

Losing the Lead: Why the United States Must Reassert Itself as a Global Champion for Robust IP Rights

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Arguments for weakening IP rights have been gaining traction in the United States to enable a redistribution agenda. But spurring U.S. competitiveness, supporting American jobs, and advancing innovation will require the federal government to step up its game in defense of a more robust global IP regime.

KEY TAKEAWAYS

- The U.S. government has long supported robust IP policies, but an increasing number of policymakers have succumbed to the progressive economic narrative that IP only benefits big firms while harming workers and consumers, at home and abroad.
- Without IP protection, revenues decline, leading entrepreneurs to reduce their investments in new innovation and content because there is a greater risk they won't be able to recoup their capital costs.
- “Alternatives” to IP, such as patronage and reward systems, cannot adequately sustain America's IP-intensive industries and the more than 45 million workers they employ.
- To reengage internationally, U.S. policymakers should oppose IP waivers, include IP in trade agreement negotiations, take measures to address China's IP threat, and lead international discussions around emerging technologies and IP.
- To strengthen domestic policies, U.S. policymakers should adopt website blocking legislation and certain royalty rights, improve public engagement and education about IP, and stop trying to weaken the Bayh-Dole Act to reduce drug prices.

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INTRODUCTION

For decades, the United States was the leading advocate for a global trading system that respected and enforced intellectual property rights (IPR), both because the U.S. economy and millions of jobs depended on IPR and because policymakers understood how important IPR were to global advancement. Without that persistent and forceful U.S. voice, IPR around the world would have been considerably weaker, to the detriment of technological and other forms of progress.

Unfortunately, today, U.S. policymakers have walked away from that critical role, all too often arguing for weaker, not stronger, IPR and enforcement. In large part this is because many, including many in the Biden administration, have come under the influence of anti-IP proselytizers who see IP as a tool for corporate enrichment that limits access by working people, both at home, and abroad, especially in developing nations.¹ For them, weak IP is a critical tool in the equity agenda: enabling cheaper drugs, free content, low-priced clean energy tech in less developed nations, and other redistributionist goals.

There are two key problems with America's abandonment of IP leadership. First, the job of the U.S. government is to first and foremost promote American welfare, not global welfare. There is no doubt that giving away valuable U.S. IP to developing nations would help the latter (at least in the short run) the same way giving them hundreds of billions of dollars would help them. But it would hurt American companies, creators, and jobs and the overall economy.

Second, weak IP will not help the rest of the world in the moderate to long term because it would reduce the incentives and resources needed for innovation to help solve global challenges. Climate change requires much better and cleaner technology. Giving U.S. clean energy IP to developing nation hurts that task, not helps it. The world needs not just drug access, but much better drugs. Weak IP hurts that. Great content—in the form of movies, books, music, photographs, and more—depends on IP.

Arguing that IP is archaic and irrelevant in the digital age and that strong IP hurts the third-world “proletariat” while only helping U.S. “capitalists,” many policymakers have succumbed to a view that supports weakening IPR and opposes expanding existing rights.

As policymakers seek to preserve and advance America's lead in a range of advanced industries, especially vis-à-vis China, they should be strengthening U.S. commitment to strong IP protection, including fighting to protect U.S. innovators and creators from IP theft.² Without that, a key tool in protecting U.S. advanced industry leadership will be tossed away.

Many nations, including the “Global South,” would like nothing more than to see a drastically weakened global IP regime. China, in particular, is in favor of this because it enables the country to more easily steal and otherwise obtain the IP that is so necessary to its continued industrial and military advance, while developing nations get free resources Americans paid hundreds of billions of dollars to develop.

Without strong IP leadership, American allies that believe in strong IPR will have a much harder time advancing their agenda.³ And that is likely to lead to countries that want everything for free to set the agenda.⁴ The result is a weaker U.S. economy and less global innovation.⁵

This report begins with an overview of the United States' past role as a leading supporter of robust IPR and how weaker U.S. IP leadership places American industries and workers at risk. It then highlights several anti-IP arguments and evidence of how U.S. policymakers are abdicating global IP leadership.

The report then provides recommendations for U.S. policymakers to re-engage on international IP policies that:

- oppose IP waivers,
- include IP in trade agreements,
- more effectively address China's IP threat, and
- lead international discussions surrounding emerging technologies and IP.

It ends with recommendations for U.S. policymakers to lead by example through strengthened domestic policies, including:

- adopting website blocking legislation and certain royalty rights,
- improving public engagement and education surrounding IP, and
- ceasing the weakening of pharmaceutical IPR.

AMERICA'S LONG TRADITION OF SUPPORTING ROBUST IP RIGHTS

The nation's founders deemed IPR so important that they provided Congress implementation powers for IP protections in the Constitution.⁶ Notably, the "Patent and Copyright Clause" of the U.S. Constitution (Art. I, Sec. 8, Clause 8) grants Congress the power "[t]o promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."

Throughout the latter half of the 20th century, the United States set much of the global tone for strong IP protection. In 1976, the United States expanded its copyright protection for works created on or after January 1, 1978.⁷ This changed U.S. copyright protection for new works from only 28 years (with the option to renew and extend) to automatic protection for the life of the author plus 70 years for all copyrighted works (or 95 to 120 years for certain anonymous works or works made for hire).⁸ Furthermore, the Uniform Trade Secrets Act (UTSA), issued in 1979, was "the first comprehensive effort to codify" trade secret protection, with most U.S. states adopting the act in some form.⁹ Federal-level protection for trade secrets followed in 1996 with the introduction of the Economic Espionage Act. The Defend Trade Secrets Act of 2016 expanded federal protection to include a private, civil cause of action.¹⁰ Within patent law, the Bayh-Dole Act (1980), Stevenson-Wydler Technology Innovation Act (1980), and Hatch-Waxman Act (1984) provided significant incentives for commercializing government-funded research, generic manufacturing, and continued innovation and collaboration across the public and private sectors.¹¹

U.S. policymakers also fought strong IP protection globally, with the United States leading an array of international dialogues and agreements, such as the United Nations' World Intellectual Property Organization (WIPO) Convention. This endeavor built upon two IP treaties, the Paris and Berne Conventions, developed by America's like-minded allies. It culminated with the founding

of WIPO in 1967.¹² Similarly, the United States played a critical role in promulgating robust IP protection through the Patent Cooperation Treaty (PCT), the North American Free Trade Agreement (NAFTA), and the Trade-Related Aspects of IP (TRIPS) Agreement, among countless other international agreements.¹³ While these agreements and provisions did not eliminate IP theft from the United States, they certainly helped reduce it.

THE NEW ANTI-IP PROGRESSIVE ORTHODOXY

Despite overwhelming evidence supporting IP's vital import, the misleading anti-IP campaign continues to influence Congress, the Biden administration, and international bodies.¹⁴

Most opponents of robust IP protection distrust big business and oppose private markets. At the heart of their opposition lies the belief that redistribution should trump growth and innovation. For them, weakening IP only hurts capitalists while helping the billions of workers and consumers around the world. For them, the impoverished masses in the developing world are hurt by IP. For them, global interests trump American interests. For them, the masses deserve free goods and services. For them, shareholders (and not employees) benefit from IP. For them, big companies benefit from IP, and not small and medium-sized enterprises (SMEs). And for them, IP hurts innovation. In other words, they know that if they are to advance their agenda of elimination of IPR they must paint IP as completely worthless, and even harmful, because it only enriches the rich and powerful.

Anti-IP advocates make claims that are flat-out wrong and ignore data, the historical record, and voluminous academic evidence to the contrary. Indeed, IP creates jobs, empowers creators, and generates export revenues.

It's a nice narrative and one that anti-IP advocates and economic progressives such as the Electronic Frontier Foundation (EFF), Public Knowledge, Joe Stiglitz, Dean Baker, and Arjun Jayadev—some of the loudest opponents of IP—assert in their quest.

Many people, including those who should know better, are taken in by it, usually because they are good-hearted individuals who support making the world a better place.

But the claims anti-IP advocates make often are flat-out wrong and ignore data, the historical record, and voluminous academic evidence to the contrary. Indeed, IP creates jobs, empowers creators and innovators, and generates export revenues. IP also promotes creativity and provides consumers with better products and services.¹⁵

The anti-IP advocates make several claims. We examine and rebut them here.

Claim 1: Information Should Be Free

EFF and Public Knowledge parrot the notion that IP—especially copyright—harms SMEs and individuals. EFF has stated, “Copyright law is at its best when it is narrowly tailored to protect individual and small business creators from losing economic opportunities to companies that could copy their work and more rapidly bring it to market.”¹⁶ However, this proclaimed fight for SMEs and individuals is merely a moralistic front to the anti-IP campaign's ulterior motives. Indeed, this is the only mention of individual and SME creators in an entire article dedicated to

“creative remixing” (i.e., derivative works) of cultural icons and stories “in spite of the legal cloud cast by copyright law.”¹⁷

These organizations’ records are littered with ad hominem attacks, misleading statements, blatant lies, fearmongering, and blanket opposition to all copyright legislation, regardless of whether SMEs and individuals would benefit over corporations.¹⁸ Rather, their true concern is the user, even at the expense of creators. Despite Public Knowledge’s catchy slogan, “Fighting for a creative and connected future for all,” the organization openly seeks (among other things) access to creative works on behalf of the public interest.¹⁹ To wit, the first line under EFF’s “Creativity & Innovation” page states, “Our digital future depends on our ability to *access, use, and build on technology*” (emphasis added).²⁰ Those who simply use another’s creative works should not be allowed to demand creators relinquish their rights solely so users may gain unfettered and free access to content and information. Yet, this unconstitutional attack is exactly what anti-IP advocates incessantly (and wrongly) claim benefits society and creators alike.

