## CP

#### TEXT: The member nations of the World Trade Organization ought to

#### increase penalties for patent abuse and evergreening fraud in the pharmaceutical industry.

#### **Evergreening links to politics and collapses innovation, BUT the downsides are empirically debunked media hype – shifting enforcement for existing patent law solves abuse without harming pharma**

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

This week, the Senate Judiciary Committee was to mark up a bill limiting patent eligibility for combination drug patents—new forms, uses, and administrations of FDA approved medicines. While the impetus was to curb so-called “evergreening” of drug patents, the effect would have been to stifle life-saving therapeutic innovations. Though the “No Combination Drug Patents Act”—reportedly to be introduced by Senator Lindsey Graham (R-SC)—was wisely withdrawn at the last minute, it’s likely not the last time that such a misconceived legislative effort will be introduced.

An Exaggerated Response to a Disputed Theory

The bill would have established a presumption of obviousness for drug or biologic patent applications whose invention was a new: dosing regimen, method of delivery, method of treatment, or formulation. While there was a rebuttal provision where the claim covered a new treatment for a new indication or “increase[d] . . . efficacy,” the latter was almost certain to introduce years of uncertainty and litigation. Further, the bill would have covered a broader class than true combination drug patents, in which one active ingredient is combined with another or with a non-drug.

Like many recent legislative efforts, the amendment sought to address a perceived lack of affordability of prescription drugs. After praising the America Invents Act of 2011 and subsequent Supreme Court rulings for strengthening the US patent system, the bill claimed that rising drug prices have outpaced “spending on research and development with respect to those drugs.” In addition to applauding Supreme Court decisions that have injected unquestionable uncertainty into patentable subject matter standards, the amendment went on to blame high drug prices on continually overstated issues related to advanced drug patents.

According to critics, combination drug patents have granted drug makers unearned and extended protection over existing drugs or biological products. But, quite simply, when properly issued by the USPTO under existing patentability standards, these are new patents for new products or processes.

Combination patents have been maligned as anticompetitive, resulting in a “thicket” of patents that impedes innovation through transaction costs and other inefficiencies. Unfortunately, notwithstanding a lack of empirical evidence validating the harm of follow-on innovation patents, patent thicket rhetoric is now being echoed by the media, the academy, courts, and policy makers in a fraught attempt to fix drug pricing.

Reports (see here, here, here, and here) from leading antitrust experts and intellectual property scholars have detailed the value of incremental innovation and challenged the notion that patent thickets are a true threat to competition and innovation. These studies have exposed patent thicket claims—much like the “troll” narrative that for years infected patent law debates—as an empty strawman theory, the repetition of which has led to undue confidence in its accuracy. The reality is that what critics point to as problematic cases of combination patents are in fact infrequent outliers, strategically highlighted to discount evidence of the value of new and innovative drug uses and administrations.

#### CP solves the aff while fostering innovation – directly comparative to the aff

Holman 20 [Christopher, Professor of Law, University of Missouri-Kansas City School of Law. “Congress Should Decline Ill-Advised Legislative Proposals Aimed at Evergreening of Pharmaceutical Patent Protection” p. 29-30 https://papers.ssrn.com/sol3/papers.cfm?abstract\_id=3593954]

