# Greenhill R6 – 1NC v Westlake MR

## 1

#### Interp: 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: the affirmative prevents a future increase in patents by eliminating beyond the first patent

#### Negate:

#### 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] Precision – anything else justifies the aff jettisoning which decks ground and prep because the aff isn’t in the rez – non-jurisdictional cuz you can’t affirm if they haven’t affirmed.

#### 3] TVA – defend the advantage to an aff about reducing patents forever – they would still apply and allows for negative disads to link.

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

#### Drop the debater to deter future abuse and set better norms.

#### Competing interps – reasonability is arbitrary and encourages judge intervention – competing interps creates a race to the top where we create the best norms.

#### No RVIs – you don’t win for being fair and incentivizes baiting theory which leads to maximally abusive practices

## 2

### 1NC – FW

#### Permissibility and presumption negate – [a] the resolution indicates the aff has to prove an obligation, and permissibility would deny the existence of an obligation [b] Statements are more often false than true because any part can be false. This means you negate if there is no offense because the resolution is probably false.

#### Yoda once said “many of the truths that we cling to depend on our point of view.” Relinquish yourself from these truths by acknowledging that ethics must begin a priori:

#### [1] Uncertainty – our experiences are inaccessible to others which allows people to say they don’t experience the same, however a priori principles are universally applied to all agents.

#### [2] Bindingness – I can keep asking “why should I follow this” which results in skep since obligations are predicated on ignorantly accepting rules. Only reason solves since asking “why reason?” requires reason which concedes its authority and equally proves agency as constitutive

#### That means we must universally will maxims— any non-universalizable norm justifies someone’s ability to impede on your ends.

#### Thus, the standard is consistency with the categorical imperative.

#### Prefer the standard: freedom is the key to the process of justification of arguments. Willing that we should abide by their ethical theory presupposes that we own ourselves in the first place. Thus, it is logically incoherent to justify the neg arguments/standard without first willing that we can pursue ends free from others

### 1NC – Offense

#### 1] Intellectual property is an inalienable personal right of economic use

**Pozzo 6** Pozzo, Riccardo. “Immanuel Kant on Intellectual Property.” Trans/Form/Ação, vol. 29, no. 2, 2006, pp. 11–18., doi:10.1590/s0101-31732006000200002. SJ//DA recut Cookie JX

Corpus mysticum, opus mysticum, propriété incorporelle, proprietà letteraria, geistiges Eigentum. All these terms mean **intellectual property, the existence of which is intuitively clear because of the unbreakable bond that ties the work to its creator.** The book belongs to whomever has written it, the picture to whomever has painted it, the sculpture to whomever has sculpted it; and this independently from the number of exemplars of the book or of the work of art in their passages from owner to owner. The initial bond cannot change and it ensures the author authority on the work. Kant writes in section 31/II of the Metaphysics of Morals: “Why does unauthorized publishing, which strikes one even at first glance as unjust, still have an appearance of being rightful? Because on the one hand a book is a corporeal artifact (opus mechanicum) that can be reproduced (by someone in legitimate possession of a copy of it), so that there is a right to a thing with regard to it. On the other hand a book is also a mere discourse of the publisher to the public, which the publisher may not repeat publicly without having a mandate from the author to do so (praestatio operae), and this is a right against a person. The error consists in mistaking one of these rights for the other” (Kant, 1902, t.6, p.290). The corpus mysticum, **the work considered as an immaterial good, remains property of the author on behalf of the original right of its creation. The corpus mechanicum consists of the exemplars of the book or of the work of art. It becomes the property of whoever has bought the material object in which the work has been reproduced or expressed.** Seneca points out in De beneficiis (VII, 6) the difference between owning a thing and owning its use. He tells us that the bookseller Dorus had the habit of calling Cicero’s books his own, while there are people who claim books their own because they have written them and other people that do the same because they have bought them. Seneca concludes that the books can be correctly said to belong to both, for it is true they belong to both, but in a different way **The peculiarity of intellectual property consists thus first in being indeed a property, but property of an action; and second in being indeed inalienable, but also transferable in commission and license to a publisher. The bond the author has on his work confers him a moral right that is indeed a personal right. It is also a right to exploit economically his work in all possible ways, a right of economic use, which is a patrimonial right. Kant and Fichte argued that moral right and the right of economic use are strictly connected, and that the offense to one implies inevitably offense to the other.** In eighteenth-century Germany, the free use came into discussion among the presuppositions of a democratic renewal of state and society. In his Supplement to the Consideration of Publishing and Its Rights, Reimarus asked writers “instead of writing for the aristocracy, to write for the tiers état of the reader’s world.” (Reimarus, 1791b, p.595). **He saluted with enthusiasm the claim of disenfranchising from the monopoly of English publishers expressed in the American Act for the Encouragement of Learning of May 31, 1790. Kant, however, was firm in embracing intellectual property. Referring himself to Roman Law, he asked for its legislative formulation not only as patrimonial right, but also as a personal right.** In Of the Illegitimity of Pirate Publishing, he considered the moral faculties related to **intellectual property as an “inalienable right (ius personalissimum) always himself to speak through anyone else, the right, that is, that no one may deliver the same speech to the public other than in his (the author’s) name”** (Kant, 1902, t.8, p.85). Fichte went farther in the Demonstration of the Illegitimity of Pirate Publishing. **He saw intellectual property as a part of his metaphysical construction of intellectual activity, which was based on the principle that thoughts “are not transmitted hand to hand, they are not paid with shining cash, neither are they transmitted to us if we take home the book that contains them and put it into our library.** In order to make those thoughts our own an action is still missing: we must read the book, meditate – provided it is not completely trivial – on its content, consider it under different aspects and eventually accept it within our connections of ideas” (Fichte, 1964, t.I/1, p.411). At the center of the discussion was the practice of reprinting books in a pirate edition after having them reset word after words after an exemplar of the original edition. Given Germany’s division in a myriad of small states, the imperial privilege was ineffective against pirate publishing. Kant and Fichte spoke for the acceptance of the right to defend the work of an author by the usurpations of others so that he may receive a patrimonial advantage from those who utilize the work acquiring new knowledge and/or an aesthetic experience. In particular, Fichte declared the absolute primacy of the moral faculties within the corpus mysticum. He divided the latter into a formal and a material part. “This intellectual element must be divided anew into what is material, the content of the book, the thoughts it presents; and the form of these thoughts, the manner in which, the connection in which, the formulations and the words by means of which the book presents them” (Fichte, 1964, t.I/1, p.411). Fichte’s underlining the author’s exclusive right to the intellectual content of his book – “the appropriation of which through another is physically impossible” (ibid.) – brought him to the extreme of prohibiting any form of copy that is not meant for personal use. In Publishing Considered anew, Reimarus considered on the contrary copyright in its patrimonial aspects as a limitation to free trade: “What would not happen were a universal protection against pirate publishing guaranteed? Monopoly and safer sales certainly do not procure convenient price; on the contrary, they are at the origin of great abuses. The only condition for convenient price is free-trade, and one cannot help noticing that upon the appearance of a private edition, publishers are forced to substantially lower the price of a book” (Reimarus, 1791a, pp.402-3). Reimarus admitted of being unable to argue in terms of justice. Justice was of no bearing, he said, for whom, like himself, considered undemonstrated the author’s permanent property of his work (herein supported by the legislative vacuum of those years). What mattered, he said, was equity. In sum, Reimarus anticipated today’s stance on free use by referring to the principle that public interest on knowledge ought to prevail on the author’s interest and to balance the copyright. Moreover, Reimarus extended his argument beyond the realm of literary production to embrace, among others, the today vital issue of pharmaceutical production on patented receipts. “Let us suppose that at some place a detailed description for the preparation of a good medicine or of any other useful thing be published, why may not somebody who lives in places that are far away from that one copy it to use it for his own profit and but must instead ask the original publisher for the issue of each exemplar?” (Reimarus, 1791b, t.2, pp.584). To sum up, Reimarus’s stance does not seem respondent to rule of law. For in all dubious case the general rule ought to prevail, fighting intellectual property with anti-monopolistic arguments in favor of free trade brings with itself consequences that are not tranquilizing also for the ones that are expected to apply the law. **By resetting literary texts, one could obviously expurgate some errors. More frequently, however, some were added, given the exclusively commercial objectives of the reprints. The valid principle was, thus, that reprints were less precise than original editions, but they were much cheaper for the simple reason that the pirate publisher had a merely moral obligation against the author and the original publisher. In fact, he was not held to pay any honorarium to the author upon handling over the manuscript, nor to paying him royalties, nor to pay anything to the original publisher. The** only expense in charge of the pirate publisher was buying the exemplar of the original edition out of which he was to make, as we say today, a free use.

