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#### Chinese IP protections strong amid reform but it’s tenuous for foreign innovators.

Shape 2/19 ~Steven M. Shape; registered patent attorney and electrical engineer who has represented preeminent technology companies in complex, high-stakes Intellectual Property litigation; 2-19-2021, "IP Law Looms Large Over U.S.-China Relations," No Publication, https://www.mondaq.com/trademark/1038030/ip-law-looms-large-over-us-china-relations //recut MHES

In late 2019, China pledged reforms of its Intellectual Property law, a move that played a major part in curtailing the U.S.-China trade war. More than a year later, the degree to which those promised reforms are actually implemented may well have similarly large effects on the nations' relationship. The U.S. and China were indisputably the two largest parties in the global trade war that consumed much of the last several years. Particularly between early 2018 and late 2019, it seemed as if one could hardly go a week, if that, without hearing something about tariffs, exports, imports, steel, soybeans, then-President Donald Trump, President Xi Jinping and the like. Accusations regarding violations of Intellectual Property law were among the biggest flashpoints, and ultimately, China announced new regulations concerning IP protection in November 2019 as a conciliatory move. Nearly 14 months later, newly inaugurated President Joe Biden has yet to fully clarify his administration's stance toward China. However, it is inevitable that IP rights and their preservation will factor into negotiations between the two economic giants. A look back at the proposed reforms (and their effects) Reports from CNN at the time claimed that China's prospective IP law reforms focused on making the penalties for IP infringement more strict. It would also put the government's increasingly modernized tech infrastructure to use in the discovery and prosecution of such crimes. Beyond that, the proposal carried few specifics. Although it is unclear whether Beijing's gambit worked as the deciding factor for Washington, it certainly did not fail. The two nations agreed in principle on "Phase One" of a new trade agreement December 12, 2019, per The Washington Post, and formalized the deal about a month later. The U.S. pledged not to impose further tariffs and roll back existing import taxes in return for China's IP reforms and agreement to buy American goods. In the 14 months that followed, so much changed. COVID-19's devastating impact on human life and the global economy made it difficult to gauge the positive effects of the tariff relief or IP reform. A report by the South China Morning Post found that China did not meet its import goal for 2020, with some analysts concluding the Phase One target was unrealistic. On the IP front, a Hong Kong news provider noted that Beijing had drafted some specific guidance to protect pharmaceutical patents, trade secrets and copyrights, but it was unclear how well they were being implemented. Additionally, a January 2021 report by the U.S. Patent and Trademark Office (USPTO) found that Chinese policies which offered subsidies for certain trademark and patent applications helped motivate a glut of fraudulent and bad-faith filings in the last few years. The bigger picture of China's IP law A casual observer or someone just learning of this issue might assume that until recently, China had little or no IP laws on the books. Of course, that is not true. However, there are many factors at play complicating the matter of Chinese IP protection policies. As noted in Harvard Business Review, China is quite strict in certain aspects of IP protection: Beijing allows (and encourages) all businesses to impose non-compete agreements to help protect trade secrets and other IP assets. In addition, according to the National Law Review, two new measures were passed in 2020 specifically to combat bad-faith trademark applications, in addition to the other new guidelines being imposed by the China National Intellectual Property Administration (CNIPA) in accordance with the Phase One agreement. All that said, it would be inaccurate to describe Chinese IP law as thoroughly protective for either domestic or foreign innovators. Along with the aforementioned trademark and patent subsidies, considerable controversy stems from "forced technology transfer" policies. According to the University of Oxford's Business Law Blog, foreign companies looking to do business in China must turn over their technology to local firms or be denied the right to operate within China. This effectively means turning over the blueprints (literal or otherwise) to such technology - which is all but equivalent to surrendering the IP. It creates considerable opportunities for infringement, fraud and corruption. Also, in disputes with foreign firms, some local IP courts still markedly favor domestic organizations. Chinese government representatives often resent such accusations of bias or corruption. In their view, the deals represent friendly agreements between businesses, and courts' decisions are not politically motivated. While Oxford noted that FTT guidelines are not as pervasive now as they were a few years ago, they have yet to disappear altogether.

#### The plan hands over the work of American innovators to China.

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On behalf of FreedomWorks’ activist community, I urge you to contact your representative and ask him or her to cosponsor H.R. 3035 - Preventing Foreign Attempts to Erode Healthcare Innovation Act, introduced by Rep. Byron Donalds (R-Fla.). This bill prohibits the Office of the United States Trade Representative from using funds to support, allow, or facilitate the negotiation or approval of any measure at the World Trade Organization (WTO) to waive intellectual property rights or support the “Waiver from Certain Provisions of the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement for the Prevention, Containment, and Treatment of COVID-19” put forth by India and South Africa. The United States is a signatory to the TRIPS Agreement. The agreement, among other things, protects intellectual property rights for the COVID-19 vaccine and related products. India and South Africa, supported by Senators Bernie Sanders (I-Vt.) and Elizabeth Warren (D-Mass.), are mounting a campaign to get access to the COVID-19 vaccine formula, which would only hurt the same American innovators who helped develop the vaccine in the first place. This waiver is being seriously considered by the Biden administration, which is why this legislation is so critical in demonstrating conservative opposition to this effort. The Biden Administration should maintain the same position as the Trump Administration and oppose this waiver at the WTO. The risks associated with giving away our vaccine formula are severe. Not only will it hinder the ability of medical innovators to act quickly in response to a future pandemic, but it will also limit the ability of property rights holders to ensure quality control of their product. To make matters worse, China -- a worldwide leader in IP theft -- is actively looking for ways to exploit our computer systems to gain access to valuable COVID-19 data. According to the Department of Justice, two Chinese hackers working with China's Ministry of State Security were charged with hacking into businesses producing the COVID-19 vaccine and related products in an attempt to steal critical intellectual property. This IP waiver is China's easy-way to access our vaccine formula and American innovators should not be at risk of having their intellectual property be taken by Beijing through this unprecedented waiver. The United States made history by developing a COVID-19 vaccine in record time under Operation Warp Speed. Many health experts and media pundits did not believe that we would be on track to vaccinate the majority of Americans by this time today. We can point to many things that contributed to our success, but chief among them, are the strong intellectual property rights protections that allowed for the swift development of the vaccine. With our country nearing the end of the COVID-19 pandemic, and with President Biden pledging $4 billion for COVID-19 Vaccines Global Access, this bill will help protect intellectual property rights by preventing a potentially dangerous and unwise decision to support this waiver at the WTO.

