# NC – Round 1

### DA

#### Current WTO legislation on IP rights promotes innovation

Ezell et al 4/29 Jaci McDole, Stephen Ezell [Stephen Ezell is 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.] 4/29/21, “Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic” Information Technology and Innovation Foundation, <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through> DD AG

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.

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

#### Reductions in protections kill medical innovation, economic growth, and knowledge building for the future

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Innovation can—and does—happen anywhere and at any time. As society ground to a halt in 2020, innovators around the world worked tirelessly to develop treatments, vaccines, and solutions to COVID-19 pandemic-related challenges. From personal protective equipment (PPE) to treatments and vaccines to autonomous delivery robots to remote and social distancing solutions for the workplace, intellectual property (IP) played an indispensable role in enabling research, development, and commercialization of many of the innovations meeting the challenges of the pandemic. IP enables start-ups to gain access to much-needed capital. IP gives innovators the confidence to invest in research and development (R&D) and provides incentives for commercialization. Indeed, it is difficult to innovate without the protection of ideas.

Despite this, some—particularly anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology. They offer seemingly simple solutions—weaken or eliminate IP rights—and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some pre-existing innovations, but it would absolutely limit future innovations. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, this time we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise.

Moreover, the blame game usually ignores the real, underlying problems. For access to innovations to fight COVID-19, especially biotechnology, vaccines, and therapeutics, the underlying problems are regulatory delays and a lack of adequate and appropriate manufacturing infrastructure.1 The lack of infrastructure has resulted in supply chain bottlenecks in places where few are currently equipped to handle the manufacturing requirements.2 Meanwhile, regulatory delays have prevented vaccines, therapeutics, and diagnostics from entering certain markets.3

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

#### Two Impacts –

#### 1] Turns their disease impact – future pandemics are more likely and more deadly which makes innovation key to stop extinction

Ceballos 5/27 Gerardo Ceballos [PhD, Dr Gerardo Ceballos is an ecologist and conservationist at the Universidad Nacional Autonoma de Mexico. He is particularly recognized for his influential work on global patterns of distribution of diversity, endemism, and extinction risk in vertebrates. He is also well-known for his contribution to understanding the magnitude and impacts of the sixth mass extinction.], 5/27/21, “THE SIXTH MASS EXTINCTION AND THE FUTURE OF HUMANITY”, Population Matters, <https://populationmatters.org/news/2021/05/sixth-mass-extinction-and-future-humanity> DD AG

Somewhere, sometime in late 2019, a coronavirus from a wild species, perhaps a bat or a pangolin, infected a human in China. This could have been an obscure event, lost without trace in the annals of history, as it is very likely this has occurred many times in the last centuries. But this particular event was somehow different. The coronavirus became an epidemic first and a pandemic later. Covid-19 became the worst pandemic since the Spanish flu in 1918. The horrific human suffering it has caused, and its economic, social and political impacts, are still unraveling.

The reason Covid-19 and more than forty other very dangerous viruses, such as Lassa fever, HIV and Ebola, have jumped from wild animals to humans in the last four decades is the destruction of natural environments and the trafficking and consumption of wild animals.

The wildlife trade is to satisfy the insatiable and extravagant demand for these species in the Asian market, in countries such as China, Vietnam and Indonesia. The illegal wildlife trade is a gigantic business. It is as lucrative as the drug trade, but without the legal implications. The immense appetite of China and other Asian societies for exotic animals has promoted exponential growth in trade and profits. Wild and domestic animals sold in “wet markets” are kept in unsanitary and unethical conditions. There, feces, urine and food waste from cages at the top spill into cages at the bottom, creating the perfect conditions for viruses to leap from wild animals to domestic animals and humans. Thousands of wildlife species or their products are traded annually.

Wildlife trade is one of several human impacts, including habitat loss and fragmentation, pollution, toxification and invasive species, that have caused the extinction of thousands of species and threaten many more. Indeed, most people are unaware that the current extinction crisis is unprecedented in human history. Extinction occurs when the last individual of a species dies. The UN recently estimated that one million species, such as the panda, the orangutan and the Sumatran rhino, are at risk of extinction.

The second finding is that population extinctions, which are the prelude to species extinctions, are occurring at very fast rates (Ceballos et al., 2017). Around 32 percent of a sample of 27,000 species have declining populations and have experienced massive geographic range contractions. Population extinctions are a very severe and widespread environmental problem which we have called “Biological Annihilation”.

Finally, our third finding indicates that the magnitude of the extinction crisis is underestimated because there are thousands of species on the brink of extinction (Ceballos et al., 2020). Those species will likely become extinct in the near future unless a massive conservation effort is launched soon.

Many times, people have asked me why we should care about the loss of a species. There are ethical, moral, philosophical, religious and other reasons to be concerned. But perhaps the one that is most tangible for most people is the loss of ecosystem services, which are the benefits that humans derive from the proper function of nature. Ecosystem services include the proper mix of gases in the atmosphere that support life on Earth, the quantity and quality of water, pollination of wild crops and plants, fertilization of the soil, and protection against emerging pests and diseases, among many others. Every time a species is lost, ecosystem services are likely to erode and human well-being is reduced.

The loss of so many ecosystems and species is pushing us towards the point of collapse of civilization. The good news is that there is still time to reduce the current extinction crisis. The species and ecosystems that we manage to save in the next 10 – 15 years will define the future of biodiversity and civilization. What it is at stake is the future of mankind.

#### 2] Anticipated economic results in nuclear war – especially for a post-pandemic world

Tønnesson 15 [Tønnesson is a research professor at the Peace Research Institute Oslo (PRIO) in Norway and the leader of the East Asia Peace program at Uppsala University in Sweden.] “Deterrence, interdependence and Sino–US peace.” International Area Studies Review, volume 18, number 3, pgs. 297-311. 2015 // recut advay

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party. Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

### CP

#### The Council for TRIPs should vote to reduce intellectual property protections for for medicines by implementing a one-and-done approach for patent protection, amending TRIPs to mandate that

#### The United States should:

#### --Publicly rescind support for the WTO waiver

#### -- Veto this motion and refuse to comply

#### The remaining member nations should initiate proceedings against the United States through the World Trade Organization, Dispute Settlement Body, which ought to find against the United States. The United States ought to comply with this ruling.

#### The counterplan has the United States oppose the plan but get overruled by the other nations. After the WTO DSB finds against them, they will comply---that solves the case but avoids politics because the US initially opposed the waiver and was forced into it.

#### Counterplan competes ---

#### 1] The plan has the “member nations” act individually, while the counterplan is the WTO through the Council and eventually the DSB. That’s distinct, since member nations are not international bodies.

**Collins Dictionary n.d.** “member nations” RJP, DebateDrills https://www.collinsdictionary.com/us/dictionary/english/member-nations

member nations

The [United](https://www.collinsdictionary.com/us/dictionary/english/unite) [Nations](https://www.collinsdictionary.com/us/dictionary/english/nation) is an [international](https://www.collinsdictionary.com/us/dictionary/english/international) organization [comprised](https://www.collinsdictionary.com/us/dictionary/english/comprise) of about 180 member nations.

Sociology (1995)

At the Nato [summit](https://www.collinsdictionary.com/us/dictionary/english/summit), he called on all the member nations to [pledge](https://www.collinsdictionary.com/us/dictionary/english/pledge) to [spend](https://www.collinsdictionary.com/us/dictionary/english/spend) at least 2% of their [national](https://www.collinsdictionary.com/us/dictionary/english/national) [income](https://www.collinsdictionary.com/us/dictionary/english/income) on [defence](https://www.collinsdictionary.com/us/dictionary/english/defence" \o "Definition of defence).

Times, Sunday Times (2015)

The [beneficiaries](https://www.collinsdictionary.com/us/dictionary/english/beneficiary) will not be [limited](https://www.collinsdictionary.com/us/dictionary/english/limit) to EU member nations, but [worldwide](https://www.collinsdictionary.com/us/dictionary/english/worldwide).

Times, Sunday Times (2012)

Definition of 'nation'

nation

(neɪʃən)[Explore 'nation' in the dictionary](https://www.collinsdictionary.com/us/dictionary/english/nation)

COUNTABLE NOUN

A nation is an individual country considered together with its social and political structures.

#### 2] Normal means---it’s countries requesting a waiver, which the counterplan does not do.

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In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the last thing the WTO needs is another debate over perceived trade obstacles to public health.

#### 3] Counterplan is neither certain nor immediate---the US reduction hinges on the outcome of DSB. That makes the counterplan competitive.

#### “Resolved” is definite and immediate

Collins 3 Collins English Dictionary – Complete and Unabridged © HarperCollins Publishers 1991, 1994, 1998, 2000, 2003

http://www.thefreedictionary.com/resolved

resolved [rɪˈzɒlvd] adj

fixed in purpose or intention; determined

#### Ought and should are used interchangeably.

Anastasia **Koltai 18**. CEO of MyEnglishTeacher, “Difference Between Ought to and Should,” MyEnglishTeacher, September 25, 2018, <https://www.myenglishteacher.eu/blog/difference-between-ought-to-and-should/>, RJP, DebateDrills.

In most cases, SHOULD and OUGHT TO are used interchangeably today. Both SHOULD and OUGHT TO are used to express advice, obligation, or duty.

#### “Should” is immediate

Summers 94 (Justice – Oklahoma Supreme Court, “Kelsey v. Dollarsaver Food Warehouse of Durant”, 1994 OK 123, 11-8, http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13)

¶4 The legal question to be resolved by the court is whether the word "should"[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn13) in the May 18 order connotes futurity or may be deemed a ruling *in praesenti*.[14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn14) The answer to this query is not to be divined from rules of grammar;[15](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn15) it must be governed by the age-old practice culture of legal professionals and its immemorial language usage. To determine if the omission (from the critical May 18 entry) of the turgid phrase, "and the same hereby is", (1) makes it an in futuro ruling - i.e., an expression of what the judge will or would do at a later stage - or (2) constitutes an in in praesenti resolution of a disputed law issue, the trial judge's intent must be garnered from the four corners of the entire record.[16](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker3fn16)

[CONTINUES – TO FOOTNOTE]

[13](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn13) "*Should*" not only is used as a "present indicative" synonymous with *ought* but also is the past tense of "shall" with various shades of meaning not always easy to analyze. See 57 C.J. Shall § 9, Judgments § 121 (1932). O. JESPERSEN, GROWTH AND STRUCTURE OF THE ENGLISH LANGUAGE (1984); St. Louis & S.F.R. Co. v. Brown, 45 Okl. 143, 144 P. 1075, 1080-81 (1914). For a more detailed explanation, see the Partridge quotation infra note 15. Certain contexts mandate a construction of the term "should" as more than merely indicating preference or desirability. Brown, supra at 1080-81 (jury instructions stating that jurors "should" reduce the amount of damages in proportion to the amount of contributory negligence of the plaintiff was held to imply an *obligation* *and to be more than advisory*); Carrigan v. California Horse Racing Board, 60 Wash. App. 79, [802 P.2d 813](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=802&box2=P.2D&box3=813) (1990) (one of the Rules of Appellate Procedure requiring that a party "should devote a section of the brief to the request for the fee or expenses" was interpreted to mean that a party is under an *obligation* to include the requested segment); State v. Rack, 318 S.W.2d 211, 215 (Mo. 1958) ("should" would mean the same as "shall" or "must" when used in an instruction to the jury which tells the triers they "should disregard false testimony"). [14](http://www.oscn.net/applications/oscn/DeliverDocument.asp?CiteID=20287#marker2fn14) *In praesenti* means literally "at the present time." BLACK'S LAW DICTIONARY 792 (6th Ed. 1990). In legal parlance the phrase denotes that which in law is *presently* or *immediately effective*, as opposed to something that *will* or *would* become effective *in the future [in futurol*]. See Van Wyck v. Knevals, [106 U.S. 360](http://www.oscn.net/applications/oscn/deliverdocument.asp?box1=106&box2=U.S.&box3=360), 365, 1 S.Ct. 336, 337, 27 L.Ed. 201 (1882).