Senator Thom Tillis, in his opening remarks prepared for one of the Senate’s hearings on drug pricing and intellectual property, expressed his concern that “[some members of Congress are] trying to take a sledgehammer to a problem that needs a fine tuned and highly efficient scalpel[, and that] by just focusing on patent protections, and the number of patent protections available to a single product, [Congress] may be doing more harm than good to our nation’s innovation economy.”112 Instead, he would support legislation that will “promote innovation and competition, allow the United States to continue to be the leader in medical and pharmaceutical research, and will ultimately lower drug prices for consumers.”113 It is important to bear in mind that the reason there has been such an uproar over the price of drugs is that these drugs provide huge benefits for society, far exceeding most other patentable innovation, and were it not for the patent incentive, it is very unlikely these products would have been made available to patients in the first place. In his testimony prepared for the same Senate hearing, Professor Olson reminded the Judiciary Committee that “even studies casting doubt on patent law’s efficacy generally tend to find that in the area of pharmaceuticals, patent law has a large, positive effect on social welfare by providing incentive for significant levels of drug development that otherwise simply would not occur.”114 By ~~impairing~~ impeding the ability of pharmaceutical companies to obtain patents on their inventions, the legislation discussed in this Article could discourage the investment necessary to bring the next generation of pharmaceutical innovation to patients. If pharmaceutical companies are deemed to be misusing patents to the detriment of patients and third-party payers, then it is that misuse of patents that should be targeted by legislation, not the patents themselves. For example, if the allegations regarding product hopping are true, and doctors are prescribing and patients using far more expensive follow-on products that provide little if any benefit to the patient, then that is a problem with the market that should be addressed, rather than denying patent protection for truly worthwhile product improvements. If pharmaceutical companies are using anticompetitive means to coerce patients and doctors into switching drugs, then antitrust laws can provide the remedy, as discussed above.115 Likewise, if the sheer number of patents that could be infringed by a single generic or biosimilar product exceeds the litigation capacity of any company attempting to bring such a product to market, then courts have it within their means to require the patent owner to limit infringement litigation to some reasonable number of patents and patent claims, and Congress could pass legislation that would encourage courts to do so, if such a reform is deemed necessary. By targeting misuse of patents by pharmaceutical companies, rather than pharmaceutical patents per se, it should be possible to address any valid concerns with the way pharmaceutical companies are using the patent system, while maintaining adequate incentives for the next generation of innovation.

## DA

#### Pharmaceutical innovation is accelerating now – new medicines are substantially better than existing treatments.

Wills, MBA, and Lipkus, PhD, 20 – Todd J. Wills [Managing Director @ Chemical Abstracts Service, MBA from THE Ohio State University] and Alan H. Lipkus [Senior Data Analyst @ Chemical Abstracts Service, PhD Physical Chemistry from the University of Rochester], “Structural Approach to Assessing the Innovativeness of New Drugs Finds Accelerating Rate of Innovation,” ACS Medicinal Chemistry Letters, Vol. 11, 2020, <https://pubs.acs.org/doi/pdf/10.1021/acsmedchemlett.0c00319> C.VC

Despite recent concerns over an innovation crisis, this analysis shows pharmaceutical innovation has actually increased over the last several decades based on the structural novelty of approved NMEs. The higher proportion of Pioneers over the most recent decade is a sign that innovation within the industry is accelerating rather than slowing. It is also an encouraging sign for the state of innovation in drug discovery that these Pioneers are significantly more likely to be the source of promising new therapies that are expected to provide substantial clinical advantages over existing treatments. Drug hunters are discovering Pioneers in newer and less explored regions of chemical space as they are increasingly found on scaffolds first reported in the CAS REGISTRY five or less years prior to their IND year or on scaffolds populated with 50 or less other compounds at the time of IND.

As scale becomes less of a strategic advantage, Big Pharma’s share of Pioneers has decreased even though the number of Big Pharma originated Pioneers has increased. This has created a structural innovation gap between Big Pharma and the Rest of Ecosystem which has widened over the last two decades as the Rest of Ecosystem is now responsible for originating almost 3 out of every 4 Pioneers. Pioneers originated by the Rest of Ecosystem are increasingly on new scaffolds, while a majority of Big Pharma originated Pioneers have historically been on new scaffolds.

The work presented here was intended as a study of drug innovation at a macro level. As a result, it included substances of various sizes with different degrees of complexity belonging to a range of functional and drug classes. Even though it was outside the scope of the present work to study specific subsets, such focused studies could yield additional insights into how innovation at a more micro level has changed over time. Other interesting subsets of our data set are the shapes and scaffolds of the Settlers and Colonists. Many of these shapes and scaffolds are privileged in the sense that they are seemingly capable of serving as ligands for a diverse array of target proteins. A separate study of the Settlers and Colonists as well as their side chains could provide insights into possible target-specific innovation trends.