#### IP infringement overturns American control of biopharma industry.

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Over the last two decades, China has successfully challenged American industrial competitiveness in many industries, but as China has gone all in on its “Made in China 2025” strategy, the challenge will increasingly be to U.S. advanced and innovation-based industries. However, America still maintains competitive advantage over many nations, including China, in the biopharmaceutical industry. In fact, since 2001, while U.S. manufacturing jobs have fallen, the number of biopharmaceutical jobs has increased over 20 percent. In short, biopharma is a U.S. manufacturing success story. However, “Made in China 2025,” as well as other plans, target life sciences for global leadership. China is taking a range of steps, including regulatory changes, funding of biomedical research and venture capital (VC), restructuring of the industry to eliminate many smaller producers, expanding medical tourism, and expediting listings on the Hong Kong exchange, to propel China to become a major global biopharma competitor—particularly by developing a world-class generics industry. However, while some of these policy actions are fair and legitimate, many are not because they are “innovation mercantilist” in nature, seeking to unfairly benefit Chinse firms at the expense of U.S. and other foreign firms. In other words, China is seeking to challenge the United States in one of the most high-value-added, innovation-intensive industries in the world—the kind of industry for which the United States has held a competitive advantage for decades. To be sure, the Chinese market is large, growing rapidly, and represents significant market opportunities for producers in the United States, so U.S. policy should continue to push for market access. However, Chinese policies, if coupled with potential U.S. policy errors—particularly drug price controls that would slow down U.S. biopharma innovation—could mean that within the next decade or two, the U.S. biopharmaceutical industry could lose significant market share and jobs to China, hurting not only the U.S. economy and workers, but also global biopharmaceutical innovation.1 However, unlike when the United States lost emerging technology industries such as solar panels to China, today, no one should be able to claim ignorance of China’s playbook and end game. Should U.S. policymakers decide it is in the U.S. national interest to have a globally leading life-sciences industry, they will need to respond appropriately, particularly ensuring U.S. policies, including drug-pricing policies, support industry investment in research and development (R&D) and innovation. This report first discusses the competitive position of the U.S. biopharmaceutical industry and why a competitive industry is in the U.S. national interest. It then examines the competitive position of China’s biopharma industry, followed by a review of Chinese mercantilist industrial policies in other industries. The report then reviews China’s strategy and policies for growing the biopharmaceutical industry. Finally, it discusses how the U.S. government should respond. IMPORTANCE OF THE BIOPHARMACEUTICAL INDUSTRY TO THE U.S. ECONOMY The biopharmaceutical sector includes research, discovery, testing, and manufacturing of medicines and therapeutics that cure disease and improve patient health. As life-sciences industry experts David Beier and George Baeder have written, there are at least four essential policy components nations need for a strong life-sciences innovation industry: “1) strong research and development infrastructure (including skilled researchers); 2) effective intellectual property protection; 3) integration in global standards of trade, IP [intellectual property], and drug regulation; and 4) functioning markets offering sufficient reimbursement.”2 The United States is one of the few nations with all four components, which is a major reason why it is highly competitive in life sciences, although with recent calls for drug price controls, it is at risk of seeing a weakening of the second and fourth factors. These strengths are why employment in the biopharmaceutical industry (classified as a manufacturing industry by the U.S. government) grew 26 percent between 1998 and 2019, while total U.S. nonfarm employment increased 23 percent, and employment in manufacturing declined 27 percent.3 Moreover, wages in the industry exceeded the average private wage by 50 percent or more in 43 states, and by more than 75 percent in 24 states.4 The sector, along with medical devices, performed $111.8 billion of R&D in 2016 (the most recent year for which public data is available), of which $85.9 billion was self-funded.5 Of the total research performed, $79.4 billion was invested in the United States. Partly because 19 percent of its domestic employment was involved in research, the pharmaceutical industry accounted for 20.4 percent of all domestic R&D in the United States.6 Moreover, the United States increased its share of pharmaceutical R&D expenditures among developed countries between 1995 and 2010 from 43 percent to 57 percent.7 One reason is U.S. firms have kept most of their research activity at home, while European and Japanese firms have shifted some R&D to the United States. This is why the United States remains the predominant powerhouse of drug discovery and production, ranking first in nearly all measures of innovation.8 The Biopharmaceutical Competitiveness and Investment Survey ranked the United States first among mature markets in 2017, followed by Switzerland, Germany, and the United Kingdom.9 The United States scored higher than the average of its top-three competitors in each of the survey’s five categories, in addition to recently being ranked as the top location for life-sciences jobs in the world.10 That same year, 11 of the top 25 pharmaceutical companies were headquartered in the United States, accounting for 48 percent of total sales from this group. Moreover, in 2015, the United States attracted 74 percent of all worldwide venture-capital investments in the biopharmaceutical industry.11 The United States leads the world in life-sciences innovation. In the 2000s, more new chemical entities were developed and approved by regulatory authorities in the United States than in the next five nations—Switzerland, Japan, the United Kingdom, Germany, and France—combined.12 Broadening the lens to the years 1997 to 2016, U.S.-headquartered enterprises accounted for 42 percent of new chemical and biological entities introduced and approved around the world, far outpacing contributions from European Union member countries, Japan, China, and other nations.13 But this has not always been the case. In the latter half of the 1970s, European-headquartered enterprises introduced more than twice as many new drugs to the world as did those in the United States (149 to 66).14 Throughout the 1980s, fewer than 10 percent of new active substances were introduced first in the United States, as figure 1 shows. And, as recently as 1990, the global research-based pharmaceutical industry invested 50 percent more in Europe than in the United States.15 As Shankar Singham of the Institute of Economic Affairs noted, “Europe was the unquestioned center of biopharmaceutical research and development for centuries, challenged only by Japan in the post-war period.”16 Figure 1: U.S. share of new active substances (NAS) launched in world market17 Yet, in recent decades, that picture has changed. Whereas less than 10 percent of new drugs were first introduced in the United States in the 1980s, by the 2010s, more than 60 percent of new drugs were first introduced in the United States.18 By 2006, pharmaceutical companies invested 40 percent more in the United States than in Europe. And the United States has been the world’s largest funder of biomedical R&D investment over the past two decades—a share some analysts have estimated has reached as high as 80 percent.19 This has contributed to an unprecedented era of life-sciences innovation, and the retention and creation of good U.S. jobs. Over the last decade, biopharmaceutical companies have invested over half a trillion dollars in R&D, while more than 350 new medicines—many firsts of their kind—have been approved by the Food and Drug Administration (FDA).20 America’s wresting of global life-sciences leadership has been no accident, but rather the result of a series of intentional policy decisions designed to make America the world’s preeminent location for life-sciences research, product commercialization, and production. For instance, the United States’ introduction of the world’s first R&D tax credit in 1981 played a catalytic role in spurring greater levels of private-sector R&D. In the life-sciences sector, this was complemented by the 1986 introduction of the orphan drug tax credit, which allows drug manufacturers to claim a tax credit on research costs for orphan drugs (i.e., drugs for rare diseases affecting 200,000 or fewer U.S. patients). The 1992 introduction of the bipartisan Prescription Drug User Fee Act, which authorized the FDA to collect user fees associated with applications from the biopharmaceutical industry for regulatory approval of new human-drug submissions, has played a pivotal role in reducing the time it takes the FDA to make safety and efficacy determinations for new drugs—from the over 30 months it took on average in the mid-1980s to less than 10 months today.21 America’s strong IP system—including allowing 12 years of data exclusivity for biologics and providing a period of marketing exclusivity for drugs independent of exclusive patent rights, as well as providing patent linkage and patent term extension through the Hatch-Waxman Act—has helped spur investment. Robust funding for the National Institutes of Health (NIH), especially the doubling of funding in the late 1990s and early 2000s, has helped lay the groundwork for robust biopharma innovation.22 The United States also benefits greatly from having a drug-pricing system that permits companies to earn sufficient revenues from one generation of biomedical innovation to reinvest in the next. That matters greatly because, as the Organization for Economic Cooperation and Development (OECD) has written, “There exists a high degree of correlation between pharmaceutical sales revenues and R&D expenditures.”23 Limited government price controls also make investing in the United States more attractive than in many other nations.24 The lesson of the U.S. gain in global competitive advantage in the biopharmaceutical industry should be clear. It was not based on absolute advantage (e.g., some nations being good in agriculture because they have a lot of arable land). Rather, it was and is based on competitive advantage (e.g., factors that are malleable by policy, such as a strong drug-approval system and reasonable drug pricing). As such, have competitive advantage in industries such as biopharmaceutical is something that has to be earned and worked at to retain. As some European nations and nations such as Japan found to their distress, competitive advantage is not a birthright; it can be lost. That should be the message for the United States: while the United States is doing well in the industry now, it could easily lose that advantage, particularly to China, which has targeted the industry for global leadership. This means that the United States needs to keep in place the right policies and make them even stronger while at the same time continuing to press China to roll back its innovation mercantilist practices in this industry. THE COMPETITIVE POSITION OF CHINA’S BIOPHARMACEUTICAL INDUSTRY As a recent Information Technology and Innovation Foundation (ITIF) report shows, China has made considerable progress in catching up to the United States in innovation.25 On an average of 36 indicators, China has cut the gap with the United States by a factor of 1.5 from a decade ago to the present. (For example, had China been 80 percent behind the United States a decade ago, it would be just 50 percent behind today.) In other words, in the span of a decade, China has made dramatic progress in innovation relative to the United States. A major reason is China has put its mind, heart, and soul into not just being an innovator, but being, in the words of Chinese president Xi Jinping, “master of its own technologies.” And China has backed that up with a powerful, often discriminatory, arsenal of state-directed industrial and trade policies. Yet, although China lags behind the United States in biopharma competitiveness, its government has targeted the industry, developing a concerted national strategy to enable China to catch up to the United States in biopharmaceutical innovation. And while China lags, it is making progress, starting with science and research. Between 2009 and 2013, Chinese government funding of medical research through the National Natural Sciences Foundation of China increased by a factor of 4, to $710 million.26 Notwithstanding this, China accounts for just 1.8 percent of global government funding for medical research, compared with the United States’ 44.2 percent.27 China has also made rapid progress in biomedical knowledge creation. From 2011 to 2015, China ranked second in the world behind the United States in international biomedical publications.28 And it quadrupled its global share of biomedical articles between 2006 (2.4 percent) and 2015 (10.8 percent).29 In 2016, it was responsible for almost as many biotechnology and applied microbiology publications as the United States.30 However, its share of documents in the top 1 percent of citations is lower than its overall share of articles.31 Moreover, while the number of China’s biology and medical-sciences articles relative to U.S. articles grew 161 percent and 147 percent, respectively, China still lags relatively far behind, publishing only 19 percent as many biology-sciences articles as the United States, and only 11 percent as many medical-sciences articles.32 However, China is making faster progress in some cutting-edge areas. As the U.S.-China Economic and Security Review Commission noted, Chinese researchers increased their share of the world’s genome-related scholarly papers, from 4.5 percent in 2010 to 17.3 percent by 2014.33 China also increased its pharmaceutical business R&D investment at a very rapid rate, by 254 percent from 2008 to 2015, compared with 7.3-percent growth for the United States.34 In 2016, Chinese biopharma R&D stood at an estimated $7.2 billion, up from just $163 million in 2000.35 However, China’s biopharma firms’ R&D-to-sales ratio was only around 2.7 percent, much lower than the U.S. average of 15 to 20 percent.36 For this reason, only 481 life-sciences patents (in medical technology, biotechnology, and pharmaceuticals) were granted to Chinese inventors in the United States in 2016. The rate of U.S. patents issued to Chinese companies for biotechnology and pharmaceuticals is only about half the overall rate of U.S. patents issued to Chinese companies. Biotechnology and pharmaceuticals patents issued to Chinese companies are only 4.1 and 4.6 percent, respectively, of the patents granted to U.S. companies. (See figure 2.) Medical technology patents increased most quickly of the three in absolute terms—more than eightfold from 2006 to 2016—but only accounted for 1.6 percent of the U.S. figure, due to significant domestic growth in U.S. patents.37 Moreover, according to OECD, in 2106, China accounted for just 0.8 percent, 0.4 percent, and 1.5 percent, respectively, of triadic patents (patents filed in Europe, Japan, and the United States) in biotechnology, medical technology, and pharmaceuticals, compared with the U.S. share of more than approximately 40 percent in each.38 Figure 2: Life-sciences patents granted to Chinese inventors as a percentage of all life-sciences patents granted in the United States, 2006–201639cid:image001.png@01D51BC3.6F75A010 China’s industrial output has grown rapidly over the past decade in part because China has dramatically expanded the share of its citizens that are eligible for health insurance.40 Chinese sales increased from $26.2 billion in 2007 to $122.6 billion in 2017 (for comparison, U.S. sales in 2017 were $466.6 billion).41 This is a key reason why China’s share of global industry value added rose from 7.2 percent in 2001 to 22.1 percent in 2016, with over two-thirds of that growth happening after 2010 (see figure 3). Some of this is due to China being the leading producer of active pharmaceutical ingredients (APIs) in drugs, accounting for between 20 and 40 percent of global output, and is the world’s largest API exporter, as well as key generics producer.42 China more than doubled its biopharmaceutical production capacity, including APIs, from 2010 to 2014.43 Per a KPMG report on China’s biopharmaceutical industry, “Thanks to substantial state support, the biopharmaceutical industry has enjoyed concentrated, high-speed growth over the past several years.”44 China is moving toward becoming a producer of innovative new drugs. As Fangning Zhang and Josie Zhou of the McKinsey Global Institute wrote, “[S]ome leading Chinese pharma companies that historically focused on generics have started building capabilities and making investments in innovative drugs.”45 They added, “[T]he number of applications of local innovative drugs entering clinical trials in China has grown from 21 in 2011 to 88 in 2016.”46 In 2017, 800 innovative molecules were under development in China, ranging from preclinical to phase III stages in the pipeline, of which 10 percent were at clinical stage III (the stage at which medicines are definitively tested for effectiveness or cure).47 A number of Chinese biopharma companies are establishing multiregional clinical trials designed to serve global markets. For example, in 2018, Chinese biologics- and biosimilars-maker Bio-Thera Solutions Ltd. started a phase III trial of its HER2 antibody conjugate drug targeting HER2-positive metastatic cancer.48 As of mid-2018, 25 Chinese companies had applied for approvals for advanced anticancer drugs based on biotechnology (PD-1/PD-L1 inhibitors).49 Moreover, in 2017, China had 139 clinical trials with chimeric antigen receptor treatment (CAR-T) cell therapy, compared with around 118 in the United States.50 Of just over 400 CAR-T clinical trials conducted in March of 2019, 166 were in China, and 165 in the United States.51 Chinese biopharma start-ups are also broader in terms of the number of drugs they make or license to make, with the average number of drugs when filing for an initial public offering (IPO) in China being 10, versus 4 in the United States.52 And in 2016, China had filed 410 clustered regularly interspaced short palindromic repeats (CRISPR gene-editing) patents, with the United States filing 447.53 In 2015, there were 173 publicly traded pharmaceutical companies in China.54 However, much of this has been based on the practice of simply copying from the leading Western companies.55 Moreover, Chinese companies still produce less than 1 percent of new molecular entities (e.g., drugs) globally. Figure 3: Global shares of value added of pharmaceutical industry56 One reason China has made such significant progress is a number of components within its policy environment for biopharma innovation are improving. The McKinsey-Bay Helix Group China Drug Innovation Index, based on a survey of 109 industry experts, shows that China made progress on all six major indicators relative to the United States from 2015 to 2018.57 China’s regulatory-environment score increased from 3.1 to 5.5; market access, including reimbursement, increased from 3.1 to 4.0; funding for start-ups increased from 4.6 to 5.4; R&D capabilities increased from 4.8 to 5.0; local innovation systems increased from 4.1 to 4.4; and integration with the global economy, including foreign licensing and talent attraction, increased from 3.6 to 5.2. Overall, China increased from 4.0 in 2015 to 5.0 in 2018 (all U.S. scores were 8). To be sure, although still behind the United States, China’s score shows it is able to make fairly rapid progress in its support system. Moreover, these policy changes are leading many global biopharmaceutical firms to expand their investments in China. For example, the Japanese biopharma firm Takeda relocated its Asia Development Center from Singapore to Shanghai. Likewise, Sanofi is building an emerging market business unit in China. In fact, virtually all of the world’s leading 20 pharmaceutical companies now have manufacturing facilities in China—and many have also established R&D centers in the country.58 China is an important market for foreign life-sciences companies (including those in the United States), with the top-10 mature drugs from foreign companies adding $2.8 billion additional revenue to China from 2014 to 2018.59 From 2010 to 2014, annualized growth in Chinese sales revenue among biopharma manufacturers was 23 percent.60 Chinese firms are also expanding internationally, especially in world-class biopharma innovation hubs. For example, numerous Chinese biotechnology companies have started new R&D facilities in the United States, generally focused in such major biotech hubs as Boston, San Francisco, and Research Triangle Park in North Carolina. Chinese companies use this strategy to gain access to new technologies they can then bring back to the mainland—more so than firms from most other nations who have shown considerable willingness to invest in U.S. R&D and production facilities.61 Chinese firms overall have made such progress largely because Chinese generics firms, which make up the lion’s share of Chinese biopharmaceutical firms, have for many years made above-average profits. As one article notes, “Among the top 100 generic drug makers [globally], Chinese firms had an 18 per cent profit margin in the third quarter, compared with a global average of 9.5 per cent.”62 One key reason for these higher margins is foreign firms face a significant number of barriers to selling in China, including waiting for import approval, while Chinese generics makers can more easily copy foreign drugs and avoid many of the costs foreign generics makers face. Notwithstanding this progress, China still faces a number of challenges. Perhaps the core challenge is as a science-based industry, it is hard to close the gap with biopharma leaders simply by copying them. In other industries, such as solar panels, high-speed rail, and robotics, China caught up to leaders by copying their technology—often through theft or forced technology transfer—and then using a variety of means, including predatory pricing supported by government subsidies, to weaken foreign competitors. Copying can certainly work if China wants to develop a globally competitive generics and biosimilar industry (biosimilars are follow-on drugs to original biotech drugs), but it will not be enough to achieve significant market share in innovative drugs. To do that, China needs to develop indigenous capabilities that allow it to develop and bring to market first-to-the-world drugs. As a KPMG report notes, “The industry also faces practical constraints, including a shortage of core technology, a subpar industrial structure, weak R&D capacity, low resource efficiency, and disorderly markets.”63 In addition, given the Chinese economy grew so rapidly for so many years and generated a large number of investment opportunities with robust near-term paybacks, the