## 1

#### Interpetation: Precluding a future increase is not a reduction

Melinda **Harmon 12**, Judge, United States District Court for the Southern District of Texas, Houston Division, 3/6/12, Zieche v. Burlington Res., Inc., 2012 U.S. Dist. LEXIS 30134, p. lexis

Zieche contends that the Court erred when it concluded that "there was no reduction in Zieche's salary or bonus percentage" that would constitute "good reason" for his resignation. Doc. 70 at 8, 9. The Court relied on the fact that Zieche received "his full 2006 performance bonus" after he began working at ConocoPhillips and that the bonus percentage increased from 30% in 2005 to 40% in 2006 as proof that Zieche did not suffer a reduction in salary.

Zieche contends that an increase in his bonus is irrelevant to a determination of whether his salary was reduced because a "bonus is not part of the salary," but is instead [\*12] "something in addition to what is expected or strictly due." Doc. 72 at 4. Additionally, Zieche alleges that "the [C]ourt's analysis ignores the specific provisions of the retention agreement," which defines "good reason" to include "any reduction from your annual rate of base salary." Id.

Initially, although Zieche alleges that ConocoPhillips reduced his salary, he introduced no summary judgment **ev**idence to support this contention. In his Response to ConocoPhillip's Motion for Summary Judgment, Zeiche repeatedly asserts that, in his new position at ConocoPhillips, he would "**not be eligible for annual merit salary *increases***" as he had previously received at Burlington. Doc. 54 at 4 (emph. added). The summary judgment evidence before the Court included Zieche's deposition, in which he admitted that his salary "remained the same . . . up to the time [he] resigned from ConocoPhillips." Doc. 48-1 at 50 (emph. added). Nevertheless, Zieche argues that the Court unnaturally should read the word "reduce" in the retention agreement to mean "**not increase**," rather than interpreting the word according to its plain meaning. **The Court does not agree with this reasoning**, and Zieche has introduced [\*13] no evidence to convince the Court otherwise.

#### Violation: they preclude patent extensions

#### 1] Limits and ground—they allow the aff to monopolize prep by precluding a future increase anytime from now allowing affs to no link from uniqueness scenarios, delay CPs, etc which kills engageability—leads to unpredictable affs that skew the debate away from whether IP is good/bad to when a reduction should occur.

#### 2] TVA – defend the advantage to a whole rez reduction. We don’t prevent new FWs, mechanisms, or advantages. PICs don’t solve – our model allows you to specify countries and medicines. Potential abuse doesn’t justify actual abuse. No prep leads to cheaty pics like word PIKS and delay CPs which are net worse

#### 3] Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative preparation because the aff isn’t bound by the resolution.

#### Fairness – debate is a competitive activity that requires fairness for objective evaluation.

#### 1NC theory is DTD – a) T indicts the whole aff so DTA is DTD b) abuse is supercharged with the 7-6 rebutal time skew

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices c] Forcing the 1NC to go all in on the shell kills substance education and neg strat which outweighs on urgency

## 2

#### Text: A nation appointed international panel of scientists including National Academies and corresponding organizations should [reduce intellectual property protections by implementing a one-and-done approach for patent and exclusivity protection] and manage similar conflicts of interest between intellectual property.

#### IT IS CONDITIONAL

#### WE DEFEND THE CONVERSE OF THE RESOLUTION IF THE CP IS KICKED- the member nations of the wto ought not to reduce IPP for medicines

#### International panel of science diplomats can rule over IP---that’s key to science diplomacy.

Hajjar and Greenbaum 18 [David; Dean Emeritus and University Distinguished Professor, and Professor of Biochemistry and Pathology at Weill Cornell Medicine, Cornell University. He is a Fellow of the American Academy of Arts and Sciences, Fellow of the American Association for the Advancement of Sciences, a Jefferson Science Fellow of the National Academies at the U.S. Department of State, and a recent Senior Fellow in Science Policy at the Brookings Institute; Steven; Professor and Chair of the Department of Physics and Astronomy at Hunter College of the City University of New York and a Fellow of the American Physical Society. He was a Jefferson Science Fellow of the National Academies at the U.S. Department of State; “Leveraging Diplomacy for Managing Scientific Challenges,” American Diplomacy; September 18; <https://americandiplomacy.web.unc.edu/2018/09/leveraging-diplomacy-for-managing-scientific-challenges-an-opportunity-to-navigate-the-future-of-science/>] Justin

At the global level, science diplomacy is defined as cooperation among countries in order to solve complex problems through scientific research and education (1). For example, science diplomacy plays an important role in resolving global issues related to the ecosystem (such as clean water, food safety, energy conservation, and preservation of the environment). It also addresses problems related to the healthcare industry. For example, scientists have served at the international level to forge the Middle Eastern Cancer Consortium a decade ago to facilitate better healthcare and improve cancer research in the region. Whether one considers science for diplomacy or diplomacy for science, international science collaborations benefit from allowing science diplomats (broadly defined as science envoys, science attaches, embassy fellows) to help establish positive international relationships between the U.S., Europe, Latin America, Africa or Asia, particularly when proprietary disputes arise (2, 3). These various types of science diplomats already exist; some, like embassy fellows and science envoys, have one-year appointments so their role may be limited, while attaches usually have two or three year appointments that may allow them to be more successful in long, protracted negotiations. In any event, we believe that scientists can play more of a role in advancing international scientific cooperation. A key point addressed here is how to balance security concerns against the need for free exchange of information needed for innovation and growth.

Both the National Science Foundation and the National Institutes of Health are already engaged in supporting American science and strengthening collaborations abroad. Such efforts take advantage of international expertise, facilities, and equipment. Here, we provide a rationale for the use of diplomacy to address scientific challenges. This approach allows some scientists working as diplomats to help manage complex and potentially conflicting situations that arise between scientific communities and their governments. Such issues include managing disputes such as licensing agreements for intellectual property (IP) and providing protection of IP.

International collaborations can not only support but also accelerate the advancement of science. However, collaborations may carry risk if IP is misappropriated for other purposes. International collaborations should have a basis in strategy and specific goals (for example, drug discovery) in order to justify the use of government and/or corporate funds.

About a decade ago, a group of academics from the University of Manchester in the United Kingdom assembled the “Manchester Manifesto,” subtitled “Who Owns Science” (6). This document addressed the lack of alignment between commercial interests, intellectual rights, and credit to the researcher. In our (and commonly held) view, the groups representing these disparate values could benefit from diplomatic mediation. More recently, it has become increasing apparent that managing China as a science and technology superpower represents another challenge for the U.S. Resolution of issues such as ownership of IP, rights to reagents, or use of skilled laboratory personnel from international collaborations may require the efforts of science diplomats. There are few international offices or “guardians” to protect junior and senior scientists in corporate or academic sectors from misuse of reagents or piracy.

China’s failure to respect IP rights, and the resulting piracy, has drawn much attention. The media have also focused on the failure of watchdog government agencies to detect and manage these unwanted activities. Industrial espionage compromises U.S. interests. Moreover, Chinese and Russian hackers have cyberattacked U.S. technology companies, financial institutions, media groups, and defense contractors. In 2018, industrial spying was even reported in a major medical school in New York City where scientists were alleged to have illegally shared research findings with Chinese companies.

The U.S. has a long history of hiring research personnel from other countries to staff its laboratories and industrial R&D centers. These scientists and engineers have made critical contributions to our nation’s well-being and security. These young Chinese and South Asian graduates of U.S. programs a generation ago now staff our research enterprise. However, recent trends in U.S. graduate school applications in science, technology, engineering and mathematics (STEM) reflect a downturn in foreign applicants, particularly from China. It is becoming increasingly apparent that the number of American-born students seeking STEM degrees is not sufficient to satisfy future demands of our high-tech workforce. While our own educational reforms must be augmented, we cannot ignore the need to continue to recruit overseas talent.

We believe that foreign scientists can continue to make critical discoveries in the U. S. provided that their talent is nurtured, developed, and harnessed for the common good. At the same time, American companies cannot hire foreign scientists if they take the ideas they generate in U.S. laboratories back to their home countries without proper credit or permission. If the advancement of science is to succeed, greater diplomatic cooperation is needed to solve and manage proprietary issues for the benefit of all (5, 6).

So, how does one strike the proper balance between security and growth? Science is a universal social enterprise; international conferences lead to friendships and productive collaborations between nations. Given that the U.S. and Chinese governments recognize the need for international communication and collaboration then surely there should be a mechanism for adjudicating anticipated conflicts. One approach would be for government, industrial, and academic stakeholders to form an international panel of scientists and engineers to manage any conflicts of interest between the need to protect proprietary information crucial to a company’s competitive edge, and the need for students and young faculty members to publish their findings. Smaller scale efforts along these lines have recently given rise to unique global partnerships, such as fellowship support by major pharmaceutical companies, which aim to address these conflicts to the benefit of both parties. An added feature of such arrangements is that they often provide corporate financing for research (9). Can this corporate-academic partnership model be adapted to multinational joint R&D efforts while protecting IP? This question falls squarely within the purview of international science diplomacy, whereby science diplomats can establish rules of conduct governing joint global technology development with proper IP protection.

Despite the highly publicized and legitimate piracy allegations against China, at least some data indicates that the Chinese legal system is responding positively to worldwide pressure to honor foreign IP. A 2016 study by Love, Helmers, and Eberhardt, for example, found that between 2006 and 2011, foreign companies brought over 10 percent of patent infringement cases in China, and won over 70 percent of those cases (10). Today, “win rates” average around 80 percent, and “injunction rates,” around 98 percent (10). As Chinese scientists and engineers increasingly enter the top tier of the innovation space, their growing awareness of their own need for IP protection could be a powerful motivating force for the protection of all IP. As stated earlier, science diplomats could catalyze this progress even further by direct negotiations with those parties involved in the conflicts. An obvious flaw in this optimistic outlook is that scientists in the U.S. wield more influence with their government than scientists in China wield with theirs. And to the extent that the Chinese government could be encouraging IP theft, this must be addressed first by those international companies/firms who want to do business with the Chinese. Chinese investments, as well as tech incubators and targeted acquisitions, can enable access to U.S. technologies for commercial development. Although this conveys a level of risk to the developers, it may provide valuable opportunities for U.S. companies as well. In many respects, the extensive engagement and collaboration in innovation between the U.S. and China, often characterized by open exchanges of ideas, talent, and technologies, can be mutually beneficial in enriching and accelerating innovation in both countries.