#### 2] The aff violates the categorical imperative and is non-universalizable- governments have a binding obligation to protect creations

**Van Dyke 18** Raymond Van Dyke, 7-17-2018, "The Categorical Imperative for Innovation and Patenting," IPWatchdog, <https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/> SJ//DA recut SJKS

As we shall see, applying **Kantian logic entails first acknowledging some basic principles; that the people have a right to express themselves, that that expression (the fruits of their labor) has value and is theirs (unless consent is given otherwise), and that government is obligated to protect people and their property. Thus, an inventor or creator has a right in their own creation, which cannot be taken from them without their consent.** So, employing this canon, **a proposed Categorical Imperative (CI) is the following Statement: creators should be protected against the unlawful taking of their creation by others. Applying this Statement to everyone, i.e., does the Statement hold water if everyone does this, leads to a yes determination. Whether a child, a book or a prototype, creations of all sorts should be protected, and this CI stands.** This result also dovetails with the purpose of government: to protect the people and their possessions by providing laws to that effect, whether for the protection of tangible or intangible things. **However, a contrary proposal can be postulated: everyone should be able to use the creations of another without charge. Can this Statement rise to the level of a CI? This proposal, upon analysis would also lead to chaos. Hollywood, for example, unable to protect their films, television shows or any content, would either be out of business or have robust encryption and other trade secret protections, which would seriously undermine content distribution and consumer enjoyment.** Likewise, inventors, unable to license or sell their innovations or make any money to cover R&D, would not bother to invent or also resort to strong trade secret. Why even create? This approach thus undermines and greatly hinders the distribution of ideas in a free society, which is contrary to the paradigm of the U.S. patent and copyright systems, which promotes dissemination. By allowing freeriding, innovation and creativity would be thwarted (or at least not encouraged) and trade secret protection would become the mainstay for society with the heightened distrust.

#### 3] The aff encourages free riding- that treats people as ­means to an end and takes advantage of their efforts which violates the principle of humanity

**Van Dyke 2** Raymond Van Dyke, 7-17-2018, "The Categorical Imperative for Innovation and Patenting," IPWatchdog, <https://www.ipwatchdog.com/2018/07/17/categorical-imperative-innovation-patenting/id=99178/> SJ//DA recut SJKS

Also, **allowing the free taking of ideas, content and valuable data, i.e., the fruits of individual intellectual endeavor**, would disrupt capitalism in a radical way. **The resulting more secretive approach in support of the above free-riding Statement** would be akin to a Communist environment **where the State owned everything and the citizen owned nothing, i.e., the people “consented” to this. It is, accordingly, manifestly clear that no reasonable and supportable Categorical Imperative can be made for the unwarranted theft of property, whether tangible or intangible,** apart from legitimate exigencies.

#### IPs are a necessary check on companies free-riding off associations of quality.

Wong et al 20 [Liana, Ian, and Shayerah; Analyst in International Trade and Finance; Specialist in International Trade and Finance; Specialist in International Trade and Finance; “Intellectual Property Rights and International Trade,” \*Updated\* 5/12/20; CRS; <https://www.everycrsreport.com/files/20200512_RL34292_2023354cc06b0a4425a2c5e02c0b13024426d206.pdf>] Justin

Trademark protection in the United States is governed jointly by state and federal law. The main federal statute is the Lanham Act of 1946 (Title 15 of the United States Code). Trademarks permit the seller to use a distinctive word, name, symbol, or device to identify and market a product or company. Marks can also be used to denote services from a particularly company. The trademark allows quick identification of the source of a product, and for good or ill, can become an indicator of a product's quality. If for good, the trademark can be valuable by conveying an instant assurance of quality to consumers. Trademark law serves to prevent other companies with similar merchandise from free-riding on the association of quality with the trademarked item. Thus, a trademarked good may command a premium in the marketplace because of its reputation. To be eligible for a trademark, the words or symbol used by the business must be sufficiently distinctive; generic names of commodities, for example, cannot be trademarked. Trademark rights are acquired through use or through registration with the PTO.

A related concept to trademarks is geographical indications (GIs), which are also protected by the Lanham Act. The GI acts to protect the quality and reputation of a distinctive product originating in a certain region; however, the benefit does not accrue to a sole producer, but rather the producers of a product originating from a particular region. GIs are generally sought for agricultural products, or wines and spirits. Protection for GIs is acquired in the United States by registration with the PTO, through a process similar to trademark registration.

## 3

#### Text: An international panel of scientists including National Academies and corresponding organizations appointed by the member nations of the World Trade Organization should release a binding ruling to [reduce intellectual property protections for medicines by implementing a one-and-done approach for patent and exclusivity protection.].

#### They have the jurisdiction to rule over intellectual property and secure 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.

## 4

#### Bipartisan infrastructure bill passing now but PC is needed – there is no margin for error.

Kapur et al 9/8 [Sahil, Frank Thorp, and Leigh Ann Caldwell; 9/8/21; Sahil Kapur is a national political reporter for NBC News, Frank Thorp V is a producer and off-air reporter covering Congress for NBC News, managing coverage of the Senate, Leigh Ann Caldwell is an NBC News correspondent; “*Democrats plow 'full speed ahead' on sweeping Biden budget, despite tensions*,” <https://www.nbcnews.com/politics/congress/democrats-plow-full-speed-ahead-sweeping-biden-budget-despite-tensions-n1278722>] Justin

