#### I affirm, resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

## Definitions

#### **First, I’d like to provide a definition.**

Saha and Bhattacharya 11, Chandra Nath Saha, Sanjib Bhattacharya, associate professor of HRDC & physics, at the JUiversity of North Bengal, "Intellectual property rights: An overview and implications in pharmaceutical industry," April-June 2011, National Center for Biotechnology Information, accessed 24 August 2021, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/> brackets for gender ~ST~

Intellectual property (IP) pertains to any original creation of the human intellect such as artistic, literary, technical, or scientific creation. Intellectual property rights (IPR) refers to the legal rights given to the inventor or creator to protect his invention or creation for a certain period of time.[[1](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/#ref1)] These legal rights confer an exclusive right to the inventor/creator or his assignee to fully utilize ~~his~~ [their] invention/creation for a given period of time. It is very well settled that IP play a vital role in the modern economy. It has also been conclusively established that the intellectual labor associated with the innovation should be given due importance so that public good emanates from it. There has been a quantum jump in research and development (R&D) costs with an associated jump in investments required for putting a new technology in the market place.[[2](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/#ref2)] The stakes of the developers of technology have become very high, and hence, the need to protect the knowledge from unlawful use has become expedient, at least for a period, that would ensure recovery of the R&D and other associated costs and adequate profits for continuous investments in R&D.[[3](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3217699/#ref3)] IPR is a strong tool, to protect investments, time, money, effort invested by the inventor/creator of an IP, since it grants the inventor/creator an exclusive right for a certain period of time for use of his invention/creation. Thus IPR, in this way aids the economic development of a country by promoting healthy competition and encouraging industrial development and economic growth. Present review furnishes a brief overview of IPR with special emphasis on pharmaceuticals.

## Framework

#### Now, on framework.

#### First, ethics begin from a priori concepts derived from practical reason. [1] Is-ought gap – we only perceive the current state of affairs, not the state of affairs that should be. It’s impossible to derive prescriptive obligation from descriptive premises.

**[2] Uncertainty – a posteriori ethics is subject to uncertainty. We could be dreaming, hallucinating, or being deceived by an evil demon. Infinitely outweighs because it would be escapable and therefore pointless.**

**[3] Infinite regress – we can always ask “why should I follow this framework,” leading to infinite regress, but asking for a reason for reason concedes its authority. Only self-justified frameworks are epistemically sound.**

**Thus, the standard is consistency with universal maxims.**

**[1] Arbitrariness – absent universal ethics, morality is arbitrary and can’t guide action, making it useless.**

**[2] Non-contradiction – there is no world in which p and ~p are both true. Acting recognizes the validity of others to take the action, which makes universal maxims a logical side constraint to other frameworks.**

**Prefer additionally:**

**[1] Performativity – freedom is key to argumentation. Abiding by their ethical theory presupposes we own ourselves, making it incoherent to justify a standard without willing ours.**

#### [2] Resource disparities – focus on evidence and statistics puts small school debaters without huge files at a disadvantage, but my framework can be won without prep, which means it’s theoretically preferable.

## Offense

#### [1] Property rights are only coherent because of the principle of rivalry

Rauscher 07 Frederick Rauscher, professor of philosophy at Michigan State University, "Kant’s Social and Political Philosophy,” 24 July 2007, Stanford Encyclopedia of Philosophy, accessed 2 September 2021, <https://plato.stanford.edu/entries/kant-social-political/> ~ST~

The “Doctrine of Right” begins with a discussion of property, showing the importance of this right for the implementation of the innate right to freedom. Property is defined as that “with which I am so connected that another’s use of it without my consent would wrong me” (6:245). In one sense, if I am holding an object such as an apple, and another snatches it from my hand, I have been wronged because in taking the object from my physical possession, the other harms me (Kant does not specify whether this harm is because one’s current use of the apple is terminated or because one’s body is affected, but the latter fits the argument better). Kant calls this “physical” or “sensible” possession. It is not a sufficient sense of possession to count as rightful possession of an object. Rightful possession must be possession of an object so that another’s use of the object without my consent harms me even when I am not physically affected and not currently using the object. If someone plucks an apple from my tree, no matter where I am and no matter whether I am even aware of the loss I am prevented from using that apple. Kant calls this “intelligible possession”.

