# 1ac

### Framing

#### I value morality – the standard is minimizing material violence

**States must use this standard. Any other standard dooms the moral theory**

**Goodin 90.** Robert Goodin 90, [professor of philosophy at the Australian National University college of arts and social sciences], “The Utilitarian Response,” pgs 141-142 //RS

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, 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 public policy-makers to use the utilitarian calculus – assuming they want to use it at all – to choose general rules or conduct.

### 1AC – Adv - Innovation

**Pharmaceutical innovation is *declining***

**Mata, 19** (Nathan Mata, 11-18-2019, accessed on 8-23-2021, Halloran Consulting Group, "Declining Innovation in the Pharmaceutical Industry | Halloran Consulting Group", https://www.hallorancg.com/2019/11/18/declining-innovation-in-the-pharmaceutical-industry/)WWPP

Despite the increasing demand for new drugs to address unmet and underserved medical needs, innovation within the pharmaceutical industry has not proceeded at the same pace. Data from numerous credible sources have shown that over past 10 years there has been very little breakthrough innovations in the large pharma sector. For example, data from the FDA revealed that from 2006-2014, there had been no increase in the average number of new drug applications (NDAs) and biologics license applications (BLAs) submitted for novel drugs. Submission numbers for novel drugs have remained relatively constant at about 35 NDAs and BLAs filed during each year (NDA and BLA Submissions). Moreover, in the first comprehensive study of evergreening—defined as artificially extending the intellectual property (IP) protection cliff—it was determined that 78% of the patents approved during the period from 2005-2015 corresponded to medications already on the market (Feldman, 2018). Therefore, rather than create new medicines, companies are largely recycling and repurposing old ones. This finding is a startling departure from the classic concept of IP protection for pharmaceuticals and is emblematic of the declining innovation in the industry. One possibility for the apparent lack of innovation to meet medical needs is an underlying scarcity of good ideas: as knowledge advances, it becomes more difficult to discover new ideas. In this case, slowdowns in productivity and innovation would be difficult to prevent or reverse. Yet, other factors may also limit innovation. For example, good ideas may not be scarce but they may be riskier to develop, and large pharma companies may prefer to focus instead on safer, but more marginal, projects. The finding that 64% of FDA-approved drugs in 2018 originated from emerging biopharma companies, not large pharma, suggests that scarcity of good ideas is not a factor underlying the declining innovation. A comprehensive analysis of innovation and R&D productivity in the large pharma sector has been conducted by Dr. Kelvin Stott (Director of R&D Portfolio Management, Novartis). In this two-part blog-post entitled “Pharma’s broken business model, An industry on the brink of terminal decline” (Part 1, Part 2), actual historic profit & loss (P&L) performance data obtained from EvaluatePharma was used to calculate Pharma’s return on R&D investment (ROI) among several large pharmaceutical companies. Dr. Stott’s analysis shows a clear downward trend for R&D ROI over the past 20+ years. A similar finding has been reported by both BCG and Deloitte in 2016 and 2018, respectively. Because the business practices of large pharma show no sign of change, it is likely that this downward trajectory will continue. Trends and Practices Underlying Declining Innovation Growing competition and decreased ROI from R&D programs are the primary reasons for down-sizing of non-core business processes among large pharmaceutical companies. Thus, companies may be prevented from pursuing innovative therapies because they lack the cash to turn their financially riskier ideas into reality. Because down-sizing in the pharmaceutical industry has typically taken essential resources away from discovery and early-stage research, the end result is reduced innovation and productivity. Another important aspect of the innovation/productivity decline is the practice of utilizing the patent system to extend existing patents beyond the initial 20-year protection (in the U.S.), rather than reinvesting profits to foster innovation and create new drugs to meet medical needs. What further exacerbates the problem is the issuance of patents with overly-wide claims that block knowledge creation and patents for what are essentially existing drugs. For example, Losec (AstraZeneca), which was developed to treat heartburn and ulcers, was later reformulated and rebranded. This enabled the company to issue a new patent with new claims for the barely modified medication, effectively extending the company’s monopoly on this type of drug well beyond the period granted by the original patent. Finally, the practice of large pharmaceutical companies to implement share buybacks to boost share prices (and stock options for executives) rather than reinvest in R&D further diminishes the opportunity for innovation. To put things in perspective, a Reuters Special Report noted that pharmaceuticals maker Pfizer spent $139 billion on share buybacks and dividends and just $82 billion on R&D over the past decade. Implications for Stakeholders and Taxpayers The trends and practices within large pharmaceutical companies noted above should be alarming not just to stakeholders in drug development, but also to taxpayers as they are largely footing the bill for drug research while pharmaceutical companies are reaping all the rewards. The development of Sofosbuvir, which treats hepatitis C, is a representative example. Sofosbuvir emerged from over 10 years of basic research science and $62.4 million of U.S. taxpayer-funded research (through the Department of Veterans Affairs and the National Institutes of Health, NIH). But when Gilead Sciences later acquired the drug (labeled as Sovaldi), it priced a 12-week course of pills at $84,000 in the U.S. market, even though a 12-week treatment course costs less than $200 to produce. By the end of 2017, Sofosbuvir had generated over $50 billion in sales. According to Bryn Gay, Hepatitis C Project Co-Director at the Treatment Action Group, “Companies have raked in profits of over $70 billion from hep C medicines, yet companies like Gilead and Janssen have walked away from additional hep C research, such as for a preventative vaccine.”. Gay further stated, “The impact of NIH-funded research again demonstrates that we need to increase government funding for infectious and neglected diseases. We can’t rely on Pharma to set R&D agendas shaped by how much profit can be generated.” Sofosbuvir is not an exception. Taxpayers in the U.S. have funded research via congressional appropriations to NIH funding for every single one of the 210 new drugs that the FDA approved from 2010-2016 (Cleary et al., 2018). Findings from the study by Cleary et al. show that the NIH contribution to research associated with new drug approvals is greater than previously appreciated. This report also highlights the risk of reducing federal funding for basic biomedical research as this would further hinder innovation in both small and large pharmaceutical sectors. Collectively, these facts lead to the inescapable conclusion that the current practice of establishing patent monopolies and price-hiking by large pharma cannot be justified by expenditures related to noble and innovative R&D endeavors.

#### Global IPR laws founded upon the TRIPS agreement exacerbate global inequality. You should reject neg args – they are probably based on unfounded assumptions

Ranjan 18 [Rajiv Ranjan is an Assistant Professor, CMS Business School, Bangalore, Karnataka, India. “Politics of Intellectual Property Rights (IPRs)

in Medicine: The Dichotomies” <https://journals.sagepub.com/doi/abs/10.1177/2319714518789762?journalCode=fiba>] //aaditg