appetite for investing in biopharmaceuticals—in which the payback is uncertain and long—has been relatively low. Moreover, China suffers from having too many small and mid-sized firms competing with each other. Many of China’s biopharmaceutical firms are quite small and do not have the scale to become true innovators. More than 70 percent of China’s pharmaceutical manufacturers have fewer than 300 employees and revenue of less than $3 million.64 And the vast majority produce either APIs or generic drugs. For example, in 2012, there were 1,272 applications for approval for generic drugs, with over 60 percent of them being submitted by different companies more than 20 times each.65 This means overproduction has been an issue, with very low profits for most of these small firms making it hard for them to scale and invest in R&D. This is why China lacks world-leading major biopharmaceutical firms with the scale and technical sophistication of EU, Japanese, and U.S. firms. In branded pharmaceuticals and biotechnology drugs, Chinese companies have less than 3 percent of global market sales.66 China’s relatively low per capita income is also a limiting factor because it makes it harder for China to pay for innovative new drugs, thus limiting the development of Chinese firms. Just 8 percent of new drugs approved globally between 2011 and 2017 are available in China.67 This is made worse by the Chinese government’s recently mandated significant price cuts on many drugs.68 However, China’s vast and growing market for drugs is likely to make up for that disadvantage. As a developing nation, drug consumption, particularly of nongenerics (original innovative drugs) in China is significantly lower than in developed nations. However, as per capita incomes continue to grow, that gap will lessen. Moreover, China’s population of 1.4 billion is more than four times larger than that of the United States. In part because of a growing economy and an aging pollution, the Chinese drug market has grown six times larger from 2005 to 2017.69 It is set to become the second largest in the world, behind the United States, by 2020.70 Tragically, China now has a third of the world’s cases of colorectal cancer, 40 percent for lung cancer, and half for gastric cancer—all factors that will lead to the growth of drug sales in China.71 According to the management consulting firm L.E.K. Consulting, China’s pharmaceutical market value is expected to grow from $123 billion in 2017 to $160 billion by 2022.72 This is important because, like many innovation-based industries, the biopharma industry is characterized by high fixed costs (e.g., R&D to develop and bring a drug to market, building a sophisticated factory, etc.) and lower marginal costs (e.g., ingredients, manufacturing processes, sales, etc.). Therefore, even if firms in China sell at a lower price than firms in the United States, Chinese biopharma companies could still earn greater revenues and profits than U.S. firms—profits they can reinvest back into the next round of innovation. This benefit will only grow as China’s economy grows. Finally, as big data and artificial-intelligence analytics play a bigger role in drug development, China will also gain an advantage because of the much larger pool of medical data available to firms there. CHINA’S INNOVATION MERCANTILIST STRATEGY IN OTHER INDUSTRIES TO DATE While the past is never prologue, to better understand the shape of China’s biopharmaceutical strategy now and going forward, it’s worth understanding China’s past innovation policies related to other industries. To be sure, this does not mean China will apply all such policies to the biopharma sector. International pressure, especially from the Trump administration, may constrain China’s worst practices. Moreover, gaining competitive advantage in a science-based industry such as biopharmaceuticals is different than in more engineering-based industries such as machine tools, aerospace, batteries, and telecommunications equipment. It’s possible this could lead China to approach the industry with innovation-supporting, rather than innovation-distorting, policies. Or it could lead China to double down on the latter policies, especially if it seeks to gain competitive advantage through low prices. As such, it’s worth reviewing China’s technology strategies to date. Foreign technology acquisition has been at the center of China’s industrial strategy for two decades. Chinese leadership knows that if China relies principally on market forces, foreign companies will provide Chinese firms with less technology than it wants and demands in order to grow the array of advanced industries China seeks global dominance in. As such, China has deployed a panoply of tools to unfairly—and often illegally—obtain needed foreign technology. And once Chinese firms have achieved that technology, the government then relies on an array of tools, including protected markets and massive subsidies, to help those firms scale up and gain global market share. Based on policies in other technology sectors targeted in Made in China 2025, U.S. industry and policymakers should be alert to the deployment of a range of discriminatory Chinese practices for growing the biopharma sector in the coming decade. Intellectual Property Theft: IP theft is an important tool in the Chinese arsenal, which China having long deployed industrial spies to obtain foreign secrets. A listing by the FBI of recent IP cases it has investigated reveals that most involve Chinese individuals attempting to steal U.S. IP.73 For example, as The New York Times has documented, a leading Chinese computer-chip maker allegedly paid employees of a Taiwanese chip company working with the U.S. company Micron to steal valuable chip designs.74 In 2018, one in five North American CEOs reported their companies experienced IP being stolen in China.75 Another vector is cybertheft , which 7 percent of U.S. firms operating in China listed as a problem—a number that presumably would be higher if every firm that had faced an intrusion were aware it had done so.76 The IP Commission Report on the Theft of U.S. Intellectual Property found that China accounted for nearly 80 percent of all IP thefts from U.S.-headquartered organizations in 2013, amounting to an estimated $300 billion in lost business.77 An updated 2017 Commission report put that figure at $600 billion.78 Former NSA Director Keith Alexander has called Chinese IP theft, calling it, “the greatest transfer of wealth in history.”79 Even though Chinese President Xi made “commitments” to end Chinese cybertheft, the Chinese government failed to follow through on his promise. As China’s National Counterintelligence and Security Center stated in its “2018 Foreign Economic Espionage in Cyberspace” report: China has expansive efforts in place to acquire U.S. technology to include sensitive trade secrets and proprietary information. It continues to use cyber espionage to support its strategic development goals—science and technology advancement, military modernization, and economic policy objectives. China’s cyberspace operations are part of a complex, multipronged technology development strategy that uses licit and illicit methods to achieve its goals.80 Meanwhile, China still has one of the highest rates of unlicensed software usage in the world, with 74 percent of the software in use unlicensed, and the market value of unlicensed software usage exceeding $8.7 billion in 2013.81 Upwards of 240,000 Internet cafés in China rely on illegal copies of entertainment software.82 Chinese firms even produce and sell technology to allow consumers around the world to circumvent encryption protection so they can pirate video games. Another vector for purloined IP is tricking companies in the United States into believing a Chinese firm wants to invest in them. For example, a seemingly independent Chinese investment fund will approach a small or mid-sized U.S. technology company and indicate a willingness to invest needed capital in the company. But before the Chinese company can do this, they must “do their due diligence” and send over employees that actually work for a state-owned Chinese company, and are there to obtain key information about the company, including trade secrets. The firm never hears back from the investment company again. Another path is through exchange visits and student enrollments in U.S. universities. Chinese exchange visitors to the United States have used opportunities to visit factories and other facilities to engage in industrial espionage, including measuring equipment, taking photos, and writing detailed technical notes to bring back to China. And as Daniel Golden wrote in Spy Schools, Chinese graduate students enrolled in U.S. universities have used their access to valuable scientific and engineering information to violate rules and provide technology and know-how to Chinese companies.83 Chinese trade-secret theft is a challenge that is growing in scale. A prime example is Boston-based American Superconductor (AMSC), which provides software, design, and hardware solutions for wind manufacturers and energy providers. AMSC’s top customer, the Chinese-based wind-turbine manufacturer Sinovel Wind Group, faced criminal and civil actions for paying an AMSC employee to steal proprietary power-converter and control-system software, which it then used illegally in its wind turbines in order to meet electricity-grid standards.84 The employee, an engineer at one of AMSC’s subsidiaries, was recently tried and found guilty of industrial espionage in Austria. In another telling case, the global agriculture firm Monsanto decided to open production and research facilities for advanced corn technology in China, and proceeded to develop experimental fields to grow genetically enhanced corn. It wasn’t long before the advanced corn was systematically stolen—which was clearly an effort by the Chinese government to gain access to the IP embedded in Monsanto’s corn.85 Weak IP Enforcement: Weak enforcement of IP law is another vector. Chinese firms can often copy and reengineer foreign technologies with impunity (what the Chinese government calls “introducing, digesting, absorbing and re-innovating”), even those protected by foreign—and sometimes Chinese—patents. As an MIT Sloan Management Review article, “Protecting Intellectual Property in China,” notes, “Intellectual property protection is the No. 1 challenge for multinational corporations operating in China.”86 According to the U.S. International Trade Commission, in 2009, U.S. IP-intensive enterprises conducting business in China reported losses of approximately $48.2 billion in sales, royalties, and license fees due to Chinese IPR infringement.87 In 2018, according to the American Chamber of Commerce in China, one-quarter of U.S. companies surveyed cited “insufficient protection offered by text of IP-related laws and regulations,” while 24 percent cited “difficulty prosecuting IP infringements in court or via administrative measures” as significant challenges.88 China also favors domestic over foreign patent applicants when it comes to strategic industries. As the 2016 report “Technology Protectionism and the Patent System: Strategic Technologies in China,” finds, “Foreign applications in technology fields that are of strategic importance to China (as defined by being listed on the MLP [Medium and Long-Term Plan for Science and Technology Development]) are 4 to 7 percentage points less likely to be approved than local applications, all else equal.”89 As the report notes, “Given the importance of industrial policy in China and the country’s strong focus on indigenous innovation and intellectual property, the empirical results provide a case of technology protectionism by means of the patent system.”90

