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## 1

#### CP: The member nations of the world trade organization should enter into a prior and binding consultation with the world health organization over reducing intellectual property rights for medicines

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs.

#### Consultation displays strong leadership, authority, and cohesion among member states which are key to WTO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

## 2

#### Infrastructure is making halting progress via reconciliation – bipartisanship is key for Manchin and Republicans to not nuke it

Litvan 9/2 [Laura] “Manchin Jolts Democrats by Urging ‘Pause’ on $3.5 Trillion Bill,” Bloomberg, September 2, 2021, <https://www.bloomberg.com/news/articles/2021-09-02/manchin-tells-democrats-to-pause-on-biden-s-3-5-trillion-plan> TG

Senator Joe Manchin is demanding a “strategic pause” in action on President Joe Biden’s economic agenda, potentially imperiling the $3.5 trillion tax and spending package that Democratic leaders plan to push through Congress this fall.

The West Virginia Democrat, a linchpin vote in the evenly divided Senate, said at an event in his home state on Wednesday and in a Thursday Wall Street Journal op-ed that rising inflation and a soaring national debt necessitate a go-slow approach and a “significantly” smaller plan than the one Democratic leaders and the White House have endorsed.

“By placing a strategic pause on this budgetary proposal, by significantly reducing the size of any possible reconciliation bill to only what America can afford and needs to spend, we can and will build a better and stronger nation for all our families,” Manchin said in the op-ed.

Manchin’s resistance to the core of Biden’s economic plan caps a politically painful month for a White House that has grappled with a chaotic withdrawal from Afghanistan, a resurgent pandemic and a massive hurricane that cut a path of death and damage from Louisiana to New York.

In comments Wednesday at an event hosted by the West Virginia Chamber of Commerce, the moderate Democrat said his party should “hit the pause button.” Lawmakers, he said, have too many other pressing issues before them, including heightening national security concerns after the Taliban takeover of Afghanistan.

“Let’s sit back. Let’s see what happens. We have so much on our plate,” he said.

Manchin’s comments come as Democratic leaders and committee chairs in the Senate and House work out the specifics of the economic package, with a goal of moving it through Congress soon after lawmakers return from a recess later this month. All members of the Senate Democratic caucus would have to back the measure for it to get the 51 votes needed to pass, with Vice President Kamala Harris providing the tie-breaking vote.

A spokesman for Senate Majority Leader Chuck Schumer didn’t immediately respond to a request for comment about Manchin’s request, and White House Press Secretary Jen Psaki did not immediately provide a comment.

The chair of the Congressional Progressive Caucus, Representative Pramila Jayapal, replied “Absolutely not” on Twitter to Manchin’s idea of a pause.

The spending package also is facing obstacles in the House. Democrats can only afford three defections in that chamber if Republicans are united in opposition, and some moderate Democrats also are balking at the size of the package being drawn up.

Manchin also called on the House to pass within a few weeks a Senate-passed $550 billion bipartisan infrastructure bill. House Speaker Nancy Pelosi has promised progressives in the chamber that she will marry that legislation with the much bigger Democrat-only tax-and-spending package, although moderates have been promised an infrastructure vote by late September.

#### General bipartisanship could spark compromise but the plan’s partisan nature tanks any shot

Montanari 21 “Biden’s Undermining Of U.S. Intellectual Property Rights Is Dangerous And Will Hurt Pandemic Response,” Lorenzo Montanari [executive director of Property Rights Alliance, an advocacy policy group in charge of publishing the International Property Rights Index], May 12, 2021 <https://www.forbes.com/sites/lorenzomontanari/2021/05/12/bidens-undermining-of-us-intellectual-property-rights-is-dangerous-and-will-hurt-pandemic-response/?sh=4a74c5004890> SM

Republican Congressman Byron Donalds (R-Fla.) is working on a new piece of legislation titled "Preventing Foreign Attempts to Erode Healthcare Innovation Act” to block the White House IP waiver position and to "prevent the Biden Administration from senselessly giving away America's intellectual property to countries like China”. IP rights are enshrined in Article 1, Section 8, Clause 8 of the U.S. Constitution of 1787, “To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries.” As a central pillar to American history and constitutionalism for 244 years, IP converges tradition and progress to enrich the lives of citizens and society.

Waiving IP rights not only goes directly against America’s core values and threatens public health but wanes potential for bipartisan efforts. “Congress has spent decades wrangling over the contours of patent protections,” WSJ’s Kimberley A. Strassel says, “producing bipartisan legislation from the Bayh-Dole Act of 1980 and the Hatch-Waxman Act of 1984 to the Leahy-Smith Act of 2011.” All these bipartisan efforts to defend American inventors with a strong and fair IP system risk being seriously damaged with this Biden move.