Introduction The health care costs are the single major impediment in pushing people out from the vicious web of poverty (Bartlett, 2011; Briesacher et al., 2010; Kent, 2002; Leone, James, & Padmadas, 2012). Poor people have neither access to a clean environment nor choices which can help them prevent diseases as they cannot afford ‘curative’ health care in the form of medicines. Lack of choice (exit mechanism as in a well-functioning market) to bargain with the companies and voice (as in a well-functioning democracy) to decide the development path and climate change policies their country follows (Ebi & Semenza, 2008; Haines, Kovats, Campbell-Lendrum, & Corvalán, 2006; Kunkel, Pielke Jr., & Changnon, 1999; McCarthy, 2001; Patz, Campbell-Lendrum, Holloway, & Foley, 2005; Patz, Epstein, Burke, & Balbus, 1996) work as a health care impediment. Environmental pollution and climate change impact health of individuals, and poor people are more vulnerable to such health impacts. Thus, there is a denial of a healthy environment to them and hence lack of ‘preventive’ health care by design. Four of the eight UN Millennium Development Goals (MDGs) pertain to health directly. The deadline for the achievement of MDGs has already come to an end in 2015 with many goals not realized and more so in the developed world. UN (2013) had forewarned of such failure. A retrospective analysis of what went wrong is an important international policy question worth inquiry. The existence of Intellectual Property Rights (IPRs) in medicine for many critical life-saving drugs, lack of generic drugs for deadly diseases and lack of research and development (R&D) for diseases related to the poor are some of the possible impediments in achievement of health-related MDG goals (Love & Hubbard, 2007; Stiglitz, 2002, 2004, 2006, 2007, 2008, 2010; Viana, 2001; Williams, 2012). Williams (2012) shows that there are a lot of market failures and government failures in case of health care. In health care, 82% of R&D happens in government organizations and publicly funded research institutions. Companies invest only 1.2% of their revenue on R&Ds. Under these conditions, the logic of existence of IPRs becomes questionable. The logic for the existence of IPRs is based on a number of untested and unverified assumptions about human behaviour. The next section discusses the global health problems through a description of the UN MDG goals related to health and their progress status. This is followed by a section on about government and market failures in health care and the present understanding of public health as an issue, and some understanding of the possible understanding on the solutions front. Public–private partnership (PPP) as an instrument for health care providers and the challenges and preconditions for its successful working as an intervention is discussed. The next section describes the rich–poor dichotomy with regards to health care and how power operates in that, followed by a section on logic of the existence of IPRs, in which what are the possible assumptions of the IPR model for providing incentives to promote medical research in the context of the adverse conditions of health care especially in the poorer developing world and non-existence of a competitive market is identified. Next, the analysis of health care R&D expenditure sharing between public and private organizations is done. Then, in the following section, the power and politics dimensions and how faces of power get reflected in this story of IPRs in medicine is discussed. The public interest versus private gains and poor versus rich debates can be found out in the previous sections. It is revealed that there are boundaries between the developed and the developing world by existence of agreements like agreement on TradeRelated Aspects of Intellectual Property Rights (TRIPS) where the developed countries have high bargaining power as opposed to the developed countries among a host of other issues that clearly show the exercise of power in one way or the other. This is followed by a section on globalization phenomenon and IPRs, the power and politics dimensions revealed and conclusions and future work that can follow from this work, respectively. MDG Goals and their Progress: A Description of the Global Health Scenarios and Mitigation Strategies This article focuses on the four goals that are concerned with health and related issues. These would be a reduction of child mortality, improvement of maternal health, combat HIV/ AIDS and other diseases, and eradicate extreme poverty and hunger. This section gives the progress on these goals as of June 2013 as shown by a report on their progress (UN, 2013). 1. Eradicate extreme poverty and hunger 2. Reduce child mortality 3. Improve maternal health 4. Combat HIV/AIDS, malaria and other diseases To comment on the overall progress of MDGs related to health care, it would not be inappropriate to say that the progress has been concentrated to the developed countries while the developing countries and regions still lack behind in terms of MDGs. It can also be seen that access to health facilities still continues to be an issue in most of the UN member states. Government and Market Failures in Health Care and Complexity of the Problem The whole health care debate is on whether the government should intervene or not, despite the understanding that there are both market failures and government failures. Neither of the two, that is, market failures and government failure, are mutually exclusive scenarios in all situations so that one can serve as a plausible answer to the other. The present understanding is that there is a need for collaborative participation of both public and private entities to address the challenges of health care. The emergence of a third entity called civil society organizations which acts as a liaison for moderation between the public welfare goals versus the private profitmaking objectives reveal the interplay of power between the different stakeholders in the health care since public policymaking is less of a technocracy and more of a social construction of politically valued ends. And hence the questions of the emergence of civil societies and NGOs and how they arose, what were the forces behind its formation and day-to-day financial requirements become critical to understand whether their pushing for a social change of the social service exercise is just a worldly exhibition of a co-optation strategy of the more powerful against the lesser as pointed out by Kivel (2007). There are mainly two types of the health care system. One, free market-based system. Second, governmentbased socialized health care system. There is the prevalence of mixed system as well with countries scattered on the continuum of the two extremes, but how the partnership gets strengthened for delivery of better public services is still a question of enquiry. In a market-based health care system, the logic is that government should not intervene as it prevents the efficient allocation of resources, that is, the efficiency criterion. The rhetoric is that invisible hand of the market will take care of resource allocation. The larger assumption is that health care market fulfils all necessary conditions of an ideal perfectly competitive market. But the ideal efficient market is hard to find and especially so in case of products and services pertaining to the poor who do not have the want due to knowledge (the verifiability of which needs to be tested) that is to say that they are unconcerned about their own health which seems implausible. If they do have the want, they lack the purchasing power to convert it into demand which is a precondition for market provisioning. The understanding of the government’s role is to plug the gaps left behind due to market failures. This is under the assumption that the people in the government are only concerned about public welfare as opposed to private benefits as the government’s critics point out and empirical evidence of corruption reveal. Health for all is a public good according to this discourse. This is motivated by Tobin’s (1970) description of specific egalitarianism and the redistributive objectives of the governments, that is, the justice and equity dimensions. Cash transfer versus direct delivery, better targeting, imposing policymakers’ preferences become some of the major debates. Government failure like market failure also happens at several counts. If the market has information failure, the government is no better. The government also does not know the exact gap due to market failures. Then there is also hypothesis and plausible evidence of markets being more efficient than the government. There are problems of moral hazard, economic sustainability, that is, concern about level and rate of growth of health spending, opportunity cost of spending, relative benefits reduction with more expenditure, fiscal sustainability, that is—ability to recover costs incurred—cost recovery ratio (which is 1.55% average across all the states of India). The challenges are ways to reduce burden, that is, reduce health expenditure, increase revenues from health services, make health services more efficient, etc. Though government intervention is needed as the ideal market is not a reality. The different levels of intervention can be: • Knowledge imparting activities • Regulation of private markets • Mandate something • Finance health care with public funds • Provide health care dire ctly In case of private, there is a misalignment of interest; in case of government, there are accountability issues and perverse incentive with no proper responsibility mechanisms to ensure proper services. The emergence of civil society organizations do offer a hope but their mode of arrival, the source of sustenance and ways of working needs to be ascertained before jumping on the conclusion that they are proper representatives of the societal preferences. Thus, both existences of public and private institutions in health care and a representative civil society are what the current state of literature suggests as important stakeholders for health care provision ing. PPPs as an Instrument for Health Provi sion The complexity of health care problems has posed several challenges in the provision of health care for the less endowed. PPPs have emerged as one of the solutions to address some of these issues. But it has been questioned on equity and distributional grounds. Though PPP is not the panacea for all ills, but with proper ownership, power, risk and responsibility sharing between the public and the private players, better health outcomes for all can be achieved as indicated by the UN MDGs. Moreover, one thing is easily agreeable that both private and public need to join hands to meet the challenge of providing quality health care services to all considering the financial and incentive lacunae faced by both of them respectively. And, most importantly it must be seen as a supplement to the public provisioning system rather than a substit ute. The reasons for the introduction of PPPs in health care provisioning are that it leads to an increased level of finance in the sector as a whole. It supplements government provision and hence leads to a reduction of pressure on government finances. It also provides for a learning curve for the private sector in the provision of health care for the poor at low cost and offers scope for innovation coming from private sector. The government authorities need to focus on their key strengths of policy, planning, regulation and quality assurance, and private in provision where they are better. There needs to be a focus on outputs and outcomes monitoring from a provider rather than only input focus. The longer time horizon leads to a better alignment of interests of the public and private. It also leads to a reduction of politicization of issues and corrupt ion. The downsides of PPP can be loss of control by public health authorities and hence lead to loss of public accountability, if not properly designed. It can lead to full privatization. The distributional aspects of benefits can be questioned leading to inequalities in provision and exclus ion. But PPPs involve a very complex design in terms of