Such advocates deem IP laws draconian, archaic, and irrelevant in the digital age—assertions often echoed by those who believe everything on the Internet is subject to the public domain or creative commons.²¹ To this point, mathematician and author Glyn Moody asserts creators should revert to the (even-more archaic) patronage system to sustain their work without copyright in the digital age. However, history proves a patronage system in the creative arts gives rise to censorship, alienates marginalized voices, benefits the rich at the expense of creators, and keeps creators poor.²² Although some creators utilize a modernized form of the patronage system to supplement the rights and royalties generated by IP, patronage alone cannot equitably sustain creators as a sole form of remuneration. Nor can a patronage system support the more than 9.6 million U.S. workers in copyright-intensive industries.²³

Claim 2: IP Doesn’t Help Small Business

Yet, to bolster the claim that IP only benefits big business, many anti-IP advocates argue that IP gives large companies monopolies. Indeed, progressive economist Joe Stiglitz wrote, “Intellectual Property Rights generate monopoly power that can be used to leverage further monopoly power.”²⁴

Unfortunately, propagating an unsupported theory as the primary basis for policy analysis and decision-making seems to be rule number one in the anti-IP playbook, despite data frequently proving these hypotheses wrong. Anticorporate opponents also know that most Americans disagree with their agenda, which is why they cloak it with claims of being for capitalism and markets. As Stiglitz wrote:

I prefer another name, “progressive capitalism,” to describe the agenda of curbing the excesses of markets; restoring a balance among markets, government and civil society; and ensuring that all Americans can attain a middle-class life. The term emphasizes that markets with private enterprise are at the core of any successful economy, but it also recognizes that unfettered markets are not efficient, stable or fair.²⁵

This kind of phraseology is reminiscent of Xi Jinping’s assertion that the Chinese Communist Party’s (CCP’s) state-directed and -dominated economy is nothing more than a “socialist market economy with Chinese characteristics.”²⁶ Likewise, in a speech decrying big businesses and

praising small ones, Senator Elizabeth Warren (D-MA) stated, “I love markets! Strong, healthy markets are the key to a strong, healthy America.”²⁷ This is a common refrain from anticorporate progressives.²⁸ The message is not only that an economy with big firms is not a market economy but also that they are supporters of business. Advocates also know that if they can frame a noncorporate economy as the true capitalist economy, it is harder to criticize them for attacking the U.S. economic system.

But as Jonathan Barnett points out in his book *Innovators, Firms, and Markets: Organizational Logic of Intellectual Property*, recent U.S. history proves these anti-IP and anticorporate claims self-contradictory.²⁹ Barnett argues that between the 1930s and 1970s, the United States operated on a weaker IP system. Much like today, proponents of weak IP claimed that innovation happens regardless of IP protection. To some extent, this is true. However, Barnett asserts that innovation during this period predominantly occurred in large, monopolistic firms, and breakthrough innovations were limited in favor of more financially secure research and development (R&D) options, such as improving existing products.

Without IP protection, SMEs and individuals cannot adequately prove their innovation is worth the risks associated with investing in a small or new venture.

Indeed, without IP, entrepreneurships and start-ups find it difficult to create commercially viable enterprises. Intangible assets, such as IPR, comprised approximately 84 percent of the corporate value of S&P 500 companies in 2018.³⁰ For start-ups, especially those in R&D-intensive industries, this means much of the capital needed to operate is directly related to IP.³¹ Investors rely on IP protections to ensure the possibility of a return on their investment. Thus, without IP protection, SMEs and individuals cannot adequately prove their innovation is worth the risks associated with investing in a small or new venture.

Yet, SMEs in R&D- and IP-intensive industries are not the only ones that benefit from IP. Indeed, from the corner bistro’s secret soup recipe to the small boutique’s brand to the local mining guild’s unique process to Cirque du Soleil’s shows, IP empowers firms of all sizes and across all industries.³² A February 2021 joint study by the European Union Intellectual Property Office (EUIPO) and the European Patent Office (EPO) shows SMEs owning some form of IP generate 68 percent higher revenue per employee than do SMEs that do not own IP.³³ Likewise, “results showed that the economic performance of SMEs benefited far more than their larger counterparts from [IP] ownership.”³⁴ Another EUIPO and EPO report from 2019 states, “SMEs and individual entrepreneurs represent 20 percent of [patent] applications filed from Europe at the EPO, and an even higher share of the trademark applications and design registrations filed with the EUIPO.”³⁵ According to the report, those SMEs that file at least one IP-related application “are 21 percent more likely to experience a subsequent growth period, and 10 percent more likely to become [a high-growth firm].”³⁶

Claim 3: IP Harms Consumers

Still, another chapter in the anti-IP playbook claims IP somehow harms consumers. At one level, this point is correct. Laws that limit consumers’ ability to stay in a hotel without paying or to steal food from grocery stores without being prosecuted certainly materially helps the individuals

engaging in these acts. Indeed, imagine the (temporary) cornucopia if most things were free. Workers would thrive, while the capitalists would starve, according to the narrative.

But if shoplifting were rampant, the result would be empty shelves or closed stores, as we are indeed seeing in many cities around that country that have failed to penalize shoplifters.³⁷ If piracy were rampant, the result would be little new content (movies, photos, music, books, etc.). If drugs were priced at their marginal costs of production, there would be no new drugs. The reality is that IP enables creators to get paid for content, just as shoplifting laws allow grocery stores to get paid for food.

Licensing agreements also allow IP owners to monitor supply chains, identifying which products are counterfeit based on the country of origin and whether a legitimate licensee is there. Likewise, licensed manufacturers are subject to quality and safety inspections to ensure all products meet regulatory standards. Counterfeit goods are not subject to the same quality and safety standards as officially licensed products.³⁸ In fact, many contain harmful (even potentially lethal) doses of chemicals, such as lead in toys, cadmium in jewelry, and arsenic in cosmetics.³⁹ Counterfeit safety equipment, such as airbags, helmets, and baby carriers, have not undergone the same rigorous testing legitimate products have; therefore, many easily break and cause injury rather than prevent it. Counterfeit electronics and lithium-ion batteries may explode or destroy the charging product because they are made from low-quality components and do not adhere to safety standards.⁴⁰ And counterfeit pharmaceuticals pose one of the greatest threats of all, accounting for 46.6 percent (the highest concentration by almost 30 percent) of all goods seized by the U.S. Customs and Border Protection (CBP) for health and safety reasons in 2021.⁴¹ Overdose deaths linked to counterfeit pharmaceuticals are on the rise.⁴² Law enforcement works with rightsholders to identify counterfeit products using IP (predominantly trademarks) and remove them from circulation.

In addition to harming consumers, counterfeit goods produce significant economic harm. According to CBP, “Purchasing counterfeit goods often supports criminal activities, such as forced labor or human trafficking.”⁴³ Every year, illegal counterfeiting generates billions of dollars globally, and much of that money is used to fund terrorism and organized crime.⁴⁴

Claim 4: IP Does Not Benefit the U.S. Economy

A related argument is that IP does little to help U.S. workers or the U.S. economy, so policymakers shouldn’t waste political capital on it. According to Lawrence Summers, companies pushing for IP protection reflect “elite concerns” and don’t contribute much to U.S. employment or tax revenue.⁴⁵

For instance, in the United States, the Department of Commerce has estimated that IP-intensive industries support at least 45 million jobs and contribute more than \$6 trillion (38.2 percent of) U.S. gross domestic product (GDP).⁴⁶ Likewise, the aforementioned 2021 joint EUIPO/EPO study shows a strong, positive correlation between IPR and economic performance.⁴⁷ It states that “IP-owning firms represent a significantly larger proportion of economic activity and employment across Europe,” with IP-intensive industries contributing 45 percent of GDP (€6.6 trillion, or US\$7.9 trillion).⁴⁸ The study also shows that IP-intensive industries directly or indirectly contribute to 38.9 percent of European employment, and IP generates higher wages and greater revenue per employee, especially for SMEs.⁴⁹

Elsewhere, Statistics Canada has reported that 18.2 percent of all Canadian businesses hold some form of IP, predominantly trademarks.⁵⁰ Of those IP-owners, 19 percent have a female as the primary decision-maker, and 10.1 percent have an Indigenous primary decision-maker. Canada also boasts that 47.8 percent of businesses in the clean technology industry and 47.8 percent in its information and cultural industries own at least one form of IP.

Similarly, reports from IP Key, EUIPO, the International Trademark Association (INTA), and others also highlight these trends in Latin America. The reports find that, in 2019, IP-intensive industries' contributions were 41.9 percent of GDP in Argentina, 47.8 percent in Mexico, 48.9 percent in Uruguay, 49.9 percent in Chile, and 55 percent in Peru.⁵¹ Trademark-intensive industries alone accounted for an average of 18 percent employment and a 19 percent wage premium in an INTA study of Argentina, Brazil, Chile, Colombia, Costa Rica, the Dominican Republic, Guatemala, Mexico, Panama, and Peru.⁵² These figures underscore the reality that robust IPR and protections fuel high-value-added, innovation-based economic growth in nations worldwide.

Take the U.S. movie industry, for example, which opponents repeatedly attack through the pejorative “Hollywood” label to dismiss their concerns in basically every copyright debate.⁵³ The lengthy, scrolling credits at the end of a big-budget movie show that each film requires hundreds of workers. One study shows a 51 percent rise in the average number of crew members listed during credits for North American cinematic releases, increasing from 185 in 2000 to 280 in 2018.⁵⁴ This same study shows a direct correlation between a film's budget and the number of crew credits (i.e., jobs). These jobs aren't limited to actors, directors, writers, and camera operators. Large films also require sound technicians, electricians, carpenters, lighting specialists, costumers, metal workers, pyrotechnical experts, choreographers, stunt coordinators, armorers, prop and set designers, drivers, hairstylists, makeup artists, speech therapists, and digital effects programmers—not to mention the thousands employed by movie theaters, advertising agencies, talent agencies, event coordinators, and the plethora of manufacturers associated with merchandising, all of whom rely on the entertainment industry (and the revenue generated thanks to its IPR) for their revenue.

Furthermore, when film and television studios invest profits in future productions (through budgets and up-front costs), they support more film-industry jobs and local economies. The investment required for big-budget shows and movies—such as *Fear the Walking Dead*, *Avengers: Endgame* (estimated \$356 million budget and \$2,797,501,328 worldwide gross), and *Avatar* (estimated \$237 million budget and \$2,922,917,914 worldwide gross)—goes into local economies daily via groceries, food services, accommodations, transportation, venues, local talent, and other service industries during filming, thus supporting the local and national economy as well as higher wages for industry workers.⁵⁵

Marvel Studios' *Black Panther: Wakanda Forever* (estimated \$250 million budget, earned \$181,339,761 opening weekend in North America, and \$832,284,914 worldwide gross) created more than 1,885 local jobs and pumped over \$314 million into Georgia's local economy.⁵⁶ Wages for local workers on the project totaled more than \$88 million, and over \$13.8 million, \$9 million, and \$4.9 million were spent on lodging, hardware and lumber supplies, and catering, respectively. Thus, almost half of the production's budget directly contributed to the local economy.