#### Comprehensive infrastructure investment is key to all facets of the economy

Condon 2/21 [(Christopher, overing the Treasury and U.S. economic policy at Bloomberg News, with Erik Wasson) “Biden’s Economic Legacy at Stake as Next Package Takes Shape,” *Bloomberg*, 2-21-2021, <https://www.bloomberg.com/news/articles/2021-02-21/biden-s-economic-legacy-at-stake-with-next-package-taking-shape>] TDI

The next phase of President Joe Biden’s legislative agenda is fast taking shape, with an economic-recovery package that will potentially far surpass his $1.9 trillion virus-relief plan in size, complexity and overall ambition. The White House and congressional Democrats are busy plotting strategy for the proposal, which could be unveiled next month, kicking off a legislative process that may culminate by August. The centerpiece will be possibly the biggest infrastructure-spending commitment since the New Deal -- including roads, bridges and rural broadband internet. Progressives are eyeing much more, such as an expansion of Obamacare and a public-sector jobs program, along with tax measures including an increase in the capital-gains levy. But stuffing it with too many controversial proposals could threaten its approval or force it to be broken up, and put in peril the Democrats’ thin majorities in the 2022 midterm elections. Still, Democrats see a narrow opening to forge Biden’s legacy: not just restoring the U.S. economy to its pre-pandemic state, but reversing the trend of sluggish growth in recent years with the most far-reaching measures in decades. U.S. economy has put up more moderate growth in the 2000s versus heydays Biden’s virus-relief package is “going to help us get us back on the growth pattern we were on before,” said Virginia Representative Don Beyer, who, as incoming chair of the Joint Economic Committee, is a leading Democratic macroeconomic-policy voice. “The genius of the second plan is that it gives us the opportunity to punch GDP up above the long-term trend,” he said in an interview. During his campaign, Biden proposed $2 trillion for economic rebuilding, a step up from the $1.5 trillion level proposed in the House last year, which Democrats are now calling a “floor.” China Card Biden is aiming to succeed where Donald Trump and other predecessors have failed, when funding disputes stymied measures that economists say are vital to boosting long-term productivity. The president is selling the package as a way to counter China, which has deployed public investment not only to boost its own growth but to build global influence as well. As challenging as it may be to enact, such arguments may make the core infrastructure piece likely to be the easiest component to get through Congress. Bipartisan support for improved highway, transit, waterway and flood-mitigation work is strong, while deficit concerns are at the lowest level in decades. There’s also a Sept. 30 deadline in Congress for reauthorizing surface-transportation funding -- offering a ready-made vehicle for pursuing infrastructure measures. “Much of our infrastructure is nearing the end of its useful design life,” said Thomas Smith, executive director of the American Society of Civil Engineers, which will issue its latest quadrennial report card on U.S. infrastructure on March 3. “We’ve neglected it for far too long, and we’ve watched other countries continue to invest and continue to move ahead of the United States.” The ASCE’s last assessment, in 2017, was a D+. Back then, it estimated the U.S. needed $4.5 trillion in infrastructure spending over the following 10 years. With about $2.5 trillion in estimated outlays already in train, that left a $2 trillion gap -- which Biden’s proposal could largely fill. Congressional Budget Office figures indicate that a $1.5 trillion package would be equivalent to all federal spending on transportation and water infrastructure in the 14 years through 2017. The Senate Environment and Public Works Committee plans a hearing on transportation investment on Wednesday, when Michigan Governor Gretchen Whitmer, a Democrat, and Maryland Governor Larry Hogan, a Republican, are