In summary, we believe that science diplomats could help address the increasingly complex issues that arise between accelerating scientific and engineering advances, and the need to protect national security and corporate IP. We also propose that this might be accomplished by asking the National Academies to **recommend** academic, corporate, and government scientific leaders to serve on an international scientific advisory board, and for the corresponding organizations in other countries to do the same. Access to the free flow of information promotes new knowledge and innovation. A return to a more restrictive intellectual environment is not only harmful to progress, but also nearly impossible to manage in the current internet age. A good place to start would be to engage the newly appointed head of the White House Office of Science and Technology Policy (the Science Advisor to the President of the United States), and working groups within established organizations. These organizations include the American Association for the Advancement of Science (AAAS) or the National Academies of Science, Engineering and Medicine, and corresponding international organizations. What incentive is there for a busy and successful scientist to serve in such capacity? It is the same altruism that motivates us to accept assignments as journal editors, manuscript reviewers, or funding agency panelists for the advancement of science toward the greater good.

#### Solves every existential threat.

Haynes 18—research associate in the Neurobiology Department at Harvard Medical School (Trevor, “Science Diplomacy: Collaboration in a rapidly changing world,” <http://sitn.hms.harvard.edu/flash/2018/science-diplomacy-collaboration-rapidly-changing-world/>, dml) // Re-Cut Justin

Today’s world is extremely interconnected. Most of us take this fact for granted, but its implications cannot be overstated. The rate at which information, resources, and people are able to move from one part of the world to another continues to accelerate at an alarming rate. Undoubtedly, this development has done society immense good. In the last century, global life expectancy has doubled, the percentage of people living in extreme poverty has dropped by about 60%, and world literacy rates have increased by a similar margin. But while these statistics paint a promising picture of human civilization, human progress rests on a fragile foundation of international cooperation; the challenges presented by an interconnected world are immense. War, natural disasters, and economic collapse now exert their effects globally, creating economic and ecological disasters and mass human migrations on an unprecedented scale. And with the US pulling out of major multilateral agreements on trade, climate change mitigation, and denuclearization, you might wonder if our ability to collaborate across borders productively is really up to the task.

Global challenges require global solutions, and global solutions require collaboration between countries both big and small, rich and poor, authoritative and democratic. There are few human enterprises capable of providing continuity across these differences, and as technological solutions are becoming available to some of our most pressing issues, two in particular will be necessary to getting the job done: science and diplomacy. While science has long been utilized as a means to reach political ends—think of British explorer James Cook’s mapping of unexplored continents or the United States’ Manhattan Project—a more formal integration of scientists into the diplomatic process is being undertaken. This effort, which has led to scientists and academics playing a direct role in foreign policy development and international relations, has given birth of a new branch of diplomacy: science diplomacy.

What is science diplomacy?

As both the term and concept of science diplomacy have only recently gained traction in scientific and diplomatic circles, it’s been given a variety of definitions. But common to them all is the focus on applying scientific expertise to an international effort. The focus of these efforts is to solve international problems collaboratively while balancing economic prosperity, environmental protection, and societal wellbeing. The challenge of reaching this balance in the face of a booming global population cannot be understated, but this new branch of diplomacy is already at work and is producing results. International agreements such as the Paris Climate Agreement and the Iran Nuclear Deal are two famous examples, and science diplomacy is also establishing international collaboration in many other important arenas. While these lesser known efforts may not dominate the headlines, they are quietly tackling the global issues of today and preparing us for those of tomorrow.

Natural disasters don’t respect national boundaries (and neither does the aftermath)

In 2013, the number of refugees displaced by natural disasters—hurricanes, droughts, earthquakes—outnumbered those displaced by war. Current projections estimate as many as 1 billion people may be displaced by natural disasters by the year 2050. That would mean 1 in 9 people on the planet displaced and looking for a home. Compare this to the estimated 12 million refugees displaced by the war in Syria, and a frightening picture begins to form. As natural disasters continue to increase in both their frequency and intensity, solutions for mitigating the risk of total catastrophe will be underpinned by science, technology, and the ability of the international community to collaborate. Many organizations are starting to tackle these problems through the use of science diplomacy. The center for Integrated Research on Disaster Risk (IRDR) is composed of ten national committees—a network of government sponsored research institutions across the world in countries ranging the political and economic scale. These working groups have committed to improving disaster-risk-reduction science and technology while providing guidance to policy makers charged with implementing disaster prevention and mitigation strategies.

IRDR is governed by a committee comprising experienced scientists and natural disaster experts. Its members come from all over the world—the US, China, Uganda, Norway, Mexico, Venezuela, and more. The diversity of this organization starts at the top and is crucial to developing comprehensive risk-reduction strategies. Data and insights from countries with varying areas of expertise are being shared and built upon, facilitating more accurate natural disaster forecasting and better strategies for mitigating their destructive power. And by including representatives from countries of varying political and economic power in its leadership, IRDR ensures that its work will consider the needs of the global community at large, rather than just nations with considerable wealth and political standing.

The results of this type of international collaboration speak for themselves. Although humanity is grappling with more natural disasters than ever before, deaths related to these incidents continue to trend downward. Operating outside of the typical political framework that dominates foreign relations, IRDR provides a model for effective collaboration across the geopolitical spectrum in the face of a major global issue.

Explore or Exploit? Managing international spaces

Over the last few decades the polar ice cap that covers much of the Arctic Ocean has been shrinking. So much so, that during the warm season vast areas of previously solid ice have become open waters, creating opportunities for new trade routes and exposing the Arctic’s enormous reserves of oil and natural gas. Depending on your values, this will sound either like an opportunity for huge economic development of the region or the inevitable exploitation of one of the last untouched natural territories on the planet. And if you live there, like the half a million indigenous people who currently do, how this territory is managed will determine where you can live, how (and if) you can make a living, and what the health of the ecosystems that have supported Arctic life for millennia will look like.

Luckily, such a scenario was predicted decades ago. In 1987, Mikhail Gorbachev, then leader of the then Soviet Union, delivered a speech outlining his aspirations for the arctic to be explored rather than exploited—to radically reduce military presence, create a collaborative multinational research effort, cooperate on matters of environmental security, and open up the Northern Sea Route for trade. This speech laid the foundation for the Arctic Council (Figure 1), which is one of the most successful examples of science diplomacy at work. Composed of the eight Arctic nations, including geopolitical rivals US and Russia, and numerous groups of indigenous peoples, the Arctic Council was established to maintain Gorbachev’s vision for the region while giving the indigenous peoples a seat at the negotiating table. The council’s activities are conducted by six scientific and technology-based working groups who conduct research in the area and provide knowledge and recommendations to the council members. As a result of this research, and allowing scientists to take part in the negotiations, the Arctic council has enacted several legally binding agreements regarding the sustainable development and environmental protection of the Arctic Ocean. These agreements have facilitated cooperation on a number of important issues including search and rescue operations, prevention and containment of maritime oil pollution, and, most recently, enhanced data sharing and scientific research collaborations. Against a backdrop of rapidly deteriorating diplomatic relations, the US and Russia have co-chaired task forces that laid the foundation for these agreements, proving to the world that meaningful results can be achieved through the avenue of science diplomacy, regardless of geopolitics.

Science diplomacy going forward

The technical expertise that characterizes science diplomacy will continue to be in demand across many realms of foreign policy. For example, synthetic biology and gene-editing technology continue to factor into matters regarding agriculture and trade. Also, digital currencies, such as bitcoin, have changed the way economists and businesses are approaching markets. Finally, machine learning and artificial intelligence are being used by governments as a means for population control, giving rise to a new type of governance—digital authoritarianism.

While this expertise will be necessary for managing such issues, building international coalitions can’t be done through a purely scientific and technical lens. Convincing others to cooperate means providing them with a convincing argument to do so, and in terms they understand and find compelling. To achieve this, scientists must be trained to communicate their expertise in a way that moves stakeholders in policy discussions to act. This means appealing to motivations they have been largely taught to put to the side—whether they be political, economic, or emotional in nature—without obscuring the data and insights they have to offer.

For our leaders, policy makers, and diplomats to effectively understand issues underpinned by science and technology, experts in these fields must continue to be integrated into the mechanisms of governance. With scientists in the US running for elections in numbers like never before, we can expect this trend to continue. And in the face of a rising wave of nationalism across the world, it is crucial that we do everything we can to foster collaboration. The future of human civilization depends on it.

## 3

#### Liquidity stays robust in 2021 despite challenges – status-quo ensures declines are controlled.

Lokeshwarri 21 [SK; Chief of Research Bureau; “3 reasons why market liquidity will stay robust in 2021,” BusinessLine; 1/3/21; <https://www.thehindubusinessline.com/data-stories/deep-dive/3-reasons-why-market-liquidity-will-stay-robust-in-2021/article33487346.ece>] Justin

As we step into 2021, investors in Indian equity market have much to be thankful for. While the deep cut in March 2020 — that made the Nifty50 and the Sensex lose almost 40 per cent from the January peak — had everyone losing their head in worry, all the losses were recouped in the following months. The benchmark indices have gained a whopping 79 per cent from the March lows and ended the year with gains of over 15 per cent.

It’s clear that investors are chasing growth, making valuation pricey in select pockets, even as value continues to exist in cyclical stocks. The question that begs an answer now is: will this rally continue in 2021? That depends, to a large extent, on the demand for stocks, also called market liquidity. There are three main reasons why liquidity will remain robust in 2021 as well. While market corrections and sporadic volatility cannot be ruled out, these factors will ensure that the declines do not get too serious.

Interest rates at rock bottom

One of the principal reasons why investors flocked to equity markets after March 2020 was due to the large interest rate cuts by all central banks including the RBI to stimulate the economy. The RBI slashed the repo rate from 5.15 per cent towards the beginning of 2020 to 4 per cent by May; the lowest level in two decades. This made banks lower their deposit rates making fixed income investments unattractive. It needs to be noted the Indian central bank has been consistently lowering rates since 2012, when the repo rate was 8.5 per cent, in a bid to boost growth. This has been one of the drivers of the structural bull-run since 2013.

