#### **Innovation DA**

Uniqueness: Innovation is key to improving healthcare worldwide right now

**Thelwell 21. “The importance of medical innovation in the wake of COVID-19” 9th June 2021. Andrew Thelwell, Chief Commercial Officer at Sky Medical Technology.**

#### **https://www.healtheuropa.eu/the-importance-of-medical-innovation-in-the-wake-of-covid-19/108850/**

#### **The COVID-19 virus has had a profound impact on global healthcare provision, focusing care on the virus and causing the postponement of many routine and serious operations for other conditions. It will likely take years for health services to catch up. Yet amid the chaos, the virus has kickstarted a fast-tracking of innovation that could be the [is] key to delivering a level of healthcare provision in the future fitting to the changing demographics of the global population. There is, as the saying goes, no harder taskmaster than necessity. The past 12 months have seen unprecedented disruption to multiple industries, but the COVID-19 pandemic has also led to change taking place in months that would previously have taken years. Restaurants have pivoted overnight to home delivery services offering chef-created food to be finished off at home, while Tesco doubled its number of weekly delivery slots to 1.2 million – a figure that, before lockdown, was planned to take at least two years. Unsurprisingly, frontline health services also had to change rapidly to face the crisis: students were thrown into frontline services; former staff were recalled; NHS workers were re-deployed from non-essential services and business facilities were repurposed into new hospitals in weeks. Healthcare systems, typically wary of untested change, sprang into action to address the crisis. But perhaps the most remarkable success story has been that of vaccines. Less than a calendar year after the world woke up to a global pandemic, there are three vaccines approved to be used in the UK and USA with several others lined up for regulatory approval. The speed of the global rollout has been nothing short of sensational – quite unlike a typical rollout of new vaccines that, in ‘normal’ circumstances, might take more than a decade to come to market. The pandemic has acted as a powerful impetus for change in the healthcare industry. Recent research from McKinsey has shown that two industries which have most increased their focus on innovation are the pharmaceutical and medical device sectors. But why is this so important and will it continue once COVID-19 is under control? Rebalancing the scales Innovation in medical technology (medtech) is uniquely important to the future of healthcare for two fundamental reasons. On an economic level, costs associated with the pandemic led to a £5.1bn deficit for the NHS in England in the first four months of the financial year, compared with the pre-pandemic budget. Some of the factors which have contributed to this deficit include extending the workforce to meet the healthcare demand; absences from sickness; providing extra bed capacity; and, at the beginning of the lockdown, higher costs of prescribing. But healthcare systems around the world were battling the demographic odds even before the first outbreak of COVID. Over the course of a century, from 1950 to 2050, it is estimated that the proportion of people in employment, compared to those in retirement, will change from 14 adults in work to every one in retirement, to two in work to every one retired. An ageing global population causes strain for healthcare systems for more than one reason: older people generally need more care but, with less people employed and more retired, there are fewer taxpayers to fund this. This is further complicated by the advances in medicine which are continuing to take place. There are now medical conditions that people can happily live with (assuming the right treatment is given), which only a few decades ago would have had a significant impact on life expectancy. This is cause for celebration, but the increased longevity of patients places yet more burdens on healthcare systems which were already squeezed, even before COVID-19. This is where technology has an important role to play. Innovation in medicine has historically been driven by pharmaceutical interventions that are expensive to develop, take time to gain regulatory approval and require significant clinical testing to ensure the interventions do no harm. Medical technology promises an alternative** – using innovation in technology to develop electronic devices that can be deployed simply and effectively **to address multiple medical issues without the risk of harmful side effects[,]. This has the potential to transform[ing] both the effectiveness and the cost of healthcare in the 21st century.** Technology is **increasingly being seen as** the bridge between unlimited demand and limited resources – enabling healthcare systems to develop new ways to treat conditions and rebalancing the scales to reduce the financial pressure on healthcare services, **while at the same time** [and] enhanc[e]ing patient outcomes**. … Carrying the torch New technologies and innovations have the potential to improve patient outcomes, reduce the strain on healthcare professionals and, ultimately, save healthcare systems money across the globe. The pandemic has been pivotal to enacting changes to the [in] infrastructure of healthcare which has assisted healthcare professionals in making the switch to innovation-enabled care. This momentum must now be maintained. Healthcare systems do not have an innovation problem; the issue is about replication: in the past, successful projects and changes to clinical practice have rarely been reproduced elsewhere in the system. The pandemic has changed this, allowing innovation to break through with greater pace. Long may it continue.**