Claim 5: Weak IP Overseas Helps the U.S. Economy

Perhaps the most outlandish part of the “IP does not benefit workers” argument holds that American workers somehow benefit from other nations growing their economies by stealing or getting American-produced IP below cost. According to Jake Werner, a researcher at Boston University’s Global Development Policy Center:

China’s growing wealth has been the most important driver of growth in the global economy for the last 30 years. That growth hasn’t just benefited people in China but also millions of U.S. workers who produce things for export, and universities in the U.S., and filmmakers in the U.S. All these American industries would have faced stagnant demand if it hadn’t been for the Chinese government’s success in enriching their society through the violation of intellectual property laws.⁵⁷

Mercantilist nations such as China gladly avail themselves of U.S. and global IP protections while violating the IPR of U.S. companies, often trampling on U.S. national security in the process.⁵⁸ Ultimately, U.S. workers have the most to lose from such double-dealing practices.⁵⁹ Indeed, this is a fight for economic survival. The United States must not allow foreign and state-sponsored entities to profit at the expense of U.S. workers and companies.

Box 1: Economic Effects of IP on Non-IP-Intensive Industries

It is not only IP-intensive industries or projects that benefit from IP. Most studies researching the effects of IP separate industries into two categories—IP-intensive and non-IP-intensive—a differentiation that indicates variation in the use of IP, not its total absence within industries. For example, the three Canadian industries with the lowest rates of IP ownership—construction (10.6 percent); mining, quarrying, and oil and gas extraction (9.8 percent); and agriculture, forestry, and fishing and hunting (8.3 percent)—show these non-IP-intensive industries still utilize IP.

Among countless other benefits, trademarks protect brands, trade secrets protect processes and recipes, and patents protect designs and methods. Indeed, industries that one country deems IP-intensive may not be in another. In Argentina, the 20 most-patent-intensive industries include manufacturing, finance, retail, construction, and veterinary activities—and education is among the country’s top copyright-intensive industries.⁶⁰ The metal ore mining industries in Chile and Peru are trademark intensive, and Uruguay’s real estate and construction industries are both trademark and patent intensive.⁶¹

Additionally, licensing agreements between IP owners and manufacturers enable both parties to profit from producing and selling goods—such as posters, greeting cards, toys, dolls, games, apparel, ornaments, décor, etc.—featuring the rightsholder’s IP.⁶² Construction companies that build facilities for IP-intensive businesses also benefit indirectly from IP. The Pharmaceutical Industry Labor-Management Association (PILMA) offers specialized, skilled union labor to build research laboratories and pharmaceutical manufacturing facilities that meet the stringent standards and specifications required by the pharmaceutical industry.⁶³ These are just a few examples of non-IP-intensive industries receiving direct and indirect revenues from IP, proving IP supports jobs and benefits workers across all industries.

Claims 6–9: Dependency Theory at Work

The U.S. Left has increasingly embraced “dependency theory” when it comes to thinking about trade and development. Dependency theory holds that less-developed economies are less developed because of actions by developed nations, controlled by capitalist forces. In this narrative, underdevelopment is not caused by the failure of policy and institutions in developing nations; rather, powerful big business—capitalist forces in the North—works to oppress the South. The fact that some formerly low-income nations, such as Korea, Singapore, Costa Rica, Taiwan, and others, have been able to grow and develop, even though they were subject to the same dependency forces as nations that have not, is ignored. The dependency theory that now informs much of the American Left plays directly into the narrative that IP is part of the constellation of forces working to oppress developing-nation victims.

The U.S. Left has increasingly embraced dependency theory when it comes to thinking about trade and development. Dependency theory holds that less-developed economies are less developed because of actions by developed nations, controlled by capitalist forces.

Claim 6: IP Harms Developing Nations

The “IP only helps big corporations” argument has a twin: IP hurts the masses in developing countries. Much of this argument focuses on trade policy (as addressed later in this report), but the claims behind the argument are that robust IP provisions prevent developing countries from accessing or enabling innovation. According to Stiglitz, “[T]he economic institutions and laws protecting knowledge in today’s advanced economies are increasingly inadequate to govern global economic activity and are poorly suited to meet the needs of developing countries and emerging markets.”⁶⁴

There is some truth to that. One way developed nations deal with their competitive disadvantage against low-wage, low-cost developing nations is to sell them IP. In fact, overall, developing nations run a balance of trade deficit on IP payments. So giving them free IP, akin to canceling all their debt with Northern financial institutions, would help them. But that doesn’t make it right. Perhaps if the developing nations imposed stronger labor and environmental rights and stopped trying to compete solely on low-costs, they might have a stronger argument. Moreover, doing so would weaken living standards in developed nations and lower overall global innovation.

Moreover, it’s not as though IPR do not provide any help to developing nations or that they have no IP that needs protecting. IPR enable scientists in Tanzania to use novel processes to regenerate indigenous plants. IPR contributed to increased crop yields and reduced environmental impact, and led to crops resistant to drought, harmful insects, and diseases.⁶⁵ IPR opened the European market to, and recognized the distinguished qualities of, Cameroon’s Poivre de Penja (Penja peppers).⁶⁶ Because of IP, local innovators in Latin America, Africa, the Middle East, and Asia are able to meet regional health needs.⁶⁷ Because of IPR, artists from South Korea reach new markets across the world.⁶⁸ Yet, despite all this and more, many still decry and seek to limit IPR in the best interest of the global proletariat.

Claim 7: IP Makes It Harder for Developing Nations to Acquire Technology

Related to the claim that IP harms developing nations is the claim that IP makes it harder for nations to get IP. Recent comments from U.S. Trade Representative Katherine Tai reflect this view:

The pandemic has reinforced the longstanding concern about the sufficiency of access to medicines and global inequity in access to medicines. This is not a new concern, but rather one that has persisted since the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) entered into force in 1995.⁶⁹

Again, to some extent, this is true—just as it is true that not giving more foreign aid to these nations also limits their ability to afford medicine. But although many of the problems developing countries face in acquiring certain innovations, such as pharmaceuticals and clean technology, are broadly attributed to IPR, the reality is IP is not the real problem.

Rather, academic research finds strong correlations between IPRs and technology transfer. Lippoldt showed that IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment.⁷⁰ Research has revealed that a country’s level of IP protection considerably affects whether foreign firms will transfer technology into it.⁷¹ That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.⁷² For instance, foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of countries.⁷³ A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IPR reduce computer software direct investment; and a 1990 study by UNCTC found that weak IPR reduce pharmaceutical investment.⁷⁴ And an Institute for International Economics study of World Bank data concluded that weak IPR reduce flows of many types of commercial activity, regardless of nations’ levels of economic development.⁷⁵

Less than 8 percent of the more than 475 medicines WHO deems essential for global basic health care are subject to IPR in low-income countries.

As discussed further in this report concerning the TRIPS waiver on COVID-19 vaccines, the barriers developing countries face in accessing medicines are often directly attributable to inadequate public health infrastructure or cumbersome regulations, not private IP ownership. Such inequalities existed long before the TRIPS Agreement; blaming IP is a misguided notion grasping at the lowest-hanging fruit.

For instance, the U.K.-based think tank Geneva Network analyzed the patent status for medicines on the World Health Organization’s biennial Essential Medicines List (EML), a “list of minimum medicine needs for a basic health-care system.”⁷⁶ Its latest analysis states that:

- as of January 2022, 35 out of the 477 total items (7.3 percent) listed on the 22nd edition of the EML hold patent(s) in at least one middle- or low-income country surveyed;

- 19 percent of lower-income countries surveyed do not have *any* active patents listed for the 35 patented medicines on the 22nd EML; and
- approximately 25 percent of all active EML patents in lower-income countries are subject to a Medicines Patent Pool license, bilateral license, and/or a commitment not to enforce patent rights.⁷⁷

In other words, less than 8 percent of the more than 475 medicines the World Health Organization (WHO) deems essential for global basic health care are subject to IPR in low-income countries, and the rightsholders for one-quarter of those few medicines still subject to patents formally agreed to either 1) work with local or regional partners to provide affordable and adequate supplies or 2) do not enforce their patent rights in those countries. This indicates that IP is not a barrier to acquiring needed pharmaceutical innovations.

Claim 8: IP Limits Innovation in Developing Nations

Some argue that IP limits innovation in developing nations. But IP is a not barrier to enabling innovation. Indeed, several international markets and growing industries provide compelling examples of the importance of a robust IP system.

Nigeria's film industry, commonly dubbed "Nollywood," is known for predominantly low-budget movies released directly to video. It produces the world's second-highest concentration of films after India's Bollywood.⁷⁸ Yet, Nollywood's high-volume and low-budget system means creators do not reap the benefits of their works. They must produce more and more content for less because it is difficult for them to recoup costs, much less profit, from existing works. And the greatest threat to Nollywood is domestic piracy. Counterfeit copies of movies sit in stalls next to legitimate copies on the same day they are released.⁷⁹ As C.C. Nwabachili stated:

Copyright under the law in Nigeria is an area of law that has not yet been fully explored. This is not because the law is not known, but because people are so reluctant to deal with the law and the awareness has not so much been canvassed. Copyright is facing a legion of problems in Nigeria and these problems are causing losses of income to authors, actors, publishers, etc.⁸⁰

Without stronger IP protection, including adequate enforcement agencies and meaningful penalties for copyright pirates, Nollywood's creators will never experience the true value of their work.

On the other hand, Singapore continues to develop as a biomedical innovation hub. In 2000, no biologic drug manufacturing facilities existed in the country, but by 2019, there were around 18.⁸¹ From 2000 to 2019, biomedical manufacturing was Singapore's fastest-growing manufacturing sector, with a compound annual growth rate of 9 percent (compared with a 5 percent average growth rate for the whole of Singapore's manufacturing sector), and it outpaced the overall manufacturing sector at a rate of 7.77 percent versus 0.68 percent. Singapore's biomedical industry now employs five times more researchers per capita than does the United States (128 biomedical researchers per 100,000 residents in Singapore versus 24 in the United States). This industry continues growing in part due to the Singapore IP Strategy 2030—the government's plan for further developing the country's knowledge-based economy—which focuses on building a robust, credible, and trusted IP regime and valuation ecosystem.⁸² Thus,

claiming that IP harms developing countries makes no sense when a lack of IP protection harms Nigeria’s creators while a robust IP system enables Singapore’s innovative industries to grow.