scheduled to testify. But infrastructure could become ensnared by a push among liberal lawmakers to tack on a raft of other items, from creating a government-run health insurance plan and making unionization easier, to a pathway to citizenship for undocumented immigrants and a carbon tax. Political Risk Meanwhile, House moderates in swing districts are facing the perils of redistricting ahead of the midterms, and could insist on limiting the scope of the bill to rein in its cost and limit partisan battles. Fights could also emerge over formulas for divvying up the money among states and cities. Congressional Progressive Caucus Chair Pramila Jayapal said Thursday her large cohort of House Democrats will decide in the coming weeks which elements to advocate in the package -- including whether to use it as an opportunity to roll back Trump’s tax cuts for the wealthy. Jayapal’s group was instrumental in attaching to the pandemic-relief plan an increase in the hourly minimum wage to $15, something that’s become easily the most controversial potential holdup for that bill. The progressive caucus has proposed a $2 trillion infrastructure bill, and is already advocating that it include expanded child and elder care. The question of funding, whether by raising taxes or issuing more debt, also looms large, and many Republicans are set to be vociferous in opposing much of the plan. Senate Finance Committee Chairman Ron Wyden is expected to propose tax hikes, including equalizing ordinary income and capital-gains levies for those making more than $1 million a year and ending the deferral of capital gains. He’d also change international tax provisions in the 2017 tax law and close the carried-interest loophole, according to a Democratic aide. Some lawmakers favor raising the federal gasoline tax -- now 18.4 cents a gallon and 24.4 cents for diesel -- for the first time since 1993, though Wyden in 2019 expressed opposition to the idea, calling it regressive. Treasury Secretary Janet Yellen, who argues that deficit spending makes more sense with interest rates historically low, said on CNBC last week that “certainly part of the package, the parts that are permanent, will be paid for in order to not raise long-term deficits.” While the yield on 10-year Treasury notes has risen markedly in recent weeks, Friday’s level of 1.34% is far below the 50-year average of about 6.16%. U.S. government's borrowing costs are historically low “There’s a lot of appetite to do something this year,” said Jeff Davis, a senior fellow at the Eno Center for Transportation. “But there seems to be no appetite to pay for it.” Despite all the hurdles, Biden has a strong hand. Upgrading and maintaining infrastructure acts as its own stimulus, unleashing real demand for equipment makers, materials suppliers and, most importantly, workers. Nucor Corp., Cleveland-Cliffs Inc. and U.S. Steel Corp., the country’s three largest steel producers, have been lobbying through their industry groups since the election to persuade lawmakers to back whatever infrastructure package the Biden administration puts forth. Productivity Potential Such spending would also be a huge boon for Caterpillar Inc., one of the world’s largest machinery makers, which attributed a drop in North American construction-equipment sales to weaker demand for pipelines and road construction. There’s also the potential for a long-term payoff, if investments translate into productivity gains -- such as savings on shipping and commuting costs when roads, rails and ports are improved, or avoiding the kind of power-grid failures on display this month in Texas. “We cannot throw all fiscal discipline to the wind, but the standards for fiscal prudence have indeed changed in light of the global decline in the normal structure of interest rates,” said David Wilcox, a senior fellow at the Peterson Institute for International Economics, and a former Federal Reserve and Treasury official. “If the rate of return on an investment exceeds your borrowing cost, it makes sense to do that investment, and with lower borrowing costs, more investments today can clear that bar.”