#### The plan would require US companies to disclose information and waive IP protections---the counterplan has the US resist to avoid political backlash, but that violates WTO disclosure requirements.

Jorge Contreras 21. Presidential Scholar and Professor of Law at the University of Utah with an adjunct appointment in the Department of Human Genetics, JD @ Harvard, “US Support for a WTO Waiver of COVID-19 Intellectual Property – What Does it Mean?” Bill of Health Harvard Law, May 7, 2021, <https://blog.petrieflom.law.harvard.edu/2021/05/07/wto-waiver-intellectual-property-covid/>, RJP, DebateDrills

The proposed WTO IP waiver is significant because it includes trade secrets. Thus, under the waiver’s original language, a country that wished to suspend trade secret protection for COVID-19 technology could do so without violating the TRIPS Agreement. Such a country could also, presumably, mandate that foreign companies operating in the country disclose their proprietary manufacturing, storage, and testing information to local producers under a compulsory license.

The details of this disclosure requirement, and any compensation payable to the originator of the information, would need to be worked out in whatever waiver is eventually adopted by the WTO, but the prospect for a mandatory trade secret transfer — something that would be unprecedented in the international arena — is worth watching carefully. [As reported by Intellectual Asset Management on May 4, 2021](https://www.iam-media.com/coronavirus/brazilian-senate-passes-compulsory-covid-19-know-how-licensing-bill), the Brazilian Congress is currently considering legislation that would nullify the patents of any company that fails to disclose know-how and data related to a compulsory COVID-19 patent license. It will also be interesting to see whether the United States stands behind such a requirement, which goes far beyond the compulsory licensing of patents.

Will the U.S. require companies to share their know-how with others?

As noted above, under the waiver, a country could impose a trade secret disclosure requirement on companies operating within its jurisdiction. But that requirement would have little effect on U.S. vaccine producers who do not, themselves, have material operations overseas. Only the U.S. government could require a U.S.-based company to disclose its trade secrets. Would the U.S. impose such a requirement? This is not known, but I think it’s unlikely. It is one thing for the U.S. to agree not to challenge other countries’ compulsory licensing regimes as violations of TRIPS, but a very different thing for the U.S. to issue a compulsory licensing order of its own, particularly in the area of trade secrets, where it would be met with significant internal opposition.

### DA

#### That gets litigated through the DSB, which we fiat finding against the United States. The DSB is underutilized currently but using it for major dispute settlement shores it up---that’s key to combat Chinese IP violations.

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Quite rightly, President Donald Trump and his Administration are targeting the transgressions of China against US intellectual property rights in their unfolding trade strategy. But why not use the WTO rules that offer a real remedy for the United States without resorting to illegal unilateral action outside the WTO?  
  
Seventeen years after China joined the WTO, China still falls considerably short of fulfilling its WTO obligations to protect intellectual property. About 70 percent of the software in use in China, valued at nearly $8.7 billion, is pirated. The annual cost to the US economy worldwide from pirated software, counterfeit goods, and the theft of trade secrets could be as high as $600 billion, with China at the top of the IP infringement list. China is the source of 87 percent of the counterfeit goods seized upon entry into the United States.  
  
One possible response by the United States is the one the Trump Administration seems to be taking: slapping billions of dollars of tariffs on imports of more than 100 Chinese products through unilateral trade action. Given its protectionist predilections, taking this approach is surely tempting to the Trump Administration. Doing so will, however, harm American workers, businesses, and consumers, and contribute to further turmoil in the global economy.

The results will likely include retaliation by China against the goods and services of American companies and workers; lawful economic sanctions imposed by China on American exports to China after the US lost to China in WTO cases; the hidden tax of higher prices for American consumers; less competitiveness in the US market and in other markets for American companies that depend on Chinese imports as intermediate goods in production; and doubtless still more American and global economic landmines from the downward spiral of tit-for-tat in international trade confrontations.  
  
These tariffs are not only self-defeating and counter-productive; they are also illegal under international law. Where an international dispute falls within the scope of coverage of the WTO treaty, taking unilateral action without first going to WTO dispute settlement for a legal ruling on whether there is a WTO violation is, in and of itself, a violation of the treaty. The WTO treaty establishes mandatory jurisdiction for the WTO dispute settlement system for all treaty-related disputes between and among WTO Members. The WTO Appellate Body has explained, “Article 23.1 of the (WTO Dispute Settlement Understanding) imposes a general obligation to redress a violation of obligations or other nullification or impairment of benefits under the covered agreements only by recourse to the rules and procedures of the DSU, and not through unilateral action.”  
  
Thus, the United States is not permitted by the international rules to which it has long since agreed to be the judge and the jury in its own case. Imposing tariffs on Chinese products without first obtaining a WTO ruling that Chinese actions are inconsistent with China’s WTO obligations is a clear violation by the United States of its WTO obligations to China – as WTO jurists will doubtless rule when China responds to the tariffs by challenging the tariffs in the WTO.  
  
Such a legal loss by the United States, with all its unforeseeable economic and geopolitical consequences, can be avoided while still confronting Chinese IP violations effectively. Before resorting to unilateral action outside the WTO and in violation of international law, the United States should take a closer look at the substantial rights it enjoys under the WTO treaty for protecting US intellectual property against abuse.  
  
Potential remedies in the WTO exist and should not be ignored. These remedies can be enforced through the pressure of WTO economic sanctions. WTO rules do not yet cover all the irritants that must be addressed in US-China trade relations. Even so, instead of just concluding that there are no adequate remedies under WTO rules to help stop IP infringement, the United States should first try to use the remedies in rules we have already negotiated that bind China along with all other WTO Members.  
  
A number of these rules have not yet been tested against China or any other country – which is not proof they will not work. Generally, when tried for the first time, WTO rules have been found to work, and, generally, when China has been found to be acting inconsistently with its WTO obligations, it has complied with WTO rulings. The actual extent of Chinese compliance with WTO judgments can be questioned; in some instances it is seen by some as only “paper compliance.” But whether any one WTO rule can in fact be enforced cannot be known if no WTO Member bothers to try to enforce it.  
  
The WTO rules in the WTO Agreement on the Trade-related Aspects of Intellectual Property Rights – the so-called TRIPS Agreement – are unique among WTO rules because they impose affirmative obligations. Yet, this affirmative aspect of WTO intellectual property rules has been largely unexplored in WTO dispute settlement. In particular, WTO Members have so far refrained from challenging other WTO Members for failing to enforce intellectual property rights.  
  
On enforcement, Article 41.1 of the TRIPS Agreement imposes an affirmative obligation on all WTO Members: “Members shall ensure that enforcement procedures… are available under their law so as to permit effective action against any act of infringement of intellectual property rights covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements. These procedures shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse.”  
  
Note that this “shall” be done by all WTO Members; it is mandatory for compliance with their WTO obligations. And yet what does this obligation mean by requiring that effective actions against infringements must be “available”? Is this obligation fulfilled by having sound laws on the books, as is generally the case with China? Or must those laws also be enforced effectively in practice, which is often not the case with China?  
  
The Appellate Body has said that “making something *available* means making it ‘obtainable,’ putting it ‘within one’s reach’ and ‘at one’s disposal’ in a way that has sufficient form or efficacy.” Thus, simply having a law on the books is not enough. That law must have real force in the real world of commerce. This ruling by the Appellate Body related to the use of the word “available” in Article 42 of the TRIPS Agreement and to a legal claim seeking fair and equitable access to civil judicial procedures. Yet the same reasoning applies equally to the enforcement of substantive rights under Article 41.  
  
In the past, the United States has challenged certain parts of the overall Chinese legal system for intellectual property protection – and successfully – in WTO dispute settlement. Despite its overall concerns about enforcement by China of US intellectual property rights, the United States has not, however, challenged the Chinese system as a whole in the WTO. Instead of indulging in the illegality of unilateral tariffs outside the legal framework of the WTO, the Trump Administration should initiate a comprehensive legal challenge in the WTO, not merely, as before, to the bits and pieces of particular Chinese IP enforcement, but rather *to the entirety of the Chinese IP enforcement system*.  
  
To be sure, a systemic challenge by the United States to the application of all China’s inadequate measures relating to intellectual property protection would put the WTO dispute settlement system to a test. It would, what’s more, put both China and the United States to the test of their commitment to the WTO and, especially, to a rules-based world trading system.  
  
As Trump’s trade lawyers will hasten to say, a systemic IP case against China in the WTO would also involve a perhaps unprecedented amount of fact-gathering. It would necessitate an outpouring of voluminous legal pleadings. It would, furthermore, force the WTO Members and the WTO jurists to face some fundamental questions about the rules-based trading system. Yet it could also provide the basis for fashioning a legal remedy that would in the end be mutually acceptable to both countries, and could therefore help prevent commercial conflict and reduce a significant obstacle to mutually beneficial US-China relations.

#### China is engaging in rampant IP theft---shoring up WTO dispute resolution will determine the trajectory of Chinese theft.

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Unquestionably, pervasive intellectual property violations are a threat to millions of U.S. jobs in critical innovative U.S. industries. The U.S. International Trade Administration has estimated that U.S. IP-intensive industries doing business in China have lost about $48 billion in sales, royalties, and license fees to various forms of encroachment on their intellectual property rights. These U.S. firms have spent $4.8 billion to address possible Chinese IP infringements. An improvement in intellectual property protection and enforcement in China to levels comparable to those in the United States would likely translate into 923,000 new jobs in the United States.[15](https://www.cato.org/policy-analysis/disciplining-chinas-trade-practices-wto-how-wto-complaints-can-help-make-china-more#endnote-015) And these most recent numbers are from 2011—before the recent intensification of China’s mercantilist industrial strategy.