WASHINGTON — The top two Democrats said they’re pushing forward with President Joe Biden’s sweeping safety net expansion, as House committees circulate legislative text with hearings scheduled Thursday to start advancing major sections of the bill. “We're moving full speed ahead,” Senate Majority Leader Chuck Schumer told reporters on a call Wednesday. The New York Democrat effectively cast aside calls by Sen. Joe Manchin, D-W.Va., for a “strategic pause” in the process of crafting the bill, as he voiced concerns about inflation and debt in a recent op-ed for the Wall Street Journal. Schumer is navigating demands by Manchin, as well as Sen. Kyrsten Sinema, D-Ariz., to reduce the price tag that Democrats set at a maximum of $3.5 trillion in the budget resolution. “There are some in my caucus who believe $3.5 trillion is too much; there are some in my caucus who believe it's too little,” Schumer said. “We're going to work very hard to have unity, because without unity, we're not going to get anything.” Speaker Nancy Pelosi said Wednesday the House is moving forward at the $3.5 trillion level. But she left open the possibility of a lower final price tag before the bill becomes law, while promising that “we will get the job done” with “a great bill” that honors Biden’s vision. “We will have our negotiations,” Pelosi, D-Calif., said, when asked by NBC News if the House could pass a bill at a lower amount. “I don’t know what the number will be. We are marking at 3.5 [trillion]. ... We will pay for more than half, maybe all of the legislation.” The remarks by Schumer and Pelosi point to a complicated balancing act, facing a broad range of opinions from centrist lawmakers skeptical of the price tag to progressives who believe $3.5 trillion should be the minimum. Democratic leaders are also juggling an aggressive timeline by seeking to ready the bill by Sept. 27 — the self-imposed House deadline to vote on the separate infrastructure bill — to ensure progressives will support the latter. They are betting Manchin can ultimately be won over on the substance of the package. Lawmakers and committees are keeping options open in case the price tag needs to be cut: For instance, they’ve privately discussed setting some provisions to expire sooner. Manchin has been somewhat vague in his demands. He has not specified what price tag he would support or what provisions of the emerging bill he wants to cut. His office did not have a comment when asked those questions Wednesday. In June, he said on ABC's "This Week" that he wants to “make sure we pay for” the bill. A source close to Manchin said he is a big proponent of targeting benefits on the basis of income and capping them so the money reaches people who need it the most — principles he believes are critical for Democrats' proposals on community college subsidies and on home-based care provisions for the disabled and elderly. Manchin also has issues with the climate change proposals in the legislation, the source said. As chairman of the Senate Energy and Natural Resources Committee, Manchin has major influence over the climate provisions. His committee was instructed to write legislation costing $198 billion for a clean electricity payment program, consumer rebates to weatherize and electrify homes, the creation of financing for domestic manufacturing of clean energy and auto supply chain technologies and climate research. “He’s not opposed to the overall bill,” the source said. “He’s going to shape the bill to what he feels is closer to the needs. People shouldn’t read into it more than that.” Senate Budget Chair Bernie Sanders, I-Vt., has said if the safety net package does not pass, the $550 billion bipartisan infrastructure package — which Manchin co-wrote — will fail as well. He told reporters the $3.5 trillion level was too low. “To my mind, this bill, that $3.5 trillion, is already the result of a major, major compromise,” Sanders said. “And at the very least, this bill should contain $3.5 trillion.” Pelosi said slashing the cost would require making difficult policy choices. “We have to talk about: What does it take? Where would you cut?” she asked. “Child care? Family medical leave paid for? Universal pre-K? Home health care?” On Thursday, the House committees on ways and means and education and labor will hold hearings on major portions of the bill they released this week. That includes 12 weeks' paid family and medical leave for all workers; expanding Medicare to cover dental, vision and hearing benefits; universal pre-K for 3- and 4-year-olds; and two years' tuition-free community college. Republicans are unified against the effort, leaving Democrats to pass the bill alone under narrow majorities. The package can bypass a Senate filibuster. Senate Minority Leader Mitch McConnell, R-Ky., said Wednesday that he hopes Manchin and Sinema “will dig in their heels” against some of the tax increases Democrats are eyeing to finance the package. “It comes down to — in the Senate — to two people,” he said. “Either one of them could kill the whole bill. I don't expect that to happen,” he said. “Either one of them could make dramatic changes in it — that could happen. Or either one of them could basically make a few cosmetic changes and throw in the towel.”

#### Aff doesn’t solve but requires negotiations that saps PC.

Pooley 21 [James; Former deputy director general of the United Nations’ World Intellectual Property Organization and a member of the Center for Intellectual Property Understanding; “Drawn-Out Negotiations Over Covid IP Will Blow Back on Biden,” Barron’s; 5/26/21; <https://www.barrons.com/articles/drawn-out-negotiations-over-covid-ip-will-blow-back-on-biden-51621973675>] Justin

The Biden administration recently announced its support for a proposal before the World Trade Organization that would suspend the intellectual property protections on Covid-19 vaccines as guaranteed by the landmark TRIPS Agreement, a global trade pact that took effect in 1995. The decision has sparked furious debate, with supporters arguing that the decision will speed the vaccine rollout in developing countries. The reality, however, is that even if enacted, the IP waiver will have zero short-term impact—but could inflict serious, long-term harm on global economic growth. The myopic nature of the Biden administration’s announcement cannot be overstated. Even if WTO officials decide to waive IP protections at their June meeting, it’ll simply kickstart months of legal negotiations over precisely which drug formulas and technical know-how are undeserving of IP protections. And it’s unthinkable that the Biden administration, or Congress for that matter, would actually force American companies to hand over their most cutting-edge—and closely guarded—secrets. As a result, the inevitable foot-dragging will cause enormous resentment in developing countries. And that’s the real threat of the waiver—precisely because it won’t accomplish either of its short-term goals of improving vaccine access and facilitating tech transfers from rich countries to developing ones. It’ll strengthen calls for more extreme, anti-IP measures down the road. Experts overwhelmingly agree that waiving IP protections alone won’t increase vaccine production. That’s because making a shot is far more complicated than just following a

recipe, and two of the most effective vaccines are based on cutting-edge discoveries using messenger RNA. As Moderna Chief Executive Stephane Bancel said on a recent earnings call, “This is a new technology. You cannot go hire people who know how to make the mRNA. Those people don’t exist. And then even if all those things were available, whoever wants to do mRNA vaccines will have to, you know, buy the machine, invent the manufacturing process, invent creation processes and ethical processes, and then they will have to go run a clinical trial, get the data, get the product approved and scale manufacturing. This doesn’t happen in six or 12 or 18 months.” Anthony Fauci, the president’s chief medical adviser, has echoed that sentiment and emphasized the need for immediate solutions. “Going back and forth, consuming time and lawyers in a legal argument about waivers—that is not the endgame,” he said. “People are dying around the world and we have to get vaccines into their arms in the fastest and most efficient way possible.” Those claiming the waiver poses an immediate, rather than long-term, threat to IP rights also misunderstand what the waiver will—and won’t—do. The waiver petition itself is more akin to a statement of principle than an actual legal document. In fact, it’s only a few pages long. As the Office of the United States Trade Representative has said, “Text-based negotiations at the WTO will take time given the consensus-based nature of the institution and the complexity of the issues involved.” The WTO director-general predicts negotiations will last until early December. That’s a lot of wasted time and effort. The U.S. Trade Representative would be far better off spending the next six months breaking down real trade barriers and helping export our surplus vaccine doses and vaccine ingredients to countries in need.