strategy, system and processes. The idea of PPPs in health care is a recent phenomenon. Public sector’s role is to define the scope of business, to specify the priorities, targets and outputs, and also to set the performance regime by which the management of the PPP is given incentives to deliver. The role of private sector is in delivering on the objectives of PPP creating value for money for the public sector. PPPs must not be confused with privatization because the former is a collaborative effort to promote financial as well as service delivery improvements without increasing the role of private over the public or the other way round. In case of primary health care, it becomes all the more important because there is a degree of public good characteristics attached to the intrinsic nature of the good. The main aim of introducing PPPs in health care is to ensure efficiency, effectiveness, quality, equity and accountabil ity. This analysis only shows the complexities involved in health care provisioning and hence jumping to solutions based on models might not be the best way to go as models are not full representation of reality and are freight with a lot of assumptions whose validity needs to be ascertained before being romanticized by the ideas expressed in the most eloquent manner and jumping into act ion. The Rich–Poor Dicho tomy As pointed out by Paul (1992) in his accountability framework that the less-endowed people are faced with lack of various ‘exit mechanisms’ such as money, vouchers and grants, lost-cost health care services, etc., and they have to resort to ‘voice mechanisms’ such as seeking NGOs help, etc. Figure A3 can be referred to see how the exit and voice mechanisms availability plays out between the poor and the rich wherein the former is not able to demand even the primary health care for him in contrast to the latter who can even demand his cosmetic needs. The contrasting reality becomes all the starker when the same medicine which can have been used for the treatment of Kalajar, a fatal disease 72 FIIB Business Review 7(2) mostly affecting poor people is sold as a hair removal cream to serve the cosmetic needs of the rich when people are dying of the Kalajar. Kivel (2007) and Chossudovsky (2010) point out the hidden dangers in seeing NGOs as representative of the societal needs without ascertaining facts about their mode of arrival, the source of sustenance and ways of working. The co-optation strategy by legitimization of NGOs as representatives of societal concerns does not help the cause of low voice of the poor with regards to health care among other basic needs. Moreover, the poor people, especially the tribal are not allowed to indulge in preventive healthcare. Also norms for curative healthcare are defined by society. People who do not follow are labelled as dissenters. The framing of the whole health care debate as curative and not preventive, which a widespread debate even in the developed world groups, especially in the US, only reveals the interplay of power between the people who can afford versus the less endowed in terms of resources. This is an exhibition of the various faces of power, namely pluralistic tradition, non-decision-making, ideological and disciplinary powers as mentioned in by Healey and Hinson (20 10). The Logic of IPR Demysti fied IPRs by definition are appropriate benefits emerging from intellect to a private entity as opposed to the public in large. For IPRs to be a part of public policy, they have to be seen as serving a public purpose, that is, helping achieve goals that are considered legitimate for and by the public. Therefore, the claims that are made in favour of IPRs are that they are necessary to incentivize innovation. The nature of claims and assumptions behind IPRs need to be investigated fully before talking about them as the only legitimate way to ensure health care innovation as it is freight with behavioural assumpti ons. Refer to Figure A4 for understanding the flow diagram of the rationale. The fundamental claim is: IPRs are necessary to incentivize innovation by private actors. Incentivizing private innovation with IPRs leads to a greater innovation. More innovation is good for the society. Therefore, public policies should support IPRs. The assumption is more innovation (regardless of kind) is good for soci ety. Plausible concern relating to IPRs in medicine is companies protect their IPRs by incremental innovations which prevents their conversion into generic medicine rasing distributional concerns (Henry & Stiglitz, 2010). By ignoring these, goals of public policy are delegitimized/reprioritized. One of the nested claim is that in the absence of IPRs, sufficient incentives for innovation would not exist, and therefore lead to reduced innovation. Which might not be true always or else Alexander Fleming would not have had incentive to discover penicillin which he did. Other assumptions are that innovation is costly, most of these costs are private, and therefore the private benefits of innovation must exceed the private costs of innovation for sufficient incentives. The concerns are ignoring costs of innovation borne by the public. There is also ignorance of non-pecuniary motives for innovation. By ignoring these, more attention to certain kinds of incentives and costs is paid. Therefore, certain kinds of innovation, the kind which was done by those with pecuniary interests and the kind which was done where there are clear pecuniary rewards, are encouraged. Thus, the whole logic is freight with a lot of assumptions about human behaviour and motivation which needs to be verif ied. Discussion R&D in Health Care Expenditures: The Public–Private De bate There is a need to analyze the extent of spending that takes place on R&D for the health care industry in comparison to other expenditures. Looking at the industry investment budget on R&D as a percentage of sales, it has stayed in the range of 1%–1.5% for a long time now (Derek, 2013). Referring to Booz for their annual survey of ‘Global Innovation 1000’, it is agreeable that semiconductor industry and the drug industry are the two largest industries where most of the money is reinvested in the l abs. The big companies have expenditures at the level of the semiconductor industry. Roche spends over 19%, Merck spends over 17% and AstraZenca spends over 16%. Other biggies such as Sanofi and GSK spend over 14% and Pfizer spends over 13%. But Pfizer spends the highest in terms of magnitude. Johnson & Johnson (J&J) and Abbott have their spending a bit lower than the biggies. But there is rarely a drug company that spends in a single-digit percentage. So nearly half of the top 20 R&D spending companies are in the drug domain. Also, the only domain surpassing them is the semiconductor industry. Referring to Figure A1 and A2, it can be seen that super drugs get cheaper and generic as times passes. The productivity of research comes down. The only way to get spikes is a discovery of new disease and not a new drug. But what really needs to be thought is that, is the spending more significant than the other expenditures of the drug companies. Finding R&D expenditures is easy because the drug companies list them as a line item in their financial reports. To compare them with the marketing expenditures, the sales, general and administration expenses, that is, SG&A, have to be looked into. The SG&A component comprises elements other than sales and marketing spend ing. For drug companies, SG&A spending is way higher than their R&D expenditures in most of the cases (Derek, 2013; Staton, 2013). The case of Biogen can be intuitively seen as an exception as specialty drugs will not require the magic of sales representatives to convince the practitioners. • Merck spends on SG&A 27%, whereas on R&D 17.3% • Pfizer spends on SG&A 33%, whereas on R&D 14.2% Ranjan 73 • AstraZeneca spends on SG&A 31.4%, whereas on R&D 15.1% • BMS spends on SG&A 28%, whereas on R&D 22% • Biogen spends on SG&A 23%, whereas on R&D 24% • J&J spends on SG&A 31%, whereas on R&D 12.5% Comparing it to the other industries like airlines where the SG&A expenditure is nearly only 5% of their revenue, a lot of time needs to be spent on why cannot drug compa nies lower their marketing and adminis trative costs and spend more on research or price discrimination to make drugs affordable to the poor. For 60 years, the AIDS drugs did not get public by renewal through incremental patents which do show the private profit-making for incentives turning into a profiteering exercise. This shows how private incentives become perverse and a mechanism to wield resource and power as the resource dependence theory (Hillman, Withers, & Collins, 2009) suggests. The TRIPS Agreement: The Developed versus Developing World Powe r Dynamics TRIPS Agreement TRIPS stands for Trade-Related Aspects of Intellectual Property Rights. The TRIPS agreement of the World Trade Organization (WTO) requires all member countries to adhere to minimum standards of intellectual property protection (e.g., all technological inventions must be protected for at least 20 years). It serves as one of the three pillars on which the WTO now rests, along with trade in goods and trade in services. The minimum standards of protection in TRIPS cover different kinds of intellectual property, including patents (which grand market exclusivity for technological inventions), copyright (for artistic and literary works) and trademarks (for names and symbols). It requires that these standards be effectively implemented by all WTO members. This means that countries should have legal and administrative procedures under the national courts that would allow holders of property rights, domestic and foreign, to seek and obtain redress in the event that their rights are infringed. If a WTO member fails to represent these standards in national law or to implement them, it can be challenged by trading partners under the WTO dispute settlement p rocedures. TRIPS and Pharm aceuticals For developing countries, the most important aspect of TRIPS agreement relates to its provisions on patents, especially because they affect pharmaceuticals industry. Prior to TRIPS, most developing countries had ‘weak protection’ for pharmaceutical patents (Subramanian, 2004). This constitutes of short patent terms, the narrow scope for definition, the invention to facilitate ease of imitation and relatively tolerant use of compulsory licensing to dilute the monopoly power of the patent holder. In the Uruguay round, which offered scope for bargaining and the exchange of concessions between nations, developing countries sought compensation for the likely negative impact of TRIPS. Thus, higher standards of protection for intellectual property in exchange for better access for clothing and agricultural goods thus constituted the grand bargain in this round between industrial and developing countries. Impact on Developi ng Nations In the TRIPS negotiations, developing countries were asked to strengthen their patent protection to levels prevailing in industrial countries. But it had an economic impact on the developing nations. According to economic theory, stronger patent protection has two conflicting effects on economic welfare. • In short run, it confers monopoly power on patent holders, reducing competition and increasing prices in the market in which the patented product is sold. • In the long run, by providing economic rents or monopoly profits, it increases the incentive to undertake R&D, by allowing the fixed costs of R&D to be recouped. For developing countries, the economic effects are different. As net users rather than net exporters of R&Dintensive products, they do not benefit from the monopoly profits that are created by patent protection. The profits directly benefit the multinational corporations instead and the consumers suffer from higher prices. Further, because the markets are small in relation to global demand, actions taken by developing countries to strengthen patent protection have little impact on the incentive to undertake additional R&D. Thus, a combination of higher costs in the short run and likely absence of dynamic gains overtime means that raising levels of protection would not benefit developin g countries.