His proof that there must be this intelligible possession and not merely physical possession turns on the application of human choice (6:246). An object of choice is one that some human has the capacity to use as means for various ends or purposes. Rightful possession would be the right to make use of such an object. Suppose that for some particular object, no one has rightful possession. This would mean that a usable object would be beyond possible use. Kant grants that such a condition does not contradict the principle of right because it is compatible with everyone’s freedom in accordance with universal law. But putting an object beyond rightful use when humans have the capacity to use it would “annihilate” the object in a practical respect, treat it as nothing. Kant claims that this is problematic because in a practical respect an object is considered merely as an object of possible choice. This consideration of the mere form alone, the object simply as an object of choice, cannot contain any prohibition of use for an object, for any such prohibition would be freedom limiting itself for no reason. Thus in a practical respect an object cannot be treated as nothing, and so the object must be considered as at least potentially in rightful possession of some human being or other. So all objects within human capacity for use must be subject to rightful or intelligible possession.

#### However, this doesn’t apply to intellectual property because it can be used by many agents simultaneously.

Lindsey and Takash 19 [Niskanen Center, “Why ‘Intellectual Property’ is a Misnomer”, September 2019, Brink Lindsey Vice President for Policy Niskanen Center, Daniel Takash Regulatory Policy Fellow Niskanen Center, accessed 28 September 2021 https://www.niskanencenter.org/wp-content/uploads/2019/09/LT\_IPMisnomer-2-1.pdf]//Lex AKu recut Lex VM

Because ideal goods are nonrivalrous, they are not scarce in the way that physical objects are. In other words, there is no either/or decision that has to be made about who gets to use and control them — that is, about who owns them. An infinite number of people can sing the same song, tell the same story, or use the same design for a widget without interfering with the ability of anyone else to do the same.7 But if one person eats a steak, nobody else can and it’s gone; if one person is shooting a basketball, nobody else can shoot that ball at the same time; if a developer wants to build a shopping center on a piece of land but the neighbors want to leave it as a park, they can’t both get their way. The inherent scarcity of rivalrous physical goods means that there is an everpresent potential for conflict over who gets what. It’s either/or, zero-sum: For every disputed object there’s one winner and a world of losers. In Hobbes’ grim vision of a state of nature without government, and thus without legally enforceable ownership claims, the “war of all against all” is ultimately a contest over who can use and control scarce valuable resources.

#### That makes IP protections unjust.

Westphal 97 Kenneth R. Westphal, Professor of Philosophy at Boðaziçi Üniversitesi, Ph.D. in Philosophy from Wisco, “Do Kant’s Principles Justify Property or Usufruct?” 1997, Jahrbuch für Recht und Ethik/Annual Review of Law and Ethics 5, accessed 5 September 2021, pg. 189-190, sci-hub.se/10.2307/43593592 RE recut