After 17 years in the WTO, China still falls far short of fulfilling its WTO obligations to protect copyrights, trademarks, patents, and other intellectual property rights. Millions of Chinese live on the illegal gains of widespread counterfeiting of U.S. and other foreign products. The Chinese, for example, are “addicted to bootleg software.”[16](https://www.cato.org/policy-analysis/disciplining-chinas-trade-practices-wto-how-wto-complaints-can-help-make-china-more#endnote-016) According to the Business Software Alliance, about 70 percent of the software used in China, valued at nearly $8.7 billion, is pirated.[17](https://www.cato.org/policy-analysis/disciplining-chinas-trade-practices-wto-how-wto-complaints-can-help-make-china-more#endnote-017) The annual cost to the U.S. economy worldwide from pirated software, counterfeit goods, and the theft of trade secrets “could be as high as $600 billion.”[18](https://www.cato.org/policy-analysis/disciplining-chinas-trade-practices-wto-how-wto-complaints-can-help-make-china-more#endnote-018) China “remains the world’s principal IP infringer,” accounting, for example, for 87 percent of the counterfeit goods seized upon entry into the United States.[19](https://www.cato.org/policy-analysis/disciplining-chinas-trade-practices-wto-how-wto-complaints-can-help-make-china-more#endnote-019)

Before taking unilateral action outside the WTO in response to widespread Chinese IP infringements, the United States should take a closer look at the substantial rights it enjoys under the WTO’s TRIPS Agreement for protecting U.S. intellectual property against theft and other abuses, in particular those obligations related to the domestic enforcement of these protections. Potential remedies in the WTO exist and should not be ignored, and these remedies can be enforced through the pressure of WTO economic sanctions.

A more specific obligation related to intellectual property is that American companies have, in effect, been forced to turn over their technology to Chinese partners—in some cases by revealing their trade secrets—in exchange for being allowed to do business in China and have access to the booming Chinese market. Here, Article 39 of the TRIPS Agreement, which establishes a WTO obligation for the “Protection of Undisclosed Information,”[20](https://www.cato.org/policy-analysis/disciplining-chinas-trade-practices-wto-how-wto-complaints-can-help-make-china-more#endnote-020) can help. The United States was among the leaders in advocating the inclusion of Article 39 in the TRIPS Agreement, but the United States has, to date, not initiated an action in WTO dispute settlement claiming a Chinese violation of this WTO obligation.

Beyond intellectual property, there have been long-standing though somewhat vague allegations from U.S. industry groups that China forces foreign companies who wish to operate in China to make investments through joint ventures, and to then transfer their technology to their Chinese partners. As they describe it, transferring technology to Chinese companies is often a condition for the ability to make an investment there. Specific details of these arrangements are difficult to uncover. The companies involved may be reluctant to complain because they fear having their investment permission revoked by the Chinese government. All the same, in response to the USTR’s request for comments under Section 301 regarding China’s trade practices, a wide range of organizations have identified forced technology transfer as a concern. There is a specific provision of China’s WTO Accession Protocol that addresses the issue of forced technology transfer. The United States should invoke it as the basis of a WTO complaint.

Finally, one of the most frequently raised concerns about Chinese trade practices is the Chinese government’s provision of subsidies to both state-owned enterprises and private companies. These subsidies are offered through a variety of programs, including the Made in China 2025 initiative and its specific implementing measures. Fortunately, the WTO has extensive and detailed rules on subsidies that can be used to challenge China’s behavior. WTO Members have brought several complaints against Chinese subsidies already, including an ongoing case related to agriculture subsidies (see Appendix 1), and there are additional complaints still to be brought.

#### Stopping tech stealing is key to avoid war

Timothy R. **Heath 18**. RAND Senior Defense and International Analyst, “Avoiding “Avoiding U.S.-China Competition Is Futile: Why the Best Option Is to Manage Strategic Rivalry”; Asia Policy; Vol 13 No 2; April 2018, RJP, DebateDrills