#### Pharma patent practices serve to keep drug prices high: evergreening, product hopping, patent thickets, pay for delay

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Practices [https://fas.org/sgp/crs/misc/R46221.pdf 2/11/2020](https://fas.org/sgp/crs/misc/R46221.pdf%202/11/2020) Congressional Research Service ] // aaditg

Intellectual property (IP) rights in pharmaceuticals are typically justified as necessary to allow manufacturers to recoup their substantial investments in research, development, and regulatory approval. IP law provides exclusive rights in a particular invention or product for a certain time period, potentially enabling the rights holder (e.g., a brand-name drug manufacturer) to charge higher-than-competitive prices. If rights holders are able to charge such prices, they have an incentive to lengthen the period of exclusive rights as much as possible. Indeed, some commentators allege that pharmaceutical manufacturers have engaged in patenting practices that unduly extend the period of exclusivity. These critics argue that these patenting practices are used to keep drug prices high, without any benefit for consumers or innovation. Criticisms center on four such practices:  “Evergreening”: So-called patent “evergreening” is the practice of filing for new patents on secondary features of a particular product as earlier patents expire, thereby extending patent exclusivity past the original twenty-year term. Later-filed patents may delay or prevent entry by competitors, thereby allowing the brand-name drug manufacturer (the brand) to continue charging high prices.  “Product Hopping”: Generic drug manufacturers allege that as patents on a particular product expire, brand manufacturers may attempt to introduce and switch the market to a new, similar product covered by a later-expiring patent—a process known as “product hopping” or “product switching.” This practice takes two forms: a “hard switch,” where the older product is removed from the market, and a “soft switch,” where the older product is kept on the market with the new product. In either case, the brand will focus its marketing on the new product in order to limit the market for any generic versions of the old product.  “Patent Thickets”: Generic and biosimilar companies also allege that the brands create “patent thickets” by filing numerous patents on the same product. These thickets allegedly prevent generics from entering the market due to the risk of infringement and the high cost of patent litigation.  “Pay-for-Delay” Settlements: Litigation often results when a generic or biosimilar manufacturer attempts to enter the market with a less expensive version of a branded pharmaceutical. Core issues usually include whether the brand’s patents are valid, and whether the generic or biosimilar product infringes those patents. Rather than litigate these issues to judgment, however, the parties will often settle. Such settlements may involve the brand paying the generic or biosimilar to stay out of the market—referred to as “reverse payment” or “pay-for-delay” settlements. These settlements are allegedly anticompetitive because they allow the brand to continue to charge high prices without risking invalidation of its patent, thus unjustifiably benefiting the settling companies at the expense of the consumer.

