# Round 2 – AC - Loyola

## FW

#### The standard is consistency with a Kantian system of equal and outer freedom:

#### Agency is constitutive and inescapable since to engage in anything one must engage in agency. Even when agents attempt to assess whether they should participate as agents, they are closed under the operation of reflective rational assessment. Thus, agents must be able to pursue their ends independent of the choices of others or else their reasoning wouldn’t produce an action and wouldn’t be practical.

#### That justifies universalizable ends

#### absent universal ethics morality becomes arbitrary and fails to guide action, making ethics useless

#### a priori principles like reason apply to everyone since they are independent of human experience and

#### any non-universalizable norm justifies someone’s ability to impede on your ends i.e. if I want to eat ice cream, I must recognize that others may affect my pursuit of that end and demand the value of my end be recognized by others. This also makes universalizability a side-constraint on ends-based frameworks.

#### It’s impossible to will a violation of freedom since deciding to do would will incompatible ends since it logically entails willing a violation of your own freedom. Constraints are necessary to retain the value of freedom which implies that one cannot hinder the freedom of others.

#### To clarify:

#### [1] The standard evaluates actions based upon their intrinsic nature, not foreseen consequences:

#### [A] To account for all foreseen impacts would prevent action because individuals would become morally culpable for all actions and states of affairs not just those that factor into the will

#### [B] Induction is circular because it relies on the assumption that nature will hold uniform and we could only reach that conclusion through inductive reasoning based on observation of past events and

#### [C] Prediction is impossible. Any action can lead to a domino effect that can have disastrous impacts in the end. For example, if I drop a pen, it could land on a Faultline triggering an earthquake.

#### Prefer the standard:

#### [1] Performativity—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 a standard without first willing that we can pursue ends free from others.

#### I affirm - The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines by implementing a one-and-done approach for patent protection.

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

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

#### Lower Drug Prices and incentivize Pharma Innovation by revitalizing the Market.

Stanbrook 13, Matthew B. "Limiting “evergreening” for a better balance of drug innovation incentives." (2013): 939-939. (MD (University of Toronto) PhD (University of Toronto))//Elmer

At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “**me too” drugs**, and demonstration that the resulting **incremental benefits** in efficacy and safety are clinically meaningful **is often lacking**. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive **sufficient incentives** to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their **drug-development resources away from innovation**. **Current patent legislation may not be optimal** for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve **denying future patents for modifications** that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the **extensive patent litigation** that contributes to the **high prices of generic drugs** in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.

#### We are in an innovation crisis – new drugs are not being developed in favor of re-purposing old drugs to infinitely extend patent expiration.

Feldman 1 Robin Feldman 2-11-2019 "‘One-and-done’ for new drugs could cut patent thickets and boost generic competition" <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/> (Arthur J. Goldberg Distinguished Professor of Law, Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the Center for Innovation)//SidK + Elmer

Drug companies **have brought great innovations** to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. **But that’s not happening**. Instead, drug companies build massive patent walls around their products, extending the protection **over and over again**. Some modern drugs have an avalanche of U.S. patents, with expiration dates **staggered across time**. For example, the rheumatoid arthritis drug Humira is **protected by more than 100 patents**. Walls like that **are insurmountable**. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, **more than three-quarters** of the drugs associated with new patents **were not new ones** coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be **obtained on minor tweaks** such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit.

#### 80% of all new patents are not new drugs but old ones.

Feldman 2 Robin Feldman 18, May your drug price be evergreen, Journal of Law and the Biosciences, Volume 5, Issue 3, December 2018, 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.

#### The only major study confirms our Internal Link – Evergreening decimates competition by resulting in functional monopolies

Arnold Ventures 20 9-24-2020 "'Evergreening' Stunts Competition, Costs Consumers and Taxpayers" <https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/> (Arnold Ventures is focused on evidence-based giving in a wide range of categories including: criminal justice, education, health care, and public finance)//Elmer