#### **China biotech heg causes a laundry list of impacts.**

Moore 19. [Scott Moore is the director of the Penn Global China Program at the University of Pennsylvania] 8 November 2019. Foreign Policy. “China’s Biotech Boom Could Transform Lives—or Destroy Them” Accessed 5 October 2021. < https://foreignpolicy.com/2019/11/08/cloning-crispr-he-jiankui-china-biotech-boom-could-transform-lives-destroy-them/ > //re-cut MHES

Clapper’s statement didn’t explicitly mention China—but it didn’t need to. As his testimony went on to make clear, while in the 20th century the United States and Soviet Union held the keys to preventing planetary catastrophe, in the 21st the principal players are the United States and China. And while in a previous age keeping Pandora’s box closed meant preventing nuclear war, today it’s about preventing biotech dangers. In just the past few years, the development of inexpensive gene-editing techniques has democratized biomedical research, producing a biotech bonanza in places such as China and creating a whole new category of security threats in the process, from the use of genetic information to persecute dissidents and minority groups to the development of sophisticated bioweapons. When it comes to the United States, China, and technology, artificial intelligence tends to grab most of the attention. But policymakers need to come to grips with the even bigger threat of biotechnology—and soon. Fortunately, though, shared concerns about China’s role in biotechnology also provide a rare chance for meaningful and productive engagement in shaping the rules of a new world. China’s starring role in preventing the 21st century’s biotech perils stems from its skyrocketing investment in biomedical research. Historically, Western countries, and especially the United States, have been the epicenter of research in the life sciences. The United States alone accounted for some 45 percent of biotech and medical patents filed in the 14-year period ending in 2013. But now, thanks to heavy state-backed investment, China is catching up. Economic plans instituted in 2015 call for the biotechnology sector to account for more than 4 percent of China’s total GDP by 2020, and estimates suggest that as of 2018, central, provincial, and local governments had already invested over $100 billion in the life sciences. Chinese venture capital and private equity investment in the life sciences, meanwhile, totaled some $45 billion just from 2015 to 2017. China has also invested considerable effort in competing with countries like the United States for biotech talent. Of some 7,000 researchers recruited under the Thousand Talents Plan since 2008, more than 1,400 specialized in the life sciences. A leading American geneticist, Harris Lewin, has warned that the United States is “starting to fall behind … the Chinese, who have always been good collaborators, [are] now taking the lead.” For the United States and other Western countries, China’s growing role in biomedical research is raising plenty of concern. Several Chinese researchers have shown a willingness to ignore ethical and regulatory constraints on genetic research. In 2018, He Jiankui became a poster child for scientific irresponsibility when he announced he had edited the genes of two twins in utero without following basic safety protocols. He reportedly dismissed them as guidelines, not laws. Yet the reaction at home was not what He had hoped for. His research had been made possible by the relatively lax standards of Chinese universities, even as he had kept the true nature of it secret from many involved – while discussing it with a small group of Western bioethicists and scientists, who stressed their disapproval. It’s not uncommon in China to break the rules and be lauded for the results anyway, whatever the field. For He, though, the vast international attention that came after the story broke cost him his career and possibly his freedom. Chinese media rushed to stress official disapproval of the experiments. Even the overt purpose of the editing – to ensure that the babies, born to HIV+ mothers, enjoyed protection against the virus – turned out to be scientifically weak. As China’s biotech sector grows, so too do fears that Chinese researchers like He will be more willing to push the limits of both science and ethics than those in the United States. Earlier this year, Chinese researchers recorded another mind-bending milestone when they implanted human genes linked to intelligence into monkey embryos—and then said that the monkeys performed better on memory tests. The dominance of the party-state in China raises serious concerns around biotechnology, especially because it carries increasingly ethnonationalist tone. When in 2018 Chinese researchers created the world’s first primate clones, for example, they dubbed them Zhong Zhong and Hua Hua, from the term zhonghua meaning “The Chinese Nation”—an oddly jingoistic moniker for a pair of monkeys. Chinese government policies often blur the line between eugenics and education, lumped together as improving the “quality” (suzhi) of the population, which received another stamp of official endorsement following the recent Fourth Plenum. These programs are carried out through the country’s huge so-called family planning bureaucracy—originally established to enforce the one-child policy. Is China the World Leader in Biomedical Fraud? Moreover, Beijing is increasingly extending its formidable social control apparatus into the realm of genetics. While there are considerable restrictions on private firms sharing biomedical data, largely because of an ugly history of popular discrimination against hepatitis carriers, the government has no such restrictions. A New York Times report earlier this year suggested, for example, that Chinese authorities had assembled a vast trove of genetic data on Chinese citizens without their consent, with the Uighur minority group having been specifically targeted. Beijing’s brand of bio-nationalism also directly threatens the United States. U.S. officials have been warning universities and research institutions that the biotech sector is a focal point for Chinese industrial espionage activities in the United States. And this past August, a senior Defense Department official warned Congress that China’s growing role in pharmaceutical manufacturing could allow it to disrupt deliveries of critical battlefield medicines, or potentially even alter them to harm U.S. forces Yet the biggest risks posed by biotech, for China, the United States, and other countries, pertain to nonstate actors. A critical feature of modern biotech, in contrast to technology like nuclear weapons, is that it’s cheap and easy to develop. A technique known as CRISPR, which the Chinese researcher He used in his illicit gene-editing work, makes it practical for just about anyone to manipulate the genomes of just about any organism they can lay their hands on. CRISPR makes it much simpler to skirt ethical restrictions and terrifyingly straightforward for terrorist groups to develop fearsome biological weapons. Researchers have already shown it’s possible to reconstruct the smallpox virus, which was eradicated in the real world in the 1970s, for as little as $200,000 using DNA fragments you can order online. If a terrorist or rogue state were to successfully do so, virtually no one alive would have any resistance to the virus—and most stockpiles of the vaccine were destroyed long ago. There is an organization, the International Gene Synthesis Consortium, that tries to screen suspicious orders for DNA fragments that might be used to build such bioweapons. And while most of the world’s major DNA synthesis firms belong to the consortium, membership is completely voluntary, and there’s also a thriving and entirely unregulated black market—much of it based in China. All of this means that biosecurity standards in places like China matter more than ever. After all, if a major bioweapon were to be unleashed, it’s unlikely that any major, globally integrated country could escape unharmed. Fortunately, there are growing signs China is open to better regulation of its biotech sector. In February, the Chinese government announced that “high risk” biomedical research would be overseen by the State Council, China’s equivalent of the cabinet—a sign of the concern with which Beijing views incidents like the He Jiankui CRISPR scandal. In a further sign of this concern, in August, the Chinese Communist Party announced the creation of a new committee to advise top leaders on research ethics.

#### Cross apply disease impacts from case.

#### China rise creates a spheres-of-influence world that causes transition wars.

**Twining 17** [Daniel Twining is the director of the Asia Program at The German Marshall Fund of the United States, based in Washington, DC, MPhil & PhD degrees from Oxford University] "Abandoning the Liberal International Order for a Spheres-of-Influence World is a Trap for America…," *Medium*, 3-21-2017, https://medium.com/out-of-order/abandoning-the-liberal-international-order-for-a-spheres-of-influence-world-is-a-trap-for-america-7bfcdbb83df4. Accessed 16 July 2021.

The liberal world order is under assault. Polls suggest an American ambivalence about upholding the rules-based global system. Populists are besieging governing elites in the West while Russia works strategically to destabilize European and American governments through propaganda and proxies. A rising China wants to create a global system that is not U.S.-centric, one in which smaller powers defer to bigger ones and norms of democracy and rule of law do not prevail. Meanwhile, the U.S. alliance system looks adrift while competitors in China and Russia appear to be on the march. If it holds, this trend could produce a spheres-of-influence world — which many, including the current presidents of the United States, China, and Russia, find intuitively attractive. But were such an order to replace one based on global integration and American leadership in the geopolitical cockpits of Europe and Asia, it would only engender insecurity and conflict. In a spheres-of-influence world, great powers order their regions. The United States would go back to a “Monroe Doctrine” version of grand strategy; Russia would dominate the former Soviet space; China would govern East Asia, and India South Asia. The problem with this kind of order, however, is several-fold. Too many spheres overlap in ways that would generate conflict rather than clean lines of responsibility. Japan would oppose Chinese suzerainty in East Asia, including by developing nuclear weapons; India and China would compete vigorously in Southeast Asia; Russia and China would contest the resources and loyalties of Central Asia; Europe and Russia would clash over primacy of Central and Eastern Europe. The Middle East would be an even more likely arena for hot war between Saudi Arabia and Iran, and Turkey would contest regions also claimed by Russia, Europe, and possibly China. Russia, like the Soviet Empire before it, would keep pushing west until it met enough hard power to stop it. A spheres of influence world would also sharpen great power competition outside of each region. Regional hegemony is a springboard for global contestation. China would be more likely to challenge the United States out-of-area if it had subdued strategic competition in its own region. Russia, like the Soviet Empire before it, would keep pushing west until it met enough hard power to stop it. (The fact that Russian troops marched through Paris during the Napoleonic Wars demonstrates that the limits of Russian power need not be confined to the former Warsaw Pact). American leaders have long understood that a “Fortress America” approach is a source of national insecurity. Franklin Roosevelt made this case in a series of “fireside chats” in the run-up to America’s participation in World War II — even before the advent of the far more sophisticated power-projection technologies that exist today. Roosevelt and his generals well understood that the United States could not be safe if hostile powers controlled Europe and Asia, despite the wide oceans separating North America from both theaters.