#### That fuels monopolies stifling innovation.

Bryan Mercurio 14, Law Professor at The Chinese University of Hong Kong, “TRIPs, Patents, and Innovation: A Necessary Reappraisal?” <https://e15initiative.org/wp-content/uploads/2015/09/E15-Innovation-Mercurio-FINAL.pdf>

Identifying the factors that stimulate innovation is difficult (Lemley 2000), and attention must be paid to the different kinds of innovation--cumulative innovation; horizontal (basic) innovation; and vertical (applied) innovation. The impact of patent protection can differ on each of these types of innovation. For instance, where cumulative innovation occurs--that is, where a single product may rely on inventions owned by a number of firms--“there is good reason to think that the patent system may discourage innovation overall rather than encouraging it” (Bessen and Maskin 2009; Chu et al. 2012). Shapiro (2001) finds that “with cumulative innovation and multiple blocking patents, stronger patent rights can have the perverse effect of stifling, not encouraging innovation.” In such a situation, multiple licences have to be purchased; uncertainty regarding the status of the technology persists; and the value of patent licensing is questioned (Heller 2008; Boldrin and Levine 2008). Lawsuits become the norm; costs rise as firms defend claims and play the game by defensively purchasing patents; and innovation suffers (Boldrin and Levine 2013; Bessen and Muerer 2008). One only needs to look at the present situation in the high-tech sector to see this cycle playing out, where as much as US$20 billion was spent in 2010-11 on patent litigation and purchases, and where a “patent tax” of up to 20 percent of R&D costs exists (Duhigg and Lohr 2012). That a limited monopoly can stifle innovation should not come as a surprise given that competition is generally seen as a positive force in a market economy. Competition is widely thought to provide incentives for the efficient use of resources; motivation for constant progress; and protection for consumers (Vickers 1995). To some, there is an inherent contradiction between innovation and patent protection, as the latter impedes diffusion and obviates potential gains to be made from collaboration and competition (Rothbard 1962; Mises 1966; Palmer 1989; Lemley 2000; Stiglitz 2008). Thus, while Shumpeter acknowledges that competition for innovation led to temporary monopolies and argues that these monopolies were in turn replaced when new firms further innovated (1976), Stiglitz demonstrates that the established monopolies became entrenched as costs and externalities reduced incentives for displacement (Stiglitz and Walsh 2005). In turn, insufficient diversity among patent holders (a lack of so-called “equilibrium diversity”) encourages them to focus R&D on improving existing technologies through incremental improvements, as opposed to investing in R&D to develop new technologies and products (Acemoglu 2011).In essence, this is what the European Commission alleged in its prosecution of Microsoft for anti-competitive behaviour. There, the Commission deemed Microsoft to be a dominant player, which used its near-monopoly power to reduce “talent and capital invested in innovation” in a manner that “limits the prospects for ... competitors to successfully market innovation and thereby discourages them from developing new products” (2004). The negative effect on innovation is exacerbated by a number of factors, including the growing problem of patent thickets. Owing to the“difficulty of determining the boundaries” of patent claims, there are often multiple and competing claims over one or more aspects of an invention- -situations which, Stiglitz states, “especially impede innovation” (2008). While patent thickets have existed for more than a hundred years (a patent thicket impeded the development and commercialization of the airplane), they have more recently become particularly widespread in the electronics industry (GAO 2013). Other factors, such as defensive patenting and the extortion-like practices of socalled patent trolls, have likewise substantially increased the risk of net welfare loss and less innovation (Bessen et al. 2011; Tucker 2011). Recent studies even find that patent pool arrangements result in reduced innovation by member-firms (Lampe and Moser 2010; Joshi and Nerkar 2011; Lampe and Moser 2012). Evidence also exists to show that stronger patent protection leads not to enhanced innovation or an improvement in overall welfare, but to firms protecting their interests by advocating even more protection (Landes and Posner 2003). In so doing, firms divert resources away from R&D, and into lobbyists and lawsuits. Boldrin and Levine (2013) refer to this as the political economy effect, where patent protection keeps increasing due to the lobbying efforts of entrenched firms, and without regard to the system as a whole. In their view, such behavior distorts the optimum range of protection and unbalances the entire system. In conclusion, while it is a certainty that patent protection increases patent applications and the number of patents granted, there is little to no solid evidence that it leads to increased innovation (Boldrin and Levine 2013; Scherer 2009; Lerner 2009; Gallini 2002; Jaffe 2000). Since the evidence suggests that “policy changes that strengthen patent protection … [do] not spur innovation” (Lerner 2002; UNCTAD 2011), it is unsurprising that “there is widespread unease that the costs of stronger patent protection may exceed the benefits” (Jaffe 2002). POTENTIAL RESPONSES To establish the economic significance and value of patents, it is necessary to weigh their social costs against their social benefits. Hall et al. (2012) explain, In principle a patent will function to increase fixed (and most likely sunk) costs of entry into a market where the invention protected by the patent is practiced. This will reduce entry and therefore competition. From a welfare perspective, this is the price society pays in order to encourage invention and innovation by the initial entrant. What results is a trade‐off between the interests of the incumbent holding the patent and the potential entrant excluded by it. In the case of patents, policy makers need to come to a view of how much protection to afford the patentee in order to create incentives for R&D. Given the trade-off between innovation and access, policy should be designed to reach the “optimal scope of IPRs protection”--that is, a “balance between the social benefit of innovation and the social cost of monopolistic distortion” (Nordhaus 1969). It is this balance that some believe is now lopsided. This section focuses on what can be done within the confines of the WTO to ensure that patent protection stimulates innovation and that the benefits are in balance with social costs. It goes beyond merely describing the available flexibilities offered by TRIPS to Members or analyzing the use of such tools. This work has been done (Mercurio 2013; Declaration on Patent Protection 2014), but does not go to the heart of the issue-- that of the link between IPRs and innovation. Moreover, given the definitional vagueness and uncertainty of the boundaries of patent claims and rights, countries have become risk averse and are unlikely to take action that may be viewed as inconsistent with the TRIPS Agreement. The discussion and debate must now move beyond the well-known but little used flexibilities to encompass the broader and more fundamental issue of whether IPRs--and correspondingly the TRIPS Agreement-- actually encourage innovation. In a sense, all the potential responses are radical in that they all require a shift from the status quo and amendment to the TRIPS Agreement. For this reason, none are likely to be feasible in the short, and perhaps even medium, term. This does not mean that potential responses should not be discussed. As the economic data and evidence against the current form and level of patent protection mounts, alternatives will become more realistic options. Radical proposals aimed at promoting innovation deserve to feature in the debate. The remainder of this section raises four alternatives to the status quo for discussion.

#### Only pharma innovation solves global pandemics that risk extinction

Jeffrey Sachs 14, Professor of Sustainable Development, Health Policy and Management @ Columbia University, Director of the Earth Institute @ Columbia University and Special adviser to the United Nations Secretary-General on the Millennium Development Goals) “Important lessons from Ebola outbreak,” Business World Online, August 17, 2014, http://tinyurl.com/kjgvyro

Ebola is the latest of many recent epidemics, also including AIDS, SARS, H1N1 flu, H7N9 flu, and others. AIDS is the deadliest of these killers, claiming nearly 36 million lives since 1981. Of course, even larger and more sudden epidemics are possible, such as the 1918 influenza during World War I, which claimed 50-100 million lives (far more than the war itself). And, though the 2003 SARS outbreak was contained, causing fewer than 1,000 deaths, the disease was on the verge of deeply disrupting several East Asian economies including China’s. There are four crucial facts to understand about Ebola and the other epidemics. First, most emerging infectious diseases are zoonoses, meaning that they start in animal populations, sometimes with a genetic mutation that enables the jump to humans. Ebola may have been transmitted from bats; HIV/AIDS emerged from chimpanzees; SARS most likely came from civets traded in animal markets in southern China; and influenza strains such as H1N1 and H7N9 arose from genetic re-combinations of viruses among wild and farm animals. New zoonotic diseases are inevitable as humanity pushes into new ecosystems (such as formerly remote forest regions); the food industry creates more conditions for genetic recombination; and climate change scrambles natural habitats and species interactions. Second, once a new infectious disease appears, its spread through airlines, ships, megacities, and trade in animal products is likely to be extremely rapid. These epidemic diseases are new markers of globalization, revealing through their chain of death how vulnerable the world has become from the pervasive movement of people and goods. Third, the poor are the first to suffer and the worst affected. The rural poor live closest to the infected animals that first transmit the disease. They often hunt and eat bushmeat, leaving them vulnerable to infection. Poor, often illiterate, individuals are generally unaware of how infectious diseases -- especially unfamiliar diseases -- are transmitted, making them much more likely to become infected and to infect others. Moreover, given poor nutrition and lack of access to basic health services, their weakened immune systems are easily overcome by infections that better nourished and treated individuals can survive. And “de-medicalized” conditions -- with few if any professional health workers to ensure an appropriate public-health response to an epidemic (such as isolation of infected individuals, tracing of contacts, surveillance, and so forth) -- make initial outbreaks more severe. Finally, the required medical responses, including diagnostic tools and effective medications and vaccines, inevitably lag behind the emerging diseases. In any event, such tools must be continually replenished. This requires cutting-edge biotechnology, immunology, and ultimately bioengineering to create large-scale industrial responses (such as millions of doses of vaccines or medicines in the case of large epidemics). The AIDS crisis, for example, called forth tens of billions of dollars for research and development -- and similarly substantial commitments by the pharmaceutical industry -- to produce lifesaving antiretroviral drugs at global scale. Yet each breakthrough inevitably leads to the pathogen’s mutation, rendering previous treatments less effective. There is no ultimate victory, only a constant arms race between humanity and disease-causing agents.