6.2 One right that is not justified by the Kantian defense of rights to use developed above is the exclusion of others from the use of something to which one has a right on those occasions when one does not need and is not likely to need to use the item in question. Property rights involve such an exclusion. To the extent that I have shown that qualified choses in possession suffice to fulfill the desiderata established by Kant’s own principles and strategy for justifying possession (in the narrow sense), I have shown that property rights cannot be justified by Kant’s metaphysical principles. This is because there are alternative sets of rights to things which meet both Kant’s sine qua non of being consistent with the freedom of all in accord with universal laws [5] and Kant’s metaphysical grounds of proof concerning freedom of overt action. Neither Kant’s own argument nor my reconstruction of it address most of the incidents of property ownership. (Though I have suggested that Kant’s principles can justify the prohibition on harmful use and very likely some version of the liability to execution.) Indeed, Kant’s sole Innate Right to Freedom, Universal Law of Right, and Permissive Law of Practical Reason appear to entail that it is illegitimate to exclude others’ use of something to which one has a qualified chose in possession provided that their use does not interfere with one’s own regular and reliable use of the item in question. Moreover, Kant’s principles give priority to use over first acquisition, and indeed they justify first acquisition only in view of legitimate and needful use. To this extent, Kant’ s principles undermine and repudiate one of the cherished hallmarks of the liberal conception of private property, namely, that first acquisition as such secures a right over the disposition of a thing, regardless of subsequent disuse (cf. §3.10).

#### Intellectual property and information behind medicines can be shared without interfering with anyone’s ability to manufacture them. That entails reducing IP protections, which arbitrarily violate people’s freedom to access information.

#### [2] Medicine is a discovery because it’s about truth statements.

Rhodes 19 Rosamond Rhodes, professor of medical education at Mount Sinai University, "The ethical concept of medicine as a profession discovery or invention?," December 2019, Journal of Medical Ethics, accessed 24 August 2021, <https://jme.bmj.com/content/45/12/786.full/> ~ST~

The Ethical Concept of Medicine as a Profession as a Discovery

The history of Western philosophy offers us two pathways to address this question. The first is the quest for certainty,2 a quest fulfilled by using methods designed to discover concepts that are independent of human thought and judgement and thus intellectually and morally authoritative for everyone. Such concepts are timeless and therefore transcultural, transreligious and transnational. Examples include Plato’s Forms,3 PF Stawson’s (1919–2006) ‘our conceptual structure’,4 Edmund Pellegrino’s (1920–2003) ‘fact of illness’ and the ‘act of profession’ in response to the vulnerability that illness creates,5 and common morality.6 Thought experiments, using what Rhodes characterises as ‘the hypethetico-deductive method’,1 aim to discover timeless concepts.

Discovering timeless concepts must address their ontological and epistemological status. Plato’s ontology of Forms,2 for example, is not clear, as evidenced in the centuries-long disputes among scholars of ancient Greek philosophy. Discovering timeless concepts assumes that we have the intellectual capacity to be free of bias, which is at least dubious given the findings of behavioural psychology.

#### Patents attempt to assert ownership over natural truth and impede individual’s abilities to pursue ends.

Long 95 Roderick T. Long, professor of philosophy at Auburn University, editor of the Journal of Ayn Rand Studies, director and president of the Molinari Institute and a Senior Fellow at the Center for a Stateless Society, “The Libertarian Case Against Intellectual Property Rights,” Autumn 1995, Free Nation Foundation, accessed 5 September 2021, http://freenation.org/a/f31l1.html JL recut

The moral case against patents is even clearer. A patent is, in effect, a claim of ownership over a law of nature. What if Newton had claimed to own calculus, or the law of gravity? Would we have to pay a fee to his estate every time we used one of the principles he discovered?

Defenders of patents claim that patent laws protect ownership only of inventions, not of discoveries. (Likewise, defenders of copyright claim that copyright laws protect only implementations of ideas, not the ideas themselves.) But this distinction is an artificial one. Laws of nature come in varying degrees of generality and specificity; if it is a law of nature that copper conducts electricity, it is no less a law of nature that this much copper, arranged in this configuration, with these other materials arranged so, makes a workable battery. And so on.

Suppose you are trapped at the bottom of a ravine. Sabre-tooth tigers are approaching hungrily. Your only hope is to quickly construct a levitation device I've recently invented. You know how it works, because you attended a public lecture I gave on the topic. And it's easy to construct, quite rapidly, out of materials you see lying around in the ravine.

But there's a problem. I've patented my levitation device. I own it — not just the individual model I built, but the universal. Thus, you can't construct your means of escape without using my property. And I, mean old skinflint that I am, refuse to give my permission. And so the tigers dine well.