# 2

#### **Counterplan text: The member nations of the World Trade Organization ought to more strictly adhere to the doctrine of obviousness.**

#### **Aff isn’t necessary– strict application of the obviousness doctrine is enough for significant improvement. We’ll read cyan-**

Feldman 3 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

I believe that one period of protection **should be enough**. We should make the legal changes necessary to prevent companies **from building patent walls** and piling up mountains of rights. This could be accomplished **by a “one-and-done” approach** for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but **not all of the above** and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through **legislative changes to the FDA’s drug approval system**, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

# Case

### Underview

#### Reject 1ar theory:

**1.  They can just blow up dropped arguments in the next speech making it impossible for me to win since I only have the 2n.**

**2. Aff gets to speak first and last and gets infinite pre-round prep time; new layers in the 1AR just exacerbate the skew.**

**3. Resolvability - every round dissolve to see if the judge thinks the 2ar answers to the 2n are good enough and the theory debate will be underdeveloped which means they have to inject bias.**

**4.  The initial 1AR shell won’t have extensive built-in framing and 2AR has special ability to weigh after I read the counterinterp. I can’t respond to 2AR weighing since there’s no 3NR, which means the aff can just restart the round with 1AR theory and win on 2AR re-contextualization every time.**

#### Even if they get 1AR theory [a] don’t drop the debater – evaluate punishment after abuse [b] yes RVIs for reciprocity – if they get to run a shell with the intention on winning on it they should be able to lose on it too [c] reasonability – k2 deter frivolous shells, competing interps incentivizes debaters go all in on theory which crowds out substance

### Advantage

#### [1] Feldman’s wrong about evergreening

Risch 17 [Michael; “Data for the Evergreening Debate,” Written Description; 11/21/17; <https://writtendescription.blogspot.com/2017/11/data-for-evergreening-debate.html>] Justin // recut MNHS NL

**Feldman and Wang** argue that the Orange Book has been used by companies to "evergreen" their drugs - that is, to extend exclusivity beyond patent expiration. The paper is on SSRN and the abstract is here:

Why do drug prices remain so high? Even in sub-optimally competitive markets such as health care, one might expect to see some measure of competition, at least in certain circumstances. Although anecdotal evidence has identified instances of evergreening, which can be defined as artificially extending the protection cliff, just how pervasive is such behavior? Is it simply a matter of certain bad actors, to whom everyone points repeatedly, or is the problem endemic to the industry?

This study examines all drugs on the market between 2005 and 2015, identifying and analyzing every instance in which the company added new patents or exclusivities. The results show a startling departure from the classic conceptualization of intellectual property protection for pharmaceuticals. Key results include: 1) Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. Every year, at least 74% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs; 2) Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, almost 80% extended their protection at least once, with almost 50% extending the protection cliff more than once; 3) Once a company starts down this road, there is a tendency to keep returning to the well. Looking at the full group, 80% of those who added protections added more than one, with some becoming serial offenders; 4) The problem is growing across time.

I think the data the authors have gathered is extremely important, and I think that their study sheds important light on what happens in the pharmaceutical industry. That said, as I explain below, my takeaways from this paper are much different from theirs.

My concerns are fourfold. First, even assuming that every one of the efforts listed by the the study were an attempt to evergreen, I have no sense for whether evergreening actually happened. This study doesn't provide any data about generic entry or pricing. For example, the study describes 13 listings for OxyContin, but I'd bet dollars to donuts that there was plenty of generic oxycodone available. Similarly, many of the new listings are changes from Drug 1.0 to "new and improved!" Drug 2.0. This, of course, has been criticized as anti-competitive (since generics rely on auto-substitution laws), but the study presents no data about whether insurers refuse to pay for Drug 2.0 and instead require the generic, nor does it explain why generics can't do their own advertisements to get doctors to prescribe Drug 1.0.

Second, many of these listings and the new patents that go with them are for advances, like extended release and dissolvables. These can be critically important advances, and they are preferred by consumers. Thus, one person's "evergreening" is another person's innovation. I take extended release drugs (and expensive generic) to avoid side effects and I gave my son dissolvable Prevacid when he wouldn't stop crying with GERD (and was glad for it). Without consumer data or patent data, it is impossible to tell just how much evergreening is going on (or how harmful it is). Now, if these patents are obvious because making them dissolvable or extended is easy, I'm all for stripping protection - but that's a different issue.

Third, the article speaks of orphan drug approvals as if they are a bad thing. This made me bristle, quite frankly. My mother has an extremely rare autoimmune disease that is very painful. I often wondered, isn't there some incentive to develop drugs to treat it? Turns out there is, and though she got no relief, apparently a bunch of other rare diseases did, and that's the whole point behind orphan drug exclusivity. Concern about this exclusivity seems misguided anyway. If it turns out that drug companies are gaming it and nobody actually needs the drug, then the the loss is not too large, because it's a small population and nobody needs the generic anyway. And if it turns out that they do need it, the Orange Book only limits labeling, and doctors are free to prescribe a generic for off-label use. Without evidence that doctors refuse to do so, there's no real evidence that Orphan exclusivity does much harm. In another personal story, my wife was prescribed a generic drug in a different formulation than the patented tablet for off-label use.

Fourth, and most generally, the article speaks of new patents as if there is no innovation. New use discoveries are important. Many of our most important drugs are not for their original uses. As far as I know, generics are not barred from finding new uses and patenting them, either, though admittedly their hands are tied for patient use. So, where the authors see evergreening, I see innovation. Maybe. Maybe it's obvious. But we can't tell that from this high level, and I'm not ready to write it all off as evergreening. It is telling that I was able to provide four personal stories about how supposed evergreening efforts benefited, would have benefited, or did not increase costs for my family or me (and thankfully none of them involved oxycodone).

#### [2] Secondary patents are only on the improvement, not the original product – also antitrust solves

IP Watch 18 9-21-2018 "Inside Views: Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection" <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/> (a non-profit independent news service that provides professional coverage of global policymaking on intellectual property and innovation.)//Elmer // recut MNHS NL

“Evergreening” – an Incoherent Concept Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.

#### [3] We’re winning uniqueness:

#### **[a] Despite challenges, pharmaceutical R&D shows signs of growth.**

Terry and Lesser 21. [Colin is a Partner in our Life Sciences practice. He has been with Deloitte since 2011 working in the US firm, until 2014 when he moved to the UK practice. Colin’s client advisory work in the Life Sciences sector ranges across strategy and operations focused on the R&D function including operating model development and implementation as well as post-merger integration (PMI). These engagements have been serving client Boards and their senior leadership teams in R&D, Commercial and Supply Chain. Neil is a principal with Deloitte Consulting LLP in the Life Sciences strategy practice and a leader in the Research & Development strategy practice. He joined Deloitte in 1998 and works with life sciences executives creating and implementing strategies that drive productivity, efficiency, and value. He leads strategy, operating model design, productivity improvement, and large transformation initiatives within R&D and Regulatory Affairs. Neil is a frequent writer and speaker on R&D productivity.] May 2021. Deloitte. “Seeds of Change: Measuring the return from pharmaceutical innovation 2020.” Accessed 19 September 2021. <<https://www2.deloitte.com/content/dam/Deloitte/uk/Documents/life-sciences-health-care/deloitte-uk-measuring-the-return-from-pharmaceutical-innovation-2021.pdf#page=6>> //MHES

