## CP

#### CP: The member nations of the World Trade Organization should create patent pools.

#### Solves the aff—eliminates exclusive rights to produce a drug and boosts cooperation between companies.

DeCamp 7 (Matthew Wayne DeCamp -- Department of Philosophy @ Duke University, “GLOBAL HEALTH: A NORMATIVE ANALYSIS OF INTELLECTUAL PROPERTY RIGHTS AND GLOBAL DISTRIBUTIVE JUSTICE”, https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/193/D\_DeCamp\_Matthew\_Wayne\_a\_052007.pdf?sequence=1, Pgs. 333-335, 25 April 2007, EmmieeM)

Patent Pools (Merges, 1999).  A final reform that has begun circulating in the past several years is the idea of a patent pool geared toward essential medicines.  A patent pool is an arrangement among multiple patent holders to aggregate their patents. A typical pool makes all pooled patents available to each member of the pool. Pools also usually offer standard licensing terms to licensees who are not members of the pool. In addition, the typical patent pool allocates a portion of the licensing fees to each member according to a pre‐set formula or procedure. (Merges, 1999 10‐11)

Historically, one of the more well‐known examples of a patent pool is the Manufacturer’s Aircraft Association of 1917, formed at the behest of Franklin D. Roosevelt (Dykman, 1964).  The two major patent holders at the time, the Wright‐Martin Aircraft Corporation and the Curtiss‐Burgess Airplane & Motor Corporation, Inc., could not agree upon reasonable royalties and licensing terms.  This nearly blocked the manufacture of aircraft at a time when the U.S. government was quite interested in their production (for World War I).  To this end, the federal government essentially stepped in and insisted upon the formation of a patent pool with fixed royalty rates to both corporations under threat of simply taking the patents. (Of course, patent pools can also be voluntary, not just imposed by the federal government.9)  How might a patent pool apply to essential medicines?  Consider Essential Inventions, Inc., and its recent proposal for an Essential Patent Pool for AIDS.  Under this proposal, a non‐profit entity, the EPPA, would identify patent relevant to HIV/AIDS treatment and request voluntary licensing to the pool for use in low‐income countries.  If a voluntary license is not obtained, a compulsory license would be sought.  Licensees also agree to “grantback” any rights obtained through use of EPPA patents.  Although the EPPA, were it formed, would seek to pool all patents necessary for HIV/AIDS treatment and prevention, of particular interest might be the use of multiple patents to create fixed dose combinations (FDCs) and products that for one reason or another are currently unsuitable for low income settings (e.g., the HIV drug Fuzeon, which requires sterile water for mixing, refrigeration once mixed, and then subcutaneous injection).10

Patent pools thus represent • A novel approach to access to essential medicines that would lower transaction costs between patent owners; • A historically useful tool for certain situations, as shown in the airplane industry; and, • Depending on licensing terms, a way to separate the innovation process from the manufacturing one, lowering costs of medicines.

#### Patent pools settle IP ownership disputes, reduce transaction costs, facilitate cooperation, and leads to FDCs without having to change existing patent law

DeCamp 7 (Matthew Wayne DeCamp -- Department of Philosophy @ Duke University, “GLOBAL HEALTH: A NORMATIVE ANALYSIS OF INTELLECTUAL PROPERTY RIGHTS AND GLOBAL DISTRIBUTIVE JUSTICE”, https://dukespace.lib.duke.edu/dspace/bitstream/handle/10161/193/D\_DeCamp\_Matthew\_Wayne\_a\_052007.pdf?sequence=1, Pgs. 356-358, 25 April 2007, EmmieeM)

Certain of the reforms noted here are worthy of consideration in particular circumstances no matter what, if anything, were to occur with global IPR reform.

Patent Pools.  One can imagine the utility of patent pools in at least two circumstances.  First, when the existence of multiple IP owners requires coordination, particularly when the IP in question is under dispute, patent pools represent a possible solution. This has been discussed in relation to genomic and biotechnology patenting, for example, to reduce transaction costs and facilitate the bringing together of multiple gene sequence owners for DNA microarrays and diagnostic tests (Clark, et al., 2000). The worry in this context is that the high transaction costs associated with negotiating between multiple IP owners could prevent inclusion of all the necessary gene sequences for a clinically effective diagnostic test.  In global health, patent pools have most recently been discussed in relation to the production of a SARS vaccine (Simon, et al., 2005).15