#### Biotech collapse wrecks the economy

Carlson 16, Robert Carlson is the managing Director at Bioeconomy Capital, “Estimating the biotech sector's contribution to the US economy”, Nature Biotechnology 34, 247–255 (2016), http://www.nature.com/nbt/journal/v34/n3/full/nbt.3491.html?WT.feed\_name=subjects\_business&foxtrotcallback=true#author-information

Biotech is now a major contributor to the US economy. When considered as an industry in itself, biotech and its economic impact rivals mining, utilities, chemicals and computing and electronics. Internationally, at least 20 countries have articulated strategies that explicitly identify biotech as critical to their future economic and employment growth1. Given this focus on economic development, it is crucial to better define the current systemic role of biotech. Moreover, ongoing discussions of funding and investment, benefit and risk, and opportunity and threat all would benefit from a more detailed understanding of where biotech is and where it is headed. In this article, I use data collected from a variety of public and private sources to assemble an initial economic assessment of biotech in the United States as a test case for an analysis at the global level. What emerges is a picture of a sector already making a remarkable and accelerating transformation of the US economy. By my estimate, total domestic US revenues generated by biotech in 2012 reached at least $324 billion—the equivalent of >2% of gross domestic product (GDP; for comparison, see Supplementary Table 1 for a list of selected industries and their contributions to US GDP). The estimate is intended to be conservative; the actual total could be 10–20% higher. Total revenues comprise three biotech subsectors: biologics (drugs), at $91 billion; crops (and seeds), at $128 billion; and industrial products (biofuels, enzymes, biomaterials and biochemicals), at >$105 billion. Over the past decade, aggregate revenues have grown on average at annual rates >10%, much faster than the economy as a whole. Remarkably, biotech revenue growth was the equivalent of >5% of annual US GDP growth every year between 2007 and 2012. It is difficult to project exactly how large the biotech sector might ultimately become, but the trends indicate that biological technologies are likely to generate an increasing share of both GDP and annual GDP growth. What is biotech, and how can it be measured? Current understanding of the biotech sector is hampered by inconsistencies in usage and definition of 'biotechnology' and 'bioeconomy' in public discussion and in print. These words may be used in reference only to pharmaceuticals (or biopharmaceuticals or biologics, depending on one's definition), genetically modified (GM) crops, or public companies whose primary revenues rely on biological technologies, thereby muddling an integrated description of the industry (Box 1). Beyond linguistic imprecision, a lack of data resulting from inadequate characterization of the economy hampers any assessment of the economic size and scope of biotech. Even in the United States, the country with the largest biotech sector, there is no official mechanism to distinguish between products made through biology and products manufactured through other technologies. At present, for example, a chemical manufactured through biological technologies is treated identically to one derived from fossil petroleum. The biological product may displace the petroleum product from the market on the basis of price or preference, yet revenues now accrue to a category that includes petrochemicals. Under the current classification system, even revenues from novel biomolecules, including those that may outperform petroleum products, will be misattributed to fossil sources. The approach I take here differs from the frequently employed tactic of describing 'biotech industry' revenues on the basis only of financial reporting from public companies. For example, this journal's 'What's Fueling the Biotech Engine' series2 focuses exclusively on the metric of domestic US sales of drug products. Another annual Feature, 'Public Biotech by the Numbers'3, defines the biotech industry as including only the companies whose revenues are derived primarily from sales of biotech products, an approach similar to that of the annual 'Beyond Borders' reports by consultants Ernst and Young (New York). Defining the biotech sector on the basis of financial reporting of qualifying companies works only as long as those companies fit the scope of that definition. If a biotech company is acquired by a company outside the biotech sector (e.g., a big pharma or a chemical company), the relevant revenues from the biotech company's products 'disappear' from estimates based on companies in the industry—for example, in these analyses, product revenues from Genentech (S. San Francisco, CA, USA) are no longer counted toward the biotech industry because Genentech is now part of Roche (Basel, Switzerland), which is classified as a large pharmaceutical company. More broadly, the above industry analyses often focus predominantly on biotech enterprises engaged in biomedical markets; companies involved in crops (and seeds) or industrial bioproducts are often given comparatively scant attention. Quantifying biotech's economic contribution The economic impact of an industry is often based on its contribution to GDP (Supplementary Table 1). GDP is a national measure of economic output, which in the United States is calculated by the government using survey and census data. According to the US Census Bureau, “the North American Industrial Classification System (NAICS) is the standard used by Federal statistical agencies in classifying business establishments for the purpose of collecting, analyzing, and publishing statistical data related to the US business economy” (http://www.census.gov/eos/www/naics/index.html). The NAICS is used to segment the economy according to a list of six-digit codes that are reevaluated every five years. The resulting data serve as the basis for constructing GDP in one of three ways: the value added to the economy for each industry, total domestic income earned and final sales of domestic products to purchasers. The algorithms used to calculate GDP are adjusted over time, with refinements intended to sharpen understanding of how goods and services are exchanged to create value. In principle, then, biotech innovations can, like any other component of the US economy, be assessed through changes in the NAICS and GDP calculations. However, there is at present no means to calculate the contribution of biotech to GDP on the basis of the value added, total income or final sales methods. Despite the intention that “producing units that use the same or similar production processes are grouped together in NAICS,” the only NAICS code for biotech-related businesses is specifically meant to identify research and development entities, and it is associated with a very broad definition of biotech (Box 2 and http://www.census.gov/eos/www/naics/reference\_files\_tools/NAICS\_Update\_Process\_Fact\_Sheet.pdf). The only code associated with biological manufacturing of any kind is a subset of pharmaceutical production. Although biotech may nominally be used in various industries that do not obviously overlap (e.g., in the production of fuels or drugs), it comprises a coherent set of tools, skills and practices that together constitute similar production processes that are very different from synthetic chemistry or resource mining. At present, the vast majority of biotech product and service revenues are evidently collected into generic categories such as chemicals, agriculture and pharmaceuticals. Consequently, among other shortcomings, in the NAICS system, what is identified as 'biochemicals' (Fig. 1) conflates chemicals produced largely via fermentation with chemicals produced from petroleum or mining. This is but one example of misaggregation of biotech revenues with those generated from entirely unrelated production processes. n lieu of standardized data classified via the NAICS, how might one estimate the contribution of biotech to GDP? One starting point is industry revenue, corrected as is feasible to remove double counting (Box 1 and Supplementary Methods). For the present analysis, I relied largely on data from the following sources: corporate financial reporting, US Department of Agriculture (USDA) crop price and GM seed usage reporting, and private consulting firms. Because these data are of varying quality and quantity, I combined available hard data with trends and anecdotes to develop estimates. I argue here that the result is a reasonable approximation of the contribution of biotech to GDP. US biotech revenues The quantitative data used were derived primarily from financial reporting and market prices, and the estimates primarily from surveys, private consulting reports and numerical interpolation of sparse time series data (sources of uncertainty are detailed in Box 3). Because of differences in the regulatory structure and financing and, consequently, the pace of innovation across the industry, the biotech sector naturally breaks down into three subsectors: biologics (biotech drugs), GM crops or seeds and industrial biotech. Although biologics development is said to run faster than small-molecule pharmaceuticals, the cost for each is frequently estimated to be >$1 billion per drug, spent over 10 years of development and clinical trials4. GM crops may cost between $500 million and $700 million to develop, with field trials running 3–5 years, depending on whether those trials are conducted simultaneously in the southern and northern hemispheres4. Finally, industrial products may cost anywhere from tens to hundreds of millions of dollars to develop—depending in part on whether the physical infrastructure (i.e., 'steel in the ground') is included in the costs—and US regulatory barriers may be so low that only a notification letter to relevant authorities is required, meaning products can be marketed as soon as they are produced4, 5. Biologics. For this analysis, I define biologics as drugs produced using GM organisms; I explicitly exclude drugs purified from nonmodified organisms. On the basis of reporting from publicly traded companies, global 2012 revenues from biologics reached at least $125 billion; McKinsey and Company (New York) estimated that 2012 global biopharmaceuticals revenues may have been as high $168 billion6 (http://www.mckinsey.com/insights/health\_systems\_and\_services/rapid\_growth\_in\_biopharma) (Supplementary Table 2). Of that total, domestic US revenues from biologics reached $91 billion. This figure includes ~$28 billion in revenues accruing to such companies as Genentech and Genzyme (Cambridge, MA, USA) that are now wholly owned by overseas entities—Roche and Sanofi (Paris), respectively. Domestic US clinical sales of biologics rose >18%, reaching $63.6 billion in 2012 (ref. 2). Beyond drugs that are produced biologically, the contemporary development and testing of virtually all small-molecule prescription drugs is highly dependent on biotech. Of the ~$337 billion in total 2012 US pharmaceutical revenues, a large fraction of the small-molecule revenues relied heavily on biotechnologies used in discovery, validation and trials7. Further complicating this estimate is the challenge of accounting for the potential double-counting of 'biologics feedstocks' produced in the United States, as some fraction of those revenues is produced from exports, and ~75% of pharmaceutical ingredients used in the United States are imported from China8. Consequently, in the interest of simplicity and of using data that are relatively easy to come by, I have chosen to include here only 'nameplate' biologics revenues that are directly attributable to biological production, even though this probably underestimates the total relevant revenues by a substantial amount. GM crops. Global planting of GM crops increased by 6% in 2012, reaching a total of 170 million hectares9. In the United States, where farmers planted 40% of the total global GM crop area, GM corn, cotton and soy continued to have ~90% penetration, with GM sugar beets at 95%. Using average crop revenue figures and the fractions of crops planted in GM seed as compiled by the USDA, I estimate that the sum of farm-scale domestic US revenues, seeds and licensing revenues reached $128 billion (Fig. 2 and Supplementary Table 3). On the basis of the global acreage of GM crops as reported by the International Service for the Acquisition of Agri-biotech Applications, and assuming approximately uniform global prices, I estimate that 2012 global farm-scale revenues for GM crops were at least $300 billion9. How should the biotechnological contribution to GM crop revenues be valued? Until 2009, revenues from GM seeds alone were widely misreported as total “revenues from GM crops”10. Seeds, however, grow into larger organisms with greater value. Some of that value would be realized without the GM component. The US National Research Council (NRC) estimates that by planting GM crops, US farmers receive an additional economic benefit that ranges between 6% and 20% of total crop revenues, depending on the crop, where it is planted and how closely farmers follow recommended practices11. Cumulative 2000–2012 GM crop and seed revenues (Fig. 3) amount to $802 billion, suggesting that US farmers received between $50 billion and $160 billion in additional economic benefit over those years. These figures substantially exceed the benefits estimated by Brookes and Barfoot12 for 1996–2011. This difference highlights the complexity of the analysis and the need to develop standards and consistency. For example, a fraction of the economic benefit estimated by the NRC is indirect, in that farmers who plant GM crops are able to spend less time tending to those crops. That time can be used in other pursuits, including earning additional income, a factor that Brooks and Barfoot intentionally exclude owing to the complexity of gathering and analyzing such data in a global context12. More recently, Klümper and Qaim found that “on average, GM technology adoption has reduced chemical pesticide use by 37%, increased crop yields by 22%, and increased farmer profits by 68%”13. Beyond the direct benefits to farmers planting GM crops, there are benefits to conventional crops in proximity to GM crops. Multiple lines of evidence demonstrate that insect-resistant crops produce area-wide pest suppression—also known as the 'halo effect'—reducing losses in nearby conventional crops. This effect both reduces pesticide requirements for conventional crops and increases their yield; consequently, by one estimate, more than 70% of the cumulative benefits of Bt corn adoption over a period of 14 years accrued to nonadopters in the US Midwest14. The economic benefits of GM crops to nonadopting farmers are difficult to assess broadly, but they should be attributed in some way to the total economic contribution GM crops. I do not attempt to include this value in the present revenue estimate. Going forward, a more thorough accounting of what revenues are produced by which crops might provide a mechanism to include only the fraction of revenues attributable to GM traits. This metric should include the value provided by nearby GM crops to farmers of conventional crops and would thereby contribute to solidifying conversations about the utility and value of various integrated pest-management approaches. This accounting strategy could be the product of work in the public or private sector, but it should be adopted at the federal level to facilitate data gathering and analysis. For simplicity, here I use the total farm-scale revenues from GM crops and seeds. This may well constitute an overestimate of GM crop revenues, but its contribution to estimated total biotech revenues is arguably offset by my use of only 'nameplate' biologics revenues, described above. Industrial biotech. The industrial subsector appears to be the fastest-growing portion of the biotech sector (Fig. 3), and the lack of resolution of this component at the level of the NAICS masks a large and accelerating shift in the US economy. US revenues from industrial biotech reached at least $105 billion in 2012. The accuracy of the industrial revenue estimate continues to suffer in comparison to estimates for biologics and GM crops, owing to the quantity and quality of available data (Fig. 3). My previous efforts have required reverse engineering of reports from private consulting firms who rarely describe data sources and methods4. For the present set of estimates, I first excluded the value of corn from annual US ethanol revenues, which I then used as a lower bound for total US revenues. To