Other central banks including the US Federal Reserve also similarly slashed rates in March and April. As the accompanying table shows, policy rates of countries such as the US, UK, Canada, Australia, Norway, etc are close to zero; while countries such as Switzerland, Denmark, Japan and the Euro zone have negative policy rates. Maximum global wealth lies in the US and Europe with most FPIs originating from these regions. It is, therefore, not surprising that the hunt for higher returns attracted these investors to Indian stocks.

With global monetary policy expected to be dovish through 2021, the FPI flows in to India equity is likely to be supportive this year.

Dollar movement and global central bank stimulus

Another factor that needs to be tracked closely to gauge liquidity in stock market is the movement of the US dollar. Dollar along with gold is a safe haven with value increasing in times of extreme risk-off sentiments, due to money flowing in to US treasury instruments.

If we track the long-term movement of the dollar index, it can be noted that the index consistently moved lower from 116 in 2002 to 73 in 2008. This was the period of an unbridled bull-run in most equity markets. The period from 2014 to 2016, when the dollar index rallied was accompanied by volatility in global stocks.

The dollar index is once again weak. The weakness is partly on account of the Federal Reserve’s next tranche of stimulus announced recently and the unlimited dollar printing. But it also signifies that there is certain degree of complacency in financial markets regarding the ability of the central banks to keep economies afloat. This is making money move out of the haven of dollar-denominated securities. Continued dollar weakness in 2021 will keep the bias of FPIs tilted towards equities in emerging markets such as India.

The other factor that is supplying liquidity to markets is the stimulus funding being unleashed by Advanced Economies. Some of this money tends to move in to risky assets as the flood of money coupled with lows interest rates in these economies boosts currency carry trades.

Vaccine roll-out, normalisation of economic activity

As far as domestic liquidity goes, there isn’t much to worry about. Though equity oriented mutual funds have witnessed outflows over the last five months, there are other indications that domestic investors have enough liquidity on their hands. One, turnover on domestic stock exchanges has been booming with cash volumes almost doubling since April 2020. Two, the massive over-subscription in IPOs shows that people have surplus on their hands which they are willing to deploy in to stocks.

Also, the Covid-led job losses has not really affected the upper and upper-middle class much. A survey by UBS of 1,508 consumers aged between 18 and 54 found that while 47 per cent of the respondents saw a decline in income in 2020, 49 per cent witnessed stable income or an increase. Also, close to two-thirds of respondents expect income to increase in 2021.

While economic growth is largely expected to contract in the 8-10 per cent range in FY21, most research houses think that growth in FY22 in India will be the fastest globally, around 8 per cent. Revival in activity, of course, hinges on the vaccine roll-out and people getting the confidence to resume activities at pre-Covid levels. With over 56 per cent of the country’s GDP being derived by consumption, success of the vaccine and elimination of the Covid virus would be the key to sustained earnings growth in companies.

One negative fall-out of easing of movement restriction and end of work-from-home would be the inability of the people to trade from offices due to the restrictions in office Wi-Fi and other protocols. This could dampen trading turnover to some extent, though it won’t have a material affect on investing behaviour.

#### The plan collapses market liquidity – our evidence is super recent and really good.

* DiD- Difference in Difference

Dass et al 21 [Nishant Dass, Vikram Nanda, Steven Xiao; Scheller College of Business, Georgia Institute of Technology Rutgers Business School; “Intellectual Property Protection and Financial Markets: Patenting versus Secrecy,” 4/22/21 (**The download site says 4/22/21 but the pdf says 11/20/20 so I just put the former – correct if wrong**); <https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2648770&download=yes>] Justin

5.2.1 TRIPS and Patents

First, we test Hypothesis H1 for the effect of TRIPS on patenting. Our prediction is that stronger international patent protection will encourage firms in patent–reliant industries to use patents over trade secrecy to protect their IPs. We formally test the effect of TRIPS on patenting and stock liquidity (H1) using the following DiD model:

Patentsi,t = α1 + β1Post–TRIPSi,t × Treatedj + γ 0 1CONT ROLi,t−1 + φi + ψt + i,t. (4)

We estimate Model (4) over a five–year window, [t−2, t+ 2], around the implementation of TRIPS. Patents are counted based on the timing of either applications or issuances. Since the implementation of TRIPS in the United States was enforced by the passage of URAA on December 8, 1994, and it became effective on January 1, 1995, we define 1995 as the event year and test the DiD model in a five–year window centered on 1995.20 Post–TRIPSi,t is a binary variable that equals one if the observation is in or after 1995, and equals zero otherwise. We consider industries that are reliant on patents as the treated group. Following Delgado, Kyle, and McGahan (2013), we categorize four–digit NAICS industries as patent–reliant or not based on a 2012 report by the Economics and Statistics Administration (ESA) and the USPTO. Our prediction based on H1 is that the estimate of β1 on the interaction term should be significantly positive.

Since our analysis focuses on firms’ patenting decisions and stock liquidity, we follow the literature and control for a set of firm and industry characteristics that are likely related to firms’ patenting activities and/or stock liquidity. We include firm size and age because older and larger firms tend to generate more patents (Atanassov, 2015). We include asset characteristics for cash holding and tangibility, because asset liquidity is correlated with stock liquidity (Gopalan, Kadan, and Pevzner, 2012). We include firm performance using Tobin’s Q and return on assets (ROA) because firms with better performance tend to be more innovative and have higher stock liquidity. We include industry concentration using the Herfindahl–Hirschman index at four–digit NAICS industry level because corporate innovation is related to the level of product market competition (Aghion et al., 2005). We include the number of analysts following the stock, which is related to higher stock liquidity (Balakrishnan et al., 2014). Standard errors are estimated with clustering at the four–digit NAICS industry level to account for within–industry correlation in patenting activity.21

We estimate this model in four different forms to account for the fact that the number of patent applications and the number of patent grants are count variables with high skewness (see Table 1). The first one is a linear regression with log one plus the number of patent applications or patent grants as the dependent variable. The second one is a negative binomial regression with the number of patent applications or patent grants as the dependent variable. The third one is a Poisson regression with the number of patent applications or patent grants as the dependent variable. The fourth one is a logit regression in which the dependent variable is a binary variable that equals one if a firm has any patent applications or patent grants in a year. Across all forms of regressions, we control for firm fixed effects and year fixed effects, and, thus, the stand–alone variables Post–TRIPS and Treated are absorbed by the fixed effects and cannot be estimated.22

Table 3 reports the coefficient estimates of Model (4). The estimates in columns 1 to 3 and 5 to 7 show that the number of both patent applications and patent grants for firms in patent– reliant industries significantly increased after the implementation of TRIPS. These increases are also economically significant. For example, the linear regression estimates in column 1 (5) suggest that the number of patent applications (patent grants) increased by 10.2% (7.7%) in the post–TRIPS period. Based on Lemley’s (1994) estimate that the average patentee received 253 additional days of protection with the new term conferred by the URAA, our estimates suggest that firms in patent– reliant industries increase the number of patent applications (patent grants) by 0.04% (0.03%) for every additional day of patent protection. In columns 2, 3, 6, and 7, where we present estimates of negative binomial regressions and Poisson regressions, the sample size falls by more than half. This is because firms with zero patents throughout the sample period are dropped from the regression as the outcome variables are perfectly explained by firm fixed effects. Nevertheless, the DiD estimates remain robustly positive in these regressions.23

In columns 4 and 8, where we present estimates of logit regressions, the sample size is even smaller because firms that have non–zero patents every year in the sample period are also dropped from the regression. In the logit regressions, the DiD estimates are insignificant. These results suggest that the increase in the number of patents is not driven by the extensive margin, which would be the case if firms that did not patents prior to TRIPS started patenting afterward. Instead, the results are driven by the intensive margin, whereby firms that patented prior to TRIPS increased their patenting activity after TRIPS. A plausible explanation is that the marginal benefits of a longer patent term and the international enforcement of patent protection conferred by TRIPS may not be sufficient to offset the fixed costs of starting to patent, such as the cost of hiring legal experts and developing the institutional knowledge about the patenting procedure. In our sample, 69% of firms in patent–reliant industries (i.e., the treated group) had at least one patent application in the pre–TRIPS period, whereas only 21% of firms in the control group did so. Hence, the treated group is more likely to increase patenting along the intensive margin. This is consistent with our assumption that firms in patent–reliant industries benefit more from a marginal improvement in the strength of patent protection.

We test the parallel–trend assumption for Model (4) by estimating a dynamic version of the model. We estimate the dynamic DiD model using the quarterly number of patents so that we have more data points when observing the pre–trends. Figure 4 reports the estimates of the dynamic DiD model. The sample includes 20 quarters for the same five–year period used in Table 3, with 1993Q1 as the base level (and hence not estimated) and 1995Q1 as quarter 0. The figure shows that the pre–trends appear parallel until quarter 0, after which the number of patent applications by the treated group sharply spikes in quarter 1 (1995Q2). As Abrams (2008) points out, the enforcement of the patent term extension of the URAA likely drives this spike. The new patent term, which is 20 years from the application date, applies to patents that are filed on and after June 8, 1995. However, subsection (c)(1) of URAA (1994) implicitly allows patents that were filed before June 8, 1995, to receive the longer of the old term and the new term. This provision incentivizes firms to rush their patent applications before June 8 to maximize the patent term. After the spike in patent filings in quarter 1, the number of patent applications by the treated group gradually but significantly increase. Overall, the parallel trend in patenting activity appears to hold in the pre–TRIPS period, supporting the validity of our DiD design.

5.2.2 TRIPS and Stock Liquidity

Given the results that firms in patent–reliant industries increase patenting more than other firms after the implementation of TRIPS, we expect these firms to also experience a greater improvement in stock liquidity post–TRIPS. We test our prediction using the following model:

Stock Illiquidityi,t = α1 + β1Post-TRIPSi,t × Treatedj + γ 0 1CONT ROLi,t−1 + φi + ψt + i,t. (5)

We measure stock illiquidity using Amihud’s measure and the annual average of daily closing bid– ask spread, because the high–frequency data used for relative effective spread are not available before 1993 and have limited coverage for the first few years. We control for the same set of control variables used in Model (4) and include firm and year fixed effects to account for time–invariant unobservable firm characteristics and the macroeconomic conditions, respectively. Standard errors are estimated with clustering at the four–digit NAICS industry level to account for within–industry correlation in stock liquidity. Based on H1, we predict the estimated β1 on the interaction term to be significantly negative, since we expect firms in patent–reliant industries to experience a greater reduction in stock illiquidity after the implementation of TRIPS relative to other firms.

