## 1

#### Ethics must began a priori rather than with experiences.

#### 1] Uncertainty – experiences are locked within our own subjectivity and are inaccessible to others, however a priori principles are created in the noumenal world and are universally applied to all agents.

#### 2] Is/Ought Gap – experience in the phenomenal world only tells us what is since we can only perceive what is, not what ought to be. But it’s impossible to derive an ought from descriptive premises, so there needs to be additional a priori premises within the noumenal world to make a moral theory.

#### The existence of extrinsic goodness requires unconditional human worth—that means we must treat others as ends in themselves.

Korsgaard ’83 (Christine M., “Two Distinctions in Goodness,” The Philosophical Review Vol. 92, No. 2 (Apr., 1983), pp. 169-195, JSTOR) OS/Recut Lex AKu \*brackets for gendered language

The argument shows how Kant's idea of justification works. It can be read as a kind of regress upon the conditions, starting from an important assumption. The assumption is that when a rational being makes a choice or undertakes an action,[they] he or she supposes the object to be good, and its pursuit to be justified. At least, if there is a categorical imperative there must be objectively good ends, for then there are necessary actions and so necessary ends (G 45-46/427-428 and Doctrine of Virtue 43-44/384-385). In order for there to be any objectively good ends, however, there must be something that is unconditionally good and so can serve as a sufficient condition of their goodness. Kant considers what this might be: it cannot be an object of inclination, for those have only a conditional worth, "for if the inclinations and the needs founded on them did not exist, their object would be without worth" (G 46/428). It cannot be the inclinations themselves because a rational being would rather be free from them. Nor can it be external things, which serve only as means. So, Kant asserts, the unconditionally valuable thing must be "humanity" or "rational nature," which he defines as "the power set to an end" (G 56/437 and DV 51/392). Kant explains that regarding your existence as a rational being as an end in itself is a "subjective principle of human action." By this I understand him to mean that we must regard ourselves as capable of conferring value upon the objects of our choice, the ends that we set, because we must regard our ends as good. But since "every other rational being thinks of his existence by the same rational ground which holds also for myself' (G 47/429), we must regard others as capable of conferring value by reason of their rational choices and so also as ends in themselves. Treating another as an end in itself thus involves making that person's ends as far as possible your own (G 49/430). The ends that are chosen by any rational being, possessed of the humanity or rational nature that is fully realized in a good will, take on the status of objective goods. They are not intrinsically valuable, but they are objectively valuable in the sense that every rational being has a reason to promote or realize them. For this reason it is our duty to promote the happiness of others-the ends that they choose-and, in general, to make the highest good our end.

#### Practical reason is inescapable - Any moral rule faces the problem of regress – I can keep asking “why should I follow this.” Regress collapses to skep since no one can generate obligations absent grounds for accepting them. Only reason solves since asking “why reason?” requires reason to do in the first place which concedes its authority.

#### Reason means we must be able to universally will maxims— [A] our judgements are authoritative and can’t only apply to ourselves any more than 2+2=4 can be true only for me.

**This the standard is consistency with the categorical imperative.**

#### I contend that reducing IP protections for medicines violates freedom.

#### 1] Patents protect private companies.

Na 19 [Blake Na, "Protecting Intellectual Property Rights in the Pharmaceutical Industry", Chicago-Kent | Journal of Intellectual Property, 4-19-2019, https://studentorgs.kentlaw.iit.edu/ckjip/protecting-intellectual-property-rights-in-the-pharmaceutical-industry/, accessed: 8-24-2021.] //Lex VM