#### **And, medical IP protections provide key incentive to innovate - it builds investment confidence, supports collaboration, and forms the basis for vaccine provision by supporting the biopharmaceutical industry**

#### **(IPFMA, No Date but they cite sources from 2020 so I assume it’s fairly recent “IP”** [**https://www.ifpma.org/subtopics/ip-2/**](https://www.ifpma.org/subtopics/ip-2/)**, Accessed on 9/11/2021)**

#### **Innovation ecosystems are sustainable when governments, research institutions, and business collectively address the elements necessary to drive investments in new technology and science, underpinned by a stable and transparent rule of law and an incentive system to attract the right talent, expertise, and investment. Open dialogue and collaboration with all stakeholders, including the private sector, is critical to the policymaking process to create policies that support the emergence of sustainable innovation ecosystems.**

#### Innovation **in technology dependent sectors,** requires a significant risk appetite**. However,** without innovation, there would not be any advancement in the science and the arts**. Recognizing this dichotomy early on, countries have rewarded and incentivized researchers through the intellectual property (IP) system to undertake the risks needed to provide the solutions. Thus, effective and predictable intellectual property systems have proven to provide an important incentive for investing in innovation and enable innovative ideas to be commercialized and scaled.**

#### **A stable intellectual property system provides the certainty necessary to build confidence for investments in the creation of technologies. Intellectual property incentives also support technological partnerships by providing the legal framework necessary for collaborative innovation and the exchange of technology and knowledge.**

#### **Effective intellectual property regimes bring clarity and certainty to the market, encouraging the introduction of technology to new places and enabling innovative ideas to be scaled. In addition, an effective enforcement regime, ensures no individual in the country is robbed of years of research, skill building, creation of arts. It lends confidence in the country to its people that their rights are protected and surety of law.**

#### **In short, IP incentivized the innovator/creator by way of a limited term protection to disclose his creation or invention to the public and spurring future research to take place, thus, striking the right balance between the interests of innovators and the wider public interest. The IP system aims to foster an environment in which creativity and innovation can flourish.[1]**

#### **Role of Intellectual Property in the Biopharmaceutical Industry**

#### **The biopharmaceutical industry’s business model is based on competitive R&D, intellectual property (IP), the incentive for innovation, and a science-based regulatory system. Our industry plays a key role in providing the world with the medicines, treatments and vaccines that save and improve the lives of people across the world. Intellectual Property Rights incentivize innovation, research and development and allow the biopharmaceutical industry to improve existing and bring new medicines, vaccines and treatments to people and in turn help improve and save lives.**

#### **The industry has developed over 650[2] new medicines for the world’s emerging health needs in the last twenty years, also focusing on treatment of cancers, cardiovascular diseases, and diabetes. Today, with more than 8400 drugs in development across all therapeutic fields[3], the industry still drives the exploratory research, taking care of translating early research into patient-ready treatments.**

#### **As shown by recent studies, a strong IP system and protection allows faster launch and access to new medicines for patients across the world, both in developing and developed countries. In fact, having a strong IP system allows for incentives for the introduction of many medicines which would not be otherwise available.[4]**

#### **With the success rate of clinical trials being less than 12%[5], inventing, developing, and launching new medicines is a long, resource-intensive and risky process. However, despite setbacks, risks and uncertainty, the industry continues to invest in pharmaceutical R&D.[6]**

#### **The temporary and limited period of protection given by patents is part of the factors incentivizing the industry to keep investing in the uncertain and long process that is pharmaceutical R&D. In return for this limited protection, the IP system requires the patent applicant to publicly disclose the invention so to allow others to learn and build upon prior advances, creating a perfectly balanced policy system.**

#### **Secondary pharmaceutical patents have been responsible for major medical innovations - empirics**

**Holman 18**

Christopher M Holman is a professor of patent law at UMKC, “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection**”,** <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/>, published 9-21-18, accessed 9-24-21 // mk

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).