According to Simon et al. (2005), the severe acute respiratory syndrome coronavirus (SARS‐CoV) might provide the test case for patent pooling in the health sciences.  This is because the research and sequencing that led to the identification of the virus following the 2002 outbreak occurred in a particular way: • over a short period of time, making the patent applications at similar stages and with few third party agreements to complicate matters;   • within four parties that hold the key patent applications for SARS‐CoV (CDC, Health Canada, Versitech, Ltd., and CoroNovative BV); • without, as yet, a market for SARS related products, providing an incentive to contain costs; and, • a close involvement with public health‐related organizations who would like to drive the process forward. (Simon, et al., 2005 709)

Thus, the SARS patent pool demonstrates the potential of pooling as a way to work within existing patent law to foster the development of an important product (i.e., the SARS vaccine).  Another area where patent pooling could be effective is in facilitating fixed dose combinations (FDCs), as the treatment of many health conditions (such as TB and HIV) often requires the administration of multiple different drugs per day – a situation that could be helped (and has been helped in the case of HIV), by FDCs (Kaplan, 2003a, Kaplan, 2003b).  Importantly, for these initiatives to go forward does not require global IPR reform.

## DA

#### Debt limit and government funding will pass now—everything else is delayed

BRESNAHAN 9/15 [JOHN BRESNAHAN, ANNA PALMER AND JAKE SHERMAN, Punchbowl News Legislataive Outlook 9/15, https://email.punchbowl.news/t/ViewEmailArchive/t/E48C6AF0C3714E452540EF23F30FEDED/C67FD2F38AC4859C/]

As we’ve been writing for you in Punchbowl News AM, we’re in the middle of the busiest legislative period in years. September has a stunning number of fiscal and legislative deadlines. The biggest of these, of course, is the end of the fiscal year on Sept. 30. This issue has become caught up in the debt-limit debate as Democrats plan to attach a debt-limit increase to a short-term funding bill. Republicans have vowed to oppose this move, raising the risk for the two sides to blunder into a government shutdown or debt crisis.

Suddenly, the Democrats’ $3.5 trillion reconciliation package and the $1 trillion bipartisan Senate infrastructure bill -- long the top priority in D.C. -- are taking a back seat to the meat and potatoes of governing. It now seems at least somewhat likely that the “Build Back Better” agenda -- made up of infrastructure and social safety net measures proposed by President Joe Biden -- could be delayed until later this fall.

One theory among Democrats is that Republicans will cave -- if not initially, then after a brief government shutdown or debt default scare during which the Democrats win the political argument that the GOP is an irresponsible partner in governing. Good luck getting someone to say that on the record, but it’s the reality we hear privately in the Capitol.

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#### Medical IP takes time, energy, and political capital away from domestic legislation – big pharma and EU allies

Bhadrakumar 5/9 M K Bhadrakumar is a former Indian diplomat. "Biden’s talk of vaccine IP waiver is political theater." Asia Times, May 9, 2021, asiatimes.com/2021/05/bidens-talk-of-vaccine-ip-waiver-is-political-theater.

On the other hand, Biden, whose political life of half a century was largely spent in the US Congress, is well aware of the awesome clout of the pharmaceutical companies in American politics. From that lobby’s perspective, the patent waiver “amounts to the expropriation of the property of the pharmaceutical companies whose innovation and financial investments made the development of Covid-19 vaccines possible in the first place,” as a senior scholar at the Johns Hopkins Center for Health Security puts it. The US pharmaceutical industry and congressional Republicans have already gone on the offensive blasting Biden’s announcement, saying it undermines incentives for American innovation. Besides, the argument goes, even with the patent waiver, vaccine manufacturing is a complex process and is not like simply flipping a switch. Senator Richard Burr, the top Republican on the US Senate Health Committee, denounced Biden’s decision. “Intellectual property protections are part of the reason we have these life-saving products,” he said. “Stripping these protections only ensures we won’t have the vaccines or treatments we need when the next pandemic occurs.” The Republican senators backed by Republican Study Committee chairman Jim Banks propose to introduce legislation to block the move. Clearly, Biden would rather spend his political capital on getting the necessary legislation through Congress to advance his domestic reform agenda rather than spend time and energy to take on the pharmaceutical industry to burnish his image as a good Samaritan on the world stage. Conceivably, Biden could be counting on the “text-based negotiations” at the WTO dragging on for months, if not years, without reaching anywhere. The US support for the waiver could even be a tactic to persuade pharmaceutical firms to back less drastic steps like sharing technology and expanding joint ventures to boost global production quickly. So far Covid-19 vaccines have been distributed primarily to the wealthy countries that developed them, while the pandemic sweeps through poorer ones such as India, and the real goal is, after all, expanded vaccine distribution. Biden is well aware that there will be huge opposition to the TRIPS waiver from the United States’ European allies as well. The British press has reported that the UK has been in closed-door talks at the World Trade Organization in recent months along with the likes of Australia, Canada, Japan, Norway, Singapore, the European Union and the US, who all opposed the idea.