This article argues that the structural drivers of U.S.-China competition are too deep to resolve through cooperative engagement and that policymakers must instead accept the reality of strategic rivalry and aim to manage it at a lower level of intensity. main argument Rising tensions between China and the U.S. have spurred fears that the two countries could end up in conflict or recreate the Cold War. To avoid these outcomes, analysts have proposed ways to defuse competition and promote cooperation. However, because these arguments do not address the structural drivers underpinning U.S.-China competition, such proposals are unlikely to end the rivalry. Conflict is not inevitable, however, and aggressive strategies that unnecessarily aggravate the sources of rivalry are likely to prove dangerously counterproductive. The best option at this point is, paradoxically, for the U.S. to accept the reality of the growing strategic rivalry and manage it at a lower level of intensity. policy implications • Maintaining a technological edge is critical for the U.S. to successfully manage the rivalry with China. Policies should be pursued to ensure that the U.S. continues to attract and nurture the best science and technology talent and retains its status as the global leader in technology. • To compete with China’s narrative about leading regional integration, the U.S. should both put forth a compelling vision for the region that encompasses widely held economic, security, and political values and continue to bolster its diplomatic and military positions in Asia. • To maintain the U.S.-China rivalry at a stable level, policymakers in both countries should prioritize measures that discourage the mobilization of popular sentiment against the other country and encourage cultural exchanges. • U.S.-China competition will likely become increasingly entwined with rivalries between China and U.S. allies and partners such as Japan and India. U.S. policymakers will need to take into account the independent dynamics of those separate rivalries when managing relations with China. The United States and China find themselves increasingly enmeshed in a strategic rivalry, the basic nature of which remains poorly understood in the United States. To be sure, disagreements between the two countries have gained widespread attention. Disputes involving Chinese confrontations with U.S. allies and partners such as Japan, the Philippines, and Taiwan have frequently grabbed the headlines. At other times, disagreements over Chinese trade practices and U.S. military activities in the South China Sea have occasioned discord. All these sources of conflict are genuine, but they mask the main drivers of rivalry, which are twofold. First, the United States and China are locked in a contest for primacy—most clearly in Asia and probably globally as well. The United States has been the dominant power, and China seeks to eventually supplant it. By definition, two different states cannot simultaneously share primacy at either the regional or global level. Second, economic, demographic, and military trajectories suggest that China has the potential to contend in a significant way for leadership at the global systemic level. At this level, the most decisive competition will be for technological leadership. Should China supplant the United States as the world’s premier country in terms of technology, its claim to regional and global supremacy will be difficult to deny. And once it has gained that supremacy, China will be well positioned to restructure institutional arrangements to privilege itself and disadvantage the United States. Although this competition is occurring simultaneously at both levels, observers have focused primarily on the struggle for primacy at the regional level and overlooked or downplayed the competition at the global systemic level.1 To counter China’s pursuit of regional primacy, the United States has bolstered its alliances in Asia (albeit inconsistently), expanded diplomatic outreach to China and rising powers in Southeast Asia, and revised its military posture—efforts captured by President Barack Obama’s “rebalance to Asia.” President Donald Trump may have abandoned the rebalance, but many of the related initiatives remain more or less in place.2 China’s challenge at the global systemic level, especially in the field of technology, has received less attention. Confidence in the proven U.S. ability to produce new technologies and facile assumptions about the difficulties China will face in promoting innovation in new industries have led many to dismiss the challenge posed by China. **But the contest for technological leadership is actually even more consequential than that for regional primacy.** Should China succeed in surpassing the United States as the world’s technological leader, U.S. diplomacy and military power will not suffice to hold the line either in Asia or around the globe**.** Under those conditions, countries throughout the world, including U.S. allies in Asia, will be forced to come to terms with the new leading economy. Military power projection could be far less relevant as China moves to consolidate its leading status at both the regional and global levels in such a scenario. Accordingly, although the United States cannot abandon its efforts to bolster its diplomatic and military position in Asia, the country must step up its efforts to strengthen its faltering lead in new technology development. While China clearly grasps the stakes, it is not clear that the United States does. For example, China’s government has promoted R&D into quantum computing. The investment appears to be paying off, as the country has leaped ahead of the United States in developing quantum communications.3 Similarly, the U.S. Congress has proposed to dispense with subsidies for the purchase of electric vehicles, even as China pushes ahead in its plan to become the lead producer of this technology.4 And while the U.S. government seeks to restrict immigration and discourage foreign students from attending U.S. universities (and staying after they receive their advanced training), China has revised its policies to welcome foreigners, prioritizing those with science and technology expertise. Moreover, Chinese investment in basic R&D is rapidly catching up to that of the United States.5 Studies have also noted a shrinking U.S. lead in science and technology as such investment is beginning to bear fruit.6 Similarly, the United States has lost its once-undisputed lead in the per capita number of engineers and scientists.7 Understanding the nature of the U.S.-China rivalry at the regional and global systemic levels, as well as how these two levels interact with one another, is essential if the United States is to successfully manage the challenge posed by China in a manner that avoids war. This study aims to contribute to that understanding. The article is organized into the following sections: u pp. 95–102 provide an overview of the growing rivalry between China and the United States, including a discussion of the meaning and role of strategic rivalry in interstate conflict and a comparison with the U.S.-China rivalry during the Cold War. u pp. 102–4 review the dynamics of the rivalry at the regional systemic level. u pp. 104–10 analyze the dynamics of the rivalry at the global systemic level. u pp. 110–15 examine why proposals to avoid rivalry through cooperation or aggressive competition are unlikely to succeed. u pp. 115–19 discuss the idea of strategic rivalry management and offer recommendations on ways to sustain the rivalry at a lower level of intensity the growing rivalry between the united states and china Strains between China and the United States have deepened in the past few years over a proliferating array of issues. President Trump has stepped up accusations against China of unfair trade practices and inadequate pressure on North Korea. He also provoked controversy early in his term when he floated the idea of increasing official contacts with Taiwan, which Beijing considers a renegade province.8 These disputes add to tensions that had expanded under President Obama, who moved to strengthen U.S. alliances in Asia, promote a regional trade pact, criticize Chinese behavior in the cyber and maritime domains, and shift more military assets to the Asia-Pacific as part of the rebalance to Asia strategy.9 China has in turn dismissed U.S. concerns about the construction of artificial islands in the South China Sea, intensified its criticism of U.S. security leadership in Asia, and tightened its grip on disputed maritime territories.10 The baleful state of bilateral relations has spurred plenty of finger-pointing. On the Chinese side, officials denounce the United States’ “Cold War mindset” and warn of conflict if Washington does not adjust its policies.11 A 2015 defense white paper described an “intensifying competition” between the great powers.12 Military officials and many Chinese analysts regard increasing tension between the two countries as unavoidable, although they do not regard war as likely. People’s Liberation Army (PLA) deputy chief of staff Qi Jianguo commented that “no conflict and no confrontation does not mean no struggle” between China and the United States.13 According to Chinese official media, polls in China suggest a large majority believes that the United States intends to pursue a containment policy.14 Reflecting this point of view, Niu Xinchun, a scholar at the China Institutes of Contemporary International Relations, argued that the “greatest obstacle to the further integration of emerging countries such as China into the international system comes from the United States.”15 Western officials and commentators tend to blame China for current strains. Senior U.S. leaders have criticized “assertive” Chinese behavior, while some analysts blame Xi Jinping for pushing a more confrontational set of policies.16 Other Western observers worry that a further souring of relations could lead to conflict.17 But even if war remains unlikely, the deepening tensions increase the risks of miscalculation, crises, and potential military clashes involving the world’s two largest powers. Echoing a view widely held among U.S. foreign policy experts and officials, former CIA director General Michael Hayden has warned that mishandling the U.S.-China relationship could be “catastrophic.”18 Rivalry at the Heart of the U.S.-China Relationship This widespread concern reflects a realistic appraisal of the dangers inherent in the U.S.-China relationship. But developing successful policies to manage an increasingly sensitive and complex situation requires an accurate assessment of the phenomenon of interstate rivalry that lies at the heart of that relationship. Rivalry is a concept that, while widely acknowledged, remains poorly understood. To be sure, most experts take for granted the idea that powerful nations compete for status and influence, and they acknowledge the danger posed by a rising power’s challenge to a status quo power. Yet investigation into the phenomenon of rivalry too often stops at these well-trodden findings. Less often discussed are the conclusions regarding the dynamics of rivalry that experts on conflict studies have arrived at within the past few years. Much of this scholarship draws from improvements to the analyses and data regarding interstate crisis and conflict.19 This research has generated useful and interesting insights regarding the start and conclusion of rivalries, crises, and war, although these remain largely unexplored outside academic circles. Analysts have established, for example, that rivalry is perhaps the most important driver of interstate conflict. As defined by political scientists, “rivals” are states that regard each other as “enemies,” sources of real or potential threat, and as competitors. At the root of rivalries thus lie disputes over incompatible goals and perceptions that countries possess both the ability (real or potential) and the intention to harm each other. Wars have historically tended to be fought by pairings of these states and their allies. Rivals have opposed each other in 77% of wars since 1816 and in over 90% of wars since 1945.20 Not only are rivals more likely to fight than non-rivals, but rivals also have a tendency to be recidivists because they are unable to resolve their political differences on the battlefield. Yet that does not always discourage them from trying to do so repeatedly. Rivals that cannot prevail due to parity frequently compete for advantage by building internal strength through arms racing or by leveraging external power through the strengthening of alliances and partnerships. Rivals are also prone to serial militarized crises**.** Mutual perceptions of each other as hostile enemies and the inconclusive outcome of previous militarized disputes typically fuel a pattern of recurrent crises characterized by deepening resentment, distrust, and growing willingness to risk escalation. Studies have also established that the risk of conflict increases sharply after three episodes of militarized crises.21 Rivalries do not progress in a linear direction, however. Their intensity can wax and wane in response to shocks and other important developments. Periods of relative stability can alternate with turbulent periods of tension and conflict. Similarly, cooperative activities can be interspersed with periods of acute tension and hostility. Nevertheless, the link between rivalry, crises, and interstate conflict is pervasive. Drawing from these sources, one can describe the Sino-U.S. relationship as a rivalry characterized as a competition between two major powers over incompatible goals regarding their status, leadership, and influence over a particular region—in this case principally the Asia-Pacific. The dynamics of this type of strategic rivalry differ in significant ways from the far more numerous rivalries over territory that have characterized conflict between so many countries, especially weaker and poorer ones. In contrast with rivalries over territories, strategic rivals do not necessarily share borders, although allies of one power may be engaged in a territorial dispute with the other major power. Strategic rivalries among major powers tend to be especially long-lived, with the average enduring for about 55 years.22 Strategic rivalries are incredibly complex phenomena that include overlapping and often reinforcing layers of disputes over leadership, status, and territory between the principal rivals and their allies. Such rivalries are almost always multilateral affairs that also involve allies and partners, some of which have their own rivalries with the other side. Competition in the economic, political, and military domains can serve as expressions as well as drivers of rivalry, as can sports and cultural competition. Strategic rivalries can be confined to one region, with the basic conflict reducible in some respects to which rival will occupy the top rung of the regional hierarchy. In other cases, however, a rivalry can span regional and global domains either sequentially or simultaneously. The U.S.-China rivalry, for instance, is already both a regional and, to a lesser extent, a global rivalry, but there is still considerable room for competition to expand. The complex and overlapping nature of the disputes makes strategic rivalries extremely crisis- and conflict-prone. Strategic rivalries come in a grim package deal that includes strained and hostile relations, serial crises, and in some cases wars. The comprehensive and multifaceted nature of the disputes also explains why such rivalries have proved so durable and why their wars have been so devastating. Conflict between strategic rivals has historically occasioned the most destructive wars, of which World Wars I and II are the most recent examples. The fact that experts at the time of each historic episode of systemic conflict consistently underestimated the duration or extent of war offers cold comfort to analysts today who seek to predict the trajectory of any conflict that might involve China and the United States. Comparisons of the Current Environment with the U.S.-China Rivalry during the Cold War How did the two countries arrive at this position? The most widely accepted narrative argues that China’s rapid economic growth has provided the resources with which it can press demands on long unresolved issues such as unification with Taiwan. China and the United States may have enjoyed stable relations in the 1980s when they cooperated on a limited basis against the Soviet Union, but that foundation of cooperation eroded considerably once the Soviet bloc dissolved in the early 1990s. Moreover, China’s rapid growth in economic power has given the country fresh resources to press its own demands on the United States and U.S. allies. By 2010, China’s economy had outpaced that of Japan to become the second-largest in the world.23 The persistence of long-standing sources of antagonism, such as the U.S. security partnership with Taiwan, has both reflected and aggravated a broader competition for leadership. For its own reasons, Washington has resisted Beijing’s demands, and the result has been growing fear and distrust.24 The intensifying rivalry between the rising power and the status quo leader is as old as antiquity itself. Indeed, Graham Allison coined the term “Thucydides trap” to describe such a situation, a term that he subsequently applied to the current U.S.-China situation.25 The popular narrative is not entirely incorrect, yet in some ways it remains incomplete. A closer look at history reminds us that antagonism between China and the United States is not unprecedented. In the 1950s and 1960s, the two countries engaged in an intense strategic competition for status and influence in Asia, one that occasionally burned hot, as it did when they clashed on the Korean Peninsula or more indirectly in Vietnam. This Cold War–era rivalry saw a complex network of competing alliances and partnerships, principally in Asia. The United States supported Taiwan and South Korea in bitter disputes with China and its allies, North Korea and the Soviet Union. This rivalry terminated in the 1970s primarily due to Beijing’s decision to counter a growing Soviet menace and the United States’ decision to pursue China as a potential partner for its own rivalry with the Soviet Union. But the existence of a period of intense U.S.-Chinese tension and competition provides a helpful baseline of comparison. What requires explanation is not the fact that the United States and China are engaged in a rivalry but the difference between today’s rivalry and that of the Cold War. What distinguishes the rivalry today from that of the earlier period is both the closer parity in relative power—albeit still more potential than real—between the two countries and the comprehensiveness, complexity, and systemic nature of the disputes between them. Paradoxically, these features make the current rivalry potentially far more threatening to the United States, despite the fact that so far U.S.-China relations have remained peaceful, and even though the U.S. and Chinese militaries fought each other in the Korean War. The dangerous potential of the current rivalry ultimately owes to the risk that China could rise to the position of global system leader and subordinate the United States accordingly. As has happened in previous power transitions, China as a system leader could exploit existing arrangements to its benefit and to the detriment of the outgoing leader, the United States. Due to the enormous rewards that accrue to a systemic leader and the high costs for the state that loses this position**,** struggles for global leadership have historically proved to be especially destructive. The possibility that China and the United States could find themselves in a similar struggle, while unlikely at this point, cannot be ruled out given the reality of the relative decline in U.S. power and the concomitant increase in Chinese comprehensive national power. At the most basic level, this fact may be measured superficially by the U.S. share of world GDP, which eroded from 40% in 1950 to 16% in 2014, adjusted for purchasing power parity. Over the same period, China’s share expanded from around 5% to 17%.26 An important consequence of the narrowing of the gap in comprehensive power has been an intensifying competition for leadership in the international economic and political order. In this way, the popular discussion of the Thucydides trap correctly recognizes the dangers of the U.S.-China competition. This feature contrasts sharply with the previous episode of rivalry. In the 1950s and 1960s, the asymmetry in power meant that the United States and China competed for influence and even clashed militarily in countries along China’s borders, but rarely elsewhere. As a largely rural, impoverished country, China had little stake in the system of global trade promoted by the industrialized West. Excluded from the United Nations, Maoist China also lacked the institutional ability to influence geopolitics and project power much beyond its immediate environs—and even that capability was sorely handicapped. Outside Asia, the United States faced minimal competition from China and generally regarded the Soviet Union as a more pressing threat. By contrast, the current competition features a China fully enmeshed in a political and economic order led by the United States. While generally supportive of this order, China is also seeking to revise aspects of the regional and international order that it regards as obstacles to the country’s revitalization as a great power. The main theater of this competition for influence and leadership is the Asia-Pacific, as it was in the Cold War, but U.S.-China rivalry increasingly is expanding globally. Moreover, unlike the largely military, regional, and ideological Cold War competition, the current contest is far more multifaceted and comprehensive in nature; it includes military, economic, technological, and political dimensions. The following two sections review the state of the competition at both the regional and the global systemic levels. the u.s.-china rivalry at the regional level At the regional level, U.S.-China competition spans the political, economic, and military realms. Politically, the two countries have feuded over the role of liberal values and ideals, a dispute that widened after the 1989 Tiananmen Square massacre. However, the 1996 Taiwan Strait crisis elevated the potential threat of conflict between the two countries and may therefore be regarded as the starting point of the current rivalry. Coinciding with impressive gains in China’s economic and military power following two decades of market reforms, the standoff saw Washington and Beijing deploy military assets to back up their respective positions regarding Taiwan’s right to hold a presidential election, elevating the risk of a clash. Since then, the competition for political influence and leadership has intensified. In 2011, the United States announced its rebalance to Asia, which was aimed in part at shoring up U.S. alliances, partnerships, and influence.27 Although on the surface Washington has abandoned the effort, the Trump administration has reintroduced a vision for Asia’s economic and security order premised on values favorable to U.S. interests.28 The 2017 National Security Strategy stated, for example, that the United States upholds a “free and open Indo-Pacific.”29 Beijing, by contrast, has increased its efforts to advance a vision for a regional order premised on Chinese leadership. In recent years, China has promoted major economic and geostrategic initiatives to deepen Asia’s economic integration through the Belt and Road Initiative, Asian Infrastructure Investment Bank (AIIB), and other initiatives.30 In 2017, China for the first time issued a white paper that outlined the government’s vision for Asia-Pacific security. The paper stated that China takes the advancement of regional prosperity and stability “as its own responsibility.”31 These policies build on directives issued by Xi Jinping in 2013, when he called for policies to bolster China’s attractiveness as a regional leader.32 Economically, the two countries are competing over the evolution of Asia’s economic future—a region anticipated to drive global growth in coming decades. Both countries are also competing to shape the terms of trade. President Trump may have abandoned the Trans-Pacific Partnership (TPP), but his advisers have advocated other measures to shape favorable trade terms.33 Meanwhile, China has stepped up advocacy of the Regional Comprehensive Economic Partnership, a proposed free trade agreement for the region that excludes the United States.34 China also has promoted the AIIB, while the United States and Japan continue to instead support the Asian Development Bank.35 Militarily, the growing arms race and the establishment of rival security institutions stand among the most obvious manifestations of an increasing competition in this domain. China and the United States have designed an array of military capabilities and doctrines partly aimed at each other. The PLA has developed weapons systems to counter potential U.S. intervention in any contingency along China’s periphery, which the United States has in turn sought to counter with its own innovations, such as the Joint Operational Access Concept.36 U.S. secretaries of defense Chuck Hagel and Ashton Carter outlined a “third offset” strategy to compete with China and Russia in military technology.37 To promote regional security, the United States has strengthened its military alliances and partnerships, while China has strengthened ties with Russia and argued that regional security is best protected through the Shanghai Cooperation Organisation, the Conference on Interaction and Confidence Building Measures in Asia, and other Chinese-led institutions. In 2014, Xi indirectly rebuked the United States for seeking to bolster its security leadership in the region, stating that “it is for the people of Asia to uphold the security of Asia.”38