Table 4 presents the estimates of Model (5). The results show that the DiD estimator is significantly negative for both measures of stock illiquidity. The effect is also economically significant: in the five–year period surrounding the implementation of TRIPS in the United States, the bid– ask spread (Amihud’s illiquidity) of treated firms decreased by 14.0% (27.1%) more than that of the control firms. Based on Lemley’s (1994) estimate of the average number of additional days of patent protection with the new term conferred by the URAA, our estimates suggest that the bid– ask spread (Amihud’s illiquidity) of firms in patent–reliant industries decreases by 0.06% (0.11%) for every additional day of patent protection. This is consistent with our prediction that the stock liquidity of firms in patent–reliant industries significantly improved more than that of other firms after the implementation of TRIPS.

Similar to Figure 4, here we also examine the pre–trends in stock illiquidity by estimating a dynamic version of Model (5) using quarterly data. Figures 5 and 6 present the estimates of the dynamic DiD models for the two measures of stock illiquidity. The figures show that the stock illiquidity of the treated firms does not exhibit a significant downward trend relative to the control firms until quarter 0, when TRIPS became effective. These results again support the parallel trends assumption of our DiD models.

#### Statistics prove liquidity is key to long-term growth.

Abdul-Khaliq 13 [Shatha; Assistant Professor, AlBlqa Applied University, Jordan; “The Impact of Stock Market Liquidity on Economic Growth in Jordan,” European Journal of Business and Management [www.iiste.org](http://www.iiste.org); 2013; <https://iiste.org/Journals/index.php/EJBM/article/viewFile/9456/9661#:~:text=Focusing%20on%20liquidity%2C%20Bencivenga%2C%20et,key%20role%20in%20economic%20growth.&text=By%20facilitating%20longer%20term%2C%20more,for%20long%20term%20economic%20growth>.] Justin

5. Data and Methodology

Generally, previous research using cross-country data supports the hypothesis that financial development leads to economic growth. Levine and Zervos (1996), use the regression equation: where X is a set of control variables, GROWTH is the real GDP growth rate and STOCK represents measurements of the stock market. So relationship of the form is :

GROWTH = β0 + β1 MC + β2MTR + e3

Where

MC = market capitalization as percentage of GDP

MTR = market turnover ratio as measure of stock market liquidity

The 20-year time-series (1991-2011) data used for this study was collected from Amman Stock Exchange Annual Reports and Accounts, Central Bank of Jordan Statistical Bulletin, various issues.

The summary descriptive statistics of the variables used (Table 1) show the mean, standard deviation and minimum and maximum value of the data. It is obvious from the table that GDP growth in Jordan ranges from 2% to 14% with an average of 5%. The average market capitalization as percentage of GDP has remained on 1.47 and its ranking continuously rise from 0.49 to 3.6 in the year 2005. The market turnover ratio is averaged at 51.9 starting from its minimum value of 11.59 in year 2000 to 102.1 in 2010.

5.1 Stationary Test: table 2 shows the unit root test using the augmented Dickey - Fuller (ADF). The objective of the unit root test is to empirically examine whether series contains a unit root or not. If the series contains a unit root, this means that the series is non-stationary. Otherwise, the series will be categorized as stationary. The unit root tests show that Economic growth, market capitalization as percentage of GDP and market turnover ratio are not stationary at the zero order both with constant and constant and trend terms. Hence, we move ahead to conduct the ADF test at first difference to further ascertain the stationary of the series. The unit root results at first difference rejects the null hypothesis of non-stationary at both 1 and 5 percent levels for Economic growth, market capitalization as percentage of GDP and market turnover ratio.

6.Results and discussions:

The methodology of the series of the regression using the Ordinary Least Squares (OLS) model to prove a significant correlation between market liquidity and economic growth. The Table 3 shows the regression results for the impact of Stock Market Liquidity on Economic Growth in Jordan. It shows that over 28 percent of the total changes in economic growth rate are explained by the included exogenous variables. The adjusted R-square result explains over 20 systemic changes in the model. The Durbin Watson Statistics indicates insignificant autocorrelation in the model represented above. The F-statistics is statistically significant at the 5 percent level The coefficient of market capitalization as percentage of GDP (MC) is negative but it is statistically insignificant. The coefficient of market turnover ratio (MTR) is significant at the 5% level and the sign is positive indicating that 1% increase in market turnover ratio will increase the growth rate of GDP by 0.06%. This means that market turnover ratio has more positive influence on economic growth in Jordan.

7. Conclusion

This study investigates the relationship of stock market liquidity and economic growth by taking market capitalization to GDP and turnover ratio as independent variables. The impact of these variables is empirically tested on economic growth as a dependant variable for the period of 1991 to 2011 using ADF unit root testing methodology and OLS regression. We find that the market turnover ratio has a stronger influence on economic growth than the of market capitalization to GDP

Finally,, governments should promote stock market liquidity by for instance propagating knowledge to the public of the benefits of investing in stock markets and to ensure higher liquidity on stock markets. These incentives would promote both domestic and foreign investments to penetrate the domestic economies, and thus help to increase economic growth.

#### Growth solves extinction.

Aschenbrenner 20 [Leopold Aschenbrenner; Student in economics at Columbia University and research affiliate at the University of Oxford’s Global Priorities Institute; "Securing posterity," Works in Progress; 10/19/20; <https://worksinprogress.co/issue/securing-posterity/>] julian // Re-Cut Justin

I argue that the opposite is the case. It is not safe stagnation and risky growth that we must choose between; rather, it is stagnation that is risky and it is growth that leads to safety. We might indeed be in “time of perils”: we might be advanced enough to have developed the means for our destruction, but not advanced enough to care sufficiently about safety. But stagnation does not solve the problem: we would simply stagnate at this high level of risk. Eventually, a nuclear war or environmental catastrophe would doom humanity regardless. Faster economic growth could initially increase risk, as feared. But it will also help us get past this time of perils more quickly. When people are poor, they can’t focus on much beyond ensuring their own livelihoods. But as people grow richer, they start caring more about things like the environment and protecting against risks to life. And so, as economic growth makes people richer, they will invest more in safety, protecting against existential catastrophes. As technological innovation and our growing wealth has allowed us to conquer past threats to human life like smallpox, so can faster economic growth, in the long run, increase the overall chances of humanity’s survival. This argument is based on a recent paper of mine, in which I use the tools of economic theory—in particular, the standard models economists use to analyze economic growth—to examine the interaction between economic growth and the risks engendered by human activity. In this model, society must choose how much of its resources to allocate to consumption and how much to safety efforts. Consumption makes us happy, but also creates risks of catastrophe. Investing in safety can in turn help mitigate that risk. For example, consuming fossil fuels can engender great prosperity, but also increases the risk of tail-end climate change. We can spend money on carbon abatement to reduce this risk. Or consider air travel. It’s very useful as well, but also facilitates the spread of infectious diseases, including potentially a pandemic that could wipe out the human race. We can spend money on pandemic preparedness to mitigate that risk. Crucially, society is impatient; it discounts the future. People generally care most about their more immediate well-being. Although they may care about their kids and grandkids, they are certainly not particularly concerned about the trillions of potential lives billions of years in the future that the aforementioned philosophers appeal to. However, an impatient society does care about not getting wiped out. Therefore, what fraction of its resources this impatient society will allocate to safety depends on how much the people in this society value their own lives. As it turns out, under the standard preferences used in economic theory, people value life more and more as they grow richer. This is because of the diminishing marginal returns of consumption. As you grow richer, using an extra dollar to purchase more consumption goods gives you less and less additional utility; meanwhile, as your life becomes better and better, you stand to lose more and more if you die. As a result, the richer people are, the greater the fraction of their income they are willing to sacrifice to protect their lives. Comparing the current pandemic to the 1918 pandemic illustrates this phenomenon. Today, we are putting much of life on hold to minimize deaths. By contrast, in 1918, nonpharmaceutical interventions were milder and went on only for a month on average in the U.S., even though the Spanish Flu was arguably deadlier and claimed younger victims. We are willing to sacrifice much more today than a hundred years ago to prevent deaths because we are richer and thus value life much more. What does this mean for our model? Initially, a poor society will start out by allocating nearly all of its resources to consumption. And so as the economy grows, so does risk. However, as people grow richer, they start valuing life more. They start investing in safety to mitigate risk, shifting more and more resources from consumption to safety. At this point, as the economy grows, risk begins to fall. The risk of a existential catastrophe then looks like an inverted U-shape over time: The dot represents where we might be right now. Over the past centuries, as we have grown out of poverty, we have overwhelmingly focused on consumption. As a result, risk is growing. But as we are growing richer, we are beginning to value life more, and are slowly investing more in safety. Eventually, we will have shifted enough resources to safety such that risk begins to fall—fall exponentially to zero, in fact, such that there is a positive probability of humanity surviving to reach a grand future. And all of this occurs despite our society’s impatience. There is an analog to this in environmental economics, called the “environmental Kuznets curve.” It was theorized that pollution initially rises as countries develop, but, as people grow richer and begin to value a clean environment more, they will work to reduce pollution again. That theory has arguably been vindicated by the path that Western countries have taken with regard to water and air pollution, for example, over the past century. The idea that we are in a unique time in history in which we are facing an elevated risk of existential catastrophe is not new either. Carl Sagan was the one who coined the term “time of perils.” Derek Parfit called it the “hinge of history.” They argue that the discoveries of the last centuries have granted humanity immense power, and so we are in a most “dangerous and decisive” period. But if we manage to survive, our descendants will be able to spread throughout the galaxy, making us much less vulnerable. They will have mastered new technologies that make us immune to bioengineered pathogens, neutralize the threat from atomic bombs, provide plentiful energy without destroying the environment, and keep artificial intelligence in check so it faithfully serves human needs. With their technology and wisdom, our descendants will be able to secure a long and safe future. Our challenge, then, is to make it through this unique perilous period. Seeing the rising levels of existential risk over the past centuries, some might call for an end to economic growth. They might argue, rightfully so, that economic growth has only led to rising risk in the past. Indeed, a period of accelerated economic growth would initially also accelerate the rise in risk. The level of risk might look something like this, where the lighter line is the path with accelerated growth: Even a few hundred years later, the critics of growth would seem to be vindicated! Faster growth just increased the risk! Except that they are missing the whole picture: The accelerated economic growth also accelerated our path along the inverted-U shape of risk. Faster growth means people are richer sooner, so they value life more sooner, so society shifts resources to safety sooner—and ultimately we will begin the decline in risk sooner. As a result, the overall probability of an existential catastrophe—the area under the risk curve—declines! Faster growth means we get through the “time of perils” more quickly. Indeed, stagnation would be the most dangerous choice of all: we would be stuck at an elevated level of risk, meaning an eventual existential catastrophe would be inevitable.