#### Post-COVID economic rebound secures geopolitical dominance---the alternative is global conflict, EU collapse and Chinese authoritarian dominance

Kempe 20 [(Frederick, best-selling author, prize-winning journalist and president & CEO of the Atlantic Council, one of the United States’ most influential think tanks on global affairs. He worked at The Wall Street Journal for more than 25 years as a foreign correspondent, assistant managing editor and as the longest-serving editor of the paper’s European edition.) “Op-ed: How the US can win the post-coronavirus race for global dominance,” CNBC, 4-18-2020, https://www.cnbc.com/2020/04/18/op-ed-how-us-can-win-the-post-coronavirus-race-for-global-dominance.html] TDI

Place your bets for the coming race to growth. It will be an epic contest among the world’s most significant economies, with generational and geopolitical consequences. For context, think back to what the United States accomplished after World War II, when it rose as an economic power to shape a better world. The post-COVID19 race could determine whether the U.S. rebounds in a manner that allows it to retain the mantle of global leadership. More likely for the moment, Beijing could leverage its first-mover advantage – alongside a faster economic recovery across Asian markets – accelerating the trend toward a Chinese-centric globalization. Elsewhere, as President Macron [argued](https://www.ft.com/content/3ea8d790-7fd1-11ea-8fdb-7ec06edeef84) this week to the Financial Times, the coming months could determine whether the European Union collapses as a political and economic project. The days ahead also could trigger a dangerous widening of the economic gap between emerging markets and the developed world – with escalating conflict and surging migration. It may seem premature to reflect on which of the globe’s economies is likely to have the most robust and lasting economic comeback – and with what geopolitical impact. After all, this was a week in which the International Monetary Fund [projected](https://www.imf.org/en/Publications/WEO/Issues/2020/04/14/weo-april-2020) a 3% contraction in global GDP for 2020, the most dramatic drop since the Great Depression. Yet it is the details behind that dismal forecast that should raise concerns within the U.S. and Europe. Their steeper economic decline and slower recovery could lay the seeds for a long-lasting shift of global tectonic plates to China’s advantage. The IMF projected a U.S. economic decline of about 6% in 2020 and a contraction of the eurozone of 7.5%. That compares to projected Chinese economic growth for 2020 of 1.2% after a first quarter real decline of 6.7% – far less than the 10%-plus dip many experts had expected. The only group of countries in the world projected to be in positive territory are East Asian, at roughly 1%. Even if one accepts that Chinese coronavirus fatalities likely are greater than their public figures and that the growth decline is likely larger, that doesn’t change the potential for a scenario that Deloitte and Salesforce this week [referred to](https://www2.deloitte.com/global/en/pages/about-deloitte/articles/covid-19/covid-19-scenarios-and-impacts-for-business-and-society-world-remade.html) as “Sunrise in the East.” Describing this scenario, as one of four possibilities they list, they write, “The global center of power shifts decisively east as China and other East Asian nations take the reigns as primary powers on the world stage and lead global coordination of the health system and other multilateral institutions.” That comes with the broader acceptance of greater surveillance mechanisms as part of the public good, a faster recovery of East Asian countries with less economic impact from COVID19, and a significant ramping up of Chinese foreign direct investment to burnish its global reputation. Still, the U.S. has a host of incumbent advantages that could serve it well if it uses its economic recovery to also strengthen its infrastructure, if it reverses runaway unemployment quickly, if it can tame political polarization and, most significantly, if it rediscovers its taste for collaborative global leadership. In the economic race, no advantage is greater than the dollar. China may be the world’s second largest economy, but the Chinese yuan [makes up](https://asiatimes.com/2019/12/yuan-globalization-remains-a-long-way-off/) only 2% of global payments and reserves while the dollar [accounts](https://asiatimes.com/2019/12/yuan-globalization-remains-a-long-way-off/) for roughly two thirds of foreign exchange reserves. The dollar [underpins](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) four-fifths of global supply chains. The Economist [reckons](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) China could chip away at U.S. economic advantages through three underestimated strengths of its own: as a trusted debtor, an attractive creditor, and increasingly as a tech partner. As a debtor, China’s $13 trillion bond market is the world’s second largest and [has weathered the crisis well](https://www.ft.com/content/41044876-6ab4-11ea-a3c9-1fe6fedcca75). Chinese debt [returned](https://www.cbsnews.com/news/china-cuts-us-treasury-debt-holding-by-13/) 1.3% in the first quarter, vastly better than the 15.5% [decline](https://www.economist.com/finance-and-economics/2020/04/16/the-dollars-dominance-masks-chinas-rise-in-finance) for other emerging market bonds. Over the same period, the Chinese market added $8.5 billion (60 billion yuan) in net inflows. As a creditor, China has remained willing and generous, an approach that served the U.S. well after World War II. For example, it [declared](https://www.ft.com/content/5f296d54-d29e-4e87-ae7d-95ca6c0598d5) its willingness to back a G20 deal to suspend bilateral loan repayments by poorer countries, a sizable benefit also at its own cost. On the tech front, few countries were as ready as China for money and people to go entirely online. Tencent and Ant Financial have more than a billion users each for their digital wallets, and they are expanding rapidly throughout Asia. OneConnect, an offshoot of China’s largest insurer, provides financial institutions in sixteen Asian countries with cloud-based services. So, what other advantages can the United States leverage in this race? Never underestimate the brittleness of an authoritarian country under stress. Its broad censorship, it’s opaque legal system, and the nature of its surveillance state are hardly models to emulate. Beyond that, Japanese Prime Minister Shinzo Abe is not alone [in proposing](https://asia.nikkei.com/Editor-s-Picks/China-up-close/Xi-fears-Japan-led-manufacturing-exodus-from-China) that his country relocate high-value supply chains from China. If many countries do the same, the manufacturing foundation of China’s economy could erode. The Financial Times’ Gideon Rachman [adds](https://www.ft.com/content/2e8c8f76-7cbd-11ea-8fdb-7ec06edeef84) that the global trust in the dollar is just one of two built-in U.S. advantages that are difficult to dislodge. The other? “Where, outside your home country, would you most like your children to go to university or to work?” he writes. Most significant in this race would be if the United States regained its appetite for political and economic leadership as the world’s premier “convening power.” That need not be done at the cost of China – or anyone else. The race still can be won if U.S. leaders see it as a marathon and recall that much of the world long embraced their global leadership because partners learned they were more likely to win as American partners. This economic rebound from COVID19 will be patchy and uneven. Being first out the gate will be significant, and that is likely to be China. Yet history has taught the United States that it’s victory will be longest lasting if it can achieved alongside partners and allies.