#### Agenda change has a cascading effect

Joly 19, [Jeroen Joly is a Doctor Assistant at Universiteit Gent, Punctuated equilibrium theory and foreign policy, The research for this chapter was financially supported by the French Ministry of the Armed Forces, Directorate General for International Relations and Strategy (DGRIS), https://www.researchgate.net/profile/Jeroen\_Joly/publication/331073786\_Punctuated\_equilibrium\_theory\_and\_foreign\_policy/links/5c66ec3092851c1c9de446f2/Punctuated-equilibrium-theory-and-foreign-policy.pdf]

Further Theorization of Existing Concepts

Finally, agenda-setting scholars have continued to improve our understanding of some mechanisms and key concepts of PET. Several agenda-setting studies, for example, examined how friction and cascading contribute to the typical pattern of policy punctuations. Cascading is best understood as a self-reinforcing process of positive feedback whereby attention from one actor generates attention from another actor, which, again, draws even more attention from the initial actor, overthrowing the existing friction mechanisms (Jones and Baumgartner 2005; Walgrave and Vliegenthart 2010). Looking at mass media and parliament, Walgrave and Vliegenthart (2010) found friction and cascading to operate independently from each other to create punctuations, and showed under which conditions these mechanisms are more likely to occur.

The notion of cascading closely relates to the wider agenda-setting literature examining how attention from one actor influences that of another. We know, for example, that political parties heavily influence each other regarding the issues they focus on in parliament (Vliegenthart et al. 2011). Several studies have also confirmed the mutual influence between news media, parliament and government influence in the issues they focus on (for a comprehensive review of the literature on the media’s influence on parliament and government, see Van Aelst and Walgrave (2016) and Walgrave et al. (2006)), also for foreign policy issues (Edwards and Wood 1999; Wood and Peake 1998).

#### Debt default is the easiest way to wreck the US economy—ruins the US dollar and financial reputation

Egan 9/8 [Matt Egan is an award-winning reporter at CNN, covering business, the economy and financial markets across CNN's television and digital platforms, "'Financial Armageddon.' What's at stake if the debt limit isn't raised", 9/8/21, <https://www.cnn.com/2021/09/08/business/debt-ceiling-default-explained/index.html>]

The easiest way to spark a financial crisis and wreck the US economy would be to allow the federal government to default on its debt. It would be an epic, unforced error — and millions of Americans would pay the price.

And yet that unlikely situation is once again being contemplated. If Congress doesn't raise the limit on federal borrowing the federal government will most likely run out of cash and extraordinary measures next month, Treasury Secretary Janet Yellen warned lawmakers on Wednesday.

In short, a default would be an economic cataclysm. Interest rates would spike, the stock market would crater, retirement accounts would take a beating, the value of the US dollar would erode and the financial reputation of the world's only superpower would be tarnished.

"It would be financial Armageddon," Mark Zandi, chief economist at Moody's Analytics, told CNN. "It's complete craziness to even contemplate the idea of not paying our debt on time."

But it's a crazy world.

Lawmakers in Washington are again playing chicken with America's creditworthiness. And the path to raising the debt ceiling is not clear.

Even though Congress has in the past raised the debt ceiling with a bipartisan vote, Senate Minority Leader Mitch McConnell vowed in July that Republicans will not vote to raise the debt ceiling.

JPMorgan Chase (JPM) CEO Jamie Dimon urged lawmakers not to even think about going down this path again. During a hearing in May, Dimon said an actual default "could cause an immediate, literally cascading catastrophe of unbelievable proportions and damage America for 100 years."

'Irreparable damage'

In her letter to Congress, Yellen said history shows that waiting "until the last minute" to suspend or increase the debt limit "can cause serious harm" to business and consumer confidence, raise borrowing costs for taxpayers and hurt America's credit rating.