## Case

### UV

#### Reasonability on 1AR shells – 1AR theory is super aff-biased because the 2AR gets to line-by-line every 2NR standard with new answers that never get responded to– reasonability checks 2AR sandbagging by preventing super abusive 1NCs while still giving the 2N a chance.

#### DTA on 1AR shells - They can blow up a blippy 20 second shell to 3 min of the 2AR while I have to split my time and can’t preempt 2AR spin which necessitates judge intervention and means 1AR theory is irresolvable so you shouldn’t stake the round on it.

#### RVIs on 1AR theory – 1AR being able to spend 20 seconds on a shell and still win forces the 2N to allocate at least 2:30 on the shell which means RVIs check back time skew – ows on quantifiaiblity

#### No new 1AR paradigm issues- they had to chance to do it in the 1AC- and 7-6 rebuttal means they’ll always win

### 1NC- Innovation

#### THE FRAMING ISSUE IS THAT ROHACS HAS READ ONE CARD FOR HIS ENTIRE INTERNAL LINK WHICH MEANS A SUFFICIENT RISK OF DEFENSE/OFFENSE MEANS YOU SHOULDN’T GRANT HIM THE AFF

#### Pharma innovation high now – monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### The affs wholesale attack on secondary patents ruins innovation---prefer contingencies that solve evergreening.

Holman 18 [Christopher; 9/21/18; Professor at the University of Missouri-Kansas City School of Law, where his primary research focus lies at the intersection of intellectual property and biotechnology; “*Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection*,” Intellectual property watch, <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/>] Justin

Why Protect Follow-On Innovation? The attack on secondary pharmaceutical patents is based in part on the flawed premise that follow-on innovation is of marginal value at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, follow-on innovation can play a critical role in transforming an interesting drug candidate into a safe and effective treatment option for patients. A good example can be seen in the case of AZT (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT began its life as a failed attempt at a cancer drug, and it was only years later that its potential application in the fight against AIDS was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include Evista (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), Zyprexa (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. Pharmaceutical development is prolonged and unpredictable, and frequently a safe and effective drug occurs only as a result of follow-on innovation occurring long after the initial synthesis and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate). “Evergreening” – an Incoherent Concept Drug innovators are often accused of using secondary patents to “evergreen” the patent protection of existing drugs, based on an assumption that a secondary patent somehow extends the patent protection of a drug after the primary patent on the active ingredient is expired. As a general matter, this is a false assumption — a patent on an improved formulation, for example, is limited to that improvement and does not extend patent protection for the original formulation. Once the patents covering the original formulation have expired, generic companies are free to market a generic version of the original product, and patients willing to forgo the benefits of the improved formulation can choose to purchase the generic product, free of any constraints imposed by the patent on the improvement. Of course, drug innovators hope that doctors and their patients will see the benefits of the improved formulation and be willing to pay a premium for it, but it is important to bear in mind that ultimately it is patients, doctors, and third-party payers who determine whether the value of the improvement justifies the costs. Of course, this assumes a reasonably well-functioning pharmaceutical market. If that market breaks down in a manner that forces patients to pay higher prices for a patented new version of a drug that provides little real improvement over the original formulation, then it is the deficiency in the market which should be addressed, rather than the patent system itself. For example, if a drug company is found to have engaged in some anticompetitive activity to block generic competition in the market for the original product once it has gone off patent, then antitrust and competition laws should be invoked to address that problem. If doctors are prescribing an expensive new formulation of a drug that provides little benefit compared to a cheaper, unpatented original product, then that is a deficiency in the market that should be addressed directly, rather than through a broadside attack on follow-on innovation. In short, if is found that secondary patents are being used in a manner that creates an unwarranted extension of patent protection, it is that misuse of the patent system which should be addressed directly, rather than through what amounts to an attack on the patent system itself.

#### Strong IP protection are the only incentive for drug innovation.

Stevens and Ezell 20 Philip Stevens and Stephen Ezell 2-3-2020 "Delinkage Debunked: Why Replacing Patents With Prizes for Drug Development Won’t Work" <https://itif.org/publications/2020/02/03/delinkage-debunked-why-replacing-patents-prizes-drug-development-wont-work> (Philip founded Geneva Network in 2015. His main research interests are the intersection of intellectual property, trade, and health policy. Formerly he was an official at the World Intellectual Property Organization (WIPO) in Geneva, where he worked in its Global Challenges Division on a range of IP and health issues. Prior to his time with WIPO, Philip worked as director of policy for International Policy Network, a UK-based think tank, as well as holding research positions with the Adam Smith Institute and Reform, both in London. He has also worked as a political risk consultant and a management consultant. He is a regular columnist in a wide range of international newspapers and has published a number of academic studies. He holds degrees from the London School of Economics and Durham University (UK).)//Elmer

The **Current System** Has **Produced a Tremendous Amount of Life-Sciences Innovation** The frontier for biomedical innovation is seemingly limitless, and the challenges remain numerous—whether it comes to diseases that afflict millions, such as cancer or malaria, or the estimated 7,000 rare diseases that afflict fewer than 200,000 patients.24 And while certainly citizens in developed and developing nations confront differing health challenges, those challenges are increasingly converging. For instance, as of this year, analysts expect that **noncommunicable** diseases such as cardiovascular disease and diabetes will account for 70 percent of natural fatalities **in developing countries**.25 Citizens of low- and middle-income countries bear 80 percent of the world’s death burden from cardiovascular disease.26 Forty-six percent of Africans over 25 suffer from hypertension, more than anywhere else in the world. Similarly, 85 percent of the disease burden of cervical cancer is borne by individuals living in low- and middle-income countries.27 To develop treatments or cures for these conditions, novel biomedical innovation **will be needed from everywhere**. Yet tremendous progress has been made in recent decades. To tackle these challenges, the global pharmaceutical industry invested over **$1.36 trillion in R&D** in the decade from 2007 to 2016—and it’s expected that annual R&D investment by the global pharmaceutical industry will reach $181 billion by 2022.28 In no small part due to that investment, **943 new active substances have been introduced** globally over the prior 25 years.29 The U.S. Food and Drug Administration (FDA) has approved more than **500 new medicines since 2000** alone. And these medicines are getting to more individuals: Global medicine use **in 2020 will reach 4.5 trillion doses**, up 24 percent from 2015.30 Moreover, there are an estimated 7,000 new medicines under development globally (about half of them in the United States), with 74 percent being potentially first in class, meaning they use a new and unique mechanism of action for treating a medical condition.31 In the United States, over 85 percent of all drugs sold are generics (only 10 percent of U.S. prescriptions are filled by brand-name drugs).32 And while some assert that biotechnology companies focus too often on “me-too” drugs that compete with other treatments already on the market, the reality is many drugs currently under development are meant to tackle some of the **world’s most intractable diseases**, **including cancer and Alzheimer’s**.33 Moreover, such arguments miss that many of the drugs developed in recent years have in fact been first of their kind. For instance, in 2014, the FDA approved **41 new medicines** (at that point, the most since 1996) many of which were first-in-class medicines.34 In that year, 28 of the 41 drugs approved were considered biologic or specialty agents, and 41 percent of medicines approved were intended to treat rare diseases.35 Yet even when a new drug isn’t first of its kind, it can still produce benefits for patients, both through **enhanced clinical efficacy** (for instance, taking the treatment as a pill rather than an injection, with a superior dosing regimen, **or better treatment** for some individuals who don’t respond well to the original drug) and by generating competition that exerts downward price pressures. For example, a patient needing a cholesterol drug has a host of statins from which to choose, which is important because some statins produce harmful side effects for some patients. Similarly, patients with osteoporosis can choose from Actonel, Boniva, or Fosomax. Or take for example Hepatitis C, which until recently was an incurable disease eventually requiring a liver transplant for many patients. In 2013, a revolutionary new treatment called Solvadi was released that boosted cure rates to 90 percent. This was followed in 2014 by an improved treatment called Harvoni, which cures the Hepatitis C variant left untouched by Solvadi. Since then, an astonishing six new treatments for the disease have received FDA approval, opening up a wide range of treatment options that take into account patients’ liver and kidney status, co-infections, potential drug interactions, previous treatment failures, and the genotype of HCV virus.36 “If you have to have Hepatitis C, now is the time to have it,” as Douglas Dieterich, a liver specialist at the Icahn School of Medicine at Mount Sinai Hospital in New York, told the Financial Times. “We have these marvellous drugs we can treat you with right now, without side effects,” he added. “And this time next year, we’ll have another round of drugs available.”37 Moreover, the financial potential of this new product category has led to multiple competing products entering the market in quick succession, in turn placing downward pressure on prices.38 As Geoffrey Dusheiko and Charles Gore write in The Lancet, “The market has done its work for HCV treatments: after competing antiviral regimens entered the market, competition and innovative price negotiations have driven costs down from the initially high list prices in developed countries.”39 As noted previously, opponents of the current market- and IP-based system contend patents enable their holders to exploit a (temporary) market monopoly by inflating prices many multiples beyond the marginal cost of production. But rather than a conventional neoclassical analysis, an analysis based on “innovation economics” finds it is exactly this “distortion” that is required for innovation to progress. As William Baumol has pointed out, “Prices above marginal costs and price discrimination become the norm rather than the exception because … without such deviations from behaviour in the perfectly competitive model, innovation outlays and other unavoidable and repeated sunk outlays cannot be recouped.”40 Or, as the U.S. Congressional Office of Technology Assessment found, “Pharmaceutical R&D is a risky investment; therefore, high financial returns are necessary **to induce companies to invest** in researching new chemical entities.”41 This is also why, in 2018, the U.S. Congressional Budget Office estimated that because of high failure rates, biopharmaceutical **companies would need to earn a 61.8 percent rate of return on their successful new drug R&D projects in order to match a 4.8 percent after-tax rate of return on their investment**s.42 Indeed, **it’s the ability to recoup fixed costs, not just marginal** costs, through mechanisms such as patent protection that lies at the heart of all innovation-based industries and indeed all innovation and related economic progress. If companies could not find a way to pay for their R&D costs, and could only charge for the costs of producing the compound, **there would be no new drugs developed**, just as there would be no new products developed in any industry. Innovating in the life sciences remains expensive, risky, difficult, and uncertain. Just 1 in 5,000 drug candidates make it all the way from discovery to market.43 A 2018 study by the Deloitte Center for Health Solutions, “Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018,” found that “the average cost to develop an asset [an innovative life-sciences drug] including the cost of failure, has increased in six out of eight years,” and that the average cost to create a new drug has risen to $2.8 billion.44 Related research has found the development of new drugs requires years of painstaking, risky, and expensive research that, for a new pharmaceutical compound, takes an average of 11.5 to 15 years of research, development, and clinical trials, at a cost of $1.7 billion to $**3.2 billion**.45 IP rights—including patents, copyrights, and data exclusivity protections—give innovators, whether in the life sciences or other sectors, the **confidence** to undertake the risky and expensive process of innovation, secure in the knowledge they’ll be able to capture a share of the gains from their efforts. And these gains are often only a small fraction of the true value created. For instance, Yale University economist William Nordhaus estimated inventors capture just 4 percent of the total social gains from their innovations; the rest spill over to other companies and society as a whole.46 Without adequate IP protection, private investors would never find it viable to fund advanced research because lower-cost copiers would be in a position to undercut the legitimate prices (and profits) of innovators, even while still generating substantial profits on their own.47 As the report “Wealth, Health and International Trade in the 21st Century” concludes, “Conferring robust intellectual property rights is, in the pharmaceutical and other technological-development contexts, **in the global public’s long-term interests.** Without adequate mechanisms for directly and indirectly securing the private and public funding of medicines and vaccines, research and development communities across the world will lose future benefits that would far outweigh the development costs involved.”48 Put simply, the current market- and IP-based life-sciences innovation system is producing life-changing biomedical innovation. As Jack Scannell, a senior fellow at Oxford University’s Center for the Advancement of Sustainable Medical Innovation has explained, “I would guess that one can buy today, at rock bottom generic prices, a set of small-molecule drugs that has greater medical utility than the entire set available to anyone, anywhere, at any price in 1995.” He continued, “Nearly all the generic medicine chest was created by firms who invested in R&D to win future profits that they tried pretty hard to maximize; short-term financial gain building a long-term common good.”49 For example, on September 14, 2017, the FDA approved Mvasi, the first biosimilar for Roche’s Avastin, a breakthrough anticancer drug when it came out in the mid-1990s for lung, cervical, and colorectal cancer.50 In other words, a medicine to treat forms of cancer that barely existed 20 years ago is now available as a generic drug today. It’s this dynamic that enables us to imagine a situation wherein drugs to treat diseases that aren’t available anywhere at any price today (for instance, treatments for Alzheimer’s or Parkinson’s) might be available as generics in 20 years. But that will only be the case if we preserve (and improve where possible) a life-sciences innovation system that is generally working. The current system does not require wholesale replacement by a prize-based system that—notwithstanding a meaningful success here or there—has produced nowhere near a similar level of novel biomedical innovation.