#### Nuclear war

Henricksen 17, emeritus senior fellow at the Hoover Institution (Thomas, “Post-American World Order,” *Hoover Institution*, <http://www.hoover.org/research/post-american-world-order>)

The tensions stoked by the assertive regimes in the Kremlin or Tiananmen Square could spark a political or military incident that might set off a chain reaction leading to a large-scale war. Historically, powerful rivalries nearly always lead to at least skirmishes, if not a full-blown war. The anomalous Cold War era spared the United States and Soviet Russia a direct conflict, largely from concerns that one would trigger a nuclear exchange destroying both states and much of the world. Such a repetition might reoccur in the unfolding three-cornered geopolitical world. It seems safe to acknowledge that an ascendant China and a resurgent Russia will persist in their geo-strategic ambitions. What Is To Be Done? The first marching order is to dodge any kind of perpetual war of the sort that George Orwell outlined in “1984,” which engulfed the three super states of Eastasia, Eurasia, and Oceania, and made possible the totalitarian Big Brother regime. A long-running Cold War-type confrontation would almost certainly take another form than the one that ran from 1945 until the downfall of the Soviet Union. What prescriptions can be offered in the face of the escalating competition among the three global powers? First, by staying militarily and economically strong, the United States will have the resources to deter its peers’ hawkish behavior that might otherwise trigger a major conflict. Judging by the history of the Cold War, the coming strategic chess match with Russia and China will prove tense and demanding—since all the countries boast nuclear arms and long-range ballistic missiles. Next, the United States should widen and sustain willing coalitions of partners, something at which America excels, and at which China and Russia fail conspicuously. There can be little room for error in fraught crises among nuclear-weaponized and hostile powers. Short- and long-term standoffs are likely, as they were during the Cold War. Thus, the playbook, in part, involves a waiting game in which each power looks to its rivals to suffer grievous internal problems which could entail a collapse, as happened to the Soviet Union.

## 3

#### Biotech industry strong now

Cancherini et al. 4/30 [(Laura, Engagement Manager @ McKinsey & Company, Joseph Lydon, Associate Partner @ McKinsey & Company, Jorge Santos Da Silva, Senior Partner at McKinsey & Company, and Alexandra Zemp, Partner at McKinsey & Company), “What’s ahead for biotech: Another wave or low tide?“, McKinsey & Company, 4-30-2021, https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/whats-ahead-for-biotech-another-wave-or-low-tide] TDI

Belying this downbeat mood, biotech has in fact had one of its best years so far. By January 2021, venture capitalists had invested some 60 percent more than they had in January 2020, with more than $3 billion invested worldwide in January 2021 alone.5 IPO activity grew strongly: there were 19 more closures than in the same period in 2020, with an average of $150 million per raise, 17 percent more than in 2020. Other deals have also had a bumper start to 2021, with the average deal size reaching more than $500 million, up by more than 66 percent on the 2020 average (Exhibit 3).6

What about SPACs?

The analysis above does not include special-purpose acquisition companies (SPACs), which have recently become significant in IPOs in several industries. Some biotech investors we interviewed believe that SPACs represent a route to an IPO. How SPACs will evolve remains to be seen, but biotechs may be part of their story.

Fundamentals continue strong

When we asked executives and investors why the biotech sector had stayed so resilient during the worst economic crisis in decades, they cited innovation as the main reason. The number of assets transitioning to clinical phases is still rising, and further waves of innovation are on the horizon, driven by the convergence of biological and technological advances.

In the present day, many biotechs, along with the wider pharmaceutical industry, are taking steps to address the COVID-19 pandemic. Together, biotechs and pharma companies have more than 250 vaccine candidates in their pipelines, along with a similar number of therapeutics. What’s more, the crisis has shone a spotlight on pharma as the public seeks to understand the roadblocks involved in delivering a vaccine at speed and the measures needed to maintain safety and efficacy standards. To that extent, the world has been living through a time of mass education in science research and development.

Biotech has also benefited from its innate financial resilience. Healthcare as a whole is less dependent on economic cycles than most other industries. Biotech is an innovator, actively identifying and addressing patients’ unmet needs. In addition, biotechs’ top-line revenues have been less affected by lockdowns than is the case in most other industries.

Another factor acting in the sector’s favor is that larger pharmaceutical companies still rely on biotechs as a source of innovation. With the top dozen pharma companies having more than $170 billion in excess reserves that could be available for spending on M&A, the prospects for further financing and deal making look promising.

For these and other reasons, many investors regard biotech as a safe haven. One interviewee felt it had benefited from a halo effect during the pandemic.