This highlights the moral problem with the notion of intellectual property. By claiming a patent on my levitation device, I'm saying that you are not permitted to use your own knowledge to further your ends. By what right?

Another problem with patents is that, when it comes to laws of nature, even fairly specific ones, the odds are quite good that two people, working independently but drawing on the same background of research, may come up with the same invention (discovery) independently. Yet patent law will arbitrarily grant exclusive rights to the inventor who reaches the patent office first; the second inventor, despite having developed the idea on his own, will be forbidden to market his invention.

## Underview

#### [1] Consequences fail – a) we don’t know if an action is bad until after it happens, meaning obligations can’t be formed, b) every consequence causes another consequence – when do we evaluate “the consequence?” c) induction fails – we know induction works because it has in the past – that relies on induction and is therefore circular, d) if you’re responsible for things other than intention, ethics aren’t binding because there are infinite events over which you have no control.

#### [2] Predictions fail – policymakers are worse than monkeys.

Menand 05 Louis Menand, professor of English at Harvard University, “Everybody’s An Expert,” 27 November 2005, The New Yorker, accessed 7 September 2021, <http://www.newyorker.com/magazine/2005/12/05/everybodys-an-expert//> FSU SS recut

Tetlock is a psychologist—he teaches at Berkeley—and his conclusions are based on a long-term study that he began twenty years ago. He picked two hundred and eighty-four people who made their living “commenting or offering advice on political and economic trends,” and he started asking them to assess the probability that various things would or would not come to pass, both in the areas of the world in which they specialized and in areas about which they were not expert. Would there be a nonviolent end to apartheid in South Africa? Would Gorbachev be ousted in a coup? Would the United States go to war in the Persian Gulf? Would Canada disintegrate? (Many experts believed that it would, on the ground that Quebec would succeed in seceding.) And so on. By the end of the study, in 2003, the experts had made 82,361 forecasts. Tetlock also asked questions designed to determine how they reached their judgments, how they reacted when their predictions proved to be wrong, how they evaluated new information that did not support their views, and how they assessed the probability that rival theories and predictions were accurate. Tetlock got a statistical handle on his task by putting most of the forecasting questions into a “three possible futures” form. The respondents were asked to rate the probability of three alternative outcomes: the persistence of the status quo, more of something (political freedom, [e.g.] economic growth), or less of something (repression, [e.g.] recession). And he measured his experts on two dimensions: how good they were at guessing probabilities (did all the things they said had an x per cent chance of happening happen x per cent of the time?), and how accurate they were at predicting specific outcomes. The results were unimpressive. On the first scale, the experts performed worse than they would have if they had simply assigned an equal probability to all three outcomes—if they had given each possible future a thirty-three-per-cent chance of occurring. Human beings who spend their lives studying the state of the world, in other words, are poorer forecasters than dart-throwing monkeys, who would have distributed their picks evenly over the three choices.

## Advantage

### Bioterrorism

#### **Terrorists are becoming increasingly interested in manufacturing bioweapons due to the immense consequences of the COVID-19 pandemic.**

Pavel and Venkatram 21 Barry Pavel, senior vice president and director of the Scowcroft Center for Strategy and Security, former senior director for defense policy and strategy on the National Security Council, Vikram Venkatram, Young Global Professional in the Scowcroft Center for Strategy and Security, "Facing the future of bioterrorism," 7 September 2021, Atlantic Council, accessed 9 October 2021, <https://www.atlanticcouncil.org/commentary/article/facing-the-future-of-bioterrorism/> ~ST~

Bioterrorism is not a new phenomenon, though past cases have been limited in scope. In the 1990s, a Japanese cult known as Aum Shinrikyo attempted to engineer an aerosolized strain of anthrax or, in other words, a strain of anthrax capable of infecting people through inhalation. The cult’s members were ultimately unsuccessful in their attempts to do so and resorted to releasing sarin gas (a chemical weapon, rather than a biological one) in Tokyo’s subway system on March 20, 1995, which killed thirteen people and sickened thousands of others. Their goal was to release an infectious pathogen in the hopes of causing an epidemic and stimulating a world war that would have allowed them to seize power. They were stymied by a lack of expertise—though cult members included former biologists and some with medical credentials.

