual property development potential **are inhibited by their own weak intellectual property protections.** For instance, the lack of effective protection for intellectual property rights in China has limited the introduction of advanced technology and innovation investments by foreign companies, thereby reducing potential benefits to local innovation capacity.67 As Cavazos Cepeda et al. found in a case study of IPR protections in that economy, “China has made progress in strengthening the protection of intellectual property over the past two decades, as attested to by indicators such as the Patent Rights Index…. However, uncertainty around the protection of intellectual property [remains] an important deterrent for foreign as well as domestic firms engaging in R&D-related activities.”68 Ironically, developing countries’ own economic development opportunities and intellectual property development potential are inhibited by their own weak intellectual property protections.

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror.

Marjanovic and Feijao 20 [(Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon.) "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, https://www.rand.org/pubs/perspectives/PEA407-1.html] TDI

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contributions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still low.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innovation conditions.

#### Pandemics cause extinction.

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “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 theWestern 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.19-2

## Case

#### 1] With weaker IP protections, pharmaceutical companies will resort to trade secrets over patents---that undermines the public scientific collaboration that informs global public health response.

Gewertz, Nevin. "Intellectual Property And The Pharmaceutical Industry: A Moral Crossroads Between Health And Propert." Journal of Business Ethics 55:3. December, 2004. Web. August 18, 2021. <https://www.jstor.org/stable/25123392?seq=1#metadata\_info\_tab\_contents>.

The granting of a United States patent establishes a form of monopoly rights to specific creative works. The granting of exclusive monopoly rights prevents others from enjoying any positive externalities de rived from the idea itself. Yet, does the right to intellectual property include the right to exclude and limit the actions of others? A simple utilitarian analysis of the potential consequences of non exclusive intellectual property elucidates the need for patent rights to incorporate exclusive monopoly rights. **Without exclusive monopoly rights granted to their products, pharma**ceutical **companies would be forced to keep product information a secret**. **The usage of public forums for intellectual dialogue such as academic journals and conferences would give way to trade secrets** (Mansfield, 1993). **This type of secretive behavior would have nefarious effects both the scientific community and the collaborative principles upon which it thrives**. The exclusive monopoly rights rewarded by the state in the form of a patent are necessary to promote intellectual dialogue and to avoid the usage of trade secrets.

#### 2] Unpatented medicine cause counterfeits—

Lynbecker 16 [(Kristina M. L. Acri née, an Associate Professor of Economics at Colorado College in Colorado Springs, where she is also the Associate Chair of the Department of Economics and Business and the Gerald L. Schlessman Professor of Economics. Dr. Lybecker’s research analyzes the difficulties of strengthening intellectual property rights protection in developing countries, specifically special problems facing the pharmaceutical industry.) “Counterfeit Medicines and the Role of IP in Patient Safety,” IPWatchDog, 7/27/16. <https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/>] RR

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated: “The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that counterfeit products accounted for up to 2.5 percent of world trade, or $461 billion, in 2013. This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount. Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1] As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines. While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3] [Kristina] According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless. Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need: inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives.

#### The affirmative can’t solve the root cause of the problems developing nations face – WTO News Briefing 20

WTO News Briefing; ; 10‐16‐2020; ”Members discuss intellectual property response to the COVID‐19 pandemic”; https://www.wto.org/english/news\_e/news20\_e/trip\_20 oct20\_e.htm, World Trade Organization News, accessed 7‐21‐2021; JPark

While a number of developing and least developed country members welcomed the proposal as a contribution to the discussion, many were still studying it in their capitals and asked for clarification on certain points, particularly regarding its practical imple‐ mentation and the possible economic and legal impact of the waiver at national level. **A number of developing and developed country members opposed the waiver proposal, noting that there is no indication that intellectual property rights (IPRs) have been a gen‐ uine barrier to accessing COVID‐19 related medicines and technologies. While acknowl‐ edging that the sustained and continued supply of such medicines and technologies is a difficult task, they observed that non‐efficient and underfunded health care and pro‐ curement systems, spiking demand and lack of manufacturing capacity are much more likely to impede access to these material**s. In the view of these members, solutions can be legitimately sought within the existing IP system as the TRIPS Agreement provides enough tools and sufficient policy space for members to take measures to protect public health. **The suspension of IPRs, even for a limited period of time, was not only unnec‐ essary but it would also undermine the collaborative efforts to fight the pandemic that are already under way.**