More innovation on the horizon

The investors and executives we interviewed agreed that biotech innovation continues to increase in quality and quantity despite the macroeconomic environment. Evidence can be seen in the accelerating pace of assets transitioning across the development lifecycle. When we tracked the number of assets transitioning to Phase I, Phase II, and Phase III clinical trials, we found that Phase I and Phase II assets have transitioned 50 percent faster since 2018 than between 2013 and 2018, whereas Phase III assets have maintained much the same pace. There could be many reasons for this, but it is worth noting that biotechs with Phase I and Phase II assets as their lead assets have accounted for more than half of biotech IPOs. Having an early IPO gives a biotech earlier access to capital and leaves it with more scope to concentrate on science.

#### Lack of IP protection makes medical innovation prohibitively risky and expensive

Grabowski et al 15 [(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

The essential rationale for patent protection for biopharmaceuticals is that long-term benefits in the form of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity. Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and intellectual property protection particularly important to innovation incentives for the biopharmaceutical industry. **5** The R&D process often takes more than a decade to complete, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), it involves more than a billion dollars in out-of-pocket costs. **6** Only approximately one in eight drug candidates survive clinical testing. **6**

As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products (the top quintile of marketed products provide the dominant share of R&D returns). **7**,**8** Once a new drug’s patent term and any regulatory exclusivity provisions have expired, competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success. Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. **11** The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, the strength of intellectual property protection plays a key role in funding and partnership opportunities for such firms.

#### IP enables critical information sharing

Simon 6/25 [(Brenda, professor at California Western School of Law, research interests focus on how technological developments affect intellectual property and information law, former teaching fellow for the Law, Science and Technology LL.M. Program at Stanford Law School, and a research fellow in the Stanford Center for Law and the Biosciences, JD from UC Berkeley School of Law) “Patents, Information, and Innovation,” Brooklyn Law Review, 6/25/2020] JL

Patents play numerous roles in encouraging the exchange of information during the investment-seeking process in the medical device industry. One role is reducing the likelihood that the medical device will be expropriated. The risks of expropriation at this stage vary depending on the circumstances, which were set forth from a theoretical perspective in Part I and will be contextualized with examples from the medical device industry in this Part. Some of the variables in assessing expropriation risks, and consequently the function of patents in enabling information exchange, include whether the medical device is self-disclosing and easily reverse engineered, the importance of reputational and industry norms, and whether staging disclosure over time is an option.222 Time and resource constraints may limit the efficacy of some of these alternative mechanisms to patents in mitigating the risks of expropriation.223

Apart from their ability to ensure exclusivity, patents have an independent function of providing a useful signal to investors about information distinct from the medical device invention, such as resource allocation and the experience of the executive team, similar to their role in the biotechnology industry.224 An issued patent can also provide an indication about the viability of the invention, such as the ability to limit competition, extend the first mover advantage, and provide an independent source of value to the company through licensing or sale.225

One survey of twenty venture capital fund managers looked at the importance of intellectual property protection in assessing the risk-return ratio of portfolio companies .226 For medical device companies, respondents ranked intellectual property protection third, after reimbursement and regulatory concerns at the FDA.227 The authors of the survey reasoned that intellectual property protection was a concern of venture fund managers, given the high patenting rates among venture-backed companies and that the size of medical device companies necessitated "their reliance on patent protection to maintain barriers to market entry by competitors ."228 Additionally, court decisions that cast doubt on whether patent protection would be available for some medical devices have also raised concerns.229

#### Biopharmaceutical innovation is key to prevent future pandemics and bioterror – turns case

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

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

#### Disease causes extinction – defense is wrong

Piers Millett 17, Consultant for the World Health Organization, PhD in International Relations and Affairs, University of Bradford, Andrew Snyder-Beattie, “Existential Risk and Cost-Effective Biosecurity”, Health Security, Vol 15(4), http://online.liebertpub.com/doi/pdfplus/10.1089/hs.2017.0028

Historically, disease events have been responsible for the greatest death tolls on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world’s population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization.

A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity’s favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6

While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also historical examples of large human populations being almost entirely wiped out by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and theWestern Abenaki (which suffered a staggering 98% loss of population).

In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-2

#### **Bioterror causes extinction**

Walsh, 20 -- Axios Future correspondent [Bryan Walsh, "The coronavirus pandemic reawakens bioweapon fears," Axios, 5-14-2020, https://www.axios.com/coronavirus-pandemic-pathogen-bioweapon-45417c86-52aa-41b1-8a99-44a6e597d3a8.html, accessed 9-7-2020]

The coronavirus pandemic reawakens bioweapon fears

The immense human and economic toll of the COVID-19 pandemic only underscores the threat posed by pathogens that could be deliberately engineered and released.