IRR – Internal Rate of Return

Breakthrough advances in science and technology continue to fuel innovation in the biopharmaceutical (biopharma) industry and shape health care. However, though biopharma R&D is under mounting pressure, this year's analysis is showing a potential for growth with our cohort seeing small improvements in returns on pharmaceutical innovation. Nevertheless, peak sales remain at much lower levels than in 2013, despite a small uptick this year, and R&D costs continue to increase. Costs are increasing due to the growing complexity of development and longer cycle times. There is a pressing need to optimise processes and fundamentally change the drug development paradigm through use of digital and transformative approaches. COVID-19 has spurred on these changes and the industry is well-positioned to build on the momentum and look optimistically for a future with higher returns on pharmaceutical innovation. Since 2010, our series of reports on Measuring the return from pharmaceutical innovation have provided insights into the state of biopharma R&D, by projecting the internal rate of return (IRR) on investment that 12 large-cap biopharma companies might expect to achieve from their late stage pipelines. In 2015, we added an extension cohort of four more specialised companies and backtracked their R&D investments to 2013. Over time, our analysis has shown that both cohorts have seen large declines in their expected returns, and there has been convergence in the performance of the original and extension cohorts. Moreover, for the first time since our research began, a company in the original cohort acquired an extension cohort company. For these reasons, and for the purpose of this and future reports, we have combined the original and extension cohorts to create a combined cohort of 15 companies. However, since this is a transition report, we also provide a comparative analysis of the performance of the separate cohorts. It should be noted that our analysis period was from May 2019 to April 2020 and, therefore, this report's pipeline of late-stage assets does not fully reflect the COVID-19 vaccines and therapies that have since emerged. Measuring the return from pharmaceutical innovation For the first time since 2014, the average IRR has had an uptick from the previous year, showing signs of a potential reversal in the declining trend. In 2020, the projected internal rate of return (IRR) for the combined cohort was 2.5 per cent, 0.9 percentage points higher than in 2019 but 3.9 percentage points lower than in 2013. The range between top and bottom performers narrowed from 2019 and was the third-lowest since 2013. While ten of the 15 biopharma companies in the combined cohort improved their average IRR from 2019, all but one are below the industry cost of capital. The projected IRR for the original cohort in 2020 was 1.7 per cent - an increase of 1 percentage point from 2019, but a decrease of 3.1 percentage points since 2013. The three company extension cohort, in contrast, had a projected IRR of 6.6 per cent in 2020, up from 5.2 per cent in 2019 but well below the 17.4 per cent achieved in 2013.

#### [b] Pharma innovation is doing great now – answers all your warrants.

Lisa Jarvis, 1-17-2020, [Biotech and pharmaceutical industries, academic drug discovery. Based in Chicago, Lisa has been covering the biotech and pharmaceutical industries at C&EN since 2006. She writes feature articles that weave together the business and science of developing drugs, while also serving as pharmaceuticals editor for the magazine. She has a particular interest in rare diseases, innovative models for drug discovery, and emerging technologies.] "The new drugs of 2019," Chemical &amp; Engineering News, <https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2019/98/i3> //Jay

Although pharmaceutical companies last year were unable to top the record-shattering [59 new drugs approved in the US in 2018](https://cen.acs.org/pharmaceuticals/drug-development/new-drugs-2018/97/i3), they were still on a roll. In 2019, the Food and Drug Administration green-lighted 48 medicines, a crop that includes myriad modalities and many new treatments for long-neglected diseases. Taken together, the past 3 years of approvals represent drug companies’ most productive period in more than 2 decades. Still, some analysts caution that the steady flow of new medicines could mask troubling indications about the health of the industry. The year brought several notable trends. The first was an uptick in the number of novel mechanisms on display in the new drugs. Roughly 42% of the medicines were first in class, meaning they had new mechanisms of action; this is a jump over the prior 4 years, when that portion ranged between 32 and 36%. Another trend was the influx of newer modalities. While small molecules continue to account for the lion’s share of new molecular entities (NMEs), making up 67% of overall approvals in 2019, the list also includes several antibody-drug conjugates, an antisense oligonucleotide therapy, and a therapy based on RNA interference (RNAi). Yet another encouraging trend was the influx of innovative therapies for underserved diseases. Standout approvals include two new drugs for sickle cell anemia (Global Blood Therapeutics’ Oxbryta and Novartis’s Adakveo), an antibiotic for treatment-resistant tuberculosis (Global Alliance for TB Drug Development’s pretomanid), and a therapy for women experiencing postpartum depression (Sage Therapeutics’ Zulresso). “The quality of the drugs over the last decade or so has steadily improved since the depths of the innovation crisis 10–12 years ago,” says Bernard Munos, a senior fellow at FasterCures, a drug research think tank. “We’re seeing stuff that frankly would have looked like science fiction back then.” Those futuristic new therapies include [Novartis’s Zolgensma](https://cen.acs.org/articles/97/i22/FDA-approves-second-gene-therapy.html), a gene therapy for spinal muscular atrophy; Alnylam Pharmaceuticals’ Givlaari, the company’s second marketed RNAi-based therapy; and several critical vaccines for infectious diseases, including Ebola, smallpox, and dengue fever. Not all those edgy therapies appear in C&EN’s list. We track approvals granted through the FDA’s main drug approval arm, the Center for Drug Evaluation and Research; drugs like vaccines and gene therapies are generally reviewed through the agency’s Center for Biologics Evaluation and Research. The new-approvals list also doesn’t include several therapies that made their way to patients for the first time, even though the FDA doesn’t consider them new drugs. For example, the agency gave its green light to Johnson & Johnson’s Spravato, making it the first new treatment option for people with major depressive disorder in more than 50 years. The drug is the S enantiomer of ketamine, an N-methyl-D-aspartate receptor antagonist that had been long approved as an anesthetic, gained notoriety as a club drug, and was used for years off label to treat severe depression ([see page 18](https://cen.acs.org/biological-chemistry/neuroscience/Ketamine-revolutionizing-antidepressant-research-still/98/i3)). Also notable in 2019 was a slight dip in the number of cancer drugs, which in recent years typically made up more than a quarter of all new medicines. Last year’s 11 cancer treatments accounted for roughly 23% of approvals.

#### [c] AT PFAD – 78% statistic comes from 2005-15 which is before the COVID pandemic. We’re seeing more innovation in these industries to respond to pandemics etc.

#### [d] We’ve got better author quals than their Ventures 20 ev – they focus on a ‘wide range of categories’ but our authors are experts in specifically the public health field. That means we have a better understanding of the industry.

#### [4] High risk nature of pharmaceutical R&D means patents are necessary to attract investments.

**Grabowski et al 15.** [Henry G. Grabowski is a professor of economics at Duke University, in Durham, North Carolina.

Joseph A. DiMasi is director of economic analysis at the Tufts Center for the Study of Drug Development, Tufts University, in Boston, Massachusetts. Genia Long is a senior advisor at the Analysis Group, in Boston, Massachusetts.] February 2015. Health Affairs, vol. 34, no. 2. “The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation.” Accessed 16 September 2021. <<https://www.healthaffairs.org/doi/10.1377/hlthaff.2014.1047>> //MHES  
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.  Universities also play a key role in the R&D ecosystem because they conduct basic biomedical research supported by sponsored research grants from the National Institutes of Health (NIH) and the National Science Foundation (NSF). The Patent and Trademark Law Amendments Act of 1980 (commonly known as the Bayh-Dole Act) gave universities the right to retain title to patents and discoveries made through federally funded research. This change was designed to encourage technology transfer through industry licensing and the creation of start-up companies. Universities received only 390 patents for their discoveries in 1980, 12 compared to 4,296 in 2011, with biotechnology and pharmaceuticals being the top two technology areas (accounting for 36 percent of all university patent awards in 2012). 13

#### **[5] Rising development times and costs mean extended patent protection is key.**

Sullivan 18. [Thomas Sullivan is Editor of Policy and Medicine, President of Rockpointe Corporation, founded in 1995 to provide continuing medical education to healthcare professionals around the world. Prior to founding Rockpointe, Thomas worked as a political consultant.] 6 May 2018. Policy & Medicine. “Pharmaceutical Companies Need Longer Patents to Fund Innovation” Accessed 6 October 2021. <<https://www.policymed.com/2012/04/pharmaceutical-companies-need-longer-patents-to-fund-innovation.html>> //MHES

The American pharmaceutical industry is seriously ill. And extended patent protection is just the medicine the drug companies need,” Dr. Bloom argued. Although “Pharmaceutical companies have long been demonized by many politicians and others as heartless behemoths that place profit ahead of people’s well-being,” Dr. Bloom asserted that this perception “couldn’t be more wrong.” He explained that the “profits these companies make on blockbuster medications support the research that produces such breakthroughs. And the scientists working in the labs are fervently committed to finding useful new medicines.” One problem, however, is that “there are far fewer of those scientists at work than there were 10 years ago, and their companies are in trouble.” Dr. Bloom explained that a “confluence of events in recent years has made drug discovery more difficult, expensive and time consuming. Most important, it has become less profitable, largely because longer development times mean companies have less time left under patents to exclusively market their discoveries.” Now, the industry faces a financial crisis because of the recent or imminent expiration of the patents on many of its most profitable drugs. “Without extended patent protection for new discoveries,” Dr. Bloom argued that, “the industry won’t be able to fund the current level of research. And the consequences are profound: decreased innovation, fewer new drugs and more job losses.” While critics and media focus on blockbuster drugs making billions of dollars, Dr. Bloom told people to consider the following: Currently, bringing one new drug to market takes roughly 14 years, at a cost of about $1.3 billion. For every drug that makes it to market, more than 50 other research programs fail. After all that, only two of every 10 newly approved drugs will be profitable. Those profits must fund not only all the research programs that failed, but also all the drugs that are launched but lose money. When the industry was producing a steady stream of blockbuster drugs, as it did beginning in the 1990s (for example, all the AIDS drugs), the math worked in its favor. But in recent years the numbers have turned against the drug industry, for several reasons. One reason is that the Food and Drug Administration (FDA) has become more risk-averse in the wake of the 2004 Vioxx debacle. Drug makers are now required to conduct more studies with many more subjects. That adds to costs and stretches out development times. And every year spent in clinical trials equals one year of lost patent coverage. In 1968, when development time was much shorter than today, most drugs had an effective patent life of about 17 years. Now companies usually have only about 11 years of market exclusivity for their drugs. And this number is expected to continue dropping as development times grow even longer—approaching a point where the costs and risks of development outweigh the rewards and research will stop.