Singapore also proves that when investors know a country’s laws and culture respect IP, they’re more likely to invest in that region. Many countries further utilize this trust to develop international partnerships and grow local industries. New Zealand’s and Australia’s idyllic sceneries naturally entice international filmmakers, so various organizations offer incentives such as grants and tax cuts to further entice IP-intensive industries to their shores.⁸³ International films that “demonstrate significant economic benefits to” the country, much like *Black Panther: Wakanda Forever* did in the U.S. state of Georgia, benefit from these incentives. Meanwhile, productions promoting indigenous cultures receive greater benefits, incentivizing investment in domestic creators.⁸⁴ Iceland, Ireland, Malaysia, Malta, and South Africa are a few additional countries bolstering their local economies and promoting local cultures via film industry incentives.⁸⁵

Likewise, Singaporean jewelers utilize IP to bring Peranakan—a community combining Chinese, Malay, and European influences—products to 23 countries worldwide.⁸⁶ Among the company’s 20 employees are Peranakan masters. Similarly, Cheekbone Beauty, Canada’s first indigenous cosmetics company, relies on IP to protect its brand and enable it to educate and connect indigenous and nonindigenous communities.⁸⁷ Geographical indicators (GIs)—IP protection related to trademarks—enable global market access for consumables and products only grown or made in a particular region. Champagne, Kentucky Bourbon, Darjeeling tea, Basmati rice, Vidalia onions, Havana tobacco, and Geneva watches are some of the more well-known products protected by GIs. Some notable GI approvals in 2022 include Penja peppers from Cameroon, Mendoza olive oil from Argentina, and four types of Greek olive oil.⁸⁸

Another form of IP protection called “traditional knowledge” offers indigenous communities a means to protect their traditional remedies, art, and music from misappropriation or exploitation. Misappropriating or exploiting traditional knowledge focuses on, for example, whether specific “genuine” African tribal art was made in Africa or China, or whether the patent for an anti-obesity drug is based on a novel improvement or merely a copy of a traditional remedy. India’s database of traditional medicine, Panama’s registration system for traditional cultural expressions, New Zealand’s Te Waka Toi’s trademarks for authentic indigenous art, and the protection of folklore via the Pacific Regional Framework for the Protection of Traditional Knowledge and Expressions of Culture all offer certain protections that encourage indigenous entrepreneurs to share their culture with the world through tradition-based products and services, while providing greater quality control over the use and sale of those cultural works.

IP not only enables creation and innovation, especially in developing markets, but also provides opportunities for indigenous groups to share their cultures with the world.

Claim 9: Requiring IP in Trade Agreements Is Wrong

A la dependency theory, proponents of the “IP harms the global proletariat” argument assert that IP provisions in trade agreements are solely a means for the United States to bully developing nations into a one-size-fits-all IP regime that only benefits the large corporations of developed nations.⁸⁹ In other words, if the United States wants to help the developing world, it should not require such countries to enforce or adopt more-robust IP standards.

Indeed, in an article decrying the general inclusion of IP in trade agreements, EFF has asserted that IP provisions in trade agreements force countries to adopt verbatim the IP laws of the heavyweight at the table.⁹⁰ This argument completely misses the point: IP provisions in trade agreements set a minimum standard to provide certainties to all businesses and investors, enable technology transfer, and facilitate global market access. Ensuring the domestic laws of signatory countries maintain a level playing field through minimum standards is called “harmonization.” Indeed, countless trade agreements require harmonization of human rights laws, with many countries maintaining stricter domestic provisions than the agreements demand.⁹¹

To this point, EFF has further stated, “There are many good reasons why countries may want to fine-tune their IP regimes to suit their own cultural and economic circumstances, and in many areas the TRIPS agreement allows this.”⁹² Thus, in true redistributionist fashion, anti-IP advocates only accept those minimum standards drafted by the party least likely to respect IP. Certainly, the TRIPS Agreement harmonizes laws to enable technology transfer and improve global market access. However, while certain countries were immediately held to high standards 1 year after the agreement entered into force, others continue to benefit from the agreement more than 25 years on without implementing all (or any) of the necessary provisions.⁹³ Despite examples such as Ireland, Singapore, and South Korea—nations that transitioned or are transitioning to predominantly knowledge-based economies—and innovation successes in Kenya and South Africa, many developing nations maintain an aversion to IP and hinder their own growth by deterring international investment in local jobs and industries. Thus, countries refusing or delaying the adoption of the TRIPS minimum standards (let alone exceeding them) create their own barriers to success, not IP.

When policy decisions are not rooted in evidence, it is the innovators, industries, workers, and consumers that pay the price.

Yet, cries that IP provisions in trade policy hurt the masses in developing countries persist. Indeed, despite the rise in digitization throughout the global economy, anti-IP proponents repeatedly assert that international trade negotiations are not an appropriate forum for IP.⁹⁴ For them, trade negotiations would be tilted deeply in the direction of the victimized developing nations.

THE WEAKENING OF IP IN U.S. ECONOMIC TRADECRAFT

In part because of the sympathies toward a redistributionist domestic and international policy, in part informed by dependency theory, the Biden administration has done little to advance IP in trade policy—and in several cases, has acted to weaken it. Indeed, the administration’s current trade negotiations do not include any substantive IP discussions or provisions. With this, the United States signals to the world its intent to abdicate IP policy leadership.

Current Trade Negotiations Missing IP Provisions

The Biden administration appears unwilling to negotiate IP terms in trade agreements. Its flagship trade initiative, the Indo-Pacific Economic Framework (IPEF) agreement, does not include chapters on IP or market access.⁹⁵ The same is true for the U.S.-Kenya Strategic Trade and Investment Partnership and the U.S.-Taiwan Initiative on 21st Century Trade.⁹⁶ Although the U.S.-Taiwan Initiative’s agenda includes topics related to IP, such as digital trade and

addressing distortive practices of state-owned enterprises, nothing indicates negotiations will include direct discussions of IP.

State-sponsored espionage hides in countries where laws do not deter such theft; unified IP provisions in trade agreements leave thieves with few options.

This is a problem for both large and small markets seeking investors to grow their knowledge-based economies. Since IP enables innovators worldwide and many of those developing countries that adopt and enforce robust IPR to grow and thrive, it stands to reason that including IP provisions in trade agreements helps developing countries. U.S. policymakers should lead by example, encouraging global partners to fully institute TRIPS Agreement provisions, actively connecting potential international partners with stakeholders, connecting U.S.-based financiers and innovators with foreign firms, and further investing in innovation hubs. Most importantly, policymakers must engage in and develop global best practices for IP policies, harmonizing the global market through trade negotiations.

Supporting the TRIPS Waiver for COVID-19 Vaccines

The mark of leadership is knowing when to speak, when to stay silent, and when to lead by example. Currently, the United States is not exemplifying this trait when it comes to IPR. International calls to waive IP only seem to apply to the United States and a handful of its allies—and, so far, the Biden administration’s actions align with this redistribution technique at the expense of American innovation, industries, and the economy.

Endorsing what would be tantamount to the forced divulsion of American IP via the TRIPS waiver for COVID-19 vaccines is inconsistent, contradictory, and harmful to the Biden administration’s other efforts to support U.S. competitiveness and innovation. It opens the door for subsequent calls to waive American IP “for the good of humanity.” Such redistribution-focused phrases sound benevolent and reasonable but are often applied too broadly and used to cover unsavory ulterior motives.

Endorsing the forced divulsion of American IP via the TRIPS waiver for COVID-19 vaccines is inconsistent, contradictory, and harmful to the Biden administration’s other efforts to support U.S. competitiveness and innovation.

In October 2020, India and South Africa petitioned the World Trade Organization (WTO) TRIPS Council, requesting a waiver to suspend all IPR associated with COVID-19 technologies and innovations, purportedly to increase access to these products. However, as the petition itself acknowledges, “To date, there is no vaccine or medicine to effectively prevent or treat COVID-19.”⁹⁷ In other words, despite the fact that no medicines or therapeutics yet existed to combat the COVID-19 pandemic, somehow, IP was a problem. Indeed, as the Information Technology and Innovation Foundation (ITIF) has argued, if IP had in any way been a “problem” at that point in time, it was simply that the global community didn’t yet know how to invent the IP necessary to combat the COVID-19 challenge.⁹⁸

Ultimately, IP played a foundational role in promoting collaboration, supporting the development of innovative COVID-19 vaccines and therapeutics, and subsequently facilitating the voluntary licensing of that IP to scale up global manufacturing.⁹⁹

Yet, dismayingly, in May 2021, the Biden administration emerged in favor of the TRIPS waiver for COVID-19 vaccines, causing the remaining countries resisting the waiver, notably the United Kingdom, to drop their opposition.¹⁰⁰ In June 2022, WTO members adopted a waiver explicitly for COVID-19 vaccines.¹⁰¹ The final text included a mandate for WTO ministers to reconvene no later than six months after that decision to determine whether to expand the waiver to include therapeutics and diagnostics. In December 2022, the ministers agreed to postpone this latter decision, allowing member countries to gather more data.¹⁰²

Thus, policymakers punished those whose risky R&D investments led to effective vaccines. This represents biting the hand that feeds you and sends a dangerous message to all industries. If governments can abrogate IP protections on technologies needed to fight a pandemic, then they can do the same for those technologies needed to feed the hungry, protect our environment, or develop renewable energy sources.

And what did the waiver accomplish other than granting the world access to American-invented IP? Manufacturers already offered the vaccine to governments at cost and donated doses to initiatives such as COVAX. IP owners already identified and entered into voluntary licensing agreements (VLAs) with local facilities capable of retrofitting and adequately manufacturing vaccines. The legal certainty that IPR confer has proven crucial in facilitating the dissemination of the know-how and technology that partners need to manufacture complex COVID-19 vaccines and therapeutics at the production standards required to do so safely and reliably. Indeed, nearly 300 vaccine partnerships and collaborations have been established among manufacturers worldwide, 229 of which have involved tech transfer and know-how sharing. Likewise, today, more than 140 collaborations for the production and distribution of COVID therapeutics are in place, over 92 percent of which entail some form of technology transfer.¹⁰³ Gilead alone has signed nine VLAs with generic manufacturers for remdesivir, covering 127 countries. Likewise, Pfizer's 38 VLAs cover 95 countries, and Merck's 31 VLAs cover 105 countries.

Once the know-how to make safe and effective COVID-19 vaccines was shared and the global community could manufacture them at scale, there was a global surplus of vaccines that forced India and South Africa to stop their respective vaccine production efforts months before the final waiver decision. To wit, some manufacturers could not sell their product: South Africa's Aspen Pharmacare did not receive a single order for its version of Johnson & Johnson's vaccine.¹⁰⁴ With 200 million unused doses, AstraZeneca's COVID-19 vaccine partner, the Serum Institute, halted production in April 2022. As the Serum Institute's CEO Adar Poonawalla noted at the time, "I have even offered to give free donations to whoever wanted to take it."¹⁰⁵ Ultimately, one of the chief advocates for the waiver, Indian Minister of Commerce and Industry Shri Piyush Goyal, unwittingly admitted to the fundamental unnecessary of the waiver, noting prior to the June 2022 WTO TRIPS decision that "vaccines have already lost relevance."¹⁰⁶ There simply was (and remains) no compelling reason for a COVID-19 vaccine, diagnostics, or therapeutics waivers.