As it often takes more than 10 years after initial discovery for an experimental drug to gain FDA approval, any measure of drug innovation that relies on the time of approval incorporates a significant time lag between initial discovery and ultimate approval. However, characterizing drug innovation based on structural novelty provides a means to assess the forward-looking innovation potential of an experimental drug at the time of initial discovery by comparing its framework information (at the scaffold and shape level) with prior FDA-approved drugs. Therefore, a separate study of drug candidates with publically disclosed structures currently in clinical development could provide additional insights into innovation trends at an FDA regulatory review level and serve as a leading indicator of innovation trends at an FDA approval level.

Given the tremendous opportunity represented by the vast amount of chemical space yet to be explored, drug-hunters of all types will continue pushing the boundaries to find promising new therapies in previously unexplored areas of chemical space. The race to discover these new drugs will be fueled by further advancements in screening approaches and in-silico methods (including innovations related to machine learning algorithms and molecular representations). However, comprehensive data on known shapes and scaffolds can fast track the identification of meaningful open areas of chemical space (shapes or scaffolds that are potentially important but have never been used as the basis for a molecule) to further explore.

#### The biopharmaceutical industry is uniquely reliant on IP protections – undermining them would kill innovation by making an already expensive process completely unfeasible.

Kristina M. Lybecker, PhD, 17 [PhD Economics, Associate Professor of Economics @ Colorado College], “Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up,” Fraser Institute, January 2017, <https://www.fraserinstitute.org/sites/default/files/intellectual-property-rights-protection-and-the%20biopharmaceutical-industry.pdf> C.VC

The unique structure of the innovative biopharmaceutical industry necessitates a variety of intellectual property protection mechanisms. In particular, the industry is characterized by a research and development (R&D) process that is lengthy, expensive, uncertain, and risky. According to DiMasi and colleagues, the estimated cost of developing a new medicine is US$2.6 billion (DiMasi, Grabowski, and Hansen, 2016).2 In addition, the time required to develop a new drug is also significant, averaging 10 to 15 years without any guarantee of success (PhRMA, n.d.). While these figures are highly controversial, biopharmaceutical innovation is unquestionably an expensive and lengthy undertaking.3 For the biopharmaceutical industry, innovation and its protection are essential and the source of both profits and growth. As such, patent protection is disproportionally more important for ensuring that the innovator appropriates the returns to R&D for the biopharmaceutical industry than virtually any other. Extending the findings of the 1987 “Yale Survey” (Levin, Klevorick, Nelson, and Winter, 1987), the “Carnegie Mellon Survey” established that while patents are again considered “unambiguously the least effective appropriability mechanisms,” the drug industry and other scholars regard them as strictly more effective than alternative mechanisms (Cohen, Nelson, and Walsh, 1996). The industry’s disproportionate reliance on patents and other forms of intellectual property protection is confirmed in numerous other studies.4

In essence, IPR protections provide innovative biopharmaceutical firms with an assurance of some return on their investment, thus creating incentives for the development of new technologies that could otherwise be easily replicated and sold by competitors. Due to the tremendous fixed costs required to develop new treatments and cures, a significant potential exists for free riding by follower firms, a market failure that would prevent investment in innovation were it not for the patents and other forms of intellectual property protections that provide a limited period of market exclusivity or other such incentives. Fundamentally, patents amount to an efficiency tradeoff. Society provides innovators with a limited period of market exclusivity to encourage innovation in exchange for public access to this knowledge. In exchange for the temporary static loss from market exclusivity, society gains complete knowledge of the innovation through disclosure, a permanent dynamic gain. Through this tradeoff, the existing patent system corrects the market failure that would stymie innovation. In its Apotex Inc. v. Wellcome Foundation Ltd. finding, Justice Binnie wrote for the Supreme Court of Canada, “A patent, as has been said many times, is not intended as an accolade or civic award for ingenuity. It is a method by which inventive solutions to practical problems are coaxed into the public domain by the promise of a limited monopoly for a limited time. Disclosure is the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the Patent Act” (para. 37).