Why it matters: New technology like gene editing and DNA synthesis has made the creation of more virulent pathogens easier. Yet security and regulation efforts haven't kept pace with the science.

What's happening: Despite some claims by the White House, overwhelming scientific evidence indicates that the novel coronavirus was not accidentally released from a lab or deliberately engineered, but naturally spilled over from an animal source.

That doesn't mean the threat from bioweapons isn't dire. Along with AI, engineered pandemics are widely considered the biggest existential risk facing humanity.

That's in part because a pathogen could be engineered in a lab for maximum contagiousness and virulence, well beyond what would arise through natural selection.

Case in point: a 2018 pandemic simulation put on by the Johns Hopkins Center for Health Security featured a fictional engineered virus called Clade X that combined the contagiousness of the common cold with the virulence of the real-life Nipah virus, which has a mortality rate of 40-75%. The resulting simulated global outbreak killed 150 million people.

COVID-19 isn't anywhere near that fatal, but the pandemic has shown the vulnerability of the U.S. and the world to biological threats both natural and manmade.

"Potential adversaries are of course seeing the same things we’re seeing," says Richard Pilch of the Middlebury Institute of International Studies. "Anyone looking for a radical leveling approach — whether a state actor like North Korea or a motivated terrorist organization — may be influenced by COVID-19 to consider pursuing a biological weapons capability."

Background: Bioweapons were officially banned by the Biological Weapons Convention in 1975, though North Korea is suspected of maintaining an offensive bioweapons program.

A particular concern about biowarfare and bioterror, though, is that many of the tools and methods that could be used to create a weaponized virus are largely indistinguishable from those used in the course of legitimate scientific research. This makes biotechnology "dual-use" — and that much more difficult to safely regulate without cutting off research that could be vitally important.

While earlier bioweapons fears focused on the possibility that a state or terror group could try to weaponize a known dangerous agent like smallpox — which would require somehow obtaining restricted pathogens — new technology means that someone could obtain the genetic sequence of a germ online and synthesize it in the lab.

"If you've been trained in a relevant technical discipline, that means you can make almost any potentially harmful agent that you're aware of," says Kevin Esvelt, a biologist at the MIT Media Lab and a member of the CDC's Biological Agent Containment Working Group. That would include the novel coronavirus that causes COVID-19, which was recently synthesized from its genetic sequence in a study published in Nature.

How it works: Currently, synthetic DNA is ordered through commercial suppliers. But while most suppliers screen DNA orders for the sequences of dangerous pathogens, they're not required to — and not all do, which means safety efforts are "incomplete, inaccurate, and insecure," says Esvelt.

Screening efforts that look for the genetic sequences of known pathogens also wouldn't necessarily be able to detect when synthetic DNA was being used to make something entirely novel and dangerous.

In the near future, desktop DNA synthesizers may be able to generate synthetic DNA in the lab, cutting out the need for commercial suppliers — and potential security screenings.

The democratization of biotechnology could unleash a wave of creativity and innovation, just as the democratization of personal computing did. But it also increases the number of people who could potentially make a dangerous engineered virus, whether deliberately or by accident.

## Case

#### IP rights are key for innovation.

**Bacchus 20:** Bacchus, James [adjunct scholar at CATO] “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” December 16th, 2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#does-novel-virus-present-novel-issues>

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. 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 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

#### Data Exclusivity is good for innovation

Eric Lawrence Levi 2017“Using Data Exclusivity Grants to Incentivize Cumulative Innovation of Biologics ' Manufacturing Processes” https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?referer=&httpsredir=1&article=1965&context=aulr AG

The BPCIA’s dual mission of promoting innovation and accessibility of biologics creates unique opportunities for biologics manufacturers. To promote innovation, the FDA grants market and data exclusivity periods. Specifically, the twelve-year market and fouryear data exclusivity periods for originator biologics prevent biosimilars or interchangeables from being approved.87 One of the most effective opportunities innovators utilize is the FDA data exclusivity grant. While market exclusivity means “simply having no competition for a product in the marketplace,” data exclusivity refers to protection of the drug and original clinical trial data, preventing manufacturers from supporting approval of their biosimilar.8