Furthermore, as of March 30, 2023, not a single country had notified the WTO of any intent to avail itself of the waiver's provisions, reiterating the futility of the agreement.¹⁰⁷ Likewise,

waiving IP did nothing to solve the real problems developing countries faced in the fight against COVID-19: vaccine hesitancy, tariffs, trade barriers, inadequate infrastructure, and domestic policies.¹⁰⁸

This is not to say that there are no access barriers for these products that governments should help address; however—as is often the case with pharmaceuticals—none of them relate to IP. Regulatory delays, logistics, and distribution infrastructure pose some of the greatest challenges for citizens of developing countries attempting to access vaccines, therapeutics, and diagnostics. In emergencies, certain regulatory procedures cause needless delays. Governments should analyze and address their countries' approval delays, additional regulatory and testing requirements unrelated to public health and safety, regulatory barriers preventing the adoption of proven methods, authorization restrictions, import or export restrictions, and manufacturing restrictions, identifying which regulatory delays hinder a rapid health care response. Governments should also work with manufacturers to identify potential collaborations, facilitate voluntary licensing and technology transfer agreements, fund adequate and appropriate facilities, develop skilled labor, and identify potential supply chain bottlenecks and solutions. Furthermore, governments and nongovernmental organizations (NGOs) should invest in appropriate distribution infrastructure, such as portable refrigeration units, pop-up clinics in remote areas, adequate staffing of health care professionals, and a national system for determining and disseminating appropriate medical supplies. These are meaningful solutions to the real pharmaceutical access barriers plaguing developing countries.

As of March 30, 2023, not a single country had notified the WTO of any intent to avail itself of the waiver's provisions, reiterating the futility of the agreement.

Within the vein of redistribution and separate standards, the notion and use of compulsory licensing (a form of forced technology transfer) and localization requirements (various forms of mandating that businesses operate facilities within the domestic market) continue to grow. Brazil recently sought to codify compulsory licensing within its legislation, and while the Bolsonaro government vetoed many of the most onerous provisions, the new Lula government will likely try to resurrect them.¹⁰⁹ Indonesia requires local manufacturing of patented medicines within three years, or else the innovators risk compulsory licensing or patent invalidation.¹¹⁰ In many sectors, China effectively mandated technology transfer as a condition for doing business in the country (i.e., trading technology for market access).¹¹¹ Such policies require U.S. innovators to unilaterally relinquish IP as a heavy-handed prerequisite for market access, contrary to the voluntary free flow of information the TRIPS agreement intended. Redistributing American IP to foreign shores and competitors threatens American jobs and industries. Meanwhile, including IP provisions in trade agreements protects them.

RECOMMENDATIONS TO RE-ENGAGE INTERNATIONALLY

The Biden administration could and should reset U.S. global IP policy leadership. There are four key areas where policymakers can re-engage: opposing IP waiver proposals, uniting against the CCP's IP theft, including IP in trade agreements, and leading discussions on IP policies surrounding emerging technologies.

Oppose IP Waiver Proposals

Many who opposed the TRIPS waiver for COVID-19 vaccines rightly feared the decision could snowball into a broader assault on IP. And indeed, this has come to pass. First, advocates expanded the push for IP waivers to COVID-19 therapeutics and diagnostics. Then they started advocating for IP waivers for other types of emerging advanced technologies. For instance, when Ngozi Okonjo-Iweala, director general of the WTO, was asked in February 2023 whether she would “support an intellectual property waiver for climate technologies in order to tackle the climate crisis,” she answered that “on the green tech, I could not agree more.”¹¹² Likewise, in June 2022, the United Nations secretary general called IPR on renewable energy technologies an “obstacle” to knowledge sharing and technology transfer.¹¹³

The Biden administration should forcefully reject and rebut this narrative that IPR constitute a barrier to access to innovative biopharmaceuticals, clean energy technologies, or other advanced technologies for developing countries. And a great way for it to do so would be to come out in opposition of the expansion of an IPR waiver for COVID-19 diagnostics and therapeutics.

As noted, in December 2022, WTO members postponed a decision on the expansion of the waiver so countries could gather more data. In the United States, this took the form of the United States Trade Representative’s office asking the U.S. International Trade Commission (ITC) to undertake an investigation into the impact of IPR on the production, supply, and availability of diagnostics and therapeutics used to detect and treat COVID-19.¹¹⁴ ITC is due to report its findings on or before October 17, 2023, and then it will be back in the Biden administration’s hands to make a determination on its position regarding the proposed waiver expansion.

Just as there was no real justification for the initial waiver for COVID-19 vaccines, there is no further reason for an extended TRIPS waiver that includes diagnostics and therapeutics.

But as ITIF has written, just as there was no serious justification for the initial waiver for COVID-19 vaccines, there is likewise no further reason for an extended TRIPS waiver that includes diagnostics and therapeutics. Once again, supply exceeds demand for COVID-19 treatments, and voluntary licensing turbocharged global production. In fact, of the more than 35 million doses of COVID-19 treatments purchased by governments and NGOs for low- and middle-income countries, only 10 million had been administered as of September 2022.¹¹⁵

As of October 2022, 36 COVID-19 treatments were authorized for use somewhere in the world with more than 850 more candidates in clinical development, and at least another 800 in preclinical development.¹¹⁶ There are currently more than 130 licensing agreements in place between pharmaceutical companies developing COVID-19 therapeutics and generic manufacturers, including several royalty-free agreements. Also, there are over 190 production sites for COVID-19 treatments spread across more than 30 countries, including Brazil, India, Indonesia, Kenya, Singapore, and South Africa.

Proceeding with an expanded TRIPS waiver for COVID-19 therapeutics and diagnostics is not only unnecessary and inappropriate, but it is also harmful to future innovation. From alternate medicinal uses to generating initial capital and further R&D incentives, waiving IP limits investments and the potential for future pharmaceutical developments, eliminates a vital incentive for innovators, and provides foreign competitors—especially companies supported by

the CCP—free access to U.S. (and allied nations’) innovations. Innovators invest revenues and capital generated via IP into future (costly) R&D efforts, including new treatments, cures for rare diseases, and alternative indications. Waiving IP jeopardizes this system, harms innovation, and disincentivizes innovators. Without IP, those risky, disruptive, and breakthrough innovations—including the start-up Moderna’s mRNA vaccine—would never reach patients. It is not that innovators do not want to “do the right thing;” they literally cannot afford to continue innovating at current levels without adequate resources.

The problem with this view is that waiving IP is neither necessary nor appropriate to enabling technology transfer, whether concerning clean-energy innovations or COVID-19 vaccines.¹¹⁷ Innovation is the only long-term solution to climate challenges, and robust IPR enable, not impede, efforts to develop innovative clean-energy technologies. IP protection and licensing is the best way to enable rapid, skilled, and quality technology transfer. The National Aeronautics and Space Administration (NASA) offers an excellent example of this.¹¹⁸

As the UN secretary general seeks to fast-track innovation and development for battery storage by combining governments, tech companies, manufacturers, and financiers, U.S. policymakers should refrain from giving U.S. IP away in favor of showing how developing nations can (and should) enable innovation and technology transfer through IP licensing.

The U.S. government must stand up against IP theft, not enable it. Policies forcing U.S. companies to give away critical IP they invested billions in creating is simply poor policymaking, particularly when it lends credence to the notion that IP harms developing countries.

Unite Against China’s IP Theft

Unfortunately, the inconsistent messages from U.S. policymakers to the world do not stop with IP waivers. On the one hand, a slate of bipartisan legislative proposals seeks to fight back against the CCP’s state-sponsored IP theft.

Throughout the height of the pandemic in 2021, China exported the most COVID-19 vaccines.¹¹⁹ Despite the life-and-death stakes, the CCP predominantly sold these vaccines with strings attached, such as diplomatic gestures, political agreements, or power plays over international disputes.¹²⁰ During negotiations for the wording of the COVID-19 vaccine waiver, China strongly opposed text excluding developing member countries which exported more than 10 percent of world exports of COVID-19 vaccine. Although the CCP agreed not to avail itself of the waiver’s provisions if the text were removed, it never agreed not to avail itself of any expanded TRIPS waiver. Without safeguards such as exclusionary text, the CCP will avail itself of U.S. IP for therapeutics and diagnostics, despite being the global leader for patent filings associated with COVID-19 therapeutics (totaling 887 as of October 2022, followed by the United States at 292).

This is cause for alarm. The CCP availing itself of U.S. COVID-19 IP threatens national security, jobs, and innovation leadership, as waiving IP for COVID-19 innovation equates to forced technology transfer of government and privately funded technologies.¹²¹ More than a decade before the pandemic began, the Defense Advanced Research Projects Agency (DARPA) researched ways to rapidly cure new pathogens soldiers might encounter in the field. This research, alongside decades of mRNA research from private-sector pioneers, helped pave the way for COVID-19 mRNA vaccines. Thus, the TRIPS waivers provide potential national security secrets free of charge and allow the CCP—whose documented mercantilist policies threaten

global innovation and whose Made in China 2025 strategy explicitly identifies dominating the biotechnology field as a goal—to profit from American innovators’ work and significant investments in time, money, and resources.¹²²

IP skeptics and opponents face the quandary of opposing strong IP in U.S. trade policy while also wanting to target unfair CCP trade practices, especially IP theft, that culminate in U.S. job losses. The CCP’s forced technology transfer practices continue dominating U.S.-China trade disputes, with the United States repeatedly condemning the CCP’s de facto technology transfer mandates.¹²³ Acting against Chinese IP theft is a rare area of bipartisan support in U.S. trade policy. Yet, the central issue it seeks to address—the impact of IP theft on U.S. firms and jobs—is exactly what strong IP in U.S. trade agreements achieves more broadly. It’s just that, in the context of China, it involves an active and concerted government effort to, directly and indirectly, support efforts to steal U.S. IP.

Thanks to the TRIPS waiver, the CCP now potentially enjoys unfettered and free access to IP generated by American investments and ingenuity. Such forced technology transfer certainly aligns more with the CCP’s values than traditional American ones. By adopting the anti-IP narrative, U.S. policymakers signal to the CCP, and others with starkly different values, that American IP is ripe for the taking. Be it entrepreneurs, start-ups, or conglomerates, all American innovators are subject to such forced technology transfer practices, and this redistribution harms individual innovators and SMEs most of all.