#### Can’t make enough vaccines vital components are too scarce

Tepper 4-10 James Tepper, 4/10 [James Tepper, (James M. Tepper is an American neuroscientist currently a Board of Governors Professor of Molecular and Behavioral Neuroscience and Distinguished Professor at Rutgers University and an Elected Fellow of the American Association for the Advancement of Science.)]. "Global Covid vaccine rollout threatened by shortage of vital components." Guardian, 4-1-2021, Accessed 8-8-2021. https://www.theguardian.com/world/2021/apr/10/global-covid-vaccine-rollout-threatened-by-shortage-of-vital-components // duongie

Vaccine-makers around the world face shortages of vital components including large plastic growbags, according to the head of the firm that is manufacturing a quarter of the UK’s jab supply. Stan Erck, the chief executive of Novavax – which makes the second vaccine to be grown and bottled entirely in Britain – told the Observer that the shortage of 2,000-litre bags in which the vaccine cells were grown was a significant hurdle for global supply. His warning came as bag manufacturers revealed that some pharmaceutical firms were waiting up to 12 months for the sterile single-use disposable plastic containers, which are used to make medicines of all kinds, including the Pfizer, Moderna and Novavax Covid-19 vaccines. But Erck and his British partners said they were confident they had enough suppliers to avoid disruption to the supply of Novavax. The vaccine is waiting for approval from the Medicines and Healthcare products Regulatory Agency (MHRA) but the first of 60 million doses ordered by the government are already in production in Teesside. The Fujifilm Diosynth Biotechnologies factory began growing the first cells for the Novavax vaccine in Billingham, County Durham this month and in a few weeks they will fill the bioreactor bag, ready to be transported to GlaxoSmithKline’s plant at Barnard Castle to be put into vials for distribution. “The first hurdle is showing it works and we don’t have that hurdle any more,” Erck said. But he added there were others still to overcome. “There’s the media that the cells have to grow in,” Erck said. “You grow them in these 2,000-litre bags, which are in short supply. Then you pour it out and you have to filter it, and the filters are in short supply. The little things count.” Novavax almost ran out of bags at one of its 20 factories earlier this year, but there had been no delays for the UK operation, according to Martin Meeson, global chief executive of Fujifilm Diosynth. “We started working on our part of the supply chain in summer last year,” he said. “We had to accelerate some of the investment here, but the commitment we made last summer to start manufacturing in February has been fulfilled.” Production of coronavirus vaccines is being ramped up. Production of coronavirus vaccines is being ramped up. Photograph: Christophe Archambault/AP Both Meeson and Erck said the UK’s vaccine taskforce had been helpful in sorting out supply issues so far, but other countries and other medical supplies might be affected. ABEC makes bioreactor bags at two plants in the US and two in Fermoy and Kells in Ireland, and delivered six 4,000-litre bags to the Serum Institute in India last year for its Covid vaccines. Brady Cole, vice-president of equipment solutions at ABEC, said: “We are hearing from our customer base of lead times that are pushing out to nine, 10, even 12 months to get bioreactor bags. We typically run out at 16 weeks to get a custom bioreactor bag out to a customer.” He said ABEC was still managing to fulfil orders at roughly that rate. “The bag manufacturing capacity can’t meet demand right now,” he added. “And on the component side, the tubes and the instruments and so forth that also go into the bag assembly – those lead times are also starting to get stretched as well. But the biggest problem we see is it really is just the ability to get bags in a reasonable amount of time.” ABEC expanded its factories last year and has now started making 6,000-litre bags, which are roughly the size of a minibus. Other firms including MilliporeSigma, part of German company Merck, have also been expanding their manufacturing facilities. American firm Thermo Fisher Scientific expects it will finish doubling its capacity this year. The US government has also blocked exports of bags, filters and other components so it can supply more Pfizer vaccines for Americans. Adar Poonawalla, the chief executive of the Serum Institute of India, said the restrictions were likely to cause serious bottlenecks. Novavax is hoping to avoid delays and “vaccine nationalism” by operating on four continents, with 20 facilities in nine countries. “One year ago, we had exactly zero manufacturing capacity,” Erck said. “We’re self-sufficient. The two main things we need to do are done in the UK. And in the EU we have plants in Spain and the Czech Republic and fill-and-finish in Germany and the Netherlands.” There was no need for vaccines to cross borders to fulfil contracts, he said. The Oxford/AstraZeneca vaccine was hit by a delay to a delivery of 5 million doses from India and a problem with a batch made in Britain, and the company has been dragged into a lengthy row between the UK and the EU over vaccine exports