#### **Innovation saves millions of lives, halves mortality rates, responds to public health crises, and reduces costs by billions and sometimes trillions**

#### **Jenner ‘16:**

#### **(Jenner, Andrew. “Value of Innovation.” IFPMA, IFPMA, 23 Feb. 2016,** [**www.ifpma.org/subtopics/value-of-innovation/**](http://www.ifpma.org/subtopics/value-of-innovation/)**. Accessed 9/11/2021)**

#### **Many lower and middle-income countries are making important investment in developing their healthcare infrastructure as part of their commitment to achieving Universal Health Coverage. Increasing access to new medicines and vaccines can help sustain such investment by reducing the need for costly surgical interventions and hospitalization. In many cases, the use of innovative medicines by health systems can pay for themselves several times over. One study found that a reduction in the age of drugs used reduces non-drug spending 7.2 times as much as it increases drug expediture, with most of the savings coming from reduced hospitalization and physician office-visit expenditures. Vaccines, for instance, have proven to be one of the most effective preventative technologies in the fight against infectious diseases with an almost unparalleled impact on public health, saving the lives of over 2.5 million children each year. Estimates show that increasing access to six vaccines (including new vaccines for rotavirus and malaria) could save USD 6.2 billion in treatment costs globally. Increased productivity due to averted illness could gain the world an additional $145bn. The upfront cost of procuring vaccines is dwarfed by these benefits. In addition to these economic benefits, the innovation we bring along has transformed the lives of millions of patients all over the world. For instance, improvements in existing cancer treatments have cut annual death rates by half in the United States. High cholesterol and other heart diseases, which required extensive treatment in the 1970s, can now be easily managed with oral therapy. Our industry has played a crucial role in researching and developing the medicines that have contributed to this.**