#### Infrastructure secures the grid against worsening and increasing cyberattacks.

Carney 21 [Chris; 8/6/21; Senior policy advisor at Nossaman LLC, former US Representative, former professor of political science at Penn State University; "*The US Senate Infrastructure Bill: Securing Our Electrical Grid Through P3s and Grants*," JDSupra, <https://www.jdsupra.com/legalnews/the-us-senate-infrastructure-bill-4989100/>] Justin

As we begin to better understand the main components of the Infrastructure Investment and Jobs Act that the US Senate is working to pass this week, it is clear that public-private partnerships ("P3s") are a favored funding mechanism of lawmakers to help offset high costs associated with major infrastructure projects in communities. And while past infrastructure bills have used P3s for more conventional projects, the current bill also calls for P3s to help pay for protecting the US electric grid from cyberattacks. Responding to the increasing number of cyberattacks on our nation’s infrastructure, and given the fragile physical condition of our electrical grid, the Senate included provisions to help state, local and tribal entities harden electrical grids for which they are responsible. Section 40121, Enhancing Grid Security Through Public-Private Partnerships, calls for not only physical protections of electrical grids, but also for enhancing cyber-resilience. This section seeks to encourage the various federal, state and local regulatory authorities, as well as industry participants to engage in a program that audits and assesses the physical security and cybersecurity of utilities, conducts threat assessments to identify and mitigate vulnerabilities, and provides cybersecurity training to utilities. Further, the section calls for strengthening supply chain security, protecting “defense critical” electrical infrastructure and buttressing against a constant barrage of cyberattacks on the grid. In determining the nature of the partnership arrangement, the size of the utility and the area served will be considered, with priority going to utilities with fewer available resources. Section 40122 compliments the previous section as it seeks to incentivize testing of cybersecurity products meant to be used in the energy sector, including SCADA systems, and to find ways to mitigate any vulnerabilities identified by the testing. Intended as a voluntary program, utilities would be offered technical assistance and databases of vulnerabilities and best practices would be created. Section 40123 incentivizes investment in advanced cybersecurity technology to strengthen the security and resiliency of grid systems through rate adjustments that would be studied and approved by the Secretary of Energy and other relevant Commissions, Councils and Associations. Lastly, Section 40124, a long sought-after package of cybersecurity grants for state, local and tribal entities is included in the bill. This section adds language that would enable state, local and tribal bodies to apply for funds to upgrade aging computer equipment and software, particularly related to utilities, as they face growing threats of ransomware, denial of service and other cyberattacks. However, under Section 40126, cybersecurity grants may be tied to meeting various security standards established by the Secretary of Homeland Security, and/or submission of a cybersecurity plan by a grant applicant that shows “maturity” in understanding the cyber threat they face and a sophisticated approach to utilizing the grant. While the final outcome of the Infrastructure Investment and Jobs Act may still be weeks or months away, inclusion of these provisions not only demonstrates a positive step forward for the application of federal P3s and grants generally, they also show that Congress recognizes the seriousness of the cyber threats our electrical grids face. Hopefully, through judicious application of both public-private partnerships and grants, the nation can quickly secure its infrastructure from cyberattacks.

#### Cyberattacks on the grid spiral to all-out nuclear conflict.

Klare 19 [Michael; November 2019; Professor emeritus of peace and world security studies at Hampshire College; “*Cyber Battles, Nuclear Outcomes? Dangerous New Pathways to Escalation*,” Arms Control Association, <https://www.armscontrol.org/act/2019-11/features/cyber-battles-nuclear-outcomes-dangerous-new-pathways-escalation>] Justin

Yet another pathway to escalation could arise from a cascading series of cyberstrikes and counterstrikes against vital national infrastructure rather than on military targets. All major powers, along with Iran and North Korea, have developed and deployed cyberweapons designed to disrupt and destroy major elements of an adversary’s key economic systems, such as power grids, financial systems, and transportation networks. As noted, Russia has infiltrated the U.S. electrical grid, and it is widely believed that the United States has done the same in Russia.12 The Pentagon has also devised a plan known as “Nitro Zeus,” intended to immobilize the entire Iranian economy and so force it to capitulate to U.S. demands or, if that approach failed, to pave the way for a crippling air and missile attack.13 The danger here is that economic attacks of this sort, if undertaken during a period of tension and crisis, could lead to an escalating series of tit-for-tat attacks against ever more vital elements of an adversary’s critical infrastructure, producing widespread chaos and harm and eventually leading one side to initiate kinetic attacks on critical military targets, risking the slippery slope to nuclear conflict. For example, a Russian cyberattack on the U.S. power grid could trigger U.S. attacks on Russian energy and financial systems, causing widespread disorder in both countries and generating an impulse for even more devastating attacks. At some point, such attacks “could lead to major conflict and possibly nuclear war.”14

#### Scientific consensus flows aff – nuke war leads to extinction and is the most probable impact scenario

Tegmark 17 Max Tegmark, 5-26-2017, "Why 3,000 Scientists Think Nuclear Arsenals Make Us Less Safe," Scientific American Blog Network, https://blogs.scientificamerican.com/observations/why-3-000-scientists-think-nuclear-arsenals-make-us-less-safe/, SJBE Max Erik Tegmark is a Swedish-American physicist and cosmologist. He is a professor at the Massachusetts Institute of Technology and the scientific director of the Foundational Questions Institute.