Patent Rights A pharmaceutical company may apply for a patent from the PTO at any time in the development lifetime of a drug.[12] A drug is patentable if it is non-obvious, new, and useful.[13] The drug must be non-obvious when comparing the drug with another previously invented drug, i.e., it does not bring the same type of information as the other drugs. The drug must also not exist, and it must have a purpose. Intellectual property rights, especially patent rights, are the foundation of the pharmaceutical industry. The industry heavily depends on the future profits which innovation (and as a result, exclusivity) enable. Drug patents grant the originator company to market exclusivity for a fixed term of 20 years from the patent’s original filing date. By giving this 20-year patent term in which the government cannot regulate the price, market exclusivity allows pharmaceutical companies to have a monopoly over the market. To maximize their profit, pharmaceutical companies work on extending the exclusivity of a drug. For example, AbbVie extended the manufacturing exclusivity of Humira by delaying generic companies from manufacturing generic entrants until 2023. The market exclusivity can be lengthened anywhere between 180 days to 7 years. Thus, due to efforts to derive profits from patents, pharmaceutical companies’ patents contribute to roughly 70-80 percent of their overall revenues. Patents in the pharmaceutical industry are normally referred to as their product portfolio and are the most effective method for protecting innovation and creating significant returns on investments. Accordingly, as mentioned above, patents help in recouping costs related to research, development, and marketing of a drug. Patents not only help pharmaceutical companies recoup investments, they can also act as a shield against infringement claims. Strong patent protection can safeguard drugs from potential infringers. Without consent from the patentee, other competing companies cannot use, make, or distribute the invention. However, because a drug can be easily imitated by competitors, bringing an infringement suit can also protect a patentee’s rights. Recently, DUSA Pharmaceuticals, Inc.—an arm of the Indian pharmaceutical company Su Pharma and ranked among the top 50 global Pharma Companies—was recently granted injunctive relief from a U.S. court against Biofrontera Inc. in a patent infringement case[14]. The court’s order prohibited Biofrontera from making use of information, including sales data, marketing data, technical information, and unpublished clinical data, of DUSA Pharmaceuticals[15]. Although bringing an infringement suit is a valuable remedial measure for patentees, pharmaceutical companies often face difficulty with the high costs and uncertainty of litigation

#### That negates – A] Promise breaking – states promised legally binding IP protections to companies who might not have otherwise developed medicines – the aff is a unilateral violation of that contract. B] That’s a form of restricting the free economic choices of individuals.

#### 2] IP is a reflection of our will and a form of property.

Merges 11 [Merges, Robert P. "Will and Object in the World of IP." Justifying Intellectual Property, Cambridge, Harvard UP, 2011, pp. 76-78. ISBN: 0674049489,9780674049482. Found on Libgen.] //Lex VM