#### **The mission of the life sciences industry – in New Jersey, across the United States and around the world – is as ambitious as it is straightforward: to research and develop new medicines, therapies, medical devices, technologies and diagnostics to detect, treat and cure disease and improve the quality of life for patients. Driven to improve global human health, for more than 100 years, the life sciences industry – which includes biopharmaceutical, biotechnology and medical technology, device and diagnostics companies – has helped people live longer, more productive and fulfilling lives. Medical innovation has consistently responded to the challenge in times of crisis and is currently at the forefront of the battle against the COVID-19 pandemic as it has been through so many other health emergencies.** Discovering and developing new medicines, **therapies, medical devices and technologies** is a complex, time-consuming, expensive and risk-laden process **that life sciences companies willingly undertake, spending more than $100 billion annually in search of alleviating human suffering.** The societal value of new medical innovation lies not only in improving human health, but in doing so in a cost-effective manner that brings efficiency to the delivery of health care. **When medical breakthroughs can cure a disease rather than requiring an organ transplant, or when chemotherapy can be administered orally rather than by infusion, the patient, the health care system and the economy all benefit. MEDICAL INNOVATION: EXTENDING LIFE – SAVING LIVES** Collectively, new therapies have been among the greatest contributors to increased life expectancy over the past century. **U.S. life expectancy at birth has risen from 47 years at the turn of the 20th century to 78 years today. New therapies accounted for 73 percent of the increased life expectancy in 30 developing and high-income countries between 2000-09. U.S. cancer survivorship alone has more than tripled since 1970, with nearly 16.9 million cancer survivors alive in the country as of January 1, 2019. This number is expected to increase to 22.2 million by 2030. As of 2018, the cancer death rate for men and women combined had fallen 31 percent from its peak in 1991. This decline translates to 3.2 million deaths avoided. Biopharmaceutical innovation, through improvements in treatment, has contributed to 76 percent of the improvements in mortality rates for HIV/AIDS patients and 60 percent of improvements in life expectancy for breast cancer patients. Heart disease mortality has been improved by 52 percent due to advancements in medicines. MEDICAL INNOVATION’S ADDED VALUE – COST SAVINGS AND ECONOMIC PRODUCTIVITY In addition to improving patient outcomes, medical innovation offers other, often underappreciated benefits – reducing costs in the health care system and increasing economic productivity. With new technologies and therapies that can detect and treat a disease earlier in its onset, and medicines to manage chronic disease, the cost of health care can be significantly reduced. Less than 10 cents of the U.S. health care dollar was spent on prescription medicines in 2019. This percentage has remained unchanged since the 1960’s. In 2013, the Congressional Budget Office (CBO) started to incorporate the savings from prescription medicines into the cost of Medicare policies. For every 1 percent increase in the number of prescriptions, the CBO incorporates a 0.2 percent decrease in spending on medical services. According to the Centers for Disease Control and Prevention, improved medication adherence can save $100-$300 billion annually in direct health care costs. Between 1980 and 2010, advanced medical technology helped cut the number of days patients spent in hospitals by 58 percent. Treating people with chronic disease (e.g., heart disease, stroke, cancer, diabetes, obesity, arthritis) (about half of all U.S. adults) accounts for 86 percent of our nation’s health care costs. By investing in prevention and treatment of the most common chronic diseases, the cost of treatment in the U.S. could decrease by $218 billion per year, and the impact of disease on the economy would be reduced by $1.1 trillion annually. MEDICATION ADHERENCE – KEY TO IMPROVED OUTCOMES AND REDUCING HEALTH CARE COSTS Medication adherence is a critical factor in improving patient outcomes and bringing efficiency and cost savings to the health care system. Of the approximately 187 million Americans who take one or more prescription medications, it is estimated that up to one-half do not take their medications as prescribed, with more than 1 in 5 new prescriptions not being filled. Non-adherence in the U.S. is estimated to result in approximately 125,000 deaths and at least 10 percent of hospitalizations. Medication non-adherence costs the U.S. roughly $330 billion annually in unnecessary medical expenses, as estimated by Express Scripts in 2015. An extra $1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol can generate $3-$10 in savings on emergency room visits and inpatient hospitalizations. Adherence to medications for congestive heart failure could result in $22.4 billion saved in the U.S. over a 10-year period. Nearly 1 million hospitalizations could be avoided with better adherence to, and treatment with, hypertensive medicines. LIFE SCIENCES RESEARCH AND DEVELOPMENT – RESOURCES AND RISK IN SEARCH OF THE NEXT TREATMENT Thousands of scientists go to their labs every day in search of the next treatment, therapy or technology to improve human health and alleviate the suffering of patients. With the odds heavily against success, life sciences companies invest billions of dollars annually to support the work of these dedicated scientists in their quest to discover the next medical breakthrough. America’s biopharmaceutical industry in total invested $102 billion in U.S. research and development in 2018.** The biopharmaceutical industry is responsible for 17 percent of R&D spending **by U.S. businesses, the single largest share of any industry. 91 percent of drugs are developed by the private sector with no direct government role. On average, it costs $2.6 billion and takes 10-15 years to discover**, develop and bring **a new medicine** to market. **Only 5 of 5,000 compounds that enter preclinical testing will enter a clinical trial, and only one will be commercialized. Only 12 percent of new molecular entities that enter clinical trials eventually receive FDA approval. Only 2 of 10 new medicines that come to market will be deemed a commercial success – meaning they will produce revenues that exceed the average R&D cost. More than 7,000 medicines currently are in development around the world for cancer, cardiovascular disease, diabetes, HIV/AIDS, immunological disorders, infectious disease and other disease states. Of these 7,000 treatments, 70 percent are potential first-in-class therapies, meaning they use a completely new approach to fighting disease.**

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The value is maximizing well-being

Avoiding pain is an objective good that should be maximized.

Thomas **Nagel**. “The View From Nowhere.” HUP. 19**86**. 156-168.