## Case

### Adv1

#### Reducing IP undermines innovation

**Bacchus 20[**member of the [Herbert A. Stiefel Center for Trade Policy Studies](https://www.cato.org/herbert-stiefel-center-trade-policy-studies), the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida, CATO Institute, “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines”, December 16, 2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines>] DD MN

**The** primary **justification** **for** granting and **protecting IP rights is** that they are **incentives for innovation**, which is the main source for long‐​term economic growth **and enhancements in the quality of human life**. **IP** rights **spark innovation by “enabling innovators to capture** enough of the **benefits of their own innovative activity to justify taking considerable risks.”**[**18**](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref18)**The knowledge from innovations inspired by IP rights spills over to inspire other innovations**. The protection of IP rights promotes the diffusion, domestically and internationally, of innovative technologies and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. **In the new pandemic world**, perhaps **an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.”** Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. **Without IP** rights as incentives, **there would be less new knowledge and thus less innovation.**

In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But **in the long term, undermining private IP rights** would **eliminate the incentives that inspire innovation, thus preventing the discovery and development of knowledge for new goods and services that the world needs**. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.[19](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#_ednref19)

#### IP incentivizes innovation k2 solving future pandemics – other underlying issues are the real problem

**McDole and Ezell 21**[Jaci McDole is a senior policy analyst covering intellectual property (IP) and innovation policy at the Information Technology and Innovation Foundation (ITIF). 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, Information Technology and Innovation Foundation,” Ten Ways IP Has Enabled Innovations That Have Helped Sustain the World Through the Pandemic”, April 29, 2021, <https://itif.org/publications/2021/04/29/ten-ways-ip-has-enabled-innovations-have-helped-sustain-world-through>] DD MN

Innovation can—and does—happen anywhere and at any time. As society ground to a halt in 2020, innovators around the world worked tirelessly to develop treatments, vaccines, and solutions to COVID-19 pandemic-related challenges. From personal protective equipment (PPE) to treatments and vaccines to autonomous delivery robots to remote and social distancing solutions for the workplace, intellectual property (IP) played an indispensable role in enabling research, development, and commercialization of many of the innovations meeting the challenges of the pandemic. IP enables start-ups to gain access to much-needed capital. **IP gives innovators the confidence to invest in research and development (R&D) and provides incentives for commercialization. Indeed,** it is difficult to innovate without the protection of ideas. Despite this, some—particularly **anti-business IP opponents—have blamed IP rights for a host of problems, including limited access to therapeutics, vaccines, and biotechnology**. **They offer seemingly simple solutions—weaken or eliminate IP rights—**and innovation will flow like manna from heaven. Eliminating IP rights might accelerate the diffusion of some *pre-existing innovations*, but it would absolutely limit future innovations. Innovators, a bit like Charlie Brown kicking the football held by Lucy, would be wary of trusting governments who might say, “Well, *this time* we won’t take away your IP rights, so go ahead and invest large amounts of time and money.” Given the nature of COVID-19, nations around the world cannot afford to take this risk. **Future pandemics and other challenges for which we will need to rely on IP-protected innovations to overcome are near certain to arise. Moreover, the blame game usually ignores the real, underlying problems**. For access to innovations to fight COVID-19, especially biotechnology, vaccines, and therapeutics, **the underlying problems are regulatory delays and a lack of adequate and appropriate manufacturing infrastructure.1 The lack of infrastructure has resulted in supply chain bottlenecks in places where few are currently equipped to handle the manufacturing requirements.2 Meanwhile, regulatory delays have prevented vaccines, therapeutics, and diagnostics from entering certain markets.**

#### Turns case- medical innovation increases access

**Bhardwaj 18** (Gunjan, Dr., Co-Founder and Chief Executive of Innoplexus AG, Forbes“Why The World Needs Health Care Innovation Now,”3/19/18, <https://www.forbes.com/sites/unicefusa/2018/06/22/bringing-hope-to-children-in-kenyas-kalobeyei-refugee-settlement/#7e3d06804326>)//AK

While some of these issues are difficult to resolve quickly, innovators in all corners of the health care industry are working to try and make improvements for patients, practitioners and companies alike. And since health care spending increased by $3.3 trillion in 2016, the opportunities for growth are replete. The following are some of the top reasons that we need health care innovation now. **Faster Development Of Treatments** It takes far too long for new drugs to make it to market. Data from research firm PhRMA identified that it takes 10 years, on average, for a new drug to be available for use. About 60-70% of that time is taken up in clinical trials, but frequently, the remainder is due to outdated regulatory systems. Fortunately, through the use of technology, we can significantly speed up that process.Sophisticated AI can increase the effectiveness of researchers, helping them find useful compounds or relevant data that might have been too difficult to find without contextual search features. Pharmaceutical companies are beginning to appreciate the powerful ways in which AI can augment drug research and development. For example, Genentech and GNS Healthcare announced a partnership last year aimed at using AI technology to analyze massive amounts of cancer patient data in order to identify novel cancer therapies. Additionally, cloud platforms can help digitize many of the regulatory processes that are still on paper. Some people have even argued that the development process itself should be more customizable and that current FDA regulations are too one-size-fits-all for certain treatments. **Increased Access To Care** Health care systems are different all around the world, and unfortunately, in many regions, it can be difficult to connect people with care. Access is frequently tied to economic status. A CDC report detailed that in the U.S., over 23% of near-poor adults ages 18-64 don’t have access to health insurance, and that number rises to 26% within the poor category. This isn’t just a challenge in the U.S., either -- even in countries with universal insurance, access to care can be limited by geography. Smaller communities may not be able to find the services they need locally.

#### Intellectual property protections key to innovation, R&D, and the economy which turns case

Nam **Pham 10**, Dr. Nam D. Pham is Managing Partner of ndplconsulting, a strategic research firm that specializes in economic analysis of public policy and legal issues. Dr. Pham was Vice President at Scudder Kemper Investments. Before that he was Chief Economist of the Asia Region for Standard & Poor's DRI and an economist at the World Bank. Dr. Pham is an adjunct professor at the George Washington University. Dr. Pham holds a Ph.D. in economics from the George Washington University, an M.A. from Georgetown University; and a B.A. from the University of Maryland. He is a member of the board of advisors to the Dingman Center for Entrepreneurship at the University of Maryland Business School and a board member of the Food Recovery Network, 4/24/2010, “The Impact of Innovation and the Role of Intellectual Property Rights on U.S. Productivity, Competitiveness, Jobs, Wages, and Exports,” Global IP Center,http://www.theglobalipcenter.com/sites/default/files/reports/documents/IP\_Jobs\_Study\_Exec\_Summary.pdf)rc//AK