A decade before, in Oregon, a cult known as the Rajneeshees spread salmonella in the hopes of incapacitating opposing candidates in local government elections. Cult members ultimately caused food poisoning in more than seven hundred and fifty people, marking the largest bioterrorism incident in US history. In 1998, al-Qaeda publicly declared its intent to pursue weapons of mass destruction, including bioweapons. The organization later conducted training courses on the use of such weapons and recruited biologists to help develop a bioweapons program. In the wake of the attacks on the United States on September 11, 2001, anthrax-laced letters were sent by mail, killing five people.

Greater access to cheap but powerful biotechnology tools—and a reduced need for expertise in operating those tools—… is making it easier for malicious actors to utilize that technology for ill.

As these cases illustrate, terrorists have already demonstrated a willingness to use biological weapons, without regard for the indiscriminate danger those weapons pose to the entire globe. As COVID-19 has shown, diseases can cross borders, particularly in the globalized world we live in today. A bioweapon released in Tokyo could spread across the world in short order, even if the initial attack is limited in scope (i.e., targeted at a specific group or starting with a relatively small volume of pathogen). These potential large-scale effects of attempted bioterrorism have been mitigated in the past by terrorists’ lack of expertise, and the inherent challenge of using biotechnology to make and release dangerous pathogens. Now, as people gain greater access to this technology and it becomes easier to use, the challenge is easing. Further, COVID-19 has shown that pandemics can have an extraordinary political impact, preying upon and worsening existing fractures in society and among nations. To terrorists, who conduct violence to achieve political aims, this reinforces the fact that a bioweapon could serve their purposes. Thus, incidents of bioterrorism soon will become more prevalent.

#### **Patent law is a barrier to defense against bioterror attacks.**

Oriola 13 Taiwo A. Oriola, Ph.D in law from the University of Cardiff, senior lecturer in law at the University of Derby Law School, programme leader for LLM Intellectual Property and Information Technology Law, "Against the Plague: Exemption of Pharmaceutical Patent Rights as a Biosecurity Strategy," 5 October 2013, University of Illinois Journal of Law, Technology, and Policy, accessed 9 October 2021, pg. 342-343, <http://illinoisjltp.com/journal/wp-content/uploads/2013/10/05-05-08_Oriola_AHW_Formatted_FINAL.pdf> ~ST~

This Article proposes the inclusion of a bioterrorism-specific pharmaceutical patents appropriation clause in national and international patent regimes. The thesis is predicated on the impropriety of the current bureaucracy-prone access to medicines paradigms in international and national patent regimes for bioterrorism-induced public health crises situations. Using highly plausible, worst-case scenarios of bioterrorism attacks, this Article argues that vast swathes of the population could become simultaneously vulnerable to deadly bioweapons, exposing millions of people to inevitable deaths, in a comparatively shorter time span than naturally-occurring diseases like HIV/AIDS or tuberculosis. In this circumstance, time is of utmost essence in saving as many lives as possible. This makes it imperative for authorities to override patents on crucial drugs or vaccines without the consent of patent holders, thus avoiding lengthy negotiations that might be destined for failure. Moreover, this Article deems a bioterrorism-specific appropriation clause in global patents regimes expedient, in light of the pervasive and dominant pro-patents forces intent on a stronger intellectual property regime. This regime rationalizes patent protection solely on utilitarianism, and would cast attempts at proportionality of rights as campaigns against innovation. A fortiori, absent a bioterrorism-specific pharmaceutical patent appropriation clause, authorities could be bogged down by political and economic expediencies of pharmaceutical patent appropriation, fostering indecision that would make securing critical medicines in bioterrorism pandemics situations nigh impossible. This article justifies the case for bioterrorism-specific pharmaceutical patents appropriation on ethical grounds, overriding public interests, and fundamental rights to health and life.