The biopharmaceutical industry is characterized by a number of legal and economic issues that distinguish it from other research-intensive industries. Danzon (1999) describes three features that are particularly noteworthy. First, given that the biopharmaceutical industry is characterized by an unusually high rate of R&D, intellectual property protection provides for the potential for significant market power and monopoly pricing that raises numerous public health policy questions surrounding prices and profits. Second, virtually every aspect of the industry is heavily regulated, from safety and efficacy to promotion and advertising, to pricing and reimbursement. Danzon describes the impact of these regulations as “profound and multidimensional even within a single country, affecting consumption patterns, productivity, R&D and hence the supply of future technologies” (Danzon, 1999: 1056). Lastly, while research and development costs are borne solely by the innovator, the resulting product is a global public good. “Each country faces an incentive to adopt the regulatory policies that best control its pharmaceutical budget in the short run, free-riding on others to pay for the joint costs of R&D and ignoring cross-national spillovers of national regulatory policies through parallel trade and international price comparisons” (Danzon, 1999: 1056). The combination of these characteristics defines a set of unique economic and legal challenges for the innovation of new drugs and the public health policies that surround their production, marketing, and distribution.

Innovative companies make far greater investments in time, resources, and financial support than do generic firms. Notably, innovation-based companies spend more than 200 times that which generic companies spend on the development of a particular drug (CIPC, 2011: 10). In addition, the investment of time, from laboratory to market, is also close to double for innovative companies relative to generic producers. Table 1 highlights the differences in the drug development processes of innovative and generic companies. For innovative biopharmaceutical companies, the development process is expensive, risky, and time consuming, all of which points to the need for strong IP protection to encourage investment and ensure companies are able to recover their investments.

The risk involved in biopharmaceutical development is starkly illustrated in a recent report by Biotechnology Innovation Organization (BIO), which reports that less than one of every 10 drugs that enter clinical trials is ultimately approved by the Food and Drug Administration in the United States. The report finds a success rate of merely 9.6%, a calculation that is significantly smaller than the widely-cited 11.8% figure from a 2014 study by the Tufts University’s Center for the Study of Drug Development.5 The International Federation of Pharmaceutical Manufacturers and Associations (2012) estimates that more than 3,200 compounds were at different stages of development globally in 2011, but only 35 new medicines were launched (Dawson, 2015).

Fundamentally, research-based biopharmaceutical companies incur greater expenses and risk in the development of their products than do generic manufactures. These investments of time and financial resources should be recognized and the effective patent life should be sufficient to recoup these investments. Continued investment and innovation are contingent upon strong, effective intellectual property protection and the ability of innovative firms to recoup their investments. Patents and other forms of intellectual property protection are disproportionally important to the research-based biopharmaceutical industry. Consequently, the legal architecture necessary to foster a robust innovation-based industry is multifaceted and is a powerful force shaping the biopharmaceutical industry, its profitability, productivity, and innovative future.

**Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.**

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As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

## Case

#### Pharma companies spend way more than 1% on R&D – it’s skyrocketed in the last year alone.

Adams 21 [Ben Adams, Fierce Biotech, April 6 2021, “Special Reports: The top 10 pharma R&D budgets in 2020”, https://www.fiercebiotech.com/special-report/top-10-pharma-r-d-budgets-2020]

While 2020 was a year to forget for almost the entire globe, the R&D engine of pharma roared to life in a never-before-seen way by creating new drugs, vaccines and tests for the pandemic that ravaged the world. Many companies saw revenue dip as it became more difficult to sell in the field with other disruptions from COVID-19 mounting, and those hurdles partly explain why a lot of this year’s top pharmas, after years of stagnation, saw some significant rises in their budgets as a percentage of sales. The roughly $70 billion total from the top 10’s budgets combined over the past five years swelled to $96 billion, with almost all seeing boosts in their research budgets (bar Novartis and Sanofi). Back in 2018, for the first time, the top 15 largest pharma companies (by sales) funneled more than $100 billion into research. Three years down the line, and our top 10 have nearly met that number on their own. While COVID clearly reshaped some budgets, there was also a major uptake in deals. Many transactions were, naturally, focused on COVID, but there were plenty in the more traditional areas such as cancer, and in more forgotten areas, like heart disease and antibiotics. Merck was a real jumper this year, finally moving from third to displace J&J, who has been second to Roche for many years now. Spending $13.6 billion on its research in the year, a huge 37% jump over the year before, Merck saw its R&D spend as a percentage of its sales leap to more than 28%.