Creativity and innovation are critical to the success of business, industry, and the economy. When ideas are developed into constructive goods and services and are protected through strong intellectual property (IP) rights, consumer interest and demand are spurred. As a result, jobs are created, economies grow, and societies advance. Studies have shown that innovation **magnified growth during the upturns and led economies out of downturns**. This report reconfirms these maxims. In brief, our findings showed that of over two dozen U.S. tradable industries during 2000-071 : (1) IP-intensive industries created highly-skilled jobs during the entire business cycle and low-skilled jobs during the economic downturns while non-IP-intensive industries lost jobs in all levels; (2) IP-intensive industries paid their highly- and low-skilled employees nearly 60 percent more than non-IP-intensive industries; (3) Output and sales per employee in IP-intensive industries were more than double that of non-IP-intensive industries; (4) IP-intensive industries promoted exports and enhance competitiveness; (5) IP-intensive industries generated trade surplus and therefore reduced U.S. trade deficits; (6) IP-intensive industries spent almost 13 times more on R&D expenditure per employee than non-IP-intensive industries; and, (7) IP-intensive industries allocated over 2.2 times the amount on capital expenditures per employee that non-IP-intensive industries allocated, which in turn stimulated jobs and economic activities in the U.S. economy. As such, protecting the intellectual property derived from innovation is essential to the future of a wide range of American industries. The protection and enforcement of IP rights are imperative for creating strong incentives for innovation and safeguarding it from counterfeiting, piracy, and other forms of IP theft. According to industry estimates, IP theft costs the American economy billions of dollars and hundreds of thousands of jobs per year. The Organisation for Economic Co-operation and Development (OECD) estimated in 2007 that global cross-border trade in tangible, counterfeit and pirated products could have been as high as $250 billion. Since the OECD report does not take into account domestically produced and consumed products or non-tangible pirated digital products, the actual economic impact of counterfeiting and piracy is much more severe. These costs are expected to grow exponentially, if enforcement is not improved, as the United States continues its transition into a knowledge-based IP-reliant economy. Given the importance of this ideas-based ecosystem, this study assesses the impact of innovation and the role of IP rights in 27 U.S. tradable industries between 2000 and 2007. We use industrial research and development (R&D) expenditures as a measure of the intensity of IP across industries since such expenditures are direct inputs for innovation and are the most widely used measures. We identify 15 IP-intensive industries–such as pharmaceuticals, aerospace, and petroleum–that have R&D expenditure per employee that exceed the national average. Similarly, we identify 12 non-IP-intensive industries–such as wood, textile, and paper–that spend less on R&D than the national average. 1 This study covers 27 tradable manufacturing and non-manufacturing industries that the U.S. International Trade Commission reports export and import values during 2000-07. Relative to non-IP-intensive tradable industries, U.S. IP-intensive tradable industries enjoy higher labor productivity, as measured by sales and value-added per employee. Consequently, they are more competitive in global markets as reflected in their higher exports. Since workers in IP-intensive industries are more productive by generating more output per person, IP-based firms pay higher salaries for both highly-skilled and low-skilled production jobs. With higher sales and higher wages, IP-intensive industries create highly-skilled jobs (including scientists, engineers, and above line-supervisor level) as well as low-skilled production jobs (up through line-supervisor level). Innovation in IP-intensive industries also generates products and services and employment in non-IP-intensive industries. IP-intensive industries far outspend non-IP-based industries on research and development (R&D) and capital investments (such as buildings and equipment) per employee. IP-intensive industry investment in R&D and capital has a cascading effect on jobs and economic growth in their own, as well as in related industries. In every case, IP-intensive industries outperform non-IP-intensive industries in economic performance for job creation, wages, sales, value-added, exports, R&D expenditure, and capital spending. Key findings of the report are summarized in Table 1 and are as follows: **1. IP-intensive industries create jobs and spur economic growth resulting from high investments in research and development (R&D)** in comparison to non-IP-intensive industries. While the direct outputs of R&D are typically the development of new forms of intellectual property, R&D spending also affects the economy by creating jobs and economic activities in R&D industries as well as in their supporting industries. During 2000-07, IP-intensive industries spent almost 13 times the R&D per employee that non-IP-intensive industries spent—averaging $27,839 and $2,164 per employee per year, respectively. **2. IP-intensive industries sustain greater long-term economic growth.** During 2000-07, workers in IP-intensive industries generated more than two times the output and sales per employee that workers in non-IP-based industries generated. Annual output (as measured by value-added) was $218,373 per employee in IP-intensive industries and only $115,239 in non-IP-intensive industries. {Table Omitted} During the same period, annual sales averaged $485,678 per employee in IP-intensive industries versus $235,438 in non-IP-intensive industries. This revenue is a contributing factor to economic growth and job expansion in other areas of the economy as well. **3. IP-intensive industries promote exports and America’s competitiveness abroad.** Investment in IP creates new products and services that strengthen America’s competitiveness in global markets. IP-intensive industries, which made up nearly half of output and sales of all 27 U.S. tradable industries and employed more than 30 percent of American workers in all 27 tradable industries, accounted for about 60 percent of total U.S. exports. During 2000-07, the annual value of exports per employee in IP-intensive industries was 235 percent higher (3.4 times) than in non-IP-intensive industries, $91,607 and $27,369, respectively. Employment and economic activities to support exports in IP-intensive industries were also higher than in non-IP-intensive industries. **4. IP-intensive industries generate trade surplus and therefore reduce U.S. trade deficits.** Of the 27 U.S. tradable industries, the collective trade deficit averaged nearly $540 billion per year during 2000-07; more than half of the deficit was attributable to non-IP-intensive industries. However, five of six industries that reported a trade surplus during 2000-07 were IP-intensive industries (basic chemicals; resin, synthetic rubber, fibers; navigational; aerospace; and, software). As a result, trade deficits during 2000-07 widened by only $112 billion in IP-intensive industries (55 percent from the 2000 level) compared to $150 billion in non-IP-intensive industries (76 percent from the 2000 level). **5. IP-intensive industries create jobs during tough economic times and are better positioned to successfully emerge from economic downturns than non-IP industries**. During the 2000-07 business cycle, IP-intensive industries created 114,500 highly-skilled jobs for scientists and engineers (a 20.9 percent increase over the 2000 level) while non-IP-intensive industries cut 4,800 highly-skilled jobs for scientists and engineers (3 percent below the 2000 level). Since the economic downturns from 2004 and the aftermath of the dot-com bubble collapse, IP-intensive firms gained 8,019 low-skilled jobs (0.3 percent above the 2004 level), while non-IP-intensive industries continued cutting 76,194 low-skilled jobs (1.1 percent below the 2004 level). **6. IP-intensive industries pay both highly-skilled and low-skilled employees more than non-IP-intensive industries**. IP-intensive companies have higher output and sale per employee and therefore pay their workers more than non-IP-intensive companies. During 2000-07, the annual salary of all workers in IP-intensive industries averaged about 60 percent higher (1.6 times) than the workers at similar levels in non-IP-intensive industries ($59,041 versus $37,202 per employee per year, respectively). Low-skilled production workers (up through the line-supervisor level) account for 65 percent of total employment in all U.S. tradable industries. Annual salaries of low-skilled workers in IP-intensive industries averaged about 40 percent higher than in non-IP-intensive industries ($43,478 and $31,345 per employee per year, respectively). **7. IP-intensive businesses are strong consumers for other IP-intensive and non-IP intensive industries.** IP-intensive industries allocated over 2.2 times (121 percent) the amount on capital expenditure per employee that non-IP-intensive industries allocated. During 2000-07, capital expenditure averaged $15,078 per employee in IP-intensive industries and $6,831 per employee in non-IP-intensive industries. Since capital acquired by firms includes such tradable products as machinery and equipment, and non-tradable items like buildings and other structures, IP-intensive industries also exert positive effects on supporting industries that add to job creation and economic growth.

### Adv 2

#### Developing countries lack the infrastructure and technology to develop drugs on their own

**Stevens and Huys 17**[Stevens - Ph.D., holds the Fund Baillet Latour supported Chair in Translational Medicine at the I³h Institute and is Associate Professor at the ULB, as well as Guest Professor at University of Leuven, Huys – advanced researcher and reporter of patents and drugs, Frontiers in Medicine, “Innovative Approaches to Increase Access to Medicines in Developing Countries”, December 7, 2017, <https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full>] DD MN

Stakeholders bundle forces in assuring essential medicines are manufactured, authorized, and distributed in low- and middle-income countries (LMICs) at affordable conditions. **But challenges remain, i.e., guaranteeing high distribution coverage, ensuring affordability, and adoption of essential medicines, both at provider level and end-user level (**[**9**](https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full#B9)**).** Developing countries lack infrastructure needed to increase access to medicines. **Most diagnostics are not designed for implementation in non-optimal laboratory conditions present in developing countries, with lack of air conditioning, stable electrical power, or refrigerators to store samples and chemicals** ([10](https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full#B10), [11](https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full#B11)). **Through microfluidic systems, high-tech technologies could find their way to the developing world laboratories. But the need for faster and more accurate diagnostics remains** ([10](https://www.frontiersin.org/articles/10.3389/fmed.2017.00218/full#B10)).

#### Developing countries rely on imports for drugs – intellectual property reduction isn’t going to change the access to drugs since they can’t make it themselves

**Hafner and Popp 11**[Hafner - Assistant Professor, Department of Public Administration and Policy, School of Public Affairs, American University, Popp – Research Associate and Syracuse University, National Bureau of Economic Research, “China and India as Suppliers of Affordable Medicines to Developing Countries”, July 2011, <https://www.nber.org/papers/w17249>] DD MN

**Developing countries** tend to **run a trade deficit on pharma**ceuticals **because most countries lack manufacturing and innovative capability**. **They** therefore **depend on imports for their domestic supply of medicines.** **Local pharmaceutical industries in developing countries**, when they exist, **tend to be small and focused on** the production of **traditional medicines or generic medicines for domestic consumption**. Some middle-income countries are an exception to that trend. Argentina, Brazil, China, Cuba, India, Mexico and South Africa, for example, have domestic pharmaceutical industries with varying levels of innovative capability (Balance, 1992). **India and China are important suppliers of medicines, particularly in products such as antibiotics and ARVs that treat diseases 5 prevalent in developing countries.** India produces both active ingredients and final products and is among the leading suppliers of antiretrovirals to developing countries. The government Pharmaceutical Organization in Thailand, for example, sources 90% of its materials for ARV production from India and produces ARVs that are up to 25 times cheaper than their branded equivalent. The Thai Public Health Ministry acknowledges that these savings would have been impossible without the Indian supply (Grace, 2004). China is also a major supplier of ingredients for antibiotics and has been ranked as the leading producer of penicillin, doxycyclin hydrochloride, cephalosporin and teramycin, producing more than 50% of the global supply (Grace, 2004). Brazil is regarded as a leader in its successful response to the HIV/AIDS epidemic which was partially facilitated by domestic production of generic antiretrovirals (Flynn, 2008). **Pharmaceutical production capabilities in Africa are far less developed** but the situation is likely to improve with recent initiatives by the African Union and the United Nations Industrial Development Organization (UNIDO) to strengthen local production (Berger et al., 2010). South Africa is the only country with the ability to manufacture active pharmaceutical ingredients and account for 70% of the estimated $1 billion in annual pharmaceutical production in Sub-Sahara Africa. Ghana, Nigeria and Kenya are also regional players but to a lesser extent.

**IP waivers doesn’t help developing countries + turns case bc decreases public trust**

**Bolle and Obstfield, 21** (Monica de Bolle (PIIE) and Maurice Obstfeld (PIIE), Maurice Obstfeld has been nonresident senior fellow at the Peterson Institute for International Economics since February 2019. He is the Class of 1958 Professor of Economics and former chair of the department of economics (1998–2001) at the University of California, Berkeley, where he has taught since 1991. He previously taught at Harvard University (1989–90), the University of Pennsylvania (1986–89), and Columbia University (1979–86).In addition to his academic positions, Obstfeld served at the International Monetary Fund (IMF) as economic counsellor and director of the research department5-12-2021, PIIE, "Waiving patent and intellectual property protections is not a panacea for global vaccine distribution", https://www.piie.com/blogs/realtime-economic-issues-watch/waiving-patent-and-intellectual-property-protections-not)//AK