The Biden administration should actively promote legislation, such as the SECRETs Act supported by Senators John Cornyn (R-TX), Chris Coons (D-DE), and Todd Young (R-IN).¹²⁴ Likewise, ITIF has proposed reforms to ITC’s Section 337 to better fight unfair Chinese practice, including IP theft.¹²⁵

Engage in Trade Agreements and Include IP Provisions in Them

Not only has the Biden administration paused new trade agreements, but it has also neglected IP provisions in less-formal trade negotiations. This practice needs to reverse course. The United States and its allies can present a united front against the CCP’s IP theft by harmonizing their IP laws that state-sponsored espionage hides in countries where laws do not deter such theft; unified IP provisions in trade agreements leave thieves with few options. If U.S. policymakers intend for America to retain its global innovation leadership, they should provide innovators and investors with protection mechanisms and market security by including robust IP in trade agreements.

Lead Discussions on IP Protections for Emerging Technologies

Emerging technologies remain at the forefront of most domestic and international policy discussions, and IP policy is no exception. As technology continues to develop and change, best practices for IP protection must evolve and adapt to further enable continued innovation. If U.S. policymakers intend to build a framework supporting American innovation leadership, they should lead all relevant international policy discussions, including on IP.¹²⁶

By comparison, the U.K. Intellectual Property Office (UKIPO) repeatedly conducts consultations concerning the intersection of IP and emerging technologies, most recently focusing on artificial intelligence (AI).¹²⁷ However, jurisdictional borders do not limit digital technologies such as AI, artificial reality (AR), and virtual reality (VR), and blockchain technologies such as non-fungible

tokens (NFTs). American policymakers should work with like-minded allies to establish IP best practices for AI, AR/VR, NFTs, and other emerging technologies.

Artificial Intelligence

Currently, AI IP debates generally address inventorship, data mining, and AI-generated works. Each of these discussions encompasses multiple complex elements; however, the core rests upon the fact AI systems are human-operated tools.

In 2018, Dr. Stephen Thaler, the inventor of the Device for the Autonomous Bootstrapping of Unified Sentience (DABUS) AI system, kicked off what has become a global debate over AI inventorship and creatorship.¹²⁸ Courts, IP offices, and legislators worldwide continue debating whether an AI system can or should be listed as an inventor or creator on a patent or copyright application.

Six jurisdictions rightfully denied Thaler patents and copyrights based on legal interpretations of rights reserved for natural persons. Only natural persons can own property, assign rights, and be held accountable in legal proceedings. AI is not a natural person by any stretch of the imagination and should not be treated as such.

Redistributing American IP to foreign shores and competitors threatens American jobs and industries.

Instead, the human conceiving of the innovation or creation (i.e., the one operating the AI system) should be named as the inventor or creator on patent and copyright applications. This part of the discussion raises questions as to the amount of human input required to be listed as an inventor or creator. But even the world's first AI-generated magazine cover utilized aesthetic judgments, edits, and parameters set by human creators.¹²⁹ AI cannot conceive of a project entirely on its own. Even if the ultimate outcome was not foreseen at the start, the innovation was brought about by a human setting the wheels in motion.¹³⁰

Policymakers should make the human inventorship or creatorship with “minimal input” clear in the laws of their respective jurisdictions to create certainty about the role of AI systems in supporting (not cognitively initiating) innovation. They should also clarify who benefits from the end results—namely, who owns the patents and copyrights.

The Metaverse and AR/VR

An emerging technology crossing global borders is AR/VR. Although society does not operate in a wholly online world such as in *Ready Player One*, the adoption of AR/VR is growing. From *Pokémon Go* to Meta's *Horizon Worlds*, society looks for new ways to interact via immersive technologies. The training and educational uses for these technologies are expanding as well.¹³¹ As interactions, harms, infringement, and more increasingly occur in digital realms irrespective of physical borders, policymakers should develop an international framework.

U.S. policymakers should set the example by updating the Digital Millennium Copyright Act (DMCA), clarifying, or expanding, the country's best practices; adequately defining “functionality” and “secondary meaning” with respect to trade dress and design patent rights in a manner that offers digital goods via immersive technologies the same protections as their physical counterparts; and ensuring IP protection within the realm of AR is adequate and appropriate.

One significant concern for AR/VR is proving infringement in a temporary setting. Obviously, brands enjoy trademark protection, and creative works enjoy copyright protection in the real world. But what if someone temporarily overlays the arches of McDonald's on the side of the Gateway Arch? Or what if they embed the words or an audio clip of Martin Luther King, Jr.'s "I Have a Dream" speech when one walks the steps of the Lincoln Memorial? What if poets virtually overlay their poems on the side of a public building, and someone else uses their creation elsewhere? What if the digital twin of K-Mart shows Coca-Cola bottles sitting on the shelves?

When the use or publication is fleeting, it might be difficult to prove infringement or harm to the IP owner. The infringement that temporarily exists within a virtual world arguably does little harm to rightsholders. However, temporary infringement is nonetheless infringement and potentially harmful to rightsholders. Additionally, content that would normally be considered fleeting can become permanent if any user decides to record the virtual interaction and share the video or screenshot on another platform. Similarly, if the infringer is in a country with lax IP laws, the rightsholder may have no remedy options.¹³² Likewise, if the infringer hides behind virtual walls, the rightsholder may have no recourse. Harmonizing international laws can help identify and hold infringers accountable wherever they may be.

Unlike today's social media, wherein users typically share content publicly and indefinitely, users in social extended reality (XR) platforms may share content semipublicly and fleetingly. For example, users in the metaverse may create "movie worlds," virtual spaces in which users watch embedded video players illegally streaming copyrighted films in real time.¹³³ These virtual spaces can be semipublic—publicly listed but with restrictions on whom can access them—making them harder for rightsholders to monitor. Although some countries provide means to stop such real-time infringement, many do not. Harmonizing international laws could help.

As immersive technologies progress to include stores, new products, complete bodies, and more, IP rightsholders may also face new and increasing challenges in navigating between physical and digital goods.¹³⁴ The most significant concern, however, is for innovators dealing entirely in immersive technology-based digital goods. Those creators relying on trade-dress and design patent rights might have difficulty acquiring and enforcing those rights in the virtual world.¹³⁵

Trade dress is a form of trademark protection covering the image and overall appearance of a product. This protection can last perpetually for as long as the trade dress is commercially used. This form of IP "must serve as a source identifier, be distinctive in the marketplace, be used in commerce, and must be primarily nonfunctional."¹³⁶ Unfortunately, it is also harder to acquire trade dress protection and easier to invalidate it for being functional. Rightsholders must prove a concept called "secondary meaning" to assert and retain trade dress protection. Proving secondary meaning requires rightsholders to show "that consumers have become conditioned to recognize the product configuration elements and associate them with the product source as a result of duration or intensity of product advertising."¹³⁷

U.S. policymakers need to act quickly to provide guidance, ensuring goods and services in the digital world receive the same protection as in the physical world.

Design patents are like trade dress, covering "visual, nonfunctional characteristics embodied in, or applied to, an article of manufacture ... [relating] to the configuration or shape of an article,

the surface ornamentation applied to an article, or to a combination of the two.”¹³⁸ Like other patents, design patents must be new and nonobvious. They must also be ornamental and “an article of manufacture.”¹³⁹ The focus here is on whether there are multiple ways to achieve the product's function; if so, the design is nonfunctional and potentially protectable by design patents. For example, the shape of a soda bottle is nonfunctional because a different design shape could still contain the liquid. Unlike trade dress, design patents do not require the rightsholder to use or practice the patent in commerce; and judges do not consider consumers or market impact in determining design patent infringement cases.

But what differentiates “functionality” under trade dress law for digital goods? Can—and if so, how does—a digital product acquire secondary meaning? Given that immersive technologies are still in their infancy, the number of potential consumers and the duration or intensity of product advertising is significantly limited. Proving secondary meaning requires these elements, so how does an early innovator adequately prove trade dress infringement against an early infringer? Will courts interpret “use in commerce” differently with respect to immersive technologies? What if the infringer usurps a foreign market that doesn’t recognize design patents or trade dress protection? And can those producing digital goods prevail against trade dress or design patent infringement by claiming transformative use—meaning the purpose or character of the digital good is fundamentally different from the original use—under copyright law?

Another concern is the licensing, transference, and ownership of IPR connected to digital goods related to physical goods. Assume a fashion designer creates a virtual clothing line, and their designs are protected by trade dress. The virtual creator enters into a licensing agreement with a physical manufacturer to produce, advertise, and sell physical versions of the virtual designs. Although the contract does not mention exclusivity, the parties agree to operate independently in their respective environments. Suppose the virtual creator does not advertise the physical products in its immersive environment. Does the licensee that manufactures physical versions of the product have the right to advertise the physical goods in that immersive environment to capitalize on the existing market?

Does it matter whether these digital goods are high or low-resolution, subject to variations based on screen settings? *Louboutin* holds IPR for heels with dark red soles.¹⁴⁰ If a new avatar clothing option sells heels with dark pink soles, could a court deem the digital product as infringing, or could the United States Patent and Trademark Office (USPTO) deny the creator’s trade dress application for potentially causing confusion with an existing mark? Even though magazine advertisements might be subject to printer variations, a physical good is still attached to the advertisement that should be submitted to the court or USPTO for evidence in infringement or invalidation cases. With purely digital goods, which resolution image is the most appropriate evidence?

Courts and policymakers should be forward thinking in their decisions. First-in-time infringers should not be able to usurp rights just because an IP owner takes time to determine the marketability or a strategy surrounding cutting-edge technological developments. Likewise, just because potential infringers are not currently monetizing the digital aspect in question does not mean they will refrain from doing so once the market, technology, and demand progress. Similarly, how should policymakers handle new combinations of physical and digital goods?¹⁴¹

What if a Chinese company operating through a subsidiary in Thailand infringes on a U.S. creator's IP in the metaverse? What recourse exists?

U.S. policymakers must work with like-minded allies to develop guidelines and trade agreements that provide best practices for protecting creators across both the virtual and real worlds. There's much regarding IPR to be clarified in these domains.

Box 2: Blockchain Technologies and Virtual Goods

Policymakers have new opportunities to establish innovation-friendly norms and best practices for IP issues relating to blockchain technologies and virtual goods.

IP protection should extend equally to virtual goods. Virtual clothing, digital media, avatar designs, NFTs, and other virtual goods are all the works of creators and innovators and should be protected by IP.¹⁴² However, to what extent do IP protections apply, and in what form (i.e., copyright, trademark, etc.)? What is the appropriate jurisdiction for violations within a virtual world? And how does one determine and prevent virtual misappropriation and counterfeits?