I shall defend the unsurprising claim that sensory pleasure is good and pain bad, no matter whose they are. The point of the exercise is to see how the pressures of objectification operate in a simple case. Physical **pleasure and pain do not** usually **depend on activities or desires which themselves raise questions of justification** and value**. They are** just **sensory experiences in relation to which we are fairly passive, but toward which we feel involuntary desire or aversion.** **Almost everyone takes the avoidance of his own pain and the promotion of his own pleasure as subjective reasons for action in a fairly simple way; they are not backed up by any further reasons.** On the other hand if someone pursues pain or avoids pleasure, either it as a means to some end or it is backed up by dark reasons like guilt or sexual masochism. What sort of general value, if any, ought to be assigned to pleasure and pain when we consider these facts from an objective standpoint? What kind of judgment can we reasonably make about these things when we view them in abstraction from who we are? We can begin by asking why **there is no plausibility in the zero position, that pleasure and pain have no value of any kind that can be objectively recognized.** That would mean that I have no reason to take aspirin for a severe headache, however I may in fact be motivated; and that looking at it from outside, you couldn't even say that someone had a reason not to put his hand on a hot stove, just because of the pain. Try looking at it from the outside and see whether you can manage to withhold that judgment. If the idea of objective practical reason makes any sense at all, so that there is some judgment to withhold, it does not seem possible. If the general arguments against the reality of objective reasons are no good, then it is at least possible that I have a reason, and not just an inclination, to refrain from putting my hand on a hot stove. But given the possibility, it seems meaningless to deny that this is so. Oddly enough, however, we can think of a story that would go with such a denial. It might be suggested that the aversion to pain is a useful phobia—having nothing to do with the intrinsic undesirability of pain itself—which helps us avoid or escape the injuries that are signaled by pain. (The same type of purely instrumental value might be ascribed to sensory pleasure: the pleasures of food, drink, and sex might be regarded as having no value in themselves, though our natural attraction to them assists survival and reproduction.) There would then be nothing wrong with pain in itself, and someone who was never motivated deliberately to do anything just because he knew it would reduce or avoid pain would have nothing the matter with him. He would still have involuntary avoidance reactions, otherwise it would be hard to say that he felt pain at all. And he would be motivated to reduce pain for other reasons—because it was an effective way to avoid the danger being signaled, or because interfered with some physical or mental activity that was important to him. He just wouldn't regard the pain as itself something he had any reason to avoid, even though he hated the feeling just as much as the rest of us. (And of course he wouldn't be able to justify the avoidance of pain in the way that we customarily justify avoiding what we hate without reason—that is, on the ground that even an irrational hatred makes its object very unpleasant!) There is nothing self-contradictory in this proposal, but it seems nevertheless insane. Without some positive reason to think there is nothing in itself good or bad about having an experience you intensely like or dislike, we can't seriously regard the common impression to the contrary as a collective illusion. Such things are at least good or bad for us, if anything is. What seems to be going on here is that we cannot from an objective standpoint withhold a certain kind of endorsement of the most direct and immediate subjective value judgments we make concerning the contents of our own consciousness. We regard ourselves as too close to those things to be mistaken in our immediate, nonideological evaluative impressions. **No objective view we can attain could possibly overrule our subjective authority in such cases. There can be no reason to reject** the appearances here.

**Government actors must be utilitarians**

Robert **Goodin**, fellow in philosophy, Australian National Defense University, THE UTILITARIAN RESPONSE, 19**90**, p. 141-2

My larger argument turns on the proposition that there is something special about the situation of public officials that makes utilitarianism more probable for them than private individuals. Before proceeding with the large argument, I must therefore say what it is that makes it so special about **public officials and their situations** that **make it both more necessary and more desirable for them to adopt** a more credible form of **utilitarianism**. **Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty,** and uncertainty of a very special sort at that. All choices – public and private alike – are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. **Public officials**, in contrast, [they] **are relatively poorly informed as to the effects that their choices will have on individuals,** one by one. What **they** typically do **know** are generalities: **averages and aggregates**. They know **what will happen most often to most people** as a result of their various possible choices, but **that is all**. That is enough to allow[s] public **policy-makers** to **use the util**itarian **calc**ulus – assuming they want to use it at all – **to choose general rules** or conduct.

#### **Evergreening is a myth – secondary patents don’t extend the life of primary patents. Banning secondary patents discourages valuable innovation without addressing the root causes.**

**Holman 18**

Christopher M Holman is a professor of patent law at UMKC, “Why Follow-On Pharmaceutical Innovations Should Be Eligible For Patent Protection**”,** <https://www.ip-watch.org/2018/09/21/follow-pharmaceutical-innovations-eligible-patent-protection/>, published 9-21-18, accessed 9-24-21 // mk

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.**