Delegates from most United Nations member states are gathering in New York next month to negotiate a nuclear weapons ban, and 30 Nobel Laureates, a former U.S. Secretary of Defense and over 3,000 other scientists from 84 countries have signed an [open letter](https://futureoflife.org/nuclear-open-letter/) in support. Why? We scientists like to geek out about probabilities, megatons and impact calculations, so we see the nuclear situation differently than many politicians and pundits. From the public debate, one might think that the cold war threat is over and that the most likely way to be killed by a nuke is by being attacked by Iran, North Korea or terrorists, but that’s not what nerdy number crunching reveals. Those media-dominating scenarios could potentially kill millions of people—except that Iran has no nukes and North Korea lacks missiles capable of reliably delivering their dozen or so Hiroshima-scale bombs. But scientific research has shown that a nuclear war between the superpowers might kill hundreds or potentially even thousands of times more people, and since it’s not a hundred times less likely to occur, the laws of statistics tell us that it’s the nuke scenario most likely to kill you. Why is superpower nuclear war so risky? First of all, massive firepower: there are more than [14,000 nuclear weapons](https://fas.org/issues/nuclear-weapons/status-world-nuclear-forces/) today, some of which are hundreds of times more powerful than North Korea’s and those dropped on Japan. Over 90 percent of these belong to Russia and the US, who keep thousands on hair-trigger alert, ready launch on minutes notice. A [1979 report by the US Government](https://www.princeton.edu/~ota/disk3/1979/7906/7906.PDF) estimated that all-out war would kill 28-88 percent of Americans and 22-50 percent of Soviets (150-450 million people with today’s populations). But this was before the risk of nuclear winter was discovered in the 1980’s.Researchers realized that regardless of whose cities burned, massive amounts of smoke could spread around the globe, blocking sunlight and transforming summers into winters, much like when asteroids or supervolcanoes caused mass extinctions in the past. A peer-reviewed analysis published by Robock et al (2007) showed cooling by about 20°C (36°F) in much of the core farming regions of the US, Europe, Russia and China (by 35°C in parts of Russia) for the first two summers, and about half that even a full decade later. Years of near-freezing summer temperatures would eliminate most of our food production. It is hard to predict exactly what would happen if thousands of Earth’s largest cities were reduced to rubble and global infrastructure collapsed, but whatever small fraction of all humans didn’t succumb to starvation, hypothermia or epidemics would probably need to cope with roving, armed gangs desperate for food. There are large uncertainties in Nuclear Winter predictions. For example, how much smoke is produced and how high up it rises would determine its severity and longevity. Given this uncertainty, there is no guarantee that most people would survive. It has therefore been argued that the traditional nuclear doctrine of Mutual Assured Destruction (MAD) be replaced by Self-Assured Destruction (SAD): even if one of the two superpowers were able to launch its full nuclear arsenal against the other without any retaliation whatsoever, nuclear winter might still assure the attacking country’s self-destruction. Recent research has suggested that even a limited nuclear exchange between India and Pakistan could cause enough cooling and agricultural disruption to endanger up to [2 billion people](https://hinwcampaignkit.org/section-4/section-4/), mostly outside the warring countries. The fact that nuclear powers are taking the liberty to endanger everyone else without asking their permission has led to growing consternation in the world’s non-nuclear nations. This has been exacerbated by a seemingly endless [series of near-misses](https://futureoflife.org/background/nuclear-close-calls-a-timeline/) in which nuclear war has come close to starting by accident, and leaders of many non-nuclear nations feel less than thrilled by the idea of being destroyed by something as banal as a malfunctioning early warning-system in a nation that they are not threatening. Such concerns prompted 185 non-nuclear nations to sign the 1970 Non-Proliferation-Treaty (NPT), promising to remain nuke-free in return for the nuclear nations phasing out theirs in accordance with NPT Article VI, whereby each party "undertakes to pursue negotiations in good faith on effective measures relating to cessation of the nuclear arms race at an early date and to nuclear disarmament, and on a Treaty on general and complete disarmament under strict and effective international control”. Nearly 50 years later, many of these "have-nots” have concluded that they were tricked, and that the "haves” have no intention of ever keeping their end of the bargain. Rather than disarming, the U.S. and Russia have recently announced massive investments in novel nuclear weapons. Russia has recently touted a cobalt-encased doomsday bomb reminiscent of the dark comedy "Dr. Strangelove,” and the U.S. plans to spend a trillion dollars replacing most of its nuclear weapons with new ones that are more effective for a first strike. Adding insult to injury, India, Pakistan and Israel have been allowed to join the nuclear club without major repercussions. "The probability of a nuclear calamity is higher today, I believe, that it was during the cold war," said former U.S. Secretary of Defense William J. Perry, who signed the open letter. This disillusionment from the “have-nots” prompted 123 of them to launch an initiative in the United Nations General Assembly, where the nuclear nations lack veto power. In late 2016, they voted to launch the aforementioned UN negotiations that may produce a nuclear weapons ban treaty this summer. But a ban obviously wouldn’t persuade the nuclear ``haves” to eliminate their nukes the next morning, so what’s the point of it? The way I see it, most governments are frustrated that a small group of countries with a minority of the world's population insist on retaining the right to ruin life on Earth for everyone else with nuclear weapons. Such “might makes right” policy has precedent. In South Africa, for example, the minority in control of the unethical Apartheid system didn't give it up spontaneously, but because they were pressured into doing so by the majority. Similarly, the minority in control of unethical nuclear weapons won't give them up spontaneously on their own initiative, but only if they're pressured into doing so by the majority of the world's nations and citizens. The key point of the ban is to provide such pressure by stigmatizing nuclear weapons. Nuclear ban supporters draw inspiration from the 1997 Ottawa treaty banning landmines. Although the superpowers still refuse to sign it, it created enough stigma that many people now associate mines not with national security, but with images of children who have had limbs blown off while playing in peace-time. This stigma caused leading arms manufactures to half production in response to investor pressure and dwindling demand. In 2014, the Pentagon announced that it was halting landmine use outside of the Korean peninsula. Today, the global landmine market has nearly collapsed, with merely a single manufacturer (South Korean Hanwa) remaining. The "have-not” negotiators hope that a nuclear ban treaty will similarly stigmatize nuclear weapons, persuading us all that we’re less safe with more nukes—even if they are our own. If this happens, it will increase the likelihood that the ``haves” trim their nuclear arsenals down to the minimum size needed for effective deterrence, reverting from SAD back to MAD and making us all safer. Here is the text of the letter. A list of some of the notable signatories follows. AN OPEN LETTER FROM SCIENTISTS IN SUPPORT OF THE UN NUCLEAR WEAPONS NEGOTIATIONS Nuclear arms are the only weapons of mass destruction not yet prohibited by an international convention, even though they are the most destructive and indiscriminate weapons ever created. We scientists bear a special responsibility for nuclear weapons, since it was scientists who invented them and discovered that their effects are even more horrific than first thought. Individual explosions can obliterate cities, radioactive fallout can contaminate regions, and a high-altitude electromagnetic pulse may cause mayhem by frying electrical grids and electronics across a continent. The most horrible hazard is a nuclear-induced winter, in which the fires and smoke from as few as a thousand detonations might darken the atmosphere enough to trigger a global mini ice age with year-round winter-like conditions. This could cause a complete collapse of the global food system and apocalyptic unrest, potentially killing most people on Earth – even if the nuclear war involved only a small fraction of the roughly 14,000 nuclear weapons that today’s nine nuclear powers control. As Ronald Reagan said: “A nuclear war cannot be won and must never be fought.” Unfortunately, such a war is more likely than one may hope, because it can start by mistake, miscalculation or terrorist provocation. There is a steady stream of accidents and false alarms that could trigger all-out war, and relying on never-ending luck is not a sustainable strategy. Many nuclear powers have larger nuclear arsenals than needed for deterrence, yet prioritize making them more lethal over reducing them and the risk that they get used. But there is also cause for optimism. On March 27 2017, an unprecedented process begins at the United Nations: most of the world’s nations convene to negotiate a ban on nuclear arms, to stigmatize them like biological and chemical weapons, with the ultimate goal of a world free of these weapons of mass destruction. We support this, and urge our national governments to do the same, because nuclear weapons threaten not merely those who have them, but all people on Earth.

## Case

### UV

You get 1AR theory but it’s contextual

[1] 7-6

[2] 2ar persuasion

[3] 2ar new

[4] reactivity

No time skew

2nr split

1ar strategic

### FW

### Advantage

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

#### 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).

#### 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.

#### Evergreening is a myth.

Lietzan 20 [Erika; Professor of Law, University of Missouri School of Law, Research interests in Pharmaceutical Regulation, Device Regulation, Intellectual Property; “The Evergreening Myth Claims that drug innovators extend their patents obscure a radical policy‐​making goal.,” Cato Institute; Fall 2020; <https://www.cato.org/regulation/fall-2020/evergreening-myth>/] Justin