#### **That causes extinction.**

Walsh 20 Bryan Walsh, Future Correspondent for Axios, Editor of the Science and Technology Publication OneZero, Former Senior and International Editor at Time Magazine, BA from Princeton University, End Times: A Brief Guide to the End of the World, Orion Publishing Group, 2020, accessed 11 October 2021, Limited Edition, p. 204-206 https://www.slideshare.net/hyzerory97501/2019-end-times-pdf-a-brief-guide-to-the-end-of-the-world-by-bryan-walsh-hachette-audio

I’ve lived through disease outbreaks, and in the previous chapter I showed just how unprepared we are to face a widespread pandemic of flu or another new pathogen like SARS. But a deliberate outbreak caused by an engineered pathogen would be far worse. We would face the same agonizing decisions that must be made during a natural pandemic: whether to ban travel from affected regions, how to keep overburdened hospitals working as the rolls of the sick grew, how to accelerate the development and distribution of vaccines and drugs. To that dire list add the terror that would spread once it became clear that the death and disease in our midst was not the random work of nature, but a deliberate act of malice. We’re scared of disease outbreaks and we’re scared of terrorism—put them together and you have a formula for chaos. As deadly and as disruptive as a conventional bioterror incident would be, an attack that employed existing pathogens could only spread so far, limited by the same laws of evolution that circumscribe natural disease outbreaks. But a virus engineered in a lab to break those laws could spread faster and kill quicker than anything that would emerge out of nature. It can be designed to evade medical countermeasures, frustrating doctors’ attempts to diagnose cases and treat patients. If health officials manage to stamp out the outbreak, it could be reintroduced into the public again and again. It could, with the right mix of genetic traits, even wipe us off the planet, making engineered viruses a genuine existential threat. And such an attack may not even be that difficult to carry out. Thanks to advances in biotechnology that have rapidly reduced the skill level and funding needed to perform gene editing and engineering, what might have once required the work of an army of virologists employed by a nation-state could soon be done by a handful of talented and trained individuals. Or maybe just one. When Melinda Gates was asked at the South by Southwest conference in 2018 to identify what she saw as the biggest threat facing the world over the next decade, she didn’t hesitate: “A bioterrorism event. Definitely.”2 She’s far from alone. In 2016, President Obama’s director of national intelligence James Clapper identified CRISPR as a “weapon of mass destruction,” a category usually reserved for known nightmares like nuclear bombs and chemical weapons. A 2018 report from the National Academies of Sciences concluded that biotechnology had rewritten what was possible in creating new weapons, while also increasing the range of people capable of carrying out such attacks.3 That’s a fatal combination, one that plausibly threatens the future of humanity like nothing else. “The existential threat that would be most available for someone, if they felt like doing something, would be a bioweapon,” said Eric Klien, founder of the Lifeboat Foundation, a nonprofit dedicated to helping humanity survive existential risks. “It would not be hard for a small group of people, maybe even just two or three people, to kill a hundred million people using a bioweapon. There are probably a million people currently on the planet who would have the technical knowledge to pull this off. It’s actually surprising that it hasn’t happened yet.”

### Innovation

#### **Medical innovation is needed for a high quality of life, especially during the current pandemic.**

Regelsberger 21 Jan Regelsberger, department chair of neurosurgery at Diakonissenkrankenhaus Flensburg, "The Need for Innovation in Healthcare," 5 July 2021, Olympus Europa, accessed 11 October 2021, <https://www.olympus-europa.com/medical/en/stories-detail/2021-07-05/The-Need-for-Innovation-in-Healthcare.html> ~ST~

Healthcare decision-makers are consistently under a huge amount of pressure to deliver quality care with limited resources. Factors such as an aging population, sharp rises in long term conditions, reduced funding, increased patient expectations and of course, the current COVID-19 pandemic, make this even more difficult and highlight a constant need for innovation in healthcare.