#### Secondary and Follow-on patents are key to innovation.

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

Why Protect Follow-On Innovation? The **attack on secondary** pharmaceutical **patents is based** in part **on** the **flawed premise** that **follow-on innovation is of marginal value** at best, and thus less deserving of protection than the primary inventive act of identifying and validating a new drug active ingredient. In fact, **follow-on innovation** **can play** a **critical role in transforming** **an interesting drug candidate into a safe and effective treatment option** for patients. A good example can be seen in the case of **AZT** (zidovudine), a drug ironically described in the Guidelines as the “first breakthrough in AIDS therapy.” AZT **began** its life **as a** failed attempt at a **cancer drug**, and it was **only years later** that its potential **application in the fight against AIDS** was realized. Follow-on research resulted in a method-of-use patent directed towards the use of AZT in the treatment of AIDS, and it was this patent that incentivized the investment necessary to bridge the gap between a promising drug candidate and a safe, effective, and FDA-approved pharmaceutical. Significantly, because of the long lag time between the first public disclosure of AZT and the discovery of its use in the treatment of AIDS, patent protection for the molecule per se was unavailable. In a world where follow-on innovation is unpatentable, there would have been no patent incentive to invest in the development of the drug, and without that incentive AZT might have languished on the shelf as simply one more failed drug candidate. Other examples of important drugs that likely never would have been made available to patients without the availability of a “secondary” patent include **Evista** (raloxifene, used in the treatment of osteoporosis and to reduce the risk of invasive breast cancer), **Zyprexa** (olanzapine, used in the treatment of schizophrenia), and an orally-administrable formulation of the antibiotic cefuroxime. **Pharmaceutical development** **is prolonged and unpredictable**, and frequently **a safe and effective drug** **occurs only as a result of** **follow-on innovation** occurring **long** **after the initial synthesis** and characterization of a pharmaceutically interesting chemical compound. The inventions protected by secondary patents can be just as critical to the development of drugs as a patent on the active ingredient itself. The Benefits of Follow-On Innovation The criticism of patents on follow-on pharmaceutical innovation rests on an assumption that follow-on innovation provides little if any benefit to patients, and merely serves as a pretense for extending patent protection on an existing drug. In fact, there are many examples of follow-on products that represent significant improvements in the safety-efficacy profile. For example, the original formulation of Lumigan (used to treat glaucoma) had an unfortunate tendency to cause severe hyperemia (i.e., redeye), and this adverse event often lead patients to stop using the drug, at times resulting in blindness. Subsequent research led to a new formulation which largely alleviated the problem of hyperemia, an example of the type of follow-on innovation that significantly benefits patients but that which would be discouraged by a patent regime that does not reward follow-on innovation. Follow-on pharmaceutical innovation can come in the form of an extended-release formulation that permits the drug to be administered at less frequent intervals than the original formulation. Critics of secondary patents downplay the significance of extended-release formulations, claiming that they represent nothing more than a ploy to extend patent protection without providing any real benefit to patients. In fact, the availability of a drug that can be taken once a day has been shown to improve patient compliance, a significant issue with many drugs, particularly in the case of drugs taken by patients with dementia or other cognitive impairments. Extended-release formulations can also provide a more consistent dosing throughout the day, avoiding the peaks and valleys in blood levels experienced by patients forced to take an immediate-release drug multiple times a day. Other examples of improved formulations that provide real benefits to patients are orally administrable formulations of drugs that could previously only be administered by more invasive intravenous or intramuscular injection, combination products that combine two or more active pharmaceutical agents in a single formulation (resulting in improved patient compliance), and a heat-stable formulation of a lifesaving drug used to treat HIV infection and AIDS (an important characteristic for use in developing countries with a hot climate).

#### EXTENDED PATENTS ARE KEY TO FUND RESEARCH, NO MONEY TO PAY FOR NEW INNOVATIONS POST PLAN

**Bloom 12** (Josh Bloom (director of chemical and pharmaceutical sciences at the American Council on Science and Health, a health-care education and advocacy group based in New York). Should Patents on Pharmaceuticals Be Extended to Encourage Innovation? 1/23/2012, https://www.wsj.com/articles/SB10001424052970204542404577156993191655000#)

The American pharmaceutical industry is seriously ill. And extended patent protection is just the medicine the drug companies need. Pharmaceutical companies have long been demonized by many politicians and others as heartless behemoths that place profit ahead of people's well-being. But that perception couldn't be more wrong. The profits these companies make on blockbuster medications support the research that produces such breakthroughs. And the scientists working in the labs are fervently committed to finding useful new medicines. Unfortunately, there are far fewer of those scientists at work than there were 10 years ago, and their companies are in trouble. What's the problem? A confluence of events in recent years has made drug discovery more difficult, expensive and time consuming. Most important, it has become less profitable, largely because longer development times mean companies have less time left under patents to exclusively market their discoveries. Now, the industry faces a financial crisis because of the recent or imminent expiration of the patents on many of its most profitable drugs. Without extended patent protection for new discoveries, the industry won't be able to fund the current level of research. And the consequences are profound: decreased innovation, fewer new drugs and more job losses. Ugly Numbers Next time you hear about a drug making billions of dollars for its maker, consider this: Currently, bringing one new drug to market takes roughly 14 years, at a cost of about $1.3 billion. For every drug that makes it to market, more than 50 other research programs fail. After all that, only two of every 10 newly approved drugs will be profitable. Those profits must fund not only all the research programs that failed, but also all the drugs that are launched but lose money. When the industry was producing a steady stream of blockbuster drugs, as it did beginning in the 1990s (for example, all the AIDS drugs), the math worked in its favor. But in recent years the numbers have turned against the drug industry, for several reasons. For one, the Food and Drug Administration has become more risk-averse in the wake of the 2004 Vioxx debacle. Drug makers are now required to conduct more studies with many more subjects. That adds to costs and stretches out development times. And every year spent in clinical trials equals one year of lost patent coverage. In 1968, when development time was much shorter than today, most drugs had an effective patent life of about 17 years. Now companies usually have only about 11 years of market exclusivity for their drugs. And this number is expected to continue dropping as development times grow even longer—approaching a point where the costs and risks of development outweigh the rewards and research will stop. Many of the diseases addressed in the 1990s were simply easier to tackle. Since then, despite increased research spending, fewer breakthrough drugs have been discovered. Difficult conditions such as cancer, Alzheimer's, Parkinson's and obesity remain problematic. Amid all these challenges, the drug industry is losing its financial cushion as patents from the 1990s expire. Since 2006, brand drugs have lost an estimated $60 billion in sales because of patent expirations; by 2015, this figure is projected to rise to $160 billion. This is the so-called patent cliff. It shouldn't be surprising, then, that the industry is showing signs of stress. The share prices of the major drug makers have fallen sharply in the past decade, and weakened companies have succumbed to mergers and acquisitions, causing the elimination of 300,000 jobs during this time. Stretch Some, Cut Others Extension of patent life for the most innovative drugs would, at the very least, postpone the rush toward the patent cliff, providing drug companies with extra time to discover the next cycle of new, innovative therapies. With U.S.-based drug companies scaling back their research, there will be fewer discoveries to fill the gap and keep new treatments coming to market. Academic researchers are very good at studying the basic biology of a disease, but this is just the very beginning of the discovery process. The lion's share of the work—progressing from basic biology to an actual drug—requires the expertise and resources that academic and government labs simply don't have. Of course, longer patents would mean that important drugs would remain relatively expensive for a longer time. But the expense of new drugs is preferable to not having them at all. The fact that drug companies thrived in the past without patent protection is irrelevant. Companies didn't face the regulatory and competitive environment of today. For example, generic competition was minimal until the 1980s. Remember that manufacturers of generic drugs contribute nothing to innovation. Yet they take up to 90% of sales away from the comparable brand-name drugs whose makers risked the time and money to bring breakthrough treatments to market. There are some drugs that deserve less patent protection. These are the so-called line extensions—where companies simply tweak existing drugs enough to earn a new patent. Virtually identical to the original compound, these provide little real innovation. When companies are under economic stress, line extensions may become an attractive way to keep revenue flowing, drawing resources away from innovative, more important work. To discourage that and to keep drug companies focused instead on innovative treatments, patents for line extensions should be shortened, perhaps by three years or so, while patents for high-risk, first-in-class drugs and those that address unmet medical needs should be extended significantly—five more years could be a starting point for discussion. (Most drugs now get 20 years of protection from the time a patent application is filed, which is effectively about 11 years after accounting for development time.) One alternative that has been suggested is that in order to gain FDA approval, new drugs should have to demonstrate superiority to existing ones. This would be unrealistic because that standard could hardly ever be met in clinical trials—in nearly all cases you can't tell the real differences between two drugs until they are in the marketplace and being taken by millions of people. A well-planned extension of patent protection, especially for innovative drugs, is both reasonable and necessary to keep what is left of the American pharmaceutical industry healthy enough to continue its crucial work. In the absence of a remedial measure like patent-life extension, the industry will continue its decline, resulting in incalculable losses to the U.S. economy and poorer medical care for its citizens. This would be a national disgrace.