#### Even if status quo innovation is ‘negative’ it’s better than no innovation.

#### [6] No incentive to innovate to address neglected diseases – they don’t access their diplomacy impact – innovation doesn’t mean we know where innovation is going. No existential risk they skipped that card – the DA ow on magnitude

#### [7] The aff deters improvements to patented medicines.

**Lee 20.** [Timothy H. Lee is the Senior Vice President of Legal and Public Affairs at CFIF] 12 March 2020. Center for Individual Freedom. “Don’t Jeopardize U.S. Pharmaceutical Innovation When We Need It Most.” Accessed 5 September 2021. <https://cfif.org/v/index.php/commentary/56-health-care/4910-dont-jeopardize-us-pharmaceutical-innovation-when-we-need-it-most> //MHES [Brackets for ableist language]

Amid today’s coronavirus pandemic, there’s an astonishing – and potentially encouraging – number to consider. The United States, with only 4% of the world’s population and 24% of the global economy, accounts for an outsized two-thirds of all new pharmaceuticals introduced worldwide. That disproportionate share of life-saving and life-improving pharmaceutical innovation didn’t occur by accident or coincidence. Rather, it’s the direct result of policy choices that we’ve made, and it’s important to consider as the world desperately seeks new drugs to mitigate or defeat coronavirus. And what most distinguishes the United States in the realm of pharmaceutical development? A comparatively market-based approach, and a legacy of protecting pharmaceutical patent rights over the years and decades like no other nation in the world. The United States has throughout its history maintained the world’s strongest intellectual property protections, including patent rights, which our Founding Fathers explicitly protected in Article I of the Constitution, even before adding the Bill of Rights. As a direct result, no nation in history rivals our legacy of innovation, including pharmaceutical innovation. Those same principles that made America the world’s leader in pharmaceutical innovation are the same ones that will help incentivize ways to address coronavirus. Unfortunately, some in Congress mindlessly seek to undermine those principles amid their political jockeying. Specifically, as the House of Representatives considers the “No BAN Act,” which would limit presidential authority to restrict alien entry into the United States in situations like the current coronavirus pandemic, some Members seek to include legislative language weakening pharmaceutical patent protections. Those proposals reflect misguided provisions introduced in recent months by the Senate Finance Committee regarding allegedly anticompetitive conduct involving patentable improvements to approved pharmaceuticals, falsely labeled “patent-thicketing” or “product-hopping.” Such proposals would only undermine pharmaceutical advancements by subjecting future improvements to drugs already approved by the Food and Drug Administration (FDA) to new Federal Trade Commission (FTC) scrutiny. They would even impose a presumption of illegality under the FTC Act that would become the innovators’ burden to rebut, thereby chilling improvements to existing therapeutic options for medical patients. A House Judiciary Committee proposal actually offers a far better option to the counterproductive Senate Finance Committee provisions. In contrast to the misguided Senate Finance Committee proposals, the House Judiciary Committee’s alternative language adheres more closely to established antitrust law; it contemplates a more reasonable enforcement timeline so that innovators don’t operate under an excessively lengthy liability window; it rightly ensures safe harbor provisions for accurate product descriptions; and it specifies that only improvements to existing pharmaceuticals – as opposed to novel drugs composed of differing ingredients – are subject to the provisions. The Senate Finance Committee proposals would introduce potentially [detrimental] ~~crippling~~ new burdens upon America’s pharmaceutical innovators by weakening the patent protections that have made us by far the world’s leading producer of new life-saving and life-improving drugs. Current laws allow patent rights for new and useful improvements to existing drugs, which rewards the multiple years of risk-taking and experimentation necessary to invest in research and development. New medicines and improvements can require ten or more years to perfect, and of all innovations that reach the clinical trial stage, only 10% or fewer ultimately secure FDA approval. Obviously, that sort of risk and investment can only be sustained by greater certainty and reliability upon regulatory incentives that the Senate Finance Committee alternative would undermine. While some dangerously dismiss improvements to existing pharmaceuticals as “patent-hopping” or “patent-thicketing,” those improvements open the door for reduced side effects, lower dosage requirements, improved potency, extended effectiveness duration and alternative uses. Advancements of that sort are particularly important as it relates to mutating viruses, changing world conditions and other evolving circumstances. Weakening existing pharmaceutical patent protections would dangerously undermine the incentive to pursue such improvements. We simply cannot risk that legacy, or American consumers’ access to the world’s most innovative pharmaceutical market, by discouraging innovation and weakening pharmaceutical patent protections. Congress must therefore reject any provisions in H.R. 2214 that would weaken existing pharmaceutical patent protections on which American consumers and innovators depend. Particularly in a moment like this, there’s far too much at stake.

#### [8] Companies will just obtain a patent in a different sector.

Thomas 15 [John R; Visiting Scholar, CRS; “Tailoring the Patent System for Specific Industries, Congressional Research Service,” CRS; 2015; <https://crsreports.congress.gov/product/pdf/R/R43264/7>] Justin

In view of the concerns noted above, commentators have gone so far to say that “it has become increasingly difficult to believe that a one-size-fits-all approach to patent law can survive.”75 To the extent the current patent system creates a blanket set of rules that apply comparably to distinct industries, it likely over-encourages innovation in some contexts and under-incentivizes it in others.76 Further, some observers have asserted that the need of firms to identify and access the patented inventions of others may differ among industries.77 As a result, the case can be made that distinct industrial, technological, and market characteristics that exist across the breadth of the U.S. economy compel industry-specific patent statutes. However, others have questioned the wisdom and practicality of such line-drawing.78 The following concerns, among others, have been identified:

• Over its long history, the U.S. patent system has flexibly adapted to new technologies such as biotechnology and computer software. Legislative adoption of technology-specific categories may leave unanticipated, cutting-edge technologies outside the patent system.79

• Defining a specific industry or category of technologies may prove to be a contested proposition.

80 • Over time, new industries may emerge and old industries may consolidate. The dynamic nature of the U.S. economy suggests greater need for legislative oversight within a differentiated patent regime.

81 • Even if an industry or technology remains relatively stable, the innovation environment within it might change. For example, technological or scientific advances might open new possibilities for research and development within hidebound industries—but also increase expense and risk for those firms.

82 • Distinct patent rights among industries or technologies may lead to strategic behavior on behalf of patent applicants. For example, a computer program that controls a fuel injector within an automobile could possibly be identified as either an automobile-related or a computer-related invention.

83 •The legislative effort to enact sector-specific patent laws may provide an opportunity for politically savvy firms to exert more lobbying and political power, at the possible expense of less sophisticated firms.

#### Squo solves--cost and bureaucracy are barriers to patent protection and other countries violate IP laws without punishment now.

Chao and Mody 15 (Tiffany Chao [Editor in Chief of Journal of Medical Insight, adjunct professor at Stanford Med School] and Gita Mody [MPH Harvard, assistant professor at UNC Chapel Hill Med School], The impact of intellectual property regulation on global medical technology innovation, BMJ Innovations, 3/5/2015, https://innovations.bmj.com/content/1/2/49) hwof

Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.[i](https://innovations.bmj.com/content/1/2/49#fn-4) High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.[4](https://innovations.bmj.com/content/1/2/49#ref-4) This means that international IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.[5](https://innovations.bmj.com/content/1/2/49#ref-5) As a result of these issues, the most prevalent strategy among global health technologies has often been to develop without regard for IP protection. A major advantage of this approach is that it can allow for open-source innovation, permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation.

#### A vaccine waiver greenlights counterfeit medicine – independently turns Case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.