In 2011, Elsa Dixler was diagnosed with multiple myeloma. That August, she was prescribed Revlimid, a drug that had come on the market six years earlier. By January 2012, she went into full remission, where she has remained since. So long as Revlimid retains its effectiveness, she will take it for the rest of her life. “I was able to go back to work, see my daughter receive her Ph.D, and have a pretty normal life,” said Dixler, a Brooklyn resident who is now 74. “So, on the one hand, I feel enormously grateful.” But Dixler’s normal life has come at a steep financial cost to her family and to taxpayers. Revlimid typically costs nearly $800 per capsule, and Dixler takes one capsule per day for 21 days, then seven days off, and then resumes her daily dose, requiring 273 capsules a year. Since retiring from The New York Times at the end of 2017, she has been on Medicare. Dixler entered the Part D coverage gap (known as the donut hole) “within minutes,” she said. She estimates that adding her deductible, her copayment of $12,000, and what her Part D insurance provider pays totals approximately $197,500 a year. Revlimid should have **been subject to competition** from generic drug makers starting in 2009, bringing down its cost by many orders of magnitude. But by obtaining **27 additional patents**, eight orphan drug exclusivities and 91 total additional protections from the U.S. Food and Drug Administration (FDA) since Revlimid’s introduction in 2005, its manufacturer, Celgene, has extended the drug’s **monopoly** **period** **by 18 years** — through March 8, 2028. “I cannot fathom the immorality of a business that relies on **squeezing people with cancer**,” Dixler said, noting her astonishment that Revlimid has obtained orphan drug protections when it treats a disease that is not rare and does not serve a very limited population. She also observed that Revlimid’s underlying drug is thalidomide, which has been around for decades. “They didn’t invent a new drug, rather, they found a new use for it,” she said. “The cost of Revlimid has imposed constraints on our retirement,” Dixler said, “but when I hear other people’s stories, I feel very lucky. A lot of people have been devastated financially.” Revlimid is a case study in a process known as “evergreening” — artificially sustaining a monopoly for years and even decades by manipulating intellectual property laws and regulations. Evergreening is most commonly used with blockbuster drugs generating the highest prices and profits. **Of the roughly 100 best-selling drugs, more than 70 percent have extended their protection** from competition at least once. More than half have extended the protection cliff multiple times. The true scope and cost of evergreening has been brought into sharper focus by a groundbreaking, publicly available, comprehensive database released Thursday by the Center for Innovation at the University of California Hastings College of Law and supported by Arnold Ventures. **The Evergreen Drug Patent Search is the first database to exhaustively track the patent protections filed by pharmaceutical companies**. Using data from 2005 to 2018 on brand-name drugs listed in the FDA’s Orange Book — a listing of relevant patents for brand name, small molecule drugs — it demonstrates the full extent of how evergreening has been used by Big Pharma to prolong patents and delay the entry of generic, lower-cost competition. “Competition is the backbone of the U.S. economy,” said Professor Robin Feldman, Director of the UC Hastings Center for Innovation, who spearheaded the database’s creation. “But it’s not what we’re seeing in the drug industry. “With evergreening, pharmaceutical companies repeatedly make slight, often trivial, modifications to drugs, dosage levels, delivery systems or other aspects to obtain new protections,” she said. “They pile these protections on over and over again — so often that 78 percent of the drugs associated with new patents were not new drugs coming on the market, but existing drugs.” Competition is the backbone of the U.S. economy. But it’s not what we’re **seeing in the drug industry**. Professor Robin Feldman Director of the UC Hastings Center for Innovation In recent decades, evergreening has systematically undermined the Drug Price Competition and Patent Term Restoration Act of 1984, which created the generic drug industry. Commonly known as the Hatch-Waxman Act, it established a new patent and market exclusivity regime in which new drugs are protected from competition for a specified period of time sufficient to allow manufacturers to recoup their investments and earn a reasonable profit. When that protection expires, generic drug makers are incentivized to enter the market through a streamlined regulatory and judicial process. Drug prices typically drop by as much as 20 percent when the first generic enters the market**, and with more than one generic manufacturer, prices can plummet by 80 to 85 percent**. “Hatch-Waxman created an innovation/reward/competition cycle, but it’s been distorted into an innovation/reward/more reward cycle,” Feldman said. “To paraphrase something a former FDA commissioner once said, the greatest creativity in Big Pharma should come from the research and development departments, not from the legal and marketing departments.” Feldman led the development of the Evergreen Drug Patent Search in response to repeated requests from Congressional committees, members of Congress, state regulators and journalists for information about specific drugs and companies. “We want to make it so anyone can have the question about drug protections at their fingertips whenever they want,” Feldman said. “It’s designed to be easy and user-friendly, and to enhance public understanding about how competition may be limited rather than enhanced through the drug patent system.” The **database** was **created through** a painstaking process of **combing** through **160,000 data points** **to examine every instance where a pharmaceutical company added a new drug patent or exclusivity**. “Most of it was done by hand,” Feldman said, “with multiple people reviewing it at every