#### EVEN IF INDIVIDUAL PATENTS DON’T FOSTER INNOVATION, THE COLLECTION OF THOSE PATENTS DRIVE INNOVATION

**Thomas 09** (John R. Thomas (Visiting Scholar, Congressional Research Studies), November 13, 2009, Patent “Evergreening”: Issues in Innovation and Competition, <https://ipmall.law.unh.edu/sites/default/files/hosted_resources/crs/R40917_091113.pdf>)

Patent law experts believe that these legal standards appropriately recognize that most technological progress occurs on an incremental basis. Attorney Ivar Kaardal explains that “most patents ... are granted for incremental, or even insignificant, technological advances.”66 Some observers believe that, on an individual or collective basis, patents on more marginal improvements may provide the public with valuable sources of technological information. As Jeanne C. Fromer, a member of the Fordham Law School faculty, states: while there are a rising number of patents for incremental technical advances, which individually might not be commercially or informationally valuable, the collectivity of incremental advances provides essential information for further innovation in many areas.... 67 Some commentators also believe the critique that many “evergreen” patents represent trivial variations of earlier technologies is misplaced. They assert that many patented improvements provide significant practical benefits. For example, a new formulation may make a known medication easier to use, leading to greater patient compliance, or cause fewer side effects.

### 1NC – AT: AMR

#### AMR TREATMENTS ARE COMING NOW, SQUO SOLVES

EurekAlert! 9/16 (science news-release distribution platform, operated by the nonprofit American Association for the Advancement of Science (AAAS), as a resource for journalists, public information officers (PIOs) and the public to communicate and engage with scientific research) 9/16/21, Ground-breaking bacteria-killing viruses unite with antibiotics to fight devastating antibiotic-resistant bacteria, <https://www.eurekalert.org/news-releases/927986>?

Mycobacterium abscessus, a relative of the bacteria that cause tuberculosis and leprosy, is responsible for particularly severe damage to human lungs and can be resistant to many standard antibiotics, making infections extremely challenging to treat. However, there is hope. Bacteria are vulnerable to naturally occurring viruses, called bacteriophages; for every species of bacteria, there is a unique bacteriophage that will destroy it. Scientists are testing new therapies that combine bacteriophages with the antibiotics that we currently use, to treat antibiotic-resistant infections. In their current Disease Models & Mechanisms article, Laurent Kremer and colleagues from Université de Montpellier, France, and University of Pittsburgh, USA, investigate the antibacterial effects of a new combination therapy, treating infections caused by the antibiotic-resistant bacteria M. abscessus with a bacteriophage and an antibiotic. Previously, the Pittsburgh team had identified one bacteriophage out of 10,000, known as ‘Muddy’, that efficiently kills bacteria in a petri dish and could be a candidate for treating these infections in humans. However, the team wanted to find an alternative to testing their new therapy in patients. Knowing that human cystic fibrosis patients are particularly vulnerable to M. abscessus infections, Kremer and colleagues decided to test their new combination therapy on zebrafish carrying the key genetic mutation that causes cystic fibrosis in humans and mimics how our immune system responds to bacterial infections. Then the team obtained samples of an antibiotic-resistant form of M. abscessus from a cystic fibrosis patient to infect the cystic fibrosis zebrafish and test their new treatment. First, they needed to find out how these cystic fibrosis zebrafish reacted to the M. abscessus infection. Monitoring the animals for 12 days, they found that the fish developed serious infections with abscesses and suffered a high death rate; only 20% survived. Next the team tested how well the infected fish recovered when injected with Muddy, the antibacterial bacteriophage, over a period of 5 days. This time, the fish had much less severe infections, increased chances of survival (40%) and had fewer of the abscesses suffered by the fish during a severe infection. Then the authors searched for an antibiotic to pair up with Muddy and found that rifabutin could treat the M. abscessus infection as effectively as the bacteriophage alone. After identifying rifabutin, Kremer and colleagues treated the infected fish for 5 days with the antibiotic and bacteriophage. With this combination treatment, the fishes’ infections were much less severe; the fishes’ survival rate rocketed to 70% and they suffered far fewer abscesses. This is a dramatic improvement compared to fish treated with only the antibiotic, which had a 40% survival rate. Having shown that it is possible to treat an antibiotic-resistant infection in vulnerable zebrafish with specially targeted bacteriophages, the authors hope this treatment can eventually be transferred to the clinic to begin saving human lives. “We need clinical trials, but there will be many other questions to be answered on our way there […] and zebrafish provide a very helpful tool for advancing these questions.” says Graham Hatfull from University of Pittsburgh, USA. Matt Johansen (Université de Montpellier, France) is optimistic that zebrafish will continue to play a key role in our battle against antibiotic-resistance, saying “We believe that zebrafish will help us understand many bacteriophage-bacteria pairings in our fight against multi-drug resistant pathogens”.

#### Low prices cause AMR.

Babu and Suma 6 Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)//Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

#### Secondary patents are key to innovation that solves AMR.

Salmieri 18 [Gregory; 2018; “*INTELLECTUAL PROPERTY AND THE FREEDOM NEEDED TO SOLVE THE CRISIS OF RESISTANT INFECTIONS*,” <http://georgemasonlawreview.org/wp-content/uploads/2019/04/26-1_7-Salmieri.pdf>] Justin