It is clear enough at this point that Kant thought reliable expectations about ongoing possession of objects enables something positive to take place. Stable possession permits the imprinting of some aspect of a person, what Kant called his will, onto objects so as to enable the person to more fully flourish. Though nuances abound, Kant’s basic idea regarding the will24 is simple enough: Will is that aspect of a person which decides to, and wants to, act on the world.25 It has three distinctive qualities: it is personal, autonomous, and active. It is highly individual, a function of each person’s preferences and desires; Lewis White Beck says that will is “bent upon the satisfaction of some arbitrary purpose.” It is this aspect or feature of ourselves that we imprint or stamp on the world through our choices and the resulting actions that carry out or manifest these choices. Right here, in this foundational element, we see a radically individualistic and autonomous view of humans. Although this is balanced by a universalizing, transpersonal sense of reason in other parts of his philosophy,26 a highly individual will is nonetheless central to Kant’s view of human thought and action, and thus an essential aspect of what he thought it means to be human.27 will and object in the world of ip. It is tempting to get caught up in the terminology and conceptual complexity of Kant’s ideas of persons, will, and objects. To prevent that happening, it seems wise at this point to talk about some specific examples. How exactly does Kantian autonomy work? What does it look like in the context of IP rights? After we have a better grasp of these ideas, and of how they relate to Kant’s rationale for property, we can turn to an equally important topic: the limits on individual autonomy that Kant built into his theory. Our earlier example of Michelangelo showed how stable possession is required for a creator to fully work his will on a found object— in that case, a block of marble. The same basic logic applies in all sorts of cases. Individual farmers and landowners generate and then bring to life a vision for the lands they work on;28 inventors transform off- the- shelf materials into prototypes, rough designs, and finished products; and artists work in media such as paint and canvas, paper and pen, textiles and wood, keyboard and iPad, and so on, to give life to a concept or mental image. Wherever personal skill and judgment are brought to bear on things that people inherit or find, we see evidence of the Kantian process of will imprinting itself on objects. It even happens when the objects at hand are themselves intangible. A composer working out a new instance of a traditional form— a fugue or symphony, blues song or tone poem— is working on found objects just as surely as the farmer or inventor. Even in our earlier example, some of the objects that Michelangelo works on in the course of carving his sculpture are intangible: received conventions about how to depict an emotion; traditional groupings of figures in a religious set piece, such as the Pieta; or accepted norms about how to depict athletic grace or youthful energy. He may take these pieces of the cultural tableau and refine them, or he may subtly resist or transform them. However he handles them, these conventions are just as much objects in his hands as the marble itself.29 As with found physical objects, extended possession of these objects- intransformation is required to fully apply the creator’s skill and judgment. And because of this, Kantian property rights come into play with intangible objects as well. Let me say a word about this complex, and perhaps controversial, possession of intangible objects. It has often been argued that this feature of IP, the control of copies of an intangible work, constitutes a form of “artificial scarcity,”30 that it runs counter to an ethically superior regime where information is shared freely— and is maybe even counter to the nature of information, which, some say, “wants to be free.”31 According to Kant, all property rights have this element of artifice, because they define a conceptual type of possession. Property is not just a matter of physical contact between person and object; it describes a relationship that is deeper and goes well beyond the basic acts of grasping and holding. I can hear one objection to this right away. Yes, Kant speaks of legal ownership as a special relation between a person and an object. But, the objection might run, in his writings he refers only to physical objects, for example, an apple (à la Locke). So maybe the ownership relation is limited to that sort of thing? No. I give no weight to the fact that Kant uses only examples of tangible, physical property in most of the sections of the Doctrine of Right (DOR).32 Kant describes an additional type of possession that makes it crystal clear that the idea is not in any way limited to physical things—the expectation of future performance under a contract. He posits that one could not properly be said to “possess” a right to performance under an executory contract (one that has been signed or agreed to, but not yet performed) unless “I can maintain that I would have possession . . . even if the time of the performance is yet to come.”33 With that legal relation established, however, “[t]he promise of the [promisor] accordingly belongs among my worldly goods . . . , and I can include it under what is mine.”34 The synonymous use of “possession,” “object,” “belonging,” and “mine” in the case of a tangible, physical thing such as an apple and an intangible thing such as a promise of future contractual performance is too clear to require much comment. “Object” is very abstract for Kant, and can of course therefore include IPRs.35

#### 3] Evergreening adv gives Kant NC uniqueness – current limitations on patents are solves by secondary patents – if we win the NC your offense negates. Bad consequences don’t link.

## 2

CP Text: The Member Nations of the World Trade Organization ought to increase the inventiveness standard for granting secondary patents.

#### Solves innovation, eliminates frivolous evergreening and allows for competition which reduces prices.

Christensen 20 [Connor Christensen, "The Evergreen Forests of Insulin Patents", Awakenwfu, The Creative Journal of Contemporary Bioethics, 9-14-2020, https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/, accessed: 9-7-2021.] //CHSTM and Lex VM