stage. And along the way we repeatedly made conservative choices. **We erred on the side of underrepresenting the evergreen gain** to be sure we were as fair and reasonable as possible.” Among the 2,065 drugs covered in Evergreen Drug Patent Search, there are many examples of the evergreening strategy used by pharma to delay the entry of competition, especially generics, often for widely prescribed drugs, including those used to treat heartburn, chronic pain, and opioid addiction. Nexium Before Nexium, there was Prilosec, a popular drug to treat gastroesophageal reflux disease (GERD). But its patent exclusivity was due to expire in April 2001. In the late 1990s, with a precipitous drop in revenue looming, Prilosec’s manufacturer, AstraZeneca, decided to develop a replacement drug. Using “one-half of the Prilosec molecule — an isomer of it,” the result was Nexium, which received approval in February 2001. Essentially an evergreened version of Prilosec, Nexium’s exclusivity was then extended by more than 15 years, as AstraZeneca received 97 protections stemming from 16 patents. These included revised dosages, compounds, and formulations. Feldman said that tinkering changes such as Nexium’s do not involve the substantial research and development required for a new drug, nor do they constitute true innovations, yet for a decade and a half, patients and taxpayers were forced to pay far more than was warranted for GERD relief. In fact, in 2016 — one year after patent exclusivity expired — Nexium still topped all drugs in Medicare Part D spending, totaling $1.06 billion. Suboxone Use of this combination of buprenorphine and naloxone for treating opioid addiction has exploded in the wake of the opioid epidemic. Since its approval, Suboxone’s manufacturer, Reckitt Benckiser (now operating as Indivior), extended its protection cliff eight times, gaining nearly two extra decades of exclusivity through early 2030. The drug maker gained six patents for creating a film version of the drug — notably around the time protection was expiring for its tablet version. (The therapeutic benefits of the film and tablet are identical.) An earlier version of Suboxone also obtained an orphan drug designation, despite an opioid epidemic that has expanded Suboxone’s customer base to millions of potential customers. Suboxone generates more than $1 billion in annual revenue and ranks among the 40 top-selling drugs in the U.S. Truvada When Truvada, commonly referred to as PrEP, was approved in 2004, this HIV-prevention drug was a breakthrough. But 16 years later — and 14 years after its original exclusivity was to expire — it retains its monopoly status. Truvada’s manufacturer, Gilead, has received 15 patents and 120 protections since it came on the market, extending its exclusivity for more than 17 years, until July 3, 2024. In countries where generic Truvada is available, PrEP costs $100 or less per month, compared to $1,600 to $2,000 in the U.S. As a result, Truvada is unaffordable to many people **who need protection from HIV**. Barred from access, they are left vulnerable to infection. “We’re establishing a precedent that a pharmaceutical company can charge whatever it wants even as it allows an epidemic to continue, and the government refuses to intervene,” said James Krellenstein, co-founder of the group PrEP4All. “That should scare every American. If it’s HIV today, it will be another disease tomorrow.” EpiPen First approved in 1987, the EpiPen has saved the lives of countless numbers of people with deadly allergies. But it is protected from competition until 2025 — 38 years after its introduction — because its owner, Mylan, has filed five patents, four since 2010, all involving tweaks to the automatic injector. The actual medication used, epinephrine, has existed for more than a century — the innovation here is in the delivery device. Because these small changes to the injector have maintained its monopoly for so long, the cost of an EpiPen package (containing two injectors) has risen from $94 when Mylan purchased the device to between $650 and $700 today. For many people, especially parents of children with severe reactions to common allergens like peanuts, EpiPen’s increasing price tag imposes an onerous financial burden. What Can Be Done As the Evergreen Drug Patent Search makes clear, the positive impact of Hatch-Waxman has been steadily and severely eroded by a regulatory system vulnerable to increasingly sophisticated forms of manipulation. “You might say that the patent and regulatory system has been weaponized,” Feldman said. “When billions of dollars are at stake, there’s a lot of money available to look for ways to exploit the legal system. And companies have become adept at this, as our work has found.” There are several key steps that Congress could take to restore the balance between innovation and competition that is the key to a successful prescription drug regulatory process. These may include: Imposing restrictions on the number of patents that prescription drug manufacturers can defend in court to discourage the use of anticompetitive patent thickets. Limiting the patentability of so-called secondary patents — which don’t improve the safety or efficacy of a drug — through patent and exclusivity reform. Reforming the 180-day generic exclusivity, which can currently be abused to block other competitive therapies. “**The Evergreen Drug Patent Search provides the publicly available, evidence-based foundation that defines the extent of the problem**, and it can be used to develop policies that solve the problem of anti-competitive patent abuses,” said Kristi Martin, VP of Drug Pricing at Arnold Ventures. “Our incentives have gotten out of whack,” Martin said. “The luxury of monopoly protection should only be provided to innovations that provide meaningful benefits in saving lives, curing illnesses, or improving the quality of people’s lives. It should not be provided to those gaming the system. If we can change that, we can save consumers, employers, and taxpayers many billions of dollars while increasing the incentives for pharmaceutical companies to achieve breakthroughs."