#### Pharma spends over 25% of revenue on R&D – it’s literally one of the highest spenders in the economy.

Investopedia 21 [“What Are the Average Research and Development Costs for Pharmaceutical Companies?”, Reviewed by EBONY HOWARD, Fact checked by SUZANNE KVILHAUG, on July 16, 2021, https://www.investopedia.com/ask/answers/060115/how-much-drug-companys-spending-allocated-research-and-development-average.asp]

The pharmaceutical industry is responsible for discovering, producing, and marketing drugs for use in the health care sector. These drugs are used to treat and cure short- and long-term medical conditions. This is considered to be one of the largest sectors in the global economy. According to research, the pharma industry recorded more than $1.23 trillion in sales in 2020, with about 46% of sales coming from North America. Sales are expected to grow to $1.7 trillion in 2025.1 Getting to this point doesn't come without R&D. R&D is the pharmaceutical industry's lifeblood. The success of major drug companies almost wholly depends upon the discovery and development of new medicines, and their allocation of capital expenditures (capex) reflects this fact. Although the average spending is over 25% of revenues, some companies spend substantially more.2 Pharmaceutical companies spent, on average, over 25% of revenues on R&D in 2018 and 2019, making it one of the biggest spenders in this area.2 Outside of the semiconductor industry, no other industry spends more on R&D. In fact, of the 20 largest R&D spending industries in the world, the pharmaceutical industry makes up nearly half the list.

### Turn

#### Vague standards for new patents are unenforceable and explode costs – the link alone turns case because the plan is unenforceable

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

While the amendment provided for a rebuttal to the presumption of obviousness, the language was ambiguous and likely to render the patent system even more unreliable than it already is. The proposed statute said that an applicant may rebut the presumption of obviousness if the covered claimed invention “results in a statistically significant increase in the efficacy of the drug or biological product that the covered claimed invention contains or uses.” It is unclear what would qualify as “statistically significant,” and proving this vague standard would be nearly impossible.

In order to show a “statistically significant increase in efficacy,” long and costly head-to-head clinical trials would be necessary. To be clear, this is not a standard required by the FDA for new drug approval, let alone patentability.

#### Eliminating evergreening ends the pharmaceutical industry – incremental developments are key to global breakthroughs on emerging pathogens

Madigan & O'Connor 19 [Kevin Madigan joined CPIP in January of 2016. As Deputy Director, Kevin works closely with CPIP scholars in their research and promotion of comprehensive intellectual property law and policy. Before joining CPIP, Kevin worked as an intellectual property Research Associate at Finnegan Henderson Farabow Garrett & Dunner and also interned at the Recording Industry Association of America. Sean O’Connor, noted innovation law scholar, is a Professor of Law and Faculty Director of the Center for Intellectual Property x Innovation Policy (C-IP2) at George Mason University, Antonin Scalia Law School. "“No Combination Drug Patents Act” Stalls, but Threats to Innovation Remain." https://cip2.gmu.edu/2019/06/27/no-combination-drug-patents-act-stalls-but-threats-to-innovation-remain/]

Like most forms of innovation, the development of medicines and therapeutics is a process by which one builds and improves upon previous discoveries and breakthroughs. Sometimes those improvements are major advancements, but often they are incremental steps forward. In the pharmaceutical field, incremental or follow-on innovation frequently results in new therapeutic uses for existing drugs, which address serious challenges related to adverse effects, delivery systems, and dosing schedules. While they might not sound like medical breakthroughs on par with the discovery of penicillin, these advancements in the administration and use of pharmaceuticals improve public health and save lives.

Additionally, follow-on innovations are—and should remain—subject to the same patentability standards as any other technologies. Patents reward advancements that are novel, useful, and nonobvious, and our patent system has long recognized that patent claims are to be presumed patentable and nonobvious. The Graham amendment would have turned this established standard on its head, creating a separate and ill-defined hurdle for certain advancements in medicine.