"A delay that calls into question the federal government's ability to meet all its obligations would likely cause irreparable damage to the U.S. economy and global financial markets," Yellen wrote.

A US default would undermine the bedrock of the modern global financial system.

"We pay our debt. That's what distinguishes the United States from almost every other country on the planet," Zandi of Moody's said.

Because of America's long track record of paying its debt, it's very cheap for Washington to borrow. But a default would force ratings companies to downgrade US debt and shatter that borrowing advantage. Markets plunged in 2011 when that debt ceiling standoff caused Standard & Poor's to downgrade America's credit rating.

Higher borrowing costs would make it much harder for Washington to borrow to pay for infrastructure, the climate crisis or to fight future recessions. And refinancing America's nearly $29 trillion mountain of existing debt would become that much more expensive. Interest expenses, which totaled $345 billion in fiscal 2020, would quickly rival what Washington spends on defense.

#### Extinction

Joshua Zoffer 20, Investor at Cove Hill Partners, Fellow at New America, JD Candidate at Yale University Law School, AB from Harvard University, “To End Forever War, Keep the Dollar Globally Dominant”, The New Republic, 2/3/2020, https://newrepublic.com/article/156417/end-forever-war-keep-dollar-globally-dominant

In early 2016, Obama Treasury Secretary Jack Lew cautioned that the dollar’s dominance as a global currency rested, in part, on the U.S. government’s reluctance to fully weaponize it. If foreign markets and governments “feel that we will deploy sanctions without sufficient justification or for inappropriate reasons,” he warned, “we should not be surprised if they look for ways to avoid doing business in the United States or in U.S. dollars.” Lew’s case stemmed from the more fundamental view that the dollar’s international role is “a source of tremendous strength for our economy, a benefit for U.S. companies and a driver of U.S. global leadership”—in other words, a role worth keeping. This view is emblematic of American financial governance since the Second World War. U.S. economic analysts, especially at the Treasury, have jealously guarded the dollar’s role and the many benefits it offers: the ability to run large deficits at low cost and disproportionate influence over the structure of the global economy, among others. Yet in their recent article in The New Republic, David Adler and Daniel Bessner argue the U.S. should abandon these advantages. In their view, the dollar’s role has encouraged American militarism and should be relinquished to curb such behavior. Dollar hegemony is not without cost, but to renounce it would be a profound mistake. Adler and Bessner’s view neglects the sizable economic benefits the dollar’s role confers on the U.S., as well as its possible use as an antidote to military adventurism. It ignores the enormous good that can be done with deficit spending, much of which has gone to the American military but could instead fund progressive programs. And it elides the inability of the U.S. and its global trading partners to shift away from dollar dominance without creating worldwide financial distress. Adler and Bessner are right that the U.S. has misused its privilege, but Washington should not abandon it; rather, American leaders should seek to transform it. Generations of American policymakers have been right to protect the dollar’s key currency role for economic reasons. Most notably, dollar hegemony affords the U.S. the ability to run large and prolonged budget and balance-of-payments deficits. The dollar represents 62 percent of allocated foreign exchange reserves, is used to invoice and settle roughly half of world trade, and accounts for 42 percent of global payments. Because governments, banks, and businesses worldwide need lots of dollars, the world market always stands ready to absorb new U.S.-dollar-denominated debt without charging higher interest rates. Adler and Bessner correctly point out that the rest of the world considers the dollar’s role as the world’s reserve currency to be an “exorbitant privilege,” a term coined in the 1960s by then French Finance Minister Valéry Giscard D’Estaing. The ability to spend beyond its means has enabled the U.S. to fund its impressive military might, whether one views that power as the fountainhead of Pax Americana or the source of illegitimate military adventurism. But these economic benefits go beyond just deficits. The demand for dollars also pushes up the dollar’s value against other currencies, enhancing American purchasing power and offering consumers access to imports on the cheap. The dollar’s role also means American firms rarely need to do business in foreign currencies, reducing transaction costs and exchange-rate risks. More broadly, America’s central economic role gives it outsize influence at crucial moments. At the height of the financial crisis that began in 2008, the Federal Reserve was able to inject vital liquidity into the global financial system by selectively offering dollar swap lines to trusted foreign central banks. Dollar hegemony enabled the U.S. to act swiftly, effectively, and on its own terms. In addition, the dollar’s role offers a potent alternative to kinetic military action as a means of pursuing foreign policy objectives. The dollar’s broad use means access to dollar liquidity—which in turn requires access to the U.S. financial system—is essential for foreign governments and businesses. For foreign banks, especially, being cut off from dollar access is essentially a death sentence. That makes sanctions that do so a powerful tool in the international arena. In 2005, for example, the U.S. used the dollar to strike a devastating blow against North Korea without firing a single shot or even formally enacting sanctions. Using authority provided by Section 311 of the Patriot Act, the Department of the Treasury crippled Banco Delta Asia, a bank accused of facilitating illegal activity by the North Korean government, by merely threatening to cut off its access to the American financial system. Deposit outflows began within days; within weeks the bank was placed under government administration to avoid a full collapse. Pyongyang was hit hard, as other banks ceased their business with it to avoid meeting the same fate. Similarly, though the Trump administration has worked hard to undo it, the Joint Comprehensive Plan of Action with Iran to limit the development of nuclear weapons was made possible, in part, by painful dollar sanctions that brought Iran to the table. Far from being a proximate cause of military conflict, the dollar’s central global role has often been used to contain adversaries without military intervention. Still, skeptics are right to point out that the dollar’s role has indirectly funded American interventionism and that dollar sanctions have been overused, provoking the ire of American allies. But these facts suggest we should use our dollar power to forge a more progressive U.S. order, not abandon the advantage altogether. America’s exorbitant privilege need not fund warships and missiles: The same low-interest borrowing could be used to fund a new universal health care system, expand access to higher education, or pursue any number of large-scale social policy objectives, including financing global public goods that no other country or consortium of countries is prepared to fund, such as climate change mitigation.