## Affirm

#### [1] The intention of intellectual property is to discriminate and help preserve rights for only a select few.

#### Kanning 12

[Kanning, Michael A., "A Philosophical Analysis of Intellectual Property: In Defense of Instrumentalism" (2012). Graduate Theses and Dissertations. [http://scholarcommons.usf.edu/etd/4094]//](http://scholarcommons.usf.edu/etd/4094%5d//) RaZ

Drahos has other reservations with proprietarianism. The historical origin of intellectual property, he argues, is in attempts by government to grant beneficial privileges to a few at the cost of “common disadvantage” (213). This general idea continues today, when the cost of the overall system is justified through an appeal to its incentivizing effects. But the contemporary couching of IP in the language of property and of rights obscures the historical origin of these practices as public privilege.

#### [2] Property rights prohibit freedom to make advancement on technologies; people are given exclusive ownership which hinder progress.

#### Kanning 12

[Kanning, Michael A., "A Philosophical Analysis of Intellectual Property: In Defense of Instrumentalism" (2012). Graduate Theses and Dissertations. [http://scholarcommons.usf.edu/etd/4094]//](http://scholarcommons.usf.edu/etd/4094%5d//) RaZ

But such a narrow focus on the autonomy of the individual creator hides the extent of the costs imposed by exclusive property rights on the autonomy of other potential creators. Property rights, by their nature, inhibit the freedom of 15 others by disallowing them from accessing or using the things covered by property rights. While Merges’ focus on enabling the highest degree of freedom for individual creators can plausibly be seen to help achieve the highest degree of freedom, it also at the same time inhibits the freedom of creators. Merges’ frequent example is that of the sculptor Michelangelo and a piece of stone. In order to realize his freedom as an artist, he needs to have control over the stone so that he may fully realize the project of turning that stone into a finished sculpture. This also requires the need to prevent others from altering or destroying the stone. In this example, prohibiting other creators from messing with Michelangelo’s stone is a reasonable infringement on the freedom of others. But intellectual property rights represent a more significant impact on the freedom of others because they are not limited to particular entities. Copyrights and patents involve exclusive ownership of broad categories of things, and can result in severe restrictions on the freedoms of creators who engage in transformative works. This objection will be covered in more depth in Chapter 2.

#### [3] Hindering a hindrance

#### [a] You can only restrict the freedoms of inventors when the invention being withheld is life saving. Death kills freedoms and autonomy.

#### Merges 11

[ROBERT P. MERGES; “JUSTIFYING INTELLECTUAL PROPERTY” HARVARD UNIVERSITY PRESS Cambridge, Massachusetts London, England 2011]//RaZ

Under Kant’s Universal Principle of Right (UPR), “laws secure our right to external freedom of choice to the extent that this freedom is compatible with everyone else’s freedom of choice under a universal law.”8 As I explained in Chapter 3, Kant’s theory of property rights expresses a special instance of this general principle: property is widely available, yet denied when individual appropriation interferes with the freedom of others. Kant says that although the need for robust property drives the formation of civil society, property rights are nonetheless subject to this “universalizing” principle. Under the operation of the UPR, property rights are constrained: they must not be so broad that they interfere with the freedom of fellow citizens. In a Kantian state, individual property is both necessary— to promote autonomy and self- development; see Chapter 3— and necessarily restricted under the UPR.9