The benefits of incremental innovation to public health and patients cannot be overstated. New formulations of malaria drugs, dosing regimens and delivery systems for AIDS patients, more efficient administrations of insulin for the treatment of diabetes, and developments in the treatment of cognitive heart disease have all been possible because of incremental innovation.

Imposing unjustified restrictions on the patentability of advancements like these would be disastrous for drug development, as the incentives that come with patent protection would be all but eliminated. Without the assurance that their innovative labor would be supported by intellectual property protection, pioneering drug developers would shift resources away from improving drug formulations and uses. The development of more effective treatments of some of the most devastating diseases would stall, as innovators would be unable to commercialize their products, recoup losses, or fund future research and development.

As critics continue to target myopically the patent system for a broader issue of drug prices in the American health care system, it’s likely not the last time that language like this will be proposed. In order to avoid the implementation of such ill-conceived standards into our patent laws, understanding what’s at stake is critical. The future of medical innovation depends on it.

#### It tips the entire industry into insolvency

Globerman & Lybecker 14 [Steven Globerman is Resident Scholar and Addington Chair in Measurement at the Fraser Institute as well as Professor Emeritus at Western Washington University. Kristina M.L. Acri, née Lybecker – Chair of the Department of Economics and Business, Colorado College. "The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY." https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf]

Incremental innovation is a financial necessity for high-tech industries such as biotechnology and pharmaceuticals. Given the paucity and unpredictability of radical innovation, incremental advances sustain the industry financially, for no mature industry can do so from income derived from breakthrough innovation alone. As described by Wertheimer, Levy, and O’Connor, “[t]he pharmaceutical industry must generate revenue based predominantly on incremental innovations, which characterize the majority of products and contribute the majority of revenue” (Wertheimer, Levy, and O’Connor, 2001: 108–109). Evidence of the prevalence of breakthrough relative to incremental innovations is shown in figure 2.2 below. Over the entire period, products based on incremental innovations outnumber breakthrough products. In addition, it is essential to recognize the importance of risk management. Any technology portfolio will comprise projects of differing risk levels. In the case of the pharmaceutical industry, incremental innovation projects are an essential—and significant—component of this portfolio. The incremental innovation projects will be characterized by lower risk and a greater probability of reaching the market (Wertheimer, Levy, and O’Connor, 2001: 110).

#### Weakening IP encourages imitation, not innovation – it removes the financial incentive to invent

Globerman & Lybecker 14 [Steven Globerman is Resident Scholar and Addington Chair in Measurement at the Fraser Institute as well as Professor Emeritus at Western Washington University. Kristina M.L. Acri, née Lybecker – Chair of the Department of Economics and Business, Colorado College. "The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY The Benefits of Incremental Innovation FOCUS ON THE PHARMACEUTICAL INDUSTRY." https://www.fraserinstitute.org/sites/default/files/benefits-of-incremental-innovation.pdf]

Finally, protecting innovation fosters economic growth and development, and that includes incremental innovation. A growing body of empirical evidence demonstrates that increasingly robust intellectual property protections, in combination with other policies, increase economic development, foreign direct investment (FDI), and innovation.5 A 2006 report from the United Nations Industrial Development Organization (UNIDO) studied the role of intellectual property rights in advanced nations in technology transfer and economic growth, concluding that protecting innovation creates benefits for countries at all levels of development. For developing countries, strengthening intellectual property rights encourages growth. For middle-income countries, evidence indicates that domestic innovation and diffusion of technology can lead to growth and that strengthening IPRs can encourage industries to shift from imitation to innovation. For advanced economies, stronger IPRs increase innovation and raise growth (Falvy, Foster, and Memedovic, 2006). Moreover, enforcing intellectual property rights and protecting innovation also drives research on cures. This is true of the diseases of both industrialized and developing nations. A recent study by Kyle and McGahan (2012) finds evidence of more research on diseases in nations with TRIPS-compliant IP provisions, as their patent provisions were put into place and implemented, than on diseases prevalent in non-TRIPS-compliant nations, controlling for the level of economic development and other factors.6