#### Patents are key to global South pharmaceutical industries that stop neglected diseases

Soyeju and Wabwire 18 [Olufemi Soyeju, Lecturer at Lagos State University, and Joshua Wabwire, educator at the Catholic University of Eastern Africa, 01-2018, “The WTO-TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework,” World Trade Review; Cambridge <https://www-proquest-com.ezproxy.library.unlv.edu/docview/1994279823?accountid=3611&pq-origsite=primo>]/Kankee

Conclusions The problem that this research has highlighted is the already too familiar tension between patent protection and access to medicines. The legal framework for patents and access to medicines in the EAC region consists of the Policy and the accompanying Protocol. What has emerged from the analysis is that the policy tools are aimed at enhancing access to medicines mainly through price reduction. This is done at the direct expense of promoting research and development of medicines, which, in line with the utilitarian justification, is achievable through patent protection. This policy position that weakens patent protection is not appropriate for developing African countries. This is because African countries are faced with peculiar, region-specific diseases. Currently, these diseases are largely neglected by the profit-driven pharmaceutical companies, which do not have economic incentives to invest in developing medicines for populations that cannot afford to pay for them. Most of these pharmaceutical companies are foreign, largely based in the Global North. Since these companies do not have economic incentives to invest in the research and development of medicines for developing countries' diseases, even patent protection has not necessarily been an attractive incentive.194T**he focus** of these companies **is now on developed countries' diseases**. In these circumstances, the only standing incentive, especially for spurring domestic innovation from within developing countries, is patent protection. Consequently, any strategy that eliminates this last straw will only worsen the already bad situation. The situation described above underscores the urgent need to develop local pharmaceutical industries and to create alternative incentives for investment in research and development of medicines for neglected diseases, for example through Public-Private Partnerships (PPPs). Both of these can be attained through an appropriate patent protection regime that does not weaken patent protection. Such a regime must, for instance, be omniscient of domestic innovators' limited capacity and, consequently, avoid strict patentability criteria, which cannot be met by the small-scale, underfunded domestic innovators. Strict patentability criteria may also discourage disclosure of certain important discoveries, for fear of not attaining the criteria and losing out by disclosure. In developing local pharmaceutical industries, it is also necessary to find ways of affording patent protection to indigenous medicines and practices, which, for centuries, have been as useful to the populations as western medicine now is. It is the failure to protect these medicines and practices in the first place that has resulted in foreign pharmaceuticals appropriating the knowledge and patenting it, only to return with expensive medicines.195 It is the argument here that a patent protection policy would only achieve the greatest good for the greatest number of people, in line with utilitarianism, if it balances the goal of price reduction with the need to encourage further research and development of medicines by ensuring that inventors are able to recoup their investments in research and development. It is only through research and development that the medicines will be made available.

#### IP protections are key to pharmaceutical investment in developing countries.

Ezell and Cory 19 [(Stephen, vice president, global innovation policy, at the Information Technology and Innovation Foundation, B.S. from the School of Foreign Service at Georgetown University, and Nigel, associate director covering trade policy at the Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies, MA in public policy from Georgetown University) “The Way Forward for Intellectual Property Internationally,” Information Technology and Innovation Foundation, 4/25/2019] TDI

Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that weak IP rights reduce pharmaceutical investment.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41

Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that developing countries can entice technology transfer from the North by providing IPR protection for incoming products (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45

#### Markets ensure affordability; competition drives down drug prices over time

Boustany 18

Charles Boustany (physician and former congressman). “Americans Fund Most of the World’s Drug Research. Here’s How Trump Can End That.” Fortune. 9 August 2018. JDN. https://fortune.com/2018/08/09/trump-drugs-prices-pharmaceutical-research/

Just consider what happened with the numerous next-generation hepatitis C medicines released in recent years. These revolutionary drugs have been shown to cure 70-99% of patients. The first medicine gained FDA approval in late 2013 and debuted with a list price of $84,000 for a full course of treatment. Over the next four years, several competing drugs flooded the market.

Prices subsequently dropped about 70% a few years later, as manufacturers heavily discounted their cures to win market share. For some of these drugs, a full course of therapy is now less expensive than the average treatment costs incurred by patients using interferon and ribavirin—the go-to prescription regimen for decades. Patients on interferon and ribavirin frequently suffered severe side effects; the new next-generation cures are comparatively painless.

Or consider PCSK9 inhibitors. These drugs can sharply lower so-called bad cholesterol levels in patients at high risk of heart disease. A recent study found that one PCSK9 inhibitor, Praluent, reduced patients’ risk of cardiovascular disease by 15% and their risk of death by 29%. Despite the drug’s effectiveness, its manufacturer recently announced a 69% price cut to win market share.

In short, free-market competition works. It delivers cutting-edge medicines at reasonable prices.