In recent years, U.S. policymakers have considered proposals intended to prevent — or at least reduce — “evergreening” by pharmaceutical companies. Some proposals would change the antitrust enforcement landscape, others the intellectual property landscape, and still others the regulatory framework that governs new medicines. Some proposals — such as those creating new causes of action under the antitrust laws or limiting the availability of patents for discoveries — are profound and their proponents cite a body of academic and policy literature that decries supposed “evergreening” by companies to justify their ideas. The term “evergreening” is a metaphor, meant to remind audiences of evergreen trees, which have green foliage year‐​round. It implies that something has been extended, and users of the metaphor view this extension as improper or undesirable. When offering descriptions and examples of evergreening, they focus on drug companies continuing to innovate after first introducing a new molecule, and on the broader marketplace for medicines after subsequent innovations have been introduced to the market. But proponents are frustratingly inconsistent and unclear about what, exactly, has been “extended” in these situations. A close look at the regulatory landscape in which continuing pharmaceutical innovation occurs shows that arguments for reform are grounded in myths, such as the myth that pharmaceutical companies continuing to innovate somehow “extend” their patents. Once the myths of “evergreening” are laid bare, it becomes apparent that proponents of these proposals really want for the government to limit medical innovators to one medical product in the marketplace for each useful new molecule discovered. They are arguing that an innovator should not enjoy an exclusive market — and the resulting advantageous pricing — for innovations that, though discrete and independently satisfying the standard for a patent under U.S. law, stem in some fashion from an earlier innovation for which that innovator separately enjoyed exclusivity and the resulting pricing advantages. Or, at least, that drug innovators should not. This is a radical proposal that merits careful reflection and discussion, and it is not ripe for action. Understanding that this is the true policymaking objective requires unpacking the regulatory landscape and market more carefully, and paying closer attention to word choice, than proponents of reform often do. The Evergreening Allegation In the United States, every new medicinal product requires premarket approval from the Food and Drug Administration. The drug statute refers to approval of a “new drug,” and ambiguity in the term “drug” provides fertile ground for confusion and rhetorical mischief, as discussed later in this article. A firm that wants to market a new drug must prove to the FDA that the drug is safe and effective. Generating this information takes years, beginning with work in the laboratory and on animals, and progressing through several rounds of “clinical” testing in humans. For new molecules, the clinical portion of this research and development program averages six years. The process is also expensive: the Tufts Center for the Study of Drug Development now estimates the average cost of developing a new molecular entity at $2.6 billion. That figure includes average out‐​of‐​pocket costs of $1.4 billion and reflects the cost of unsuccessful projects. Most research and development programs fail. When new drugs are first launched by innovators, they tend to be sold under brand names and protected by patents as well as statutory rights in the data that supported FDA approval (known as “data exclusivity”). Although the pricing of these products may reflect competitive pressure from other branded products, it also reflects the fact that patent rights and statutory data exclusivity delay the launch of cheaper copies. But no more than five years later, and often earlier, the innovator’s competitors may file applications seeking approval of their own products based on the innovator’s research, rather than performing their own. They file what are known as “abbreviated applications” — abbreviated because they omit some, or all, of the research needed to prove safety and effectiveness. Abbreviated applications are much less expensive and time‐​consuming to assemble, and the competitors’ drugs correspondingly much less expensive than the original drugs they copy. When a competitor seeks to market an exact copy through an abbreviated application, we call its drug a “generic” drug. Pharmacists usually dispense generic copies even when doctors prescribe the corresponding branded products by name. Some people use the “evergreening” label when an innovator holds more than one patent protecting its product, especially if some patents expire later than others. More often, though, these people use the label when an innovator introduces a newer version of its own product that is already on the market. These newer products tend to be sold under brand names and protected by their own patents and statutory data exclusivity. Sometimes the innovator also stops selling its older product. If purchasers shift to the innovator’s newer product rather than purchasing cheap copies of the innovator’s older product, some say the innovator has engaged in evergreening. Although the term “evergreening” is a metaphor and signifies an extension of something, proponents of reform proposals do not agree on the particulars of the term’s use. Some say the company has evergreened its invention, its drug, or its product. Others say the company has evergreened the drug’s patent or patent life, or its exclusivity. Some say it has extended the drug’s patents, or the drug’s patent coverage or patent life, or the drug’s exclusivity period. Some say the company has evergreened the drug’s price, or its own profits or monopoly, or the company has extended its market power. Many argue that through evergreening — whatever the term means — the innovator has improperly blocked other firms from competing with it. On this basis, they seek government intervention. For instance, one recent proposal would allow the Federal Trade Commission to bring antitrust actions against innovators who introduced newer products to replace their older products. Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an approved application. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, useful, non‐​obvious invention, including a process, a composition of matter, and an improvement to an existing process or composition of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows. Myth of evergreening patents / The first myth is that innovators extend their patents. This is legally impossible. In the United States, a patent expires 20 years after its application date. There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a patent term extension within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does not extend the patent on another invention. Myth of blocked competitors / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its competitors have substantial freedom to operate. This freedom reflects two facts that are often overlooked. First, the innovator’s competitor does not have to propose an exact copy. Federal law permits the competitor to rely on the innovator’s research but propose competing products that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the company shows in the ANDA that its product has the same active ingredient, route of administration, dosage form, strength, and labeling as the innovator’s product. The generic must also be “bioequivalent” to the original drug that it references, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the referenced product. But even a generic can be a little different. For example, it usually does not need the same inactive ingredients in the same quantities. And the generic competitor need not use the same manufacturing process. If a competitor wants to offer a different route of administration, dosage form, or strength — for instance, to avoid infringing a patent — it may still be able to use the generic drug approval pathway. It simply files a “suitability petition” asking the FDA’s permission. The agency will approve the petition unless more data are needed to establish the proposed product’s safety and effectiveness. And at this point, the competitor may file an ANDA. More significantly, though, a competitor can always use a different abbreviated application pathway: a “505(b)(2)” application for a product that differs more substantially from the innovator’s product. Although the changes proposed in this hybrid application must be supported by new data, the competitor otherwise relies on the innovator’s data, avoiding the expensive and time‐​consuming research and development process the innovator went through. In addition to using this mechanism to propose modifications that avoid a patent, a competitor might use the mechanism to propose innovations that will offer an advantage in the market — such as changes to the active ingredient and new medical uses. Second, an abbreviated application cites a specific innovative product, not the active ingredient or brand writ large. The competitor selects one innovative product as the reference product on which it relies — for instance, one of the 12 products in the hypothetical above. Its regulatory burden is tied to that specific product alone. The requirement to show sameness and bioequivalence (for an ANDA) and, critically, the obligation to contend with patents and wait for statutory exclusivity to expire are linked to the one specific product, alone. (In rare circumstances, when filing a hybrid application, a competitor might cite two innovative products, but the same point applies.) To be sure, the patents associated with the cited innovative product affect when the FDA may approve the abbreviated application. Whether it files an ANDA or a hybrid application, a competitor must address the unexpired patents listed in the FDA’s “Orange Book” for the specific innovative product it has chosen to cite. For each listed patent, it has two choices, and its selection dictates the timing of FDA approval as far as that patent is concerned. The competitor may state the date on which the patent will expire, signaling that it does not plan to market its product until expiry. This precludes final approval