II. THE RIGHT TO THE VALUE CREATED BY RESPONSIBLE STEWARDSHIP Consider how the two-fold problem of growing resistance to our current antimicrobial drugs and the dearth of new antimicrobials under development looks once the specifics are omitted. Forget for a moment that the subject is drugs and microbes—or even inventions as opposed to other sorts of property—and just focus on the structure of the predicament.35 There is a resource of immense value that is being used myopically in a way that destroys existing stocks of the resource, and little is being done to find or develop new stocks of it. This is a pattern one expects to see with unowned resources, but not with owned ones. It is the classic “tragedy of the commons.” When a patch of grazing land is owned in common by everyone—which is just to say it is unowned—everyone has an incentive to make what use of it he can, leading to its overuse and destroying its value. By contrast, an owner can use land judiciously in ways that preserve its value or even to invest in improving the land. This is possible because the owner has exclusive control of the land in the present and therefore can control its uses, and because the owner expects to reap the benefit of the land’s future value. If deeds to land expired after twenty years, with the land reverting to the commons, land owners would have no financial incentives to preserve or enhance the land’s value past the twenty-year window. In this scenario, they could not afford to forgo shortterm gains that came at the expense of the land’s later value. Nor could they afford to invest in long-term improvement projects, such as clearing new land for grazing. This is the predicament with antimicrobial drugs. The profligate use of such drugs in the present destroys their value in a future in which they are unowned. This suggests the simple solution of extending the patent terms for antimicrobial drugs. So long as the drug remains under patent, the patent holder has both an interest in preserving its usefulness and the ability to control its use so as to preserve its value. How long should the patent term be extended? The five years of extra market exclusivity offered by the GAIN Act is calculated with a view to incentivizing companies to invest in developing new drugs. The aim of the present proposal is different. It is to enable the creators of drugs to profitably exercise their rights over the drugs in a manner that preserves the drugs’ effectiveness over time—ideally into the indefinite future. This requires extending the term of exclusivity not just a few years or decades, but as far into the future as there is reason to hope that the drugs’ effectiveness can be maintained. There are various ways in which this suggestion could be further developed; perhaps the most promising is simply to allow patents on antimicrobial drugs to be renewed indefinitely, so long as the drugs’ continued effectiveness can be demonstrated. (How exactly continued effectiveness should be demonstrated is a matter of detail, but likely by showing resistance to be below a certain threshold—perhaps 20 percent—in clinical isolates of interest.36) This would allow for a potentially infinite patent term. “Perpetual patents” have occasionally been proposed, 37 but the lack of a fixed term may do violence to the notion of a patent, so it may be better to conceive of this as a proposal for a new type of IP right that combines features of patents and trademarks. Conceptualizing the relevant right in this way highlights its basis. Like a patent, the right would pertain to an invention and would confer market exclusivity; like a trademark, however, it would be renewable in perpetuity on the grounds that the continued value of the property depends on the owner taking continuous action to maintain it. In the case of the right under consideration, the relevant actions would be those of stewarding the drug in such a manner as to prolong its continued effectiveness in the face of resistance. This new sort of property right could, in principle, be applied to drugs that are already off patent or otherwise ineligible for patent protection. The Chatham House Working Group proposes granting “delinkage rewards” to “firms registering a new antibiotic without patent protection (such as new uses for old drugs),”38 and it may be that the sort of IP protection proposed here would be applicable in such cases as well. If so, the right would be justified by the discovery of the new use for the drug and by the fact that intelligent management of this use is required for it to retain its value. A more difficult case is granting such rights to already known antibiotics that have gone off patent and are now available as generics. Removing these drugs from the commons would make it possible for an owner to profit by stewarding them responsibly. The difficulty here is determining who would own them. Professor Kades considers the possibility of granting a new patent to the original patent holder, but suggests “auctioning the patent rights [to such drugs] to the highest bidder.”39 Both are plausible solutions. Another option, in light of the issue of cross-resistance (which will be discussed in Part III) would be to apportion the IP rights to the relevant drugs among the owners of other drugs with similar mechanisms of action. Instituting the sort of property right described here (whether or not it is extended to drugs that are currently unpatentable and/or in the public domain) would create an environment in which pharmaceutical companies and other private entities can compete to develop new policies and business models that maximize the total value derived from antimicrobial drugs over time. An important advantage of this proposal is that it does not require policymakers (or authors of law review articles) to know in advance which specific practices would have this auspicious effect. However, some obvious possibilities suggest themselves. Pharmaceutical companies could sell new antimicrobials at a price high enough to make it prohibitive to use them as anything other than treatments of last resort. In addition to extending the drugs’ useful lives, the high prices would compensate for the lower initial volume of sales, and the drugs could eventually be repriced for wider use as second- and then first-line treatments. This repricing would have to be paced both to the growth of the resistant bacterial population and to the development of new antimicrobial drugs to take their predecessors’ place as treatments of last resort. One can imagine many variations of this strategy with different price points and development cycles. Pharmaceutical companies could also extend the effective lifespan of their antimicrobials through contractual arrangements with healthcare providers, which restrict the latter’s use of the drugs to certain protocols or best practices. Imagine the new business practices whereby pharmaceutical companies might profit from drugs that are never or hardly ever used. Licensing plans like the one proposed by Commissioner Gottlieb might be employed in innovative ways.40 For example, healthcare providers or insurance companies might pay a monthly fee for the right to use these drugs should it ever become necessary to do so. Or the various parties might negotiate a system whereby a pharmaceutical company (or an entity that has licensed drugs from multiple companies) charges a fixed price for treatment in accordance with a proprietary antimicrobial protocol that makes use of several of their drugs, specifying which drugs can used under which conditions. The suggestions in the last paragraph all amount to ways in which revenues from the creation of a new drug might be “delinked” from sales volume. In principle, this delinkage could occur simply through market forces, without any additional policy interventions, but since governments and multinational organizations account for most of the spending in the healthcare sector in much of the world, their adopting policies favoring delinkage would likely stimulate the development of these sorts of business models under an IP regime of the sort suggested. Indeed, such delinkage–promoting policies would likely fare better under the proposed IP regime than under the current IP system because, as The Chatham House Working Group observes, “patent expiry” creates some difficulties for such policies. Obligations for responsible use can be carefully crafted and functional when monopoly rights are in place, but are likely to fail once generic antibiotics are introduced upon the termination of the period of exclusivity. Generic manufacturers ordinarily rely on volume-based rewards, and low prices and large volume of sales without appropriate measures to conserve the antibiotics may be an important driver of indiscriminate use and resistance. A sustainable system will require controls on market entry after termination of the patent, and regulation of the way the generic products are marketed and prescribed.41 It bears emphasizing at this point that the best stewardship policies for antimicrobial drugs remain to be discovered. The Chatham House Working Group report (quoted several times above) represents the cutting edge of research on this issue, and it offers precious few details about the new “delinked” business model it says “needs to be developed.” Successful business models are rarely if ever specified from on high by public policy makers. Securing a long-range IP right to antimicrobial drugs would create the conditions in which the healthcare industry as a whole could invest the resources required to discover the practices, protocols, and business models that maximize the value of these substances. In addition, the ability to capture this value as profit would create an incentive to develop new drugs as needed. IP rights, and patents in particular, are sometimes understood as bargains between creators and society. The proposal under consideration grants a lot more to the developers of any new antimicrobial drugs than they are granted under current law, but it asks a lot of these developers in return—for it requires them to become good stewards of their drugs by discovering and implementing the means necessary to preserve the drugs’ value over time, so that the maximum potential benefit from them is realized.42 This is work that needs to be done by someone, and the sort of IP regime proposed here would enable those people and firms most qualified to do this work to profit by doing it. This leads to a deeper point. Although IP rights are often understood as special privileges granted by government and justified on utilitarian grounds, the dominant strand in early American jurisprudence, taking its inspiration from John Locke, regards all property rights as securing to a creator the fruits of his productive work.43 Among the reasons why patents and copyrights are finite in duration, whereas rights to chattels or land can be passed on from generation to generation indefinitely, is that chattels and land generally need to be maintained in order to retain their economic value over time, whereas this is not true of the economic value of an artwork or a method.44 But the case under consideration reveals that the continued economic value of certain methods does depend on an ongoing process of intelligent management by which one uses the method sparingly. It is this very fact that (according to the argument of this Part) justifies extending the IP right to the drug indefinitely. This raises the question of whether there are structurally similar cases in other fields, where the continued commercial value of a potential invention depends on its judicious use. If so, it may be that there are other values being destroyed (or never created) because of tragedies of the commons that could be rectified by policies analogous to the one suggested here.

### 1NC – AT: Feldman and Wang

#### THIS ALSO APPLIES TO ARNOLD VENTURES- THAT’S WHAT THEY CITE FROM

#### Your author pulls warrants from a misleading and incomplete database – dates aren’t updated, protections are misidentified, and years are wrong.

**C-Ip 3/4** (C-Ip2, 3-4-2021, "UC Hastings’ Evergreen Drug Patent Search Database: A Look Behind the Statistics Reveals Problems with this Approach to Identifying and Quantifying So-Called “Evergreening”," Center for Intellectual Property x Innovation Policy, <https://cip2.gmu.edu/2021/03/04/uc-hastings-evergreen-drug-patent-search-database-a-look-behind-the-statistics-reveals-problems-with-this-approach-to-identifying-and-quantifying-so-called-evergreening/#_ftn1>)The problems we have identified with the statistics provided by the Evergreening Database are numerous and multifaceted, and it would be beyond the scope of a single blog post to try to address them all. Instead, we have decided to focus on a single drug, ranolazine, which is used to treat angina and marketed by Gilead under the tradename Ranexa. There is nothing particularly unique about ranolazine—the problems with its statistics are representative of what we have generally observed to be pervasive throughout the Database. The ranolazine entry caught our attention because it purports to show that the drug was a subject of a relatively large number of “protections” (24 of them) and 13 years of “additional protection time,” even though the total time between the approval of the drug and expiration of all associated patents and exclusivities was only a little more than 13 years—about five years less than the average term of a U.S. patent. We will start with an initial explanation of the methodology underlying the Evergreening Database. As mentioned above, the statistics are derived from out-of-date versions of the FDA’s Orange Book, which is published on the FDA’s website and provides information on patents and “exclusivities” associated with FDA-approved drugs. The exclusivities can be any of a variety of non-patent regulatory exclusivities that Congress created to reward innovators that have achieved certain outcomes that Congress sought to incentivize. Examples include the “NCE exclusivity”—five years of data exclusivity awarded for the initial approval of a new active ingredient, i.e., a “new chemical entity”—and the seven years of orphan drug exclusivity awarded to an innovator that develops a drug for a rare disease or condition. The Orange Book provides a listing of these exclusivities, as well as a list of patents relating to the approved drug (i.e., patents claiming the drug’s active ingredient, formulations of the drug, and methods of using the drug). It also provides expiration dates for the patent and exclusivities. The FDA periodically revises the Orange Book, and when it does, it removes from the lists any patents and exclusivities that have expired. The creators of the Evergreening Database compiled this historical data in a Comma Separated Values file (“the CSV file”). The Database uses the patents and exclusivities derived from the CSV file to generate various statistics for each drug, including a total number of “protections” and “extensions,” as well as the “earliest protection date,” “latest protection date,” and the number of “months of additional protection” (which is the time between the earliest protection date and the latest protection date). Presumably, these statistics are intended to shed some light on the purported evergreening practices of pharmaceutical companies. Now let us turn to ranolazine. The Evergreening Database entry for ranolazine provides the New Drug Application (“NDA”) number for the drug (21526), the branded product name (Ranexa), the name of the innovator company associated with the branded drug (Gilead), and the date of FDA approval (January 27, 2006). The ranolazine entry also provides various statistics derived from the raw data, including the number of “protections” (26) and the amount of “additional protection time” (156 months, i.e., 13 years). This seems to provide an example of evergreening. The statistics appear to show that Gilead gamed the system to “artificially extend the protection horizon of its patents” by 13 years. However, a closer examination of the raw data tells a quite different story. First, what are the 26 purported “protections” that Gilead has apparently secured with respect to Ranexa? Eleven of them are patents that were once listed in the Orange Book for the drug. All the listed patents have expired, so none appear in the current Orange Book. While the Database lists the patents, it does not include expiration dates, which are necessary to understand the “protection time” statistics. Worse, the Database provides no information with respect to the other 15 “protections,” i.e., non-patent exclusivities. With some effort, the missing information can be found in the CSV file. The following step-by-step instructions will hopefully make it easier for others interested in following this path. Beginning on the homepage for the Evergreening Database, click on the “About the Data” hyperlink, which will take you to another page which states: To download the original dataset, that was used to develop the results for the article May Your Drug Price Be Evergreen, along with information about researching the FDA’s Orange Book, please see:

#### Feldman [\*\*and Wang\*\*] is a joke.

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

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

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

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

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

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

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

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

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

### 1NC – AT: Climate Change

#### 1] The card just mentions “life sciences” not medical pharma- no IL and alt methods solve

#### 2] Don’t let them weigh the total sum of life sciences- only the amount they spillover

### 1NC – AT: Health Diplomacy

#### 1] No uniqueness again- current levels of health diplomacy due to vaccine sharing in COVID solves