NFTs are digital certificates of ownership for either physical or digital assets. Each NFT is unique and stored on a blockchain, and can use programmable “smart contracts” to automatically execute when certain conditions are met.¹⁴³ Companies such as Nike, Dolce & Gabbana, Tiffany & Co., and *Time* magazine have sold NFTs to create a new source of revenue.¹⁴⁴ Many collectors and consumers spend thousands of dollars on NFTs of sneakers, tattoo designs, artworks, virtual real estate, characters, and more.¹⁴⁵ Tattoo artists typically paid by the hour now earn royalties on the sale—and potentially resale—of NFTs of their work.¹⁴⁶ Architects create and sell digital dream homes overlooking Mars, the Caribbean Sea, the Eiffel Tower, or Mount Fuji.¹⁴⁷

Alongside these possibilities, NFTs pose several interesting questions related to IP protection, particularly with respect to infringement, theft, and counterfeits. A phishing scam cost creator Seth Green an NFT featuring a character set to star in a show Green was producing.¹⁴⁸ Since the initial purchase agreement stated all rights transferred with the NFT, Green potentially lost all IPR associated with the character. This theft could have effectively ended Green's significant investments and work in the new show; however, he was able to repurchase the NFT for 13 times its original amount.

Green is not alone. Yuga Labs, the company that developed Green's NFT, instituted a trademark infringement case against Ryder Ripps and Jeremy Cahen for selling essentially identical NFTs on the same marketplaces.¹⁴⁹ Similarly, two creators not affiliated with Hermès created NFTs using the company's iconic Birkin brand.¹⁵⁰

According to a Federal Trade Commission (FTC) report, scams related to crypto technologies (including NFTs) cost consumers upwards of \$1 billion since 2021.¹⁵¹ Likewise, musicians and choreographers sued online gaming platforms Roblox and Epic Games (owner of *Fortnite*) for infringing content on their sites.¹⁵² Nike also initiated a trademark infringement lawsuit against StockX, a sneaker resale marketplace, for featuring Nike's brand on NFTs as proof of ownership over the company's physical stock.¹⁵³ This suit raises questions about the licensing, transference, and ownership of IPR connected to digital goods representing ownership of physical goods.

Maintaining control over physical counterfeits is difficult enough, and some slip through the cracks of even the best enforcement regimes. Controlling IP-infringing goods in the fast-moving digital world is more difficult. And as the market connection between digital and physical goods

becomes increasingly entangled, rightsholders and consumers need greater clarity surrounding their respective rights and potential recourse. U.S. policymakers and their like-minded allies should provide guidance to ensure goods and services in the digital world receive the same protection as in the physical world.

RECOMMENDATIONS TO IMPROVE DOMESTICALLY

One of the most meaningful ways U.S. policymakers can demonstrate their commitment to robust IP protection to the international community is by improving America's domestic IP landscape. Four ways policymakers can achieve this are adopting website blocking and related legislation, harmonizing U.S. royalty rights with European neighboring and *droit de suite* rights, improving public engagement and IP education, and stopping legislation to weaken IPR, especially related to Bayh-Dole. U.S. policymakers must do what is best for American economic growth, which includes implementing U.S. allies' good, proven practices and ignoring bad ones.

Website Blocking

In the battle between legal and pirated content, the U.S. status quo still clearly favors piracy. This is despite the rise of easily accessible legal digital content. One proven practice in response is website blocking, which allows rightsholders to get Internet service providers (ISPs) to block access to illegal content sites. Many nations, including Europe ones, Australia, India, Indonesia, Israel, Singapore, and the United Kingdom, have adopted successful and effective website-blocking laws. It's past time for the United States to adopt this best practice.

It's still far too easy to access pirated content in the United States. As ITIF detailed in a January 2022 report, a growing body of research proves the intuitive basis of website blocking: Given the growing number of legitimate services, people will shift to these legal sources if governments and stakeholders block enough piracy sites.¹⁵⁴ As one study points out, online piracy is like the mythological Hydra: Effective website blocking must cut off every head by affecting a broad range of major piracy sites.¹⁵⁵ Blocking just one site is ineffective; however, research from the United Kingdom and elsewhere around the world proves that blocking access to a large group of prominent piracy websites on an ongoing basis shifts many people from illegal to legal content services.¹⁵⁶

Since the SOPA/PIPA debate, policymakers worldwide have realized that, to fight digital piracy, website blocking is an effective tool that does not “break the Internet.”

In 2011, U.S. legislators introduced the Stop Online Piracy Act (SOPA) and Protect IP Act (PIPA), which would have allowed website blocking of piracy sites.¹⁵⁷ Following a series of protests led by anti-IP organizations seeking the “freedom to steal,” SOPA and PIPA died in January 2012.¹⁵⁸ Yet, despite the doomsday claims that such legislation is tantamount to censorship, would not be effective, and would “break the Internet,” dozens of countries, including Australia, Europe, India, Indonesia, Israel, Singapore, and the United Kingdom, have demonstrated that website blocking is a fair, effective, and proportionate tool to target major piracy sites without undermining human rights, free speech, or net neutrality.¹⁵⁹ Thirty-three countries allow rightsholders to use website blocking for copyright enforcement. Not only that, but of these, 20 countries also allow dynamic blocking injunctions (to block the proxy and mirror

sites piracy operators shift to after the primary site is blocked), and 7 allow for live blocking injunctions (to block illegal streams of live events).¹⁶⁰ This shows that since the SOPA/PIPA debate, policymakers worldwide realize that, to fight digital piracy, website blocking is an effective tool that does not in any way “break the Internet.”

Royalty Rights

Royalty rights are another area where U.S. policymakers could adopt the proven policies of like-minded allies. Despite leading the charge to extend copyright protection throughout the latter half of the 20th century, the United States has yet to adopt certain so-called “neighboring rights” (royalty rights paid to artists or sound recording owners) for sound recordings played on terrestrial radio.¹⁶¹ Congress introduced legislative proposals addressing each of these rights—the American Music Fairness Act (AMFA) and the American Royalties Too (ART) Act—but neither has passed (yet). Most music is directly associated with the artist performing the work, yet, under the current U.S. royalty system, terrestrial broadcast stations via AM/FM radio do not compensate these same musicians. This means the traditional broadcast industry, which relies on sound recordings for most of its content, does not compensate those who make the sound recordings. The United States is currently one of only four countries without neighboring rights for terrestrial broadcasts, the others being China, Iran, and North Korea. (That’s almost always bad company for the United States.)

National or regional Collective Management Organizations (CMOs) overseeing equivalent royalties engage in bilateral agreements and compensate artists around the world for their work. Under reciprocity rules, not having neighboring rights for terrestrial radio means creators, especially American creators, are forced to leave money on the table.

In June 2021, 33 cosponsors introduced the AMFA in the House of Representatives.¹⁶² In December 2022, the Judiciary Committee approved the bill, but it still awaits full House and Senate approval. The AMFA would fill a significant gap in the U.S. royalty system, providing artists and sound recording owners with compensation for U.S. terrestrial broadcasts of their work. These royalties are just pennies on the dollar, as the proposed figures would cost broadcasters less than 0.05 percent of their annual revenue. Moreover, establishing or identifying a U.S. CMO tasked with collecting these royalties would allow American creators to be compensated for performances of their works on foreign terrestrial broadcast stations.

Congress should pass the AMFA to better compensate creators for the fruits of their labor.

Establishing neighboring rights for terrestrial broadcasts would allow American creators to be compensated for performances of their works on foreign terrestrial broadcast stations.

Education and Engagement

Another area where the United Kingdom sets the IP policy bar is its IP Education Framework and other public engagement endeavors.¹⁶³ After all, education is one of the three main pillars of the UKIPO IP enforcement strategy. From online training tools for academia and business concerns to a series of short videos about IP basics released on YouTube, UKIPO has set an excellent example for engaging with and educating the public on IPR. Such endeavors can increase

respect for and awareness of these rights, reducing IP theft by users and increasing IP applications and usage for creators and innovators.

For example, what purpose would an ideal vacation resort serve if no one knew it existed or how to book a stay there? The same is true for IP protection. The average person is unaware that there are many ways to monetize IPR (without going to court) or that many forms of IP protection exist beyond the commonly known copyrights, trademarks, and patents. From fashion to the food industry and icons to manufacturing industries, design patents, trade dress rights, and utility patents can benefit any sector if an organization understands each and how to apply for them.¹⁶⁴ Horticulture industries utilize plant breeders' rights to bring, among other things, better-smelling and more-colorful flowers to market.¹⁶⁵

If creators, innovators, and businesses are unaware of all the options available to them, or the nuances in IP laws across international jurisdictions, how can policymakers expect them to utilize those rights for the good of their business and the economy? Likewise, in an increasingly interconnected world where creators literally take elements from their inspiration to develop new content, how are these creators supposed to understand the lines between inspiration and violation if they are never educated on these aspects? How are users supposed to understand that the illegal, free version of a movie or song they downloaded harms the artist or industry and potentially undermines future content from their favorite creators? Will anyone explain to the mother who bought an "off-brand" Halloween costume online to save money that such counterfeit purchases are often harmful and used to fund terrorism?¹⁶⁶

The U.S. government needs to be more proactive and unified in its public education and engagement concerning IPR. To its credit, USPTO, Copyright Office, and other government branches offer various resources, webinars, and educational materials, but very few programs are widely publicized or meet the people where they are.¹⁶⁷ Instead, most require creators or innovators to actively seek out information. Still, as ITIF has written, users frequently find most federal agency websites challenging to navigate and use.¹⁶⁸ This can be overwhelming or off-putting for individuals or SMEs, especially when they suddenly face costly lawyer fees to assist them in the process.

The U.S. government needs to be more proactive and unified in its public education and engagement concerning IPR.

Both potential rightsholders and government agencies (both authorizing and enforcing) would benefit from a singular, government-run website that is user friendly. The website should clearly explain the different IPR available and walk the user through as much of the process as possible. It could include a questionnaire to aid applicants in selecting the appropriate form. Granted, there may be instances where an application is too complex for an applicant to walk through step by step via an online questionnaire; however, the option should still exist to streamline simpler applications for individuals and SMEs.

Community engagement is also vital, both for users and creators/innovators. Underrepresented communities often lack access to legal services; thus, state bar associations should facilitate and encourage local IP attorneys to participate in biannual or quarterly community events offering basic services pro se or at reduced rates to educate creators and innovators or assist them in

filing IP applications. UKIPO's educational videos on YouTube are also a great example of using social media to meet people where they are and educate them about IP.