## Case

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

#### The US will keep leading in biotech now because of funding and IPPs, but China’s trying to catch up.

**Moore 20** — (Scott Moore, Scott Moore is a political scientist whose interests center on environmental sustainability, technology, and international relations. Scott holds doctoral and master’s degrees from Oxford University and an undergraduate degree from Princeton. He is a Truman, Fulbright, and Rhodes Scholar., “China’s role in the global biotechnology sector and implications for US policy“, Brookings, 04-2020, Available Online at https://www.brookings.edu/research/chinas-role-in-the-global-biotechnology-sector-and-implications-for-us-policy/, accessed 8-25-2021, HKR-AS)  
Thanks to extensive government funding for biomedical research, **an unparalleled ability** to translate basic research into commercial products and applications, and **strong intellectual property protections**, the United States has been the **dominant global player in developing and commercializing biotechnology for decades**.1 This dominance is reflected in the fact that United States accounted for almost half of all biotechnology patents filed worldwide from 1999 to 2013.2 However, in the intervening years, and just as in the case of artificial intelligence and other emerging technologies, other nations, including South Korea and Singapore, have invested heavily in developing their biotechnology sectors and industries. These efforts pale, however, in comparison to those of China, and the sheer size and scale of the Chinese biotechnology industry pose a range of economic, security, and regulatory issues for American policymakers. **The determination of China’s one-party state to become a leading player in biotechnology is reflected by the rapid growth in investment in the sector**. Some estimates claim that collectively, China’s central, local, and provincial governments have invested over $100 billion in life sciences research and development. Regardless of the true figure, official encouragement has led to a torrid place of investment. In just the two-year period from 2015 to 2017, venture capital and private equity investment in the sector totaled some $45 billion.3 The value of commercial deals concluded in the fields of biology, medicine and medical machine technology, meanwhile increased from 25.8 billion renminbi (RMB), or $3.6 billion, in 2011 to over 75 billion RMB ($10.6 billion) in 2017.4 Annual research and development expenditures by Chinese pharmaceutical firms, the foundation of the biotechnology sector, rose from some 39 billion RMB in 2014 ($5.5 billion) to over 53 billion RMB (US$7.5 billion) by 2017. Expenditure on new product development among these firms, an important indicator of future growth potential, increased from just over 40 billion RMB ($5.6 billion) to almost 60 billion ($8.4 billion).5 **By Western standards, some of these figures are still low**. Swiss drugmaker Roche, the world leader in biotechnology research and development, spent some $11 billion in 2018 alone.6 GLOBAL CHINA CHINA’S ROLE IN THE GLOBAL BIOTECHNOLOGY SECTOR AND IMPLICATIONS FOR U.S. POLICY TECHNOLOGY 2 As these figures suggest, the development of China’s biotechnology sector paints a nuanced picture for U.S. policymakers. On one hand, the sector’s rapid growth, and high-level commitment to continued investment, means that China will inevitably become an increasingly important player in the global biotechnology sector, with implications for national security, economic competitiveness, and regulation. An executive from In-Q-Tel, the U.S. government’s inhouse national security venture capital fund, warned Congress in a November 2019 hearing, for example, that China “intends to own the biorevolution… and they are building the infrastructure, the talent pipeline, the regulatory system, and the financial system they need to do that.”7 The CEO of European drugmaker AstraZeneca has similarly opined that “Much of [China’s] innovation in the last three to four years has been ‘me too,’ but now on the horizon we can see firstin-class innovation.”8 Yet on the other hand, while China’s biotechnology sector will almost certainly continue to grow in scale, sophistication, and competitiveness, **there is little reason to believe on current trends that the United States will lose its edge** in the sector. Indeed, the biggest risk to the global competitiveness of the U.S. biotechnology industry likely comes from the prospect of declining public investment and reduced mobility for world-class researchers and industry professionals. Moreover, the COVID-19 crisis underscores both the importance of continued investment in biotechnology and the many challenges to promoting effective international cooperation on global health security.