The Biden administration's decision in early May 2021 to support temporary waivers of intellectual property rights (IPRs) on COVID-19 vaccines produced by the world's largest pharmaceutical companies is a welcome step intended to help countries with low access to vaccines. Unfortunately, however, the waivers by themselves will do little to aid global vaccination in the near term. In fact, these actions could be counterproductive if governments become complacent and fail to finance and organize vaccine supply chains worldwide, without which vaccines will not get to those who need them. As the pandemic has exploded in India and fears for Africa have intensified, the pressure on the United States, the European Union, and other advanced vaccine-producing countries to relax IP protections in World Trade Organization (WTO) agreements has intensified. Policymakers have also increasingly understood that no one is safe from COVID-19 until everyone is safe. Led by India and South Africa, the developing world ha[ve] been arguing on moral and practical grounds that IP waivers are essential to accelerating vaccine distribution and containing the pandemic worldwide. Absent widespread vaccination in less prosperous countries, experts say, all countries, even those with high vaccination rates, would remain vulnerable. But IP waivers alone will not necessarily accomplish that goal. Among the obstacles to getting wide distribution of vaccines are bureaucratic hurdles within the WTO, the difficulty for many poor countries of producing vaccines even if they have the legal right to do so, and the fact that vaccine production depends on global supply chains that cannot quickly be mobilized to deliver shots to low- and middle-income countries. Navigating the procedural obstacles to get WTO agreement on a streamlined mechanism for suspending IP protections is not as easy as it would seem. It is already possible to waive protections in the 1994 WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). But the WTO's track record suggests that roadblocks may lie ahead in expanding the scope of its waiver procedure. Since August 2003, the WTO has explicitly allowed emergency departures from the TRIPS agreement, enabling countries with manufacturing capacity to suspend IP protections to produce life-saving drugs and vaccines, not just for domestic use but also for export to countries that lack manufacturing capacity of their own. However, the process of negotiating the August 2003 decision—which created a temporary procedure for export waivers—took 14 months, and it was not until January 2017 that two-thirds of WTO members had ratified it as a formal amendment to the TRIPS agreement. Because of this painful negotiation process, the bureaucratic procedures for exercising IP flexibility are so cumbersome that there are very few instances of its use. The best known (though not very successful) example occurred with Canadian exports of an AIDS treatment to Rwanda in 2007. Complicating matters further has been the opposition of some major countries to revisiting the issue, as well as the likely need for WTO members to revise their domestic legal frameworks to accommodate patent waivers. These factors make it clear that renewed negotiations within the WTO are unlikely to yield results with the speed that the current health emergency demands or result in a meaningfully better framework. Recognizing the likely difficulty of negotiations, WTO Director-General Ngozi Okonjo-Iweala has suggested a December 3, 2021 deadline for completion—but like past initial deadlines in this space, this one could well prove overoptimistic. The second, and arguably more intractable, challenge is technical: Even if they overcome IP obstacles and get permission to produce vaccines, less prosperous countries lack the know-how, facilities, and trained personnel to produce them. Despite the abysmal decades-long record of vaccine distribution in those countries, existing TRIPS flexibilities have done nothing to improve the situation. A smoother IP waiver process might help, but only as a component of a broader effort. True, patent protection is the main obstacle to creation of generic small-molecule drugs, which chemists can synthesize. But other major obstacles exist for vaccines, which are biologics. For the latter category of drugs, an identical product requires an identical production technology, with most steps categorized as hard-to-replicate trade secrets rather than patentable innovations. Thus, Moderna announced in October 2020 that it would not enforce its COVID-19-related patents during the pandemic. But this step, however laudable, is of limited immediate help to would-be producers of a "generic" version of the Moderna vaccine. Without precisely replicating all steps of Moderna's production process, including the many quality controls, a generic version would have untested immunogenicity (the ability to induce the body to generate an immune response) and thus would require extensive clinical trials before release. Production glitches—such as those that afflicted the Janssen/Johnson & Johnson vaccine in the United States—could prompt widespread vaccine skepticism, damaging pandemic control efforts. The replication hurdle is especially high for the new and more sophisticated messenger ribonucleic acid (mRNA) vaccines, which have proven most effective against SARS-CoV-2 (the virus that causes COVID-19) and which are likely to provide the most adaptable platforms for the vaccines of the future. The genetic vaccines produced by Pfizer-BioNTech and Moderna require considerable technical knowledge and sophisticated techniques to generate a version of the viral spike protein that elicits a strong immune response.1 Therefore, from a biological standpoint, patent and IP waivers alone cannot resolve the existing lack of capacity in most countries to produce genetic vaccines at scale locally. A final challenge is that vaccine supply chains are intricate and global in scope. Different stages of vaccine manufacturing are spread across different parts of the globe, with various countries supplying key inputs and equipment. Patent and IP waivers cannot resolve export restrictions that these countries may decide to impose—and in fact have imposed—throughout the pandemic. Nor can poor countries with production waivers easily integrate into global supply chains. At the moment, current production capacity and quality standards continue to constrain global supply. A streamlined mechanism for IP waivers can be useful, but the back and forth of waiver negotiations within the WTO will prove counterproductive if it distracts from necessary immediate and longer-term measures to contain the pandemic and prepare for future threats. In the short run, global vaccine production by existing producers should be ramped up with more global sharing, and at subsidized prices for poor countries. All countries can start by renouncing export restrictions that threaten global supply chains. Rich countries must also step up to provide financial support for vaccine purchases and immunization programs and also to directly share vaccine doses that are now in oversupply. Political leaders in the rich countries should explain to their citizens that aiding poor countries is in their own interest. That is because the pandemic is producing potentially more transmissible and deadlier variants that will inevitably spread worldwide. Over the long run, the global community needs to build a cooperative infrastructure to address the likelihood of the current pandemic lasting a long time, while preparing for future pandemics that could arrive with increasing frequency. In February 2021, the Group of Seven nations proposed a global health treaty that would help create a framework for more effective and coordinated pandemic response. Systematic worldwide genomic surveillance of current and potential pathogens is one aspect of such a treaty that would be imperative in order to inform public health policymakers and guide rapid vaccine development. Another useful step could be a vaccine investment and trade agreement, as suggested by Thomas J. Bollyky and Chad P. Bown, which would enable countries to coordinate vaccine development, supply chains, and production to eliminate beggar-thy-neighbor policies and speed vaccine development and deployment worldwide. The public-private partnerships underlying such an agreement might incorporate reform of the TRIPS patent and IP flexibilities acceptable to all parties. Unfortunately, finance ministers and central bank governors did little more than rehearse broad principles at their April 2021 Group of Twenty (G20) meeting, even as the COVID-19 outlook has deteriorated in India and elsewhere. Italy will host the next important international public health meeting on May 21, 2021 at a Global Health Summit in Rome. Participants may consider proposals by the High Level Independent Panel on Financing the Global Commons for Pandemic Preparedness and Response, which the G20 established in January 2021 and which Dr. Okonjo-Iweala co-chairs. International engagement over patents and other IP protections will be immensely more beneficial as a component of much broader commitments to speed vaccine deployment in the near term and build a robust cooperative framework for ongoing pandemic response. By the time of their October leaders' meeting, G20 countries should be well along in implementing an ambitious global public health framework rather than squabbling over the narrower issue of IP protections.

### Solvency

#### No brightline as to what evergreening even would stop/indicate – covid 19 booster shot could be viewed as tweaking one vaccine – its necessary to prevetn spread aff makes it so it stops future diseases and even pandemic rn to be in a tough and risky situation

#### Big pharma companies are now turning to developing countries to distribute drugs for cheap – solvency in squo

**McNeil Jr. 19**[science and health reporter specializing in plagues and pestilences. He covers diseases of the world’s poor and wider epidemics, The New York Times, “Drug Companies Are Focusing on the Poor After Decades of Ignoring Them”, June 24, 2019, <https://www.nytimes.com/2019/06/24/health/drugs-poor-countries-africa.html>] DD MN

Nearly **20 million Africans are now on H.I.V. treatment — for less than $100 a year. Top-quality drugs for malaria, tuberculosis,**[**hepatitis C**](https://www.nytimes.com/2015/12/16/health/hepatitis-c-treatment-egypt.html)[**and some cancers**](https://www.nytimes.com/2017/10/07/health/africa-cancer-drugs.html)**are now sold at rock-bottom prices in poor countries.**

Once demonized as immoral profiteers, many of **the world’s biggest 20 pharmaceutical companies now** boast about how they **help poor countries and fight neglected diseases**. They [compete](https://www.globenewswire.com/news-release/2018/11/20/1654460/0/en/Novartis-rises-to-second-place-in-2018-Access-to-Medicine-Index.html) on the Access to Medicine Index,[which scores their charitable efforts](https://accesstomedicinefoundation.org/access-to-medicine-index/2018-ranking).

**Several** of them even **cooperate with the Indian generics companies** they once dismissed as “pirates” **by sub-licensing patents so the generics makers can produce cheap drugs for Africa, Asia and Latin America.**

But there is still opportunity for growth. Most of the industry’s remarkable progress [is limited to a few companies, and their efforts are too reliant on donor dollars](https://accesstomedicinefoundation.org/news/new-study-from-the-foundation-analyses-10-years-of-data-on-pharma-companies-and-access-to-medicine), according to a report issued last month by the Access to Medicine Foundation, which publishes the index, and interviews with experts.

#### Reducing intellectual property rights controls drug prices

**Khullar and Bach, 20** (Dhruv Khullar and Peter Bach, MD, is a physician at NewYork-Presbyterian Hospital, an assistant professor of hospital medicine and health care policy at Weill Cornell Medicine, and director of policy dissemination at the Physicians Foundation Center for the Study of Physician Practice and Leadership, is a physician and the director of the Center for Health Policy and Outcomes at Memorial Sloan Kettering Cancer Center. , 2-21-2020, accessed on 8-24-2021, Harvard Business Review, "3 Actions Congress Can Take to Reduce Drug Prices", https://hbr.org/2020/02/3-actions-congress-can-take-to-reduce-drug-prices)//AK

To bring down the high prices of drugs in the United States, Congress should not just focus on regulating prices themselves; it should reform the whole system that governs competition and innovation. Specifically, it should link innovation-friendly policies to price concessions, revamp how long and how thoroughly new drugs enjoy monopoly protection, and remove obstacles to competition from generics. The high prices Americans pay for drugs has emerged as a major health policy concern. A majority of voters in both the Democratic and Republican parties want the government to take action to lower prices, and lawmakers in both houses of Congress have introduced bills aimed at doing so. Drug companies, meanwhile, argue (as they long have) that negotiating or regulating prices would cripple research budgets, stifle innovation, and lead to fewer treatments in the future. In a new article in the New England Journal of Medicine, we describe the three-stage journey that every successful drug makes during its life cycle and how adjusting the incentives during each period and tying them to price concessions could achieve the best of both worlds: stimulate innovation and lower prices. First comes the “innovation period,” during which new products are developed, tested, and prepared to be submitted to the Food and Drug Administration for its approval. If they win FDA approval (most don’t), drugs enter a “monopoly period” and are protected from competition through patents and by the FDA. When these protections end, the “competitive period” starts: Other companies can now make and sell copies of the brand-name drug. Policies — laws passed by Congress and regulations enforced by presidential administrations — strongly influence how long these periods last and how much profit or loss companies experience in each. The ability to charge high prices is only one part of the risk-reward calculus for drug manufacturers. Conceptualizing the market as a whole opens up other avenues for reform. To help patients, lawmakers should take three actions. The process of drug development is uncertain and expensive, but there are many ways to reduce both the risk of failure and the cost of innovation that don’t require allowing drug companies to charge exorbitant prices. In 1981, for example, Congress created tax credits to offset research costs, and in 2000, Medicare began covering medical expenses for patients in clinical trials. More recently, regulations have been introduced to speed drugs through the FDA’s review process, which can save companies hundreds of millions of dollars. These innovation-friendly policies have never been linked to explicit price concessions from drug companies, but in the future, they should be. New drugs enjoy two types of monopoly protection: one through patents, the other through market exclusivity granted by the FDA. The FDA generally gives companies five to 12 years of exclusive rights to sell a new drug after approval, but patent protections can last decades because manufacturers often patent not just the original molecule but also minor changes to the drug like its coating or how it can be given. Enbrel, which is used to treat inflammatory conditions like rheumatoid arthritis, was developed in the 1990s, but it’s thicket of patents runs more than 100 deep and doesn’t run out until 2029. Meanwhile, the drug costs nearly $70,000 a year. Reducing the number and types of patents available to drug manufacturers would limit how long patients and taxpayers are exposed to those price tags. Absent action that limits the duration of drug monopolies, money that should be encouraging the development of new drugs will continue to flow to companies that are best at blocking competitors to older drugs. In addition to guaranteed monopolies, policymakers often hamstring insurers from using their market muscle to obtain price concessions. For example, not only is Medicare prohibited from negotiating drug prices, it is also required to cover every FDA-approved drug across six “protected” classes — regardless of how effective a drug is. Allowing Medicare and other payers to exclude some drugs from their formularies would improve their bargaining leverage and could lower prices. Both the Obama and Trump administrations considered this approach, but their efforts eventually stalled. Competition is a sacred American ideal — and a central mechanism through which drug prices ultimately fall — but policymakers have been slow to remove the barriers generic drugs face when trying to enter the market. Most people are familiar with “pay-for-delay” tactics through which companies pay would-be competitors not to bring generics to market, but they also use other tricks to smother competition before it begins. By citing safety concerns, for example, some companies refuse to provide the samples that generic manufacturers need to prove that their products are equivalent to branded drugs. The CREATES Act, which was signed into law in December, could put an end to some of these shenanigans, but other competitive challenges remain. Some pharmaceutical companies use a technique known as “evergreening” or “product hopping” to extend monopoly prices and prevent the use of generic drugs. A company product hops when shortly before the expiration of monopoly protection, it introduces minor changes to a branded drug — tablet to film administration, for example, or twice-daily to once-a-day dosing — and removes the original product from the market, thereby delaying generic drug approvals and substitutions. The Federal Trade Commission could more aggressively enforce antitrust laws against such tactics, and the FDA should not grant cosmetically different products market exclusivity immediately before branded products are set to lose monopoly protection. In some drug classes like biologic drugs, where competitors are simply hard to make, lawmakers may ultimately have to regulate prices if they can’t make the market work. Today, the United States has a system that has allowed the prices for drugs to skyrocket, often outstripping the value they offer patients. But by reforming the whole system and not just focusing on prices alone, lawmakers can bring down the cost of drugs and stimulate the development of new therapies.