these figures I added a conservatively scaled fraction of the international industrial biotech revenue figures reported by consulting firms (Box 1 and Supplementary Table 4). For the 2012 data, I relied on data provided by by Agilent Technologies (Santa Clara, CA, USA), of $125 billion15. Although it would be preferable to categorize industrial biotech products under biofuels, enzymes, biomaterials and biochemicals (biologically derived chemicals), the Agilent report categorizes revenues differently. Its internal breakdown of the $125 billion in business-to-business sales for 2012 was as follows: $66 billion in biochemicals, $30 billion in biofuels, $16 billion in biologics feedstocks (active pharmaceutical ingredients), $12 billion in food and agricultural applications (including enzymes) and $1 billion in new markets. Darlene Solomon, senior vice-president and CTO of Agilent, later clarified that the “industrial biotechnology market analysis was developed via analysis of corporate financial reports, equity analyst reports, private consulting firms reports, and third party market research reports” (personal communication).No further information is available at present. For the revenue estimate reported here, I have scaled the 2012 Agilent biofuels revenues to avoid double counting the substantial contribution of corn feedstocks (on average, ~68% of the wholesale cost of ethanol) (Supplementary Table 4). This reduces the 2012 value added of biofuels production to no more than $10 billion. Notably, biochemicals have eclipsed fuels as the largest component of industrial biotech revenues. The magnitude of the disparity between biofuel and biochemical revenues is informative for understanding the state of the bioeconomy and may inform ongoing policy debates about the relative levels of federal support received by each type of product. The estimates presented here suggest that biochemicals may already generate the equivalent of ~0.4% of the US GDP (compared with ~3% for petrochemicals; see below and Supplementary Table 4). Last, the ultimate contribution of industrial biotech to GDP could be 10–15% larger than that quoted here, depending on the actual retail margin and value added for consumers by biotech beyond business-to-business transactions. The total 2012 impact on the US economy could therefore have been as much as $155 billion, which would bring the total 2012 biotech revenues to >$374 billion. Contribution to US GDP To what extent is it sensible to refer to a 'biotech industry' and its contribution to GDP? Just as cell culture and fermentation are quite different from mining or petroleum refining, so are they different from agriculture. But biological production methods, and their underlying bioengineering techniques and tools, are similar in many ways, particularly when contrasted with mining and refining. These distinctions are likely to be of increasing importance in policy discussions around renewable biological manufacturing and its potential to replace processes and manufacturing based on fossil energy and materials. Moreover, aggregate revenues from GM organisms are now a large and rapidly growing contribution to the US economy (Fig. 3). How well does the sum of biotech revenues in Figure 3 approximate the contribution of biotech to GDP? The overall quality of the data available supports treating any aggregate as only an estimate. As argued above, 'nameplate' biologics revenues are probably a substantial underestimate of subsector revenues. Similarly, although use of total GM crop revenues overestimates the value added to these crops by genetic modification, the total impact is probably underestimated, owing to the direct benefits for conventional crops via the halo effect. Historically, industrial revenues are the least precise owing to the quantity and quality of data, although I eliminated obvious double counting where feasible. In all three cases I sought to produce conservative estimates whenever possible. Taken together, until better data are available, the resulting revenue figure is a reasonable proxy for a direct measure of 'GM domestic product' (GMDP). Therefore, it is arguably both useful and approximately correct to aggregate the revenues from GM organisms as the GMDP to assess the economic impact of biotech. With this approximation in hand, the interpolation in Figure 3 enables a direct historical comparison of biotech revenues to GDP and GDP growth in the United States over the past three decades. This comparison reveals that the US economy, and in particular annual US GDP growth, is becoming increasingly dependent on biotech. Biotech revenues have increased as a fraction of GDP gradually since 1980, reaching the equivalent of at least 2% in 2012. This development is driven by annual increases in biotech revenues that, by 2012, contributed the equivalent of at least 5.4% of annual GDP growth. The apparent peak between 2007 and 2011 is due to the poor overall performance of the US economy rather than any particular trend in biotech. This phenomenon, also visible in 1991 and 2001–2003, suggests that biotech as a sector is relatively robust in the face of general economic downturn. Now, as the broader economy recovers, the annual biotech revenue growth contribution appears to be realigning with the multidecadal trend; several more years may yet be required to resolve the actual annual rate. The model is sensitive to the size of the 2012 industrial biotech revenues; using a biotech revenue estimate of $350 billion would raise the contribution of biotech to GDP to 2.26% and the 2012 contribution to GDP growth to 8.6% (data not shown). The code used to generate historical estimates can also be used to project future revenues. However, because of both the uncertainty in the size of 2012 biotech revenues (between $324 billion and $374 billion) and the sensitivity of the revenue interpolation and growth rates to the size of 2012 industrial revenues, I will not speculate on the magnitude of more recent revenues or quantitatively predict future performance. The code used to generate Figures 3 and 4 is available is available from Biodesic (http://www.biodesic.com). Better tracking of the bio-based economy Box 2 summarizes how NAICS could be used to track biotech products and revenues. Looking forward, one necessary change to the NAICS would be to institute a 'nonpharmaceutical, cell-based manufacturing' code. This code would capture the majority of industrial biotech revenues, which even at the business-to-business 2012 total of $105 billion exceeded the $101 billion in direct contribution to GDP claimed by the mining industry (Supplementary Table 4 compares the contributions to GDP of biotech and selected manufacturing and extractive industries)16. An additional code could be used to specify cell-based manufacturing that relies on modified genomes. These updates for biotech would not constitute a departure from previous practices; indeed, there is precedent to fine grain the measurement of any industry, and there are multiple NAICS codes to characterize aspects of mining and mineral processing, as well as related services and equipment manufacturing. The US government should examine the bioeconomy at a similar resolution. The current NAICS codes either miss substantial biotech revenues and employment or misaggregate them with entirely dissimilar means of production. Of more general concern, the misattribution of sector revenues obscures the broader raw economic contribution of biotech. The resulting ignorance impedes quantitative assessment of key features of sector growth and health, such as the number of firms, the rate of firm creation and destruction, firm longevity, employment and returns on public and private sector investment. I hope that, by calling attention to these and other shortcomings, this analysis will encourage private and public sector efforts to gather and share data that support a more detailed understanding of the biotech sector and its contributions to innovation and physical and economic security. The NAICS is under review for an update in 2017. New codes specifically designed to elicit information about biological production would address serious shortcomings in the way the US government assesses its economy. The continued use of NAICS codes adopted in previous years will explicitly confuse chemicals directly produced through biological systems with those refined from fossil sources and ores. For example, a recent attempt by the Battelle Memorial Institute (Columbus, OH, USA) to use the NAICS to define 'bioscience-related' employment was hampered by antiquated industrial groupings that not only excluded many companies that derive revenue from biotech products (including GM seeds, nonagricultural industrial chemicals and industrial enzymes) but also included companies that manufacture farm equipment and irradiation instruments that are clearly not biotech related17. Consequently, using the current NAICS to estimate biotech employment is a difficult proposition, because the current codes do not map well onto existing and emerging bioproduction methods18. Modernizing the NAICS must be a priority of both the public and private sectors to enable accurate economic analyses, employment measurements and appropriate marshaling and allocation of resources. The mechanisms to better characterize the bioeconomy throughout North America appear to exist in the form of NAICS and the North American Product Classification System (NAPCS). Ongoing revisions to industrial coding and classification provide opportunities to untangle biotech revenues from other industries and to clarify the contribution of biological production to the economy. The broader bioeconomy The estimates of the economic contribution of the biotech sector provided here are relatively inaccurate compared with those describing other parts of the US economy. Not only are there whole areas of biotech activity for which no data are collected, there is also a lack of detail for biotech products where data are available. A critical question for any analysis of the 'biotech sector' is that of what falls within the scope of biotech. For example, in excess of the biologics estimate provided here, there are almost certainly additional billions of dollars in revenues attributable to the creation, maintenance and production of GM model animals, such as knockout microbes and rodents, which are increasingly sold as services to industry and academia. Similarly, companies produce many types of modified cells and antibodies for sale, and vaccines are increasingly produced via biotechnological techniques such as reverse genetics. Marketing reports for sale on the Internet suggest that sales of chemically synthesized peptides, oligonucleotides and genes generate between hundreds of millions and several billion dollars annually. Other reports (http://www.bccresearch.com/market-research/biotechnology/synthetic-biology-bio066c.html; http://www.transparencymarketresearch.com/synthetic-biology-market.html) define a new category of 'synthetic biology' that is putatively already worth several billion dollars a year and that will purportedly climb to tens of billions by 2020. In principle, all of these contributions could be tracked with appropriate NAICS codes, because the value provided by biotech tools should be reflected in their price and thus in the revenues of the vending companies. Properly accounting for these contributions could add tens of billions of dollars in additional revenue to the biotech tally provided here, but such a calculation is not obviously feasible with current data. Clearly defined metrics are critical for formulating policy and allocating resources for research, development and market incentives. For example, policy discussions about alternatives to fossil fuels and reducing carbon emissions should consider metrics not only on biofuels but also on the contribution of biochemicals to plastics and solvents, given that ~15% of a barrel of petroleum is processed into such materials (http://www.eia.gov/energyexplained/index.cfm?page=oil\_refining and http://www.eia.gov/dnav/pet/PET\_PNP\_PCT\_DC\_NUS\_PCT\_A.htm). In other words, although the energy content of petroleum might be replaced by many sources, more consideration should be given to replacing the atoms in petroleum, given their crucial role as materials in the existing economy. Addressing the shortcomings of present data through better measurement would benefit strategy development and policy-making across the public and private sectors. For example, adequate planning to educate an appropriate labor force requires understanding the current skill base and overall sector employment. More broadly, accurate and precise historical revenue estimates would facilitate efforts to understand the long-term return on public and private investments in the bioeconomy and would benefit conversations both practical and political. Beyond the United States, better data would help governments assess biotech's contributions to their own economies. Yet assessing the specific economic roles of modified DNA and biomanufacturing should be undertaken as part of a larger effort. It is often said that this is the century of biology and that biology is the technology of the twenty-first century. Private investments continue to flow into biotech, motivated by hopes of developing new medical treatments, crops, chemicals and production processes.Public investments seek the same returns, with additional expectations for education, employment and economic development. How can the returns from these investments be tallied, and how should this tally be used to assess the contribution of biology to the larger economy? It is well past time for governments around the world to collaborate in developing a standardized and comprehensive understanding of the role of biology in their economies. Standardized data would be invaluable in an assessment of the economic importance of biotech and would enable a direct comparison with GDP. In the long term, it would be ideal to have an industry-wide reference metric that is comparable to GDP. Some governments track—to varying degrees—healthcare, domestic agricultural productivity and biofuels production, but data collection and analytical standards are far from uniform (e.g., see the variable quality and quantity of data in the European Commission's Bioeconomy Observatory (http://biobs.jrc.ec.europa.eu/)). As a step toward clarity, nascent efforts are under way to assemble a unified picture of the value provided by biological goods and services in the form of the biobased economy. The definition of 'biobased economy' varies internationally. In the United States, it is typically defined as “economic activity and jobs generated by the use and conversion of agricultural feedstocks to higher value products; the use of microbes and industrial enzymes as transformation agents or for process changes; and the production of bio-based products and biofuels”19. Responding to a mandate from the US Congress, the USDA has elaborated a list of potential “biobased economy indicators” and also described the difficulties in fleshing out those metrics20. Yet even in the current data-poor environment, the biobased economy was recently valued at an estimated $1.25 trillion in the United States for 2012, the equivalent of about 7% of the GDP21. As impressive as these numbers are, they may still exclude a wide variety of economically important biological goods and services. The preceding definition of biobased economy, and the one used by the USDA, omit fisheries, forestry and agriculture20. Depending on who is counting, those industries generate between $300 billion and $800 billion in revenue annually, bringing even a conservative estimate of the total size of the broader US bioeconomy to nearly 10% of GDP4. For comparison, a recent estimate of the European Union's bioeconomy sectors that included all biobased activity put the total at >$2 trillion and 9% of GDP22. Yet even if a more detailed and thorough accounting were to raise the total bioeconomy to 15% or 20% of GDP, that number would underestimate the larger importance of biological systems in supporting countries and their economies. Without biological production in the form of food, water, oxygen and raw materials, the rest of the economy would be worthless. Precisely because the biobased economy is intertwined with, and depends on, agriculture and natural resources, a thorough understanding of the relationship between biological systems and the economy requires a broader systematic accounting that extends across land and water resources, agriculture, food, textiles and paper, to cutting-edge products of metabolic engineering. Simply put, we should measure everything better.