Death is the ultimate restraint on autonomy; there is no more “self” to guide after a person dies. So when a claim to property by person A leads to the death of person B, Kant’s Universal Principle would seem to rebut that claim. As with other issues, however, Kant’s views in this regard are not so simple. In par tic u lar, he expressed complex views on the legal defense of “necessity,” which bears a close resemblance to the property- limiting principle I am attributing to him here.10 Kant says, in effect, that in at least one important example of necessity— where A kills B, or at least puts B in immediate grave danger, to save A’s own life— one who commits a necessary act is culpable but not punishable.11 As with so much in the Kantian canon, there is a great deal of debate over just what Kant was trying to say about necessity. One view— at least as plausible as most others, and more plausible than some— holds that Kant thought of necessity as something like an excuse or defense: a wrong act is not made right by necessity, but it is insulated from formal legal liability.12 This view, well described by among others the Kant scholar Arthur Ripstein, depends on the distinction between formal, positive law (“external,” in Kant’s terminology; see Chapter 3) and “internal” morality. Property for Kant is an absolute right, and taking it without permission is always objectively wrong. But at the same time, some takings are not punishable by the state because they fall outside the proper bounds of legitimate lawmaking Because Kant did not explicitly discuss the necessity defense as it pertains to property rights, any application of his thinking to the case of pharmaceutical patents can only be speculation. Even so, there is one point to make. As I explained in some detail in Chapter 3, there is generally a high degree of symmetry between Kant’s thinking on law and his theory of property. The UPR is a good example; as I explained in Chapter 3, the idea that property can extend only up to the point that it interferes with the freedom of others is simply one specific application of the general Kantian take on law and freedom. Thus, the analysis of the pharmaceutical patents problem would turn on the issue of property’s effect on the freedom of those suffering from treatable diseases. To put it simply, it is difficult to be sure of the exact conclusion Kant would reach with regard to the issue, but I am sure that the analysis would turn on the freedom- restricting qualities of pharmaceutical patents. It is hard to know the right answer, but not hard to pose the right question: should property extend so far as to cut off or restrain the freedom of those who might be treated? In my view, the freedom of disease sufferers is so constrained that the property rights in pharmaceutical patents must give way. As I said, this is not the only plausible reading of Kant’s Universal Principle with respect to the problem at hand. But I think it is the best reading, and it is certainly the best I can do, given Kant’s text and the problem of pharmaceutical patents as I understand it.

#### [b] Medicines are created with the intention of saving lives.

#### Nemours

[TeensHealth from Nemours ;Understanding Medicines and What They Do; https://kidshealth.org/en/teens/meds.html]//RaZ

Medicines are chemicals or compounds used to cure, halt, or prevent disease; ease symptoms; or help in the diagnosis of illnesses. Advances in medicines have enabled doctors to cure many diseases and save lives.

#### [4] Evergreening – exploitation of patents is anti-ethical to the intrinsic nature of medical duty – that affirms.

McHenry 6, Leemon. "Ethical issues in psychopharmacology." Journal of Medical Ethics 32.7 (2006): 405-410.

It is often claimed that corporations that are profit driven could not be expected to behave in any other manner than they do. The nature of business demands maximisation of the market share and shareholder value. **Pharmaceutical companies**, however, **present** themselves **as responsible producers of healthcare products**. The **very nature** of the product **involves trust** in the science that produced it **and** an **ethical commitment to** the **wellbeing of the patients** who are their consumers. Despite appearances, nothing of this sort is true in the pharmaceutical industry. As we have seen above, the serotonin hypothesis sold to consumers of pharmaceuticals is flawed. Making questionable claims for the efficacy and safety of SSRIs involves the pharmaceutical companies in further deception. Expanding the market for these drugs by creating dubious disease categories and then luring vulnerable individuals into SSRI therapy by direct to consumer advertising would represent, if perpetrated by a doctor, an abuse of the trust implicit in the relationship between patient and doctor. I do not argue that SSRIs should be withdrawn from the market thus depriving clinicians and patients of this therapeutic option. Rather I argue that **full disclosure** of the data for efficacy and safety **is a basic moral obligation** of the pharmaceutical industry. Until such data is available to the public, prescribing clinicians and patients are relying on drug promotion rather than rigorous science. When **Kant discusses** the **motivation of acting from duty** **as opposed to** the motivation of **self interest**, he mentions the case of the merchant who keeps a fixed price for everyone so that a child who buys from him pays the same price as everyone else.53 The **only actions that have moral worth are those done from the motive of duty alone**. And similarly, **only when** the **pharmaceutical companies act from** the motive of **duty** in fully disclosing all information they possess about the risks and benefits of their drugs **do their actions have any moral worth**. The SSRI marketing story provides a lens through which we can view a much larger problem. The **integrity of medicine is endangered by** an industry that profits from illness and distorts the process of scientific inquiry by marketing strategy, public relations campaigns, and the **sheer power of buying influence** in high places. The House of Commons health committee in the UK has made the point: “It is not in the long term interest of industry for prescribers and the public to lose faith in it. We need an industry which is led by the values of scientists not those of its marketing force” (House of Commons health committee,23 p 6). Medicine desperately needs to win back the territory lost to business. If and when it does, it is not likely to be a result of industry and government regulators facing up to the problems, but rather a matter of the sheer weight of legal actions filed by victims and public outcry about the moral concerns of the sort raised in this paper.