Shortages in the availability of skilled staff is also a serious challenge for healthcare providers, who must appear as attractive as possible to appeal to the most talented and sought-after potential employees. Groundbreaking technologies and the ever-growing digitalization of healthcare can help provide this much-needed innovation, creating opportunities to boost attractiveness to patients and staff while improving patient outcomes and efficiency.

#### **However, the current patent system is proven to decrease innovation for much-needed medicines.**

Feldman 18 Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, accessed 15 October 2021 Pages 590–647, <https://doi.org/10.1093/jlb/lsy022> Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation (Study Notes: Presenting the first comprehensive study of evergreening, this article examines the extent to which evergreening behavior—which can be defined as artificially extending the protection cliff—may contribute to the problem. The author analyses all drugs on the market between 2005 and 2015, combing through 60,000 data points to examine every instance in which a company added a new patent or exclusivity.)//sid

The study results demonstrate definitively that the pharmaceutical industry has strayed far from the patent system's intended design. The patent system is not functioning as a time-limited opportunity to garner a return, followed by open competition. Rather, companies throughout the industry seek and obtain repeated extensions of their competition-free zones. Moreover, the incidence of such behavior has steadily increased between 2005 and 2015, especially on the patent front and for certain highly valuable exclusivities. Most troubling, the data suggest that the current state of affairs is harming innovation in tangible ways. Rather than creating new medicines—sallying forth into new frontiers for the benefit of society—drug companies are focusing their time and effort extending the patent life of old products. This, of course, is not the innovation one would hope for. The greatest creativity at pharmaceutical companies should be in the lab, not in the legal department.115 The following sections describe the results obtained through our analysis in detail, but below are the key takeaways from the study: Rather than creating new medicines, pharmaceutical companies are recycling and repurposing old ones. In fact, 78% of the drugs associated with new patents in the FDA’s records were not new drugs coming on the market, but existing drugs. In some years, the percentage reached as high as 80%. Adding new patents and exclusivities to extend the protection cliff is particularly pronounced among blockbuster drugs. Of the roughly 100 best-selling drugs, more than 70% extended their protection at least once, with more than 50% extending the protection cliff more than once. Looking at the full group, almost 40% of all drugs available on the market created additional market barriers by having patents or exclusivities added to them. Many of the drugs adding to the Orange Book are ‘serial offenders’—returning to the well repeatedly for new patents and exclusivities. Of the drugs that had an addition to the Orange Book, 80% of those had an addition to the Orange Book on more than one occasion, and almost half of these drugs had additions to the Orange Book on four or more occasions. The number of drugs with a high quantity of added patents in a single year has substantially increased. For example, the number of drugs with three or more patents added to them in one year has doubled. Similarly, the number of drugs with five or more added patents has also doubled. Overall, the quantity of patents added to the Orange Book has more than doubled, increasing from 349 patents added in the year 2005 to 723 in 2015. The number of drugs that had a patent added to them in the Orange Book almost doubled. There were striking increases in certain exclusivities, such as orphan drug exclusivity, new patient population exclusivity, and new product exclusivity. In particular, the number of drugs with an added orphan drug exclusivity tripled. In addition, the number of times a use code was added to a patent more than tripled, suggesting that this has become a new favored game. To provide a broad sense of the types of metrics we are using, some could be characterized as ‘intensity’ measures, which capture the breadth and depth of patent and exclusivity activity in the industry. Another set of our metrics can be characterized as ‘temporal’ measures, which evaluate whether there are any trends in the behavior under examination across time during our 11-year timeframe from 2005 to 2015.

#### Because patents prevent true innovation by taking over rights on old medicines, people are negatively harmed by the unavailability of new medicines.