#### Drug price controls harm innovation

**Dearment, 20** (Alaric Dearment, Alaric DeArment is a senior reporter at MedCity News covering biotech and pharma and its convergence with information technology, 2-19-2020, accessed on 8-24-2021, MedCity News, "How much will drug price controls harm innovation? It depends - MedCity News", https://medcitynews.com/2020/02/how-much-will-drug-price-controls-harm-innovation-it-depends/)//AK

Get the latest industry news first when you subscribe to our daily newsletter. BioPharma, Policy By Alaric DeArment For all their differences, particularly in election season, Democrats and Republicans seem to agree on one thing: Drug prices, both list and out-of-pocket, are out of control. Both parties have backed efforts to use the power of government to bring them down. In response, the biopharma industry has said that policies forcing it to lower list prices would stifle innovation. But on closer examination, the picture gets a little more complicated than the diametrically opposed positions of politicians and drugmakers would lead one to believe. While studies support the argument that forcing lower revenues for drug companies across the board would mean less innovation, factors like geography, patent protections and public investment in life sciences are also crucial components to keeping the drug pipeline flowing. “It’s clear that if you basically reduce total spending on patent drugs, there will be some effect,” University of Calgary economics professor Aidan Hollis said in a phone interview. “How large the effect is is a questionable issue.” The U.S. pays more for prescription drugs than any other country. According to the Organization for Economic Co-operation and Development, the U.S. spent $1,220 per capita in 2018. Not surprisingly, drug companies derive the largest share of their quarterly and annual revenues from the U.S., which also tends to be their first stop when they seek regulatory approval. Medicare accounts for much of that and, unlike health authorities in other developed countries, is statutorily prohibited from negotiating drug prices directly with manufacturers. In December, the House passed H.R. 3, a bill that would require Medicare to negotiate list prices on the drugs covered under Medicare Part D that account for most U.S. drug spending. The Trump administration has proposed international reference pricing, which would peg prices for drugs covered under Medicare Part B to average prices paid abroad. Medicare Part B covers certain outpatient drugs administered by physicians, while Part D covers prescription drugs. Countries with universal healthcare systems typically have government drug-pricing watchdogs tasked with ensuring that the prices paid are cost-effective. These include the U.K.’s National Institute for Health and Care Excellence (NICE), Germany’s Institutes for Quality and Efficiency in Health Care (IQWiG), Italy’s Italian Medicines Agency (AIFA) and others that drugmakers must negotiate with after securing primary approval from regulators like the European Medicines Agency or Health Canada. NICE imposes especially strict cost-effectiveness criteria, typically requiring that the cost per quality-adjusted life year (QALY) remain below 30,000 pounds ($39,000) as a condition for recommending a drug’s use by the National Health Service in England and Wales. A QALY is a metric used to represent one year of perfect health. If the cost per QALY exceeds the 30,000-pound threshold, NICE will initially turn the drug down, followed by the manufacturer offering confidential discounts and rebates. Thus, the list prices that drugmakers take to European countries usually do not reflect the amounts that governments pay, which are trade secrets and usually unknown even to other countries. According to the OECD, drug spending in the U.K. was well below most developed countries in 2018 — $469 per capita. It’s because of those lower prices that the Trump administration accuses other countries of getting a “free ride” on the backs of American patients, who bear the costs of innovation through higher prices. Some in the industry echo that view. “What has happened is that the U.S. has been subsidizing innovation for the rest of the world,” said Pascal Prigent, CEO of Lille, France-based drugmaker Genfit, in an interview at the 2020 BIO CEO and Investor Conference. Were the U.S. to pay the same amount for drugs as France, it would harm innovation, he said. France spent $653 per capita in 2018, according to the OECD. The bigger question is how much lowering prices would affect innovation and how much spending would need to come down for there to be a significant impact. In a review of H.R. 3, the Congressional Budget Office estimated that it would reduce federal direct spending under Medicare by $345 billion between 2023-2029. Reduced industry revenues would, in turn, reduce R&D spending, with a $500 billion-$1 trillion revenue reduction yielding 8-15 fewer drugs over 10 years. The Food and Drug Administration, it noted, approves an average of about 30 drugs per year. The effect of increased use of drugs but fewer drugs entering the market on overall public health is not clear, the CBO stated. But revenues don’t just pay for the drugs of the future – they also pay for the ones that could have been. “That price not only needs to pay for the price of development, but it also needs to pay for the price of failed development,” Prigent said. Moreover, while the reduction of 8-15 drugs from the 300 that the FDA would approve over 10 years may not seem like much, it’s impossible to know which specific drugs those could be – me-too drugs that do little to advance treatment or novel therapies that significantly change the trajectories of diseases. “That’s a significant amount of innovation,” said Scynexis CEO Marco Taglietti in an interview at the BIO CEO conference. What drug companies need to do is be more transparent about what they spend on research and development, said Olivier Wouters, assistant professor of health policy at the London School of Economics and Political Science. “Companies need to be more open about the costs they incur in drug development, and then we can look more closely into these issues,” Wouters said in a phone interview. Some of the public’s distrust of drugmakers comes from the perception that they spend more on marketing than on R&D. While some drugmakers have appeared to spend more on marketing in certain years, Regulatory Focus writer Zachary Brennan has pointed out that it is due in part to how companies define marketing and R&D, which may not be entirely clear when one looks at financial statements. Nonetheless, it can’t be denied that drug development is a risky business. It’s heavily regulated, very expensive and fraught with the unpredictability inherent in biology. A small biotech company can spend hundreds of millions of dollars painstakingly raised from venture capital and public markets to develop its first drug, only to have everything fall apart when randomized Phase III trial data show it is too toxic, insufficiently effective or both, or it fails to secure physician uptake or payer coverage. But by the time a drug is in commercial clinical development, a considerable amount of the risk has already been removed, especially if it has shown promising signs of efficacy and at least manageable toxicity. And many drugs are born in labs at universities, academic medical centers or government research institutes – often with the aid of government grants – before their inventors spin them off into startups or companies or investors swoop in to license them. Where that early development happens is another important factor. An additional question that the debate around pricing and innovation raises is why there is often a disconnect between the size of a country’s drug industry and the amount of money it pays for drugs. Prigent said the amount of innovation that drugmakers in Europe do is thanks to the high prices they can get for drugs in the U.S. “The pharma companies in the U.K. are conducting a lot of research, and they make their profit like everyone else in the U.S.,” he said. “GlaxoSmithKline and AstraZeneca innovate, but they need the prices in the U.S. to do so – the same with Sanofi in France.” Based on the OECD figures and their quarterly earnings, there’s no question that London-based GSK and AstraZeneca and Paris-based Sanofi are not deriving the lion’s share of their profit from their relatively thrifty home countries. Other examples exist of countries with low domestic spending on drugs but lots of innovation. Switzerland has the OECD’s second highest spending level, $963 per capita, and is both highly innovative and home to two of the world’s largest drugmakers, Novartis and Roche. Spending $310 and $318 per capita, Israel and Denmark rank near the bottom of the OECD – only Costa Rica and Mexico spend less – but also have significant biopharma innovation, with Israel in particular known for its startup scene. But there are also cases where the reverse is true. Canada spends the fourth highest amount on drugs per capita, $832, and borders the highest-spending and most innovative country, but is “bottom of the barrel” when it comes to drug industry R&D spending, said Doug Clark, executive director of the Patented Medicine Prices Review Board, Canada’s official drug-pricing watchdog. “So if there’s a correlation, it must be a very weak one,” Clark said in a phone interview. He added that Canada’s sparse population and lack of good health databases probably don’t increase its attractiveness for biopharma R&D despite its low corporate tax rate. “We’ve never been a heavy hitter when it comes to pharma research and development,” Clark said. Clark said that to the extent there is a connection between drug pricing, intellectual property protection and pharmaceutical innovation, “it’s not an organic one.” Otherwise, he said, the situation in Canada would be different. And then there’s the odd case of Cuba, whose state-owned Center for Molecular Immunology has leveraged state support for biomedical research and the country’s comprehensive healthcare system to develop a small number of novel drugs, without the benefit of revenues from the U.S. Indeed, there are likely factors dictating the size of a country’s biopharma industry that go beyond simply high drug prices, Wouters said. Drugmakers in the U.S., for example, benefit from a strong academic sector, public investment in basic research and a strong patent system. A 2018 paper illustrates the importance of investment in basic research. Published in the journal Proceedings of the National Academy of Sciences, the study showed that more than $100 billion in funding from the National Institutes of Health contributed to published research for every one of the 210 drugs that the FDA approved between 2010 and 2016, most of it associated with basic research related to biological targets for drug action. The same paper cited research showing that companies invest an average of $1.4 billion out of pocket for each new molecular entity launched, with the total cost of capital being more than $2.5 billion. Another study cited in the paper found that for 38% of new drugs approved by the FDA, the first synthesis or purification of the molecule came from an academic institution. “The reason there’s a lot of innovation in the U.S. is because of a big population of scientists who work on biopharmaceuticals,” Hollis said. Hollis pointed out that while Americans spend more on drugs than anyone else, much of the development that takes place is centered on a few locations. The Boston and San Francisco areas are the largest centers for biotechnology, with areas around cities like San Diego, New York, Seattle and Philadelphia growing rapidly as well. “Lots of money is spent in Illinois, and probably much more than in Massachusetts, but there’s more innovation in Massachusetts,” Hollis said. There’s no denying that sales revenues and the profits they generate are critical for maintaining a healthy product pipeline and encouraging drugmakers to take the risks involved in developing new medicines. But as with so much else in biopharma, there’s a lot more to drug development than money alone.