of its product until patent expiry. Or it may assert that the patent is invalid or will not be infringed by its product, notifying the innovator of this position. If the innovator sues within 45 days, the drug statute stays final approval of its abbreviated application for 30 months. Under changes to the law made in 2003, though, unless the competitor changes its position on a patent after filing its abbreviated application, approval of its application is stayed only once. At the end of the 30 months, the FDA must approve the abbreviated application if the approval standard is met, even if there is ongoing patent litigation. Although a competitor using the abbreviated application pathway must contend with the innovator’s patents and approval of its product may be delayed because of those patents, this is true of only the patents associated with the specific product that it references. The competitor does not have to contend with patents associated with other products that happen to contain the same active ingredient or bear the same brand name. Similarly, the competing applicant grapples with only the statutory exclusivity associated with the product it references. The drug statute provides five years of exclusivity in the data supporting new chemical entities and three years of exclusivity for most new products that are not new chemical entities. Separately, if an innovator introduces what the FDA calls a new “condition of approval” — such as a new strength or dosage form — the drug statute may provide three years of exclusivity. This delays approval of abbreviated applications proposing products with the same active ingredient for the same condition of approval. But a competitor that proposed a different strength or dosage form — or that cited a product with a different strength or dosage form (such as the innovator’s original product) — would not need to grapple with that exclusivity. This debunks the myth that an innovator with later‐​expiring patents and an innovator that introduces newer products can prevent its competitors from bringing copies to market. Instead, competitors have several options. For instance, empirical studies show that competitors file abbreviated applications as early as the law permits them to do so, arguing that the innovator’s patents are invalid or, if applicable, not infringed by the new drug. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win if a formulation patent is at issue. If a competitor believed it would infringe a patent or feared it would lose the patent infringement suit brought by the innovator, it could seek a license. Settlements of patent litigation between innovators and competitors seeking to market generic copies usually include a license allowing the competitor to bring its product to market earlier than the date of patent expiry. There are also other options. Once the patent on the active ingredient expires, a competitor can use the ingredient in its own product and file an abbreviated application, relying on the research performed and submitted by the innovator. Even in an ANDA, a true generic application, only the active ingredient must be the same. A competitor may be able to design around patents claiming other aspects of the innovator’s product (such as its strength and route of administration) and still file a true generic application. The competitor would simply file a suitability petition and, upon approval of that petition, a generic application proposing the difference that allowed it to avoid patent infringement. Then it would assert non‐​infringement in its application. If it could not file a generic application (for instance, because the FDA requested data to support the changes made), it could always file a hybrid application. It would still rely on the innovator’s research and it would similarly assert non‐​infringement in its application. In either case, the innovator might not sue if the competitor clearly avoided its patents. It is thus misleading for advocates of intervention to complain about the number of “patents” associated with a “drug.” A competitor filing an abbreviated application does not copy a “drug” in the broad sense of the term. Accurately describing a company’s freedom to operate in the market would require focusing on discrete products that can serve as references for abbreviated applications and on the number, scope, and breadth of the patent claims held by the innovator for those products. This would tell policymakers more about the market effects of a firm’s innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient. Myth that automatic substitution is critical / The final myth of evergreening is that continuing innovation — especially when an innovator introduces a newer version of its product and stops selling its old version — precludes uptake of less expensive medicines by interfering with automatic pharmacy substitution under state pharmacy law. This myth reflects an assumption that competitors who file abbreviated applications depend on automatic pharmacy substitution — rather than the ordinary rough and tumble of a competitive marketplace — to obtain market share. The truth may be more complicated. Automatic pharmacy substitution arises through a combination of longstanding FDA practices and state pharmacy law. Once the agency has approved two products with the same active ingredient, it assesses whether they are “therapeutically equivalent.” Designating two as therapeutically equivalent means that they have the same clinical profile and that they can be “substituted”: either can be dispensed instead of the other. A true generic drug, an exact copy of the innovator’s product approved based on an ANDA, will be deemed therapeutically equivalent. Every state either permits or requires pharmacists to dispense a therapeutically equivalent generic drug when a doctor prescribes an innovator’s drug by its brand name, unless the doctor has said not to. The notion advanced by critics of alleged “evergreening” is that once an innovator introduces a newer version of its branded product, doctors will prescribe the newer version. And because the generic company instead copied the older version, pharmacists will not — cannot under state law — substitute the generic product when the patient presents a prescription for the newer innovator product. The problem with this argument is that actual dispensing decisions probably reflect a more complex interaction of prescriber decisions, payer preferences, and state law. To begin with, a doctor may specify either branded drugs or generic drugs. A doctor could write the brand name, to be sure, but the doctor could also simply identify the active ingredient, which will usually lead the pharmacist to dispense one of the available generic drugs. In theory, the doctor could even identify a particular generic company’s drug containing a particular active ingredient. And while drugmakers rarely promote generic drugs to doctors and patients, nothing prevents them from doing so. They do promote their therapeutically equivalent generic drugs to pharmacies and payers, focusing on the lower prices they offer. And a company that filed a hybrid application for a product that differed from the innovator’s product might brand its product and promote the distinguishing features, or (depending on the reason it filed the hybrid application) position the product as a near‐​duplicate of the more expensive branded alternatives and promote it as such. In short, an innovator’s newer product creates a new choice for doctors and payers. To be sure, if doctors select this product, pharmacists will dispense it rather than generic copies of the innovator’s older product. Doctors might shift their prescribing to the newer product for many reasons, including persuasive advertising and promotion — meaning they come to believe (based on advertising that, per FDA rules, must be truthful and not misleading) that there are benefits to the newer product. They might shift for other reasons, including experience treating patients with the two options. But companies may advertise and promote generic products to doctors and patients as well, and based on this advertising (or for other reasons, such as experience with the older innovative product that the competitor copied) doctors might not select the innovator’s newer product. They might specify the innovator’s older product (which would lead to automatic substitution, even if the innovator no longer markets the product) or, again, a generic product itself. Generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. The assumption that competing companies depend on automatic substitution for market share may be simplistic. Only a minority of states require substitution; most instead have permissive laws. In these states, if a generic product is therapeutically equivalent to the prescribed product and the payer requires its use, the permissive state pharmacy law makes it possible for a pharmacist to substitute, in accordance with the patient’s insurance, without consulting the physician. In these cases, the patient’s insurance drives the product selection. State law just makes it possible to comply with the insurance without contacting the doctor. If a payer perceives the innovator’s new product as less cost effective than available generic drugs containing the same active ingredient, it may decline to cover the product. A rational payer will adopt strategies that steer doctors and patients to less expensive products that are equally or adequately effective — not only those that are therapeutically equivalent, but also those that are not. In these cases, even if a doctor specifies a branded product, the patient’s insurance might prompt a conversation among the doctor, pharmacist, and patient, ultimately leading to modification of the prescription and dispensing of the cheaper copy of the innovator’s first‐​version product. In short, when an innovator introduces a new product into the market, generic companies will be able to introduce copies of the innovator’s first product and they may or may not enjoy sales depending on the choices they make and the choices made by others in the market. In this scenario, products compete for the business of rational payers based on their comparative benefits and cost. Substitution may play almost no true role, and whether the innovator still markets its older branded product may be irrelevant.