#### The plan only hurts manufacturing moving bottlenecks to less efficient manufacturers

Alex **Knapp, 5/7** [Alex Knapp, (senior editor at Forbes covering healthcare, science, and cutting edge technology.)]. "Patent Waivers Won’t Impact Big Pharma’s Bottom Line—But Could Slow Covid Vaccine Rollouts." Forbes, 5-7-2021, Accessed 8-5-2021. https://www.forbes.com/sites/alexknapp/2021/05/07/patent-waivers-wont-impact-big-pharmas-bottom-line-but-could-slow-covid-vaccine-rollouts/?sh=78866f727862 // duongie

On Wednesday, the Biden Administration stated that it would support a proposal to temporarily waive protection of intellectual property (IP) rights for Covid vaccines during the pandemic, in a bid to boost production and accelerate vaccine distribution throughout the world. Industry trade groups immediately criticized the move, and investors reacted simultaneously—share prices plummeted, though they’ve been slowly recovering Thursday and Friday. Wall Street analysts at Morgan Stanley, Jefferies and Brookline Capital Markets, however, said in reports this week that waiving vaccine IP was unlikely to impact the financials of major vaccine makers, noting that current bottlenecks in vaccine production are related to supply chain, technical knowledge and difficulty in scaling up production. However, they caution that for the same reason, waivers could slow down current production by disrupting the market for raw materials. “Manufacturing supplies, raw materials, vials, stoppers and other key materials are in limited supply for 2021, and certainly for the 2021 calendar year,” wrote analysts from Jeffries, meaning that waivers can’t solve immediate vaccination needs in India and South Africa, where Covid-19 cases are surging. That report also notes that the mRNA vaccines from Pfizer and Moderna have yet to be authorized for use in India, as regulators desired local clinical trial data, which is another hurdle to overcome. Morgan Stanley commented that U.S. support alone doesn’t necessarily mean that a World Trade Organization agreement on the waiver would happen, especially since Germany has expressed opposition. The firm additionally notes that “manufacturing vaccines is a much more complicated process than making chemical drugs, and a patent waiver by itself would not enable other entities to manufacture their own copies of complex vaccines.” Jefferies analysts also remarked that another barrier to increased vaccine production is “ensuring the quality of the product, which is also not trivial.” Contractors for vaccine makers Pfizer, AstraZeneca and Johnson & Johnson have all run into quality-control issues that have led to millions of vaccine doses being discarded. On a company earnings call yesterday, Moderna CEO Stéphane Bancel said he doubted that waiving IP rights would impact his company much, because it would take months or even years for other companies to scale up manufacturing.

Meanwhile, the biotech company has recently committed to expanding its own manufacturing capacity and expects to be able to make up to 3 billion doses of vaccine in 2022. Morgan Stanley analysts noted that in October 2020, Moderna “stated it would not enforce its patents during the pandemic, but to our knowledge, no one else has started manufacturing a vaccine that would violate Moderna’s patents.” The team at Brookline Capital markets noted that if a company did begin manufacturing vaccines based on Moderna’s patents, the upside would be an additional licensing revenue stream for the company. On Friday, vaccine manufacturer Novavax, which has reached an agreement with the private-public global health partnership Gavi to provide 1.1 billion vaccine doses to low income countries, stated its opposition to the WTO waiving patents, arguing that it “could further constrain resources by diverting them to entities incapable of manufacturing safe and effective vaccines in the near term.” Jeffries analysts note that a waiver wouldn’t put Novavax at immediate risk, as a key component of the company’s vaccine “is in limited supply and a majority of the raw material has already been locked up” by the company. That said, Morgan Stanley struck a similar point to Novavax about the risk involved in waiving patents. The analysts point out waivers could be counterproductive and actually slow down vaccine manufacturing. “An IP waiver now may exacerbate supply issues,” they write, “if some countries start to try to secure raw materials ahead of being able to produce a vaccine and cause shortages and disruptions in the supply chain.”