#### Reducing IP rights guts US pharmaceutical innovation and leadership – profit incentive is key to undertaking the risks.

James M. Roberts, PhD Candidate, 21 [PhD Candidate in Public Policy @ VA Tech, MA International and Development Economics from Yale, MA Business Administration from the University of Pittsburgh, Research Fellow For Economic Freedom and Growth @ Heritage], "Biden’s OK of Global Theft of America’s Intellectual Property Is Wrong, Dangerous," Heritage Foundation, 6-25-2021, <https://www.heritage.org/public-health/commentary/bidens-ok-global-theft-americas-intellectual-property-wrong-dangerous> C.VC

Practically speaking, countries such as India and South Africa are unlikely to manufacture the vaccines. They lack an advanced infrastructure for cold supply-chain distribution and many other crucial resources required by these products’ capital-intensive, state-of-the-art manufacturing process.

But the Biden policy is bad for many other reasons.

Developing breakthrough medications takes tremendous ingenuity and immense financial investments. It’s an extraordinarily high-risk endeavor, and the prospect of making a profit is what convinces private companies to undertake those risks.

Signaling that the United States will not fight to defend their intellectual property rights actively undermines innovation and manufacturing in American health care and medicines.

It also erodes patient protections by undermining quality control. Foreign companies may take the president’s policy as a green light to produce reverse-engineered, counterfeit substitutes. Already there are reports of ineffective and even dangerous counterfeit COVID-19 vaccines being sold around the world.

Those pushing to break U.S. pharmaceutical patents say they want to do so for altruistic reasons. Consequently, they also insist that the prices for the medications be set far below their actual value.

But history shows us that forcing private companies to provide vaccines at an “affordable price,” regardless of the cost to the companies, actually impedes the manufacture of high-quality vaccines. Moreover, it inhibits the future development of vaccines needed to meet as-yet-unknown diseases.

Washington first imposed vaccine price controls as part of Hillary Clinton’s 1993 healthcare-for-all crusade. As the Wall Street Journal later noted, it was a body blow to the U.S. vaccine industry. Ironically, government-decreed prices left the companies unable to produce enough vaccines to meet Mrs. Clinton’s admittedly admirable goal of universal immunization of children. Since then, U.S. firms have largely eschewed the vaccine market because they could not recoup their R&D and manufacturing costs and earn enough profit to fund future innovation.

Ultimately, compulsory licensing legalizes the theft of intellectual property. Recognizing this, senators from both sides of the aisle have joined with other government officials and industry leaders to call on the administration to reverse this bad decision.

The U.S. patent protection system has served the nation well since its founding. It is and has been a bulwark of American prosperity, but the strength of that protection has been weakening in the past few decades. Compulsory licensing contributes to the erosion of that protection.

As the U.S. and the rest of the world emerge from the pandemic, it is clear that more innovative medicines and vaccines will be needed for future protection from viruses and other emerging biological threats.

The best way to prevent and treat those new diseases is to ensure that private American pharmaceutical companies continue their innovative research and vaccine production.