A potential solution to prevent patent evergreening would be to modify the “inventiveness” standard required to obtain a new patent on drugs.[[27]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn27) By modifying this standard, the goal would be to stop non-inventive and commonly practiced pharmaceutical techniques from receiving patent protection.[[28]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn28) Moreover, each incremental improvement must be worth the burden on the consumer, especially in a country where the price of insulin has reached unconscionable levels.[[29]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn29) Therefore, to be considered inventive, the newer formula or methodology should be demonstratively safer or clearly more efficacious.[[30]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn30) Increasing the scrutiny would help control drug companies receiving patents on non-inventive, incremental improvements on insulin while still rewarding them for making sizable leaps forward.[31] Further, increasing the “inventiveness” standard would also encourage generic drug companies to enter the market. Previously, generic companies were precluded from producing generic insulins because patents protected the original formulas for such long periods of time that they were obsolete when it became possible to make a generic version.[[32]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn32) These obsolete versions of insulin were not viewed as a worthwhile investment to generic drug companies, so the market has been mostly devoid of generic versions.[[33]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn33) However, generic drug companies have shown some interest in creating generic versions of the next-generation of insulin. Reducing evergreening by raising the inventiveness standard required for new insulin patents could be enough to make manufacturing generics a worthwhile investment.[[34]](https://awakenwfu.com/2020/09/14/the-evergreen-forests-of-insulin-patents/#ftn34) Affording greater scrutiny to the issue of whether an incremental improvement is truly “inventive” is just one piece of the solution to reducing the price of insulin to affordable levels. Evergreens are a symbol of vitality; the irony is tangible that something of the same name can be depriving people of life.

#### Solves best.

Newsome 17, A [(JD candidate George Washington School of Law). (2017). Side effects of evergreening may include decreased competition & increased prices in the pharmaceutical industry. AIPLA Quarterly Journal, 45(4), 791-822] Justin

Pharmaceutical patents are inherently different from software or manufacturing patents. 144 Pharmaceutical companies create life-saving drugs that carry a very serious benefit for a vulnerable group of consumers - patients. Because of this, the pharmaceutical industry should be held to a higher standard if its companies seek to prohibit affordable generic drugs from coming to the marketplace. An Efficacy-Focused Standard Will Motivate Pharmaceutical Companies to Channel Resources to Creating Real Innovation Pharmaceutical companies argue that patent-life-cycle-management strategies (their preferred name for those tactics described herein as evergreening) are essential to ensuring they recoup R&D costs. 145 However, creation of a standard such as the one proposed here would ensure that pharmaceutical companies are properly incentivized to channel R&D resources to creating measurable change in the drugs, rather than creating minor changes that prolong the time they can profit off of monopolies at the expense of patients. For those industries in which R&D is more productive, like the pharmaceutical industry, "patent procedures should be refined to tighten the relationship between patents and the underlying inventions."14 6 A Higher Standard for Secondary Pharmaceutical Patents Will Increase Competition & Lead to Lower Prices The patent system enables pharmaceutical companies to retain market exclusivity for their drugs, allowing them to set high prices without an eye toward competition.1 47 The companies cite the need to recoup R&D costs as the driving factor for their pricing decisions,148 but critics say their main motivation is making a profit.'49 While the pharmaceutical companies' argument may hold weight, high prices for drugs have a negative impact on those patients who need those drugs, but cannot afford them.150 Tightening patent laws to prevent pharmaceutical companies from retaining patent protection for minor changes in their patented drugs will allow other companies to enter the marketplace sooner and drive prices down through competition. 5

#### It’s competitive [1] We allow renewals on patents but they don’t.

Solves useless evergreening while maintaining incentives for good things.

#### Rvis on 1AR theory if I didn’t read NC theory – a) reciprocity – otherwise they are the only ones that get access to the theory layer which gives them more routes to the ballot than me b) deters friv theory – rvi creates an opportunity cost to theory and makes them think twice before spamming frivolous shells. Outweighs they are more likely to debate substance which outweighs since norms can be set whenever BUT this is one of the last chance to debate this topic.

#### Only 1 theory shell – anything else splits the 2NR too many ways since we need to beat back both offs and win substance while the 2AR can win on either shell or substance which is a 3-1 skew. A combo shell solves their offense against this spike and gives them a better abuse story.

## 3

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

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

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

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

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

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