### AT Evergreening

#### First, “incremental” innovations are a key aspect of R&D, Jones 6

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

As already mentioned, **the costs and time necessary to bring a drug to the market are considerable**. While the initial patents covering the basic chemical or protein entity are important to encourage the further investment to bring the drug to the market, **the length of time afforded protection** by such patents ‐ due to the considerable amount of time necessary to develop a suitable formulation and presentation of the drug, and the time to conduct clinical trials ‐ **usually does not provide sufficient protection to balance the overall financial investment.** Further, **many inventions** made during the develop‐ ment of the drug formulation or presentation, while possibly **viewed as ’incremental inventions’ by some, are actually critical to bringing the drug to the market**. Indeed, as a proportion of all patents granted worldwide, very few relate to what may be termed “breakthroughs”. **The vast majority cover innovations which build on inventions of others, with the benefit of full disclosure of those inventions in patent specifications**. That is what the patent system was designed to encourage. **By its very nature**, there‐ fore**, it encourages inventors to adapt and modify the developments** patented by others **incrementally** or in any other way. It would therefore, in ICC’s view, be wholly in‐ appropriate not to allow patents for such forms of innovation; and any such change would adversely affect the ability to finance future drug research. **The innovation process in the pharmaceutical sector, as for all other scientific sectors, is one of evolution**. The criteria for patentability are clear. Patents are available for any invention, whether product or process, in any field of technology, provided it is new, involves an inventive step and is capable of industrial application. **If an invention meets these criteria, it is entitled to patent protection. If it does not, it is not patentable. Of these criteria, the most relevant here is inventive step**. The invention must not have been obvious to a person skilled in the relevant art at the time the application for a patent was first filed, taking into account the state of the art at that time. There is no common understand‐ 192 7 Negative Evidence ing around the world on how this criterion should be applied and TRIPS provides no guidance. The precise manner in which it is applied differs from country to country. It even differs over time within the same country. Significant progress has, however, been made in harmonizing the standard, particularly in the US, Japan and Europe. This harmonized standard should, in ICC’s view, in time become the “gold standard” for patents globally. In the meantime, it may be necessary and appropriate, to encourage investment in local research and manufacturing, for developing countries to adopt a lower threshold to provide easy access to patents for local entrepreneurs. But in ICC’s view, it cannot be right to require such countries to adopt a higher standard of inventive step. In any event, neither the inventive step requirement, nor the other basic criteria, make any distinction between different types of innovation œ for example between “in‐ cremental” and “discrete”, or between “me too” and “breakthrough” innovations. As with any innovation, all of these have to be judged against the same basic rules, and that, in ICC’s view, is entirely appropriate. To the extent that genuine concerns about patent quality exist, they relate to the whole range of patents**. They are not specific to patents for healthcare products, nor to patents for so‐called incremental innovations. If such inventions fail to meet the fundamental criteria set out above, patents should not be granted for them; and where patents have wrongly been granted, courts should (and have) corrected those errors** œ all as part of the international efforts referred to above to ensure that an appropriate balance is achieved between all entities affected by patents. **However, the fact that there have been some examples of patent‐granting authorities ap‐ plying the criteria incorrectly does not justify fundamental change to those underlying principles.**

#### Second, evergreening only proves flaws in the application process, not the legitimacy of patents themselves, Jones 6

Nigel Jones (International Chamber of Commerce; Barrister for Gatehouse Cham‐ bers). “The importance of incremental innovation for development.” Submission to the World Health Organization’s Commission on Intellectual Property Rights, Innovation and Public Health. March 2006. JDN. https://www.lesi.org/publications/les‐ nouvelles/les‐nouvelles‐online/2006‐2015/2006/march‐2006/2011/08/08/the‐importance‐ of‐incremental‐innovation‐for‐development

In the context of pharmaceuticals, it has been suggested that patent protection should not be given to inventions comprising different salts, esters or other derivatives of known drugs, different dosage forms or means of administration of existing products, combinations of known products (including fixed dose combinations), nor “mere” new uses of known compounds, (all of which might qualify for the misnomer “incrementally modified drugs”); nor for modifications to medical devices (such as a single‐, rather than multiple‐dose, syringe). These suggestions are, in ICC’s view, misconceived. As stated above, if any such inventions do not satisfy the basic patentability criteria, patents should not be granted for them; and if patents are found wrongly to have been granted, courts and patents offices should correct those errors, just as they should for patents in any field and for any category of innovation. This approach should address, and is addressing, concerns about illegitimate extension of patent term, or “evergreening”. There is no need for separate, or new, legislation to deal with this issue. Further, the suggestion that such inventions do not benefit society is wrong. These types of so‐called “incremental” innovation generally result in better health outcomes2, for example by increasing efficacy, reducing side effects and/or making administration easier, resulting in improved compliance and greater effectiveness

### AT Generics