### 1AC - Solvency

#### Plan: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines

**Feldman, 19** (Robin Feldman, Robin Feldman is professor of law and director of the Institute for Innovation Law at UC Hastings College of the Law in San Francisco and author of “Drugs, Money, and Secret Handshakes” (Cambridge University Press, March 2019). 2-11-2019, accessed on 8-13-2021, STAT, "Drug patent protection: it's time for a 'one-and-done' approach - STAT", <https://www.statnews.com/2019/02/11/drug-patent-protection-one-done/)WWPP>

-bans method such as evergreening, patent thickets, fake orphan patents, and pay for delay

Why isn’t the system working as it should? Some experts believe the U.S. can rein in drug process with value-based pricing, which aims to tie the prices we pay for drugs to the benefits they provide, either in terms of longer life or better quality of life. Others call for dismantling pharmacy benefit managers. Still others want large groups like Medicare to negotiate with drug companies for better drug prices. While each of these might help, they cannot solve the problem alone. Why? Because they do not reach the heart of the problem. As I explain in my new book, “Drugs, Money, and Secret Handshakes,” the government itself is giving pharmaceutical companies the power they are wielding through overly generous drug patent protection. Effective solutions must address that problem. Drug companies have brought great innovations to market. Society rewards innovation with patents, or with non-patent exclusivities that can be obtained for activities such as testing drugs in children, undertaking new clinical studies, or developing orphan drugs. The rights provided by patents or non-patent exclusivities provide a defined time period of protection so companies can recoup their investments by charging monopoly prices. When patents end, lower-priced competitors should be able to jump into the market and drive down the price. But that’s not happening. Instead, drug companies build massive patent walls around their products, extending the protection over and over again. Some modern drugs have an avalanche of U.S. patents, with expiration dates staggered across time. For example, the rheumatoid arthritis drug Humira is protected by more than 100 patents. Walls like that are insurmountable. Rather than rewarding innovation, our patent system is now largely repurposing drugs. Between 2005 and 2015, more than three-quarters of the drugs associated with new patents were not new ones coming on the market but existing ones. In other words, we are mostly churning and recycling. Particularly troubling, new patents can be obtained on minor tweaks such as adjustments to dosage or delivery systems — a once-a-day pill instead of a twice-a-day one; a capsule rather than a tablet. Tinkering like this may have some value to some patients, but it nowhere near justifies the rewards we lavish on companies for doing it. From society’s standpoint, incentives should drive scientists back to the lab to look for new things, not to recycle existing drugs for minimal benefit. I believe that one period of protection should be enough. We should make the changes necessary to prevent companies from building patent walls and piling up mountains of rights. This could be accomplished by a “one-and-done” approach for patent protection. Under it, a drug would receive just one period of exclusivity, and no more. The choice of which “one” could be left entirely in the hands of the pharmaceutical company, with the election made when the FDA approves the drug. Perhaps development of the drug went swiftly and smoothly, so the remaining life of one of the drug’s patents is of greatest value. Perhaps development languished, so designation as an orphan drug or some other benefit would bring greater reward. The choice would be up to the company itself, based on its own calculation of the maximum benefit. The result, however, is that a pharmaceutical company chooses whether its period of exclusivity would be a patent, an orphan drug designation, a period of data exclusivity (in which no generic is allowed to use the original drug’s safety and effectiveness data), or something else — but not all of the above and more. Consider Suboxone, a combination of buprenorphine and naloxone for treating opioid addiction. The drug’s maker has extended its protection cliff eight times, including obtaining an orphan drug designation, which is intended for drugs that serve only a small number of patients. The drug’s first period of exclusivity ended in 2005, but with the additions its protection now lasts until 2024. That makes almost two additional decades in which the public has borne the burden of monopoly pricing, and access to the medicine may have been constrained. Implementing a one-and-done approach in conjunction with FDA approval underscores the fact that these problems and solutions are designed for pharmaceuticals, not for all types of technologies. That way, one-and-done could be implemented through legislative changes to the FDA’s drug approval system, and would apply to patents granted going forward. One-and-done would apply to both patents and exclusivities. A more limited approach, a baby step if you will, would be to invigorate the existing patent obviousness doctrine as a way to cut back on patent tinkering. Obviousness, one of the five standards for patent eligibility, says that inventions that are obvious to an expert or the general public can’t be patented. Either by congressional clarification or judicial interpretation, many pile-on patents could be eliminated with a ruling that the core concept of the additional patent is nothing more than the original formulation. Anything else is merely an obvious adaptation of the core invention, modified with existing technology. As such, the patent would fail for being perfectly obvious. Even without congressional action, a more vigorous and robust application of the existing obviousness doctrine could significantly improve the problem of piled-up patents and patent walls. Pharmaceutical companies have become adept at maneuvering through the system of patent and non-patent rights to create mountains of rights that can be applied, one after another. This behavior lets drug companies keep competitors out of the market and beat them back when they get there. We shouldn’t be surprised at this. Pharmaceutical companies are profit-making entities, after all, that face pressure from their shareholders to produce ever-better results. If we want to change the system, we must change the incentives driving the system. And right now, the incentives for creating patent walls are just too great.

#### These practices stunt competition by preventing other companies from entering the market and increassing drug prices. The plan solves.

**Ventures, 20** (Arnold Ventures, Arnold Ventures is a philanthropy dedicated to tackling some of the most pressing problems in the United States. We invest in sustainable change, building it from the ground up based on research, deep thinking, and a strong foundation of evidence. We drive public conversation, craft policy, and inspire action through education and advocacy.We are a team of more than 90 subject-matter experts headquartered in Houston with offices in New York and Washington, D.C. We work in four key issue areas: Criminal Justice, Education, Health, and Public Finance. Our work is guided by Evidence-Based Policy, Research, and Advocacy., 9-24-2020, accessed on 8-13-2021, Arnold Foundation, "“Evergreening” Stunts Competition, Costs Consumers and Taxpayers", https://www.arnoldventures.org/stories/evergreening-stunts-competition-costs-consumers-and-taxpayers/)WWPP

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

**Innovation is critical to the pharma industry**

**Petrova 14** [Elina Petrova works at Washington State University. “ Innovation in the Pharmaceutical Industry: The Process of Drug Discovery and Development “ Jan 2014 DOI:10.1007/978-1-4614-7801-0\_2 <https://www.researchgate.net/publication/278655429_Innovation_in_the_Pharmaceutical_Industry_The_Process_of_Drug_Discovery_and_Development> ] //aaditg

***The pharmaceutical industry is essentially defined by innovation***. Research on the forefront of science, the creation of new knowledge bases, ***the invention of new medicines, and the improvement of existing drugs constitute the fuel that propels the firms in this industry.*** The occasional triumph of creating a novel therapy in an area with no prior treatments counts among the pharmaceutical industry’s most defi ning hallmarks. This is the only industry whose output can make a difference by affecting the very molecules we are made of. ***Modern era medications can influence the quality and the duration of human life in ways that were never possible before***. As recently reported by the Pharmaceutical Research and Manufacturers of America (PhRMA), over ***the last 25 years prescription drugs have successfully improved the wellbeing of arthritis and Alzheimer’s sufferers around the world, and have significantly reduced deaths from heart disease, several types of cancer, and HIV/AIDS. The death rate for cardiovascular disease has fallen by a dramatic 28 % between 1997 and 2007, while the average life expectancy for cancer patients has increased by 3 years since 1980. Most of these gains are attributable to new medicines.*** In the USA, since the approval of antiretroviral treatments in 1995, the death rate from HIV/AIDS has dropped by more than 75 %. As predicted by IMS Health, innovative treatment options for stroke prevention, arrhythmia, melanoma, multiple sclerosis, breast cancer, prostate cancer, and hepatitis C are also imminent.***Successful and continuous new drug introductions constitute the source of sustainable competitive advantage for the firms in this industry.*** The sales potential is gigantic: the global pharmaceutical market was estimated at $837 billion in 2009 and was expected to reach $1.1 trillion by 2015. As reported by the IMS Institute for Healthcare Informatics (www.imshealth.com), in the USA alone, a total of $307 billion dollars, or $898 per capita, was spent on ethical drugs in 2010, representing 2.1 % of the GDP. The USA is poised to remain the single largest pharmaceutical market, with four billion dispensed prescriptions and a total revenue of $380 billion expected by 2015. Some estimates indicate that 46 % of the people living in the USA take at least one prescription drug. Not only is the USA the largest market for ethical drugs, but it is also recognized as the world leader in drug discovery and development, as well as a global hub for scientifi c and medical research. The pharmaceutical sector is the second largest US export sector, just behind the aerospace industry. It is also a major employer, estimated to provide jobs to 655,000 people. In total, directly and indirectly, the sector supports over 3.1 million jobs nationwide. It is also one of the few industries that are projected to keep adding jobs in the years to come despite the recent slowdown in the economy (PhRMA and the Bureau of Labor Statistics). ***Although innovation is the lifeblood of any industry, the discovery and development of new medicines is accompanied by a host of unique challenges, ethical implications, and social responsibilities. One will be hard pressed to think of another industry where meticulous research, rigorous testing, and stringent product standards (or the lack thereof) can have such a profound impact on human wellbeing.*** E. Petrova 21 The fundamental role of the pharmaceutical industry in maintaining and enhancing human life is further refl ected in the magnitude of its R&D activity. By some accounts, pharmaceutical R&D holds an impressive 19 % share of all business spending on R&D worldwide—an impressive fi nancial commitment for a single industry. The USA is accountable for the lion’s share of pharmaceutical innovation as it fi nances about 36 % of the global expenses in pharmaceutical R&D