Yet, the most important thing the U.S. government can do to engage and educate is to ensure schools discuss IPR. Whether it's a favorite brand, a secret recipe, creative ideas, works made for hire, R&D, or licensing agreements, everyone encounters IPR in some form or another every day. Thus, these concepts should be discussed in schools, at both the secondary and university levels, if not earlier. For instance, UKIPO developed online training tools for educators, researchers, and tutors at multiple levels.¹⁶⁹ Again, such tools are only useful if they are user friendly and make complex yet important IP issues understandable to lay people. The U.S. government doesn't have to reinvent the wheel; it just needs to provide appropriate resources and incentives to further education and engagement on the issue.

Limit Attempts to Reduce Drug Prices by Misusing IP Policy

Many progressives have called for the misuse of march-in rights under the Bayh-Dole Act and reasonable compensation requirements under 28 U.S.C. §1498(a).¹⁷⁰

The United States is the global leader in pharmaceutical R&D, due in no small part to the enactment of Bayh-Dole. The Bayh-Dole Act gives universities, small businesses, nonprofit research institutions, and other contractors rights to IP generated from research supported by federal funding. These entities often license IPR to private-sector entities, which then invest the hundreds of millions—often billions—of dollars required to bring safe and effective drugs to market. In the case of university technology transfer programs, those IP licenses funnel revenue back to the university to support labs, faculty, and graduate students, thereby increasing U.S. knowledge capital and infrastructure-supporting innovation. Many universities also maintain start-up incubators, courtesy of the public-private partnerships Bayh-Dole enables.

Congress passed the bipartisan Bayh-Dole Act to decentralize technology transfer because the federal government had a weak track record in commercializing federally funded IP. In fact, as late as 1978, the federal government had licensed less than 5 percent of the as many as 30,000 patents it owned.¹⁷¹ When the innovation doesn't reach those it was developed to help, it's often just a waste of resources. As the act states, "It is the policy and objective of the Congress to use the patent system to promote the utilization of inventions arising from federally supported research and development."¹⁷²

A provision in the act termed "march-in rights" was designed as a fail-safe for limited instances in which a licensee might not be making good-faith efforts to bring an invention to market or when national emergencies require a greater supply than a licensee can produce. March-in rights grant the government the right to step in and compel licensing of owners' IP under four specific, limited circumstances:

1. If the contractor or assignee has not taken, or is not expected to take within a reasonable time, effective steps to achieve practical application of the subject invention
2. If action is necessary to alleviate health or safety needs not reasonably satisfied by the patent holder or its licensees

3. If action is necessary to meet requirements for public use specified by federal regulations and such requirements are not reasonably satisfied by the contractor, assignee, or licensees
4. If action is necessary, in exigent cases, because the patented product cannot be manufactured substantially in the United States¹⁷³

The eponymous senators who proposed the bill explicitly rejected the idea of using the “march-in” power to dictate the prices of resulting products that benefitted from Bayh-Dole. Among other objectives, Bayh-Dole intended to encourage investment in the complicated and risky business of developing drugs from basic research, enabling new cures and treatments to get to patients sooner.¹⁷⁴ Despite this fact and the success of the Bayh-Dole Act, some advocates and elected officials have called for using an expanded definition of march-in rights to give the government the authority to compel the divulsion of the underlying IP (if the underlying IP is traceable in part to federally funded research) for the purpose of controlling drug prices (e.g., by forcing a licensor to divulge their IP so that other licensees could manufacture a drug, and which in theory would be sold at a lower price).¹⁷⁵

The Bayh-Dole Act works as its architects intended and does not require changing. Since 1980, the Bayh-Dole has contributed to the discovery of over 200 new drugs and vaccines.¹⁷⁶ As addressed further on, (mis)using march-in rights or establishing new ones to control drug prices would result in fewer new drugs. Companies would be highly reticent to spend billions developing a drug if they knew the government could come in as long as two decades later and seize or compulsorily license their IP in order to control drug prices.

The Bayh-Dole Act works as its architects intended and does not require changing.

Section 1498

Similarly, some advocates and elected officials seek to misuse Section 1498, claiming it gives the government a right of eminent domain in all U.S. patents and, thus, the power of compulsory licensing.¹⁷⁷ 1498 states:

Whenever an invention described in and covered by a patent of the United States is used or manufactured by or for the United States [by a contractor, a subcontractor, or any person, firm, or corporation for the Government and with the authorization or consent of the Government] without license of the owner thereof or lawful right to use or manufacture the same, the owner’s remedy shall be by action against the United States in the United States Court of Federal Claims for the recovery of his reasonable and entire compensation for such use and manufacture.¹⁷⁸

In other words, if the government directs an entity (public or private) to manufacture or use a patented innovation for the government’s use, the patent owner can recover reasonable and entire compensation for infringement by bringing a suit in the U.S. Court of Federal Claims.

This legislation originated to stimulate the manufacturing of items needed during World Wars I and II and later to immunize contractors who manufactured patented innovations under the direction of the U.S. government for the war effort. 1498 does not grant the government

unlimited eminent domain over patents. Rather, the law relinquishes the U.S. government's sovereign immunity with respect to patented innovations used or manufactured for the government's use. In other words, the government agrees to submit to a civil action for infringement, allowing the private citizen (i.e., patent owner) to be adequately compensated as it would by any other infringer. Thus, the federal government must compensate the patent holder by paying damages of not less than a reasonable royalty.

However, spurred on by a single article by Amy Kapczynski and Aaron S. Kesselheim in 2016, advocates have sought to expand and redefine 1498 as a means for the federal government to assert price controls over pharmaceuticals.¹⁷⁹ Basically, the authors claimed that if an innovator has a patent in the United States, the government essentially owns the patent and does not have to respect the innovator's rights if it chooses not to, so long as it throws a little money their way. This approach to IP is a surefire way to ruin a thriving innovation ecosystem.

Moreover, the entire premise behind reducing drug prices via 1498 ignores two facts written into the law: 1) 1498 does not entitle the government to engage in negotiations to lower prices; rather, it says the patent owner must bring a suit before the U.S. Court of Federal Claims to obtain a financial remedy (a costly endeavor for both the rightsholder and the government); and 2) the law states patent owners are entitled to reasonable "and entire" compensation, including certain fees related to court proceedings. Therefore, the U.S. government would have to litigate (not negotiate) in the hopes the costly procedure and "reasonable and entire compensation" might somehow reduce pharmaceutical costs (an unlikely outcome). The government's efforts would be much better spent investing in further biopharmaceutical R&D rather than IP infringement.

Advocates further argue that government funding for Medicare and Medicaid constitute substantial-enough interests to assert such activity as being "for the government." However, precedent proves otherwise, including a case the authors relied upon for their own (misleading) assertions. According to the U.S. Court for Federal Claims' website, *Advanced Software Design Corp. v. Federal Reserve Bank of St. Louis*:

interpreted the term 'for the government' to mean that the government derives a benefit from the use or manufacture of the patented technology. [If] the government simply has an 'interest in the program generally, or funds or reimburses all or part of its costs,' that interest is too remote to support a finding of a government benefit. In other words, the government's mere funding of an infringing activity does not establish that such activity is 'for the government' within the meaning of §1498(a).¹⁸⁰

Delinkage, R&D, and Funding Biopharmaceutical Innovation

Ultimately, those in the anticorporate pharmaceutical movement advocate for reduced patent protections so as to reduce company revenues while increasing government responsibility for drug discovery, hoping to create a life-sciences industry with many fewer large firms wherein the government plays a much larger role in drug development.¹⁸¹ For instance, Sen. Bernie Sanders (I-VT), as part of his campaign to become the 2020 Democratic presidential nominee, called for the creation of a Medical Innovation Prize Fund that would launch a fund equal to 0.55 percent of GDP (more than \$80 billion per year), with the federal government funding half and private health insurance companies the other half.¹⁸² Stiglitz also backed drug prizes, as did liberal U.S.

economist Dean Baker of the Center for Economic and Policy Research, who wrote that “a prize system would have enormous advantages over the current [life-sciences innovation] system.”¹⁸³ In other words, the government would take over funding drug discovery in order to limit the role of pharmaceutical companies, specifically large corporations.

However, these proposals are impractical. Claims by economic progressives that the government already funds most biopharmaceutical R&D are unfounded. A National Science Foundation report finds that pharmaceutical manufacturing companies account for approximately 90 percent of all their R&D funding.¹⁸⁴ Furthermore, as ITIF has written, “delinkage,” or separating the cost of pharmaceutical research and development from the final market price of medicines, would misalign incentives, raise bureaucratic costs, and limit innovation.¹⁸⁵ A prize-based system simply could not replace the existing market-based system that delivers a tremendous amount of biomedical innovation.

Claims by economic progressives that the government already funds most pharmaceutical R&D are unfounded.

Moreover, the scholarly literature is clear that efforts to limit IP in the biopharmaceutical industry would reduce both R&D and new drug development.¹⁸⁶ One study finds that every \$2.5 billion of additional revenue leads to one new drug approval.¹⁸⁷ Pharmaceutical R&D requires earnings that can cover high failure rates, as drug development represents an 11- to 15-year process wherein only 0.05 to 0.1 percent of compounds make it from basic research into clinical trials, and less than 12 percent of those in trials are ultimately approved by the U.S. Food and Drug Administration.¹⁸⁸ In other words, the price of a single drug doesn't just have to cover that drug's development and production costs; it also has to cover the costs of other drugs that didn't make it to market.

Whether it comes to the drug price controls in the Inflation Reduction Act, the misuse of Section 1498, or the attempted effort to misuse Bayh-Dole march-in rights provisions, it's not in the interests of American consumers, innovation, or competitiveness to follow suit in the drug price controls of other countries that have significantly harmed and impeded innovation from those countries' pharmaceutical industries.¹⁸⁹

CONCLUSION

It's not too late for U.S. policymakers to reverse course and once again assert a leadership role in advancing international IP best practices. Working with like-minded allies offers U.S. policymakers the chance to set a precedent for emerging technologies and establish a united front against the CCP. Likewise, reforming certain domestic IP policies enables America to lead by example. The result will be a more competitive American economy, more innovation, and more jobs in IP-dependent industries.

Acknowledgments

The author would like to thank Robert Atkinson, Jaci McDole, Daniel Castro, Hodan Omaar, Juan Londoño, and Nigel Cory for their assistance with this publication.

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About ITIF

The Information Technology and Innovation Foundation (ITIF) is an independent, nonprofit, nonpartisan research and educational institute focusing on the intersection of technological innovation and public policy. Recognized by its peers in the think tank community as the global center of excellence for science and technology policy, ITIF's mission is to formulate and promote policy solutions that accelerate innovation and boost productivity to spur growth, opportunity, and progress. For more information, visit us at itif.org.

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