#### Prefer legal studies.

Parker and Mooney 7 [Scott and Kevin; “Is ‘evergreening’ a cause for concern? A legal perspective,” Journal of Commercial Biotechnology; 2007; <https://link.springer.com/article/10.1057/palgrave.jcb.3050066>] Justin

THE LEGAL BACKGROUND The patent system provides an incentive for companies to incur the cost and risk of research by providing the time-limited exclusive right to commercialise a patented product. At the heart of the patent system in the UK (and all other fully TRIPs compliant countries) is the requirement that to qualify for the monopoly right that the patent confers (20 years from the date of filing the patent application) the invention covered by the patent must be novel, non-obvious (ie it involves an inventive step) and capable of industrial application (‘utility’ or ‘usefulness’ in the US). The novelty and inventiveness of the patent is evaluated against the ‘state of the art’, which consists in general of every item of information which has ever been made available to the public by any kind of publication, or by use, anywhere in the world, at any point in time before the first filing date of the patent. It is a basic principle of patent law that once details of a product have entered the public domain (by being published anywhere without patent protection, or when any patents for the product or proposal expire or lapse), then everyone has freedom to use that information and any obvious developments of it. So before assuming that any new development relating to a known compound can be patented, we have to ask: 1 Is this new? Any previous publication or use, no matter how obscure, of the same invention destroys novelty and prevents a patent being issued or, if issued in ignorance of such a publication, this will subsequently cause the patent to be declared invalid if sought to be enforced. 2 Is there an inventive step? A patent cannot be granted for anything which is simply an obvious development or variant on any individual piece of information which is part of the state of the art. It is no answer that the piece of information in question may never have come to the attention of the fictitious ‘person skilled in the art’ who is central to any determination of ‘obviousness’. 3 Is there a proposed industrial application for the invention (in the broad sense of having some useful purpose)? The invention does not have to demonstrate an improvement on what is already known, but it cannot be speculative. It must have a use. For example, a DNA sequence for a recombinant gene fragment with a well-defined function is a patentable invention whereas a DNA sequence alone without any indication of function or of its useful attributes is not. 4 Does the patent describe how to put the invention into effect? The patent must be ‘enabling’; it must add to public knowledge, and contribute in its own right to the state of the art. In this way each new patent moves the frontier of the state of the art forward and makes it more difficult to find improvements which are neither old nor obvious. This disclosure enables third parties to implement the invention once the patent has expired and, is the consideration (in the legal sense) for the monopoly right granted by a patent. HOW THE PATENT SYSTEM DEALS WITH ‘EVERGREENING’ The criteria of patentability set out above apply equally to all inventions from the most basic mechanical patent to the most complex microelectronic or biotechnological invention. Similarly patent law does not distinguish between the invention of a wholly new product and inventions relating to improvements upon an existing product. The same criteria for patentability apply. ‘Double patenting’ is prohibited. That is to say the same invention cannot be covered by more than one patent. Thus for an improvement upon an existing pharmaceutical product to be patentable in its own right it will need to satisfy the criteria of novelty and non-obviousness taking into account the earlier product and all that is known about it in the public domain at the time that the second patent is applied for. If a patent is granted in respect of this improvement it will only cover the improvement to which it relates and will not extend to the originator product. That is to say a patent for a new product in a class will always be broader than any subsequent patent covering an improvement, modification or derivative of that product and so the exclusivity granted is in broad terms commensurate with the scope of the scientific advance that it reflects. An important corollary to the prohibition on ‘double patenting’ is that a patent covering an improved version of a pharmaceutical (or any other) product does not preclude a generic company from copying all forms of the originator product once the patents protecting these forms have expired. For example, if a company selling a patented pharmaceutical reformulates that product as a syrup for paediatric administration and then patents the new formulation, generic competition to the original adult formulation will be possible once the patents covering it expire or are invalidated. The existence of the patent on the paediatric formulation will not delay or prevent generic competition on the original formulation. The innovator company will, however, continue to have the exclusive right to sell the paediatric formulation for the remainder of the life of the patent covering this specific improvement. If in the above example the improvement made is not a paediatric formulation but a slow release formulation that allows once daily dosing and so improves patient compliance as a result of increased convenience, doctors and patients will have a choice between generic versions of the original formulation or the new once-daily product once any patent on the original formulation expires. The patents on the slow release formulation will not delay or prevent marketing of the original formulation. The market will then decide whether the benefits offered by the improved formulation make it worth paying for in the face of cheaper versions of the original product. The answer to this question will inevitably vary from market to market and between different patient populations. Either way the patient would appear to benefit from the increased choice available. A simple and further example of this is ibuprofen. The supermarket shelf carries premium-priced ibuprofen formulations which typically are quicker acting or easier to take than the traditional tablet. These formulations may be patent protected. Customers can, however, decide for themselves whether the added benefit is worth the extra cost. The patents do not prevent anybody from buying the ordinary, cheapest kind of tablet. Reference to patents covering the colour and scoring of tablets has been made in several articles criticising the pharmaceutical industry (without the specific patents that are complained of being identified).4 It is informative to consider how the patent system would apply to such ‘developments’. To the best of the authors’ knowledge no patents have ever been granted for the colour of pharmaceutical products. In fact, since UK patent law (and most others) expressly excludes the patenting of ‘aesthetic creations’ the colour of a pharmaceutical product could only ever be patentable if either: (a) it could be established that the colour itself produces a technical effect, such as a therapeutic benefit caused by increased compliance, that is novel and not obvious; or (b) that the means of obtaining that colour, the manufacturing process of colouring the tablet, is itself novel and not obvious. It goes without saying that for a ‘pink pill’ patent application the technical effect, novelty and inventiveness would be scrutinised carefully. Nevertheless, the application would be looked at on its own facts and applying the patentability criteria described above. Similarly, as regards the scoring of tablets, the same standard of patentability and scrutiny must be satisfied. It would need to be established that tablets had never been scored in this way before and that to do so was not an obvious departure from what has gone before. Without further investigation it should not be assumed that such an invention would be of no value to patients (eg it could be that compliance among children would be improved if the tablet is more cleanly cut as a result of the means of scoring employed). There are plenty of examples of developments (reformulations, new salts, combinations and the like) that have real therapeutic benefit but which at first blush may seem trivial. Again, the more minor that a variation is (eg a pink tablet or means of scoring the tablet) the more narrow the relevant patent protection will be and the easier it should be for a competitor to design around the patent without needing to seek to invalidate it. For example, if a patent is (or has been) granted that covers a particular colour of tablet or a particular means of scoring such tablet then such a patent would not stop a competitor from marketing (respectively) a different colour tablet or a tablet that is not scored or that is scored in a different way. In summary, therefore, the patent system is inherently adapted to reflect how much innovation in fact takes place (by way of improvements to existing technology) and to prevent ‘evergreening’. It allows the use of ‘old’ technology while protecting (and thus providing incentives for) improvements to that technology. Another factor to be taken into account in any debate on the patenting of ‘minor variations’ is that it is not only the company that owns the patents covering the originator product that can patent improvements thereto. Other companies (including generics) can (and do) do this, with the consequence that there may be a number of companies having similar products (some of which may for a variety of reasons be better suited to particular patients) and healthy competition in the marketplace. ‘STRATEGIC PATENTING’ A related charge that is sometimes made against innovator companies is that they file numerous patents on multiple attributes of a single product so as to create a ‘patent thicket’ that so complicates third-party research that it strangles innovation, or that they are guilty of what is sometimes referred to as ‘strategic patenting’.5 Implicit in these charges is that the only reason for filing these patents is maintenance of market share for as long as possible after the expiry of the patents covering the originator product itself. This is a serious charge that deserves to be looked at in more detail. Of course, pharmaceutical and biotechnology companies (like companies in all other R&D-based industries) have patenting strategies. In no other industry is there any suggestion that companies should restrict themselves to patenting inventions that meet some higher standard over and above the basic criteria for patentability or that companies should not seek protection for certain types of technological advance or that exceeding a certain number of patents in a technical area is per se reprehensible. When one considers that intellectual property rights are the life-blood that propels pharmaceutical advances in the private sector (and to an increasing extent in the public sector as well) and takes into account the sums that are typically spent on a new product during the 10–15-year-period from discovery through pre-clinical and clinical trials to regulatory approval and market launch, any company that did not do all that it could to protect its inventions would be acting negligently towards its shareholders. On the subject of patenting strategies in the pharmaceutical industry the UK Patents Court judge Mr Justice Jacob (now Lord Justice Jacob) said in the case of Synthon v SmithKline Beecham ‘I ask myself whether SB have done anything blameworthy…and I cannot see that they have. On the contrary, so far as I can see, they have employed competent and careful patent agents to obtain for them the best patent position which they think they can get. It may be good, it may be bad, but they are doing their job and I see no criticism whatever in the conduct of SB’.6 If one accepts that the nature of pharmaceutical and biotechnological innovation (as with other R&D based industries) is most often incremental and cumulative then it follows that the patent system should reflect this reality. This is indeed the case. As we have seen above, the patent system does not distinguish between ‘breakthroughs’ and ‘incremental improvements’ in terms of the patentability requirements that apply. At the same time a greater reward (a broader patent) is granted in respect of the ground breaking research than for inventions directed at solving further technical hurdles and optimisation of the initial invention. In the experience of the authors most of the patents that have been challenged by generic companies wishing to enter the market were applied for during the development of the originator product rather than once it has been established as a commercial success. This reflects the organic process of drug discovery and development and the time lag between drug discovery development, clinical testing and regulatory approval (ie that inventions are made in overcoming the various technical challenges faced during drug development). Nevertheless, some innovations are made at a later stage. For example, it may be that it is only after the product has been prescribed to a population of patients post-launch that it will become evident that further improvements need to be made to improve efficacy, deal with a compliance (or other) problem or expand the target patient population or disease indications. Such improvements may stem from greater experience of the product, problems unexpectedly encountered in particular patient populations or other advances made in the field. Given that the purpose of the patent system is to encourage innovation and (in the pharmaceutical sector) to lead to better medicines, it would be strange indeed if this incentive was removed or diminished once the first product of a particular type has been launched.