## Framework

#### I affirm resolved: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

#### I value morality as per the word ought in the resolution denoting moral obligation.

#### Thus, the standard is minimizing oppression/ maximizing communal wellbeing.

#### The reasons to prefer the standard are:

#### 1 - Minimizing structural violence is essential to preventing conflict – focusing only on international conflicts ignores the root cause of violence

**Barash 2000** - **Professor of Psychology, University of Washington** (David P. “Approaches to Peace: A Reader in Peace Studies”, 2000, http://www.questia.com/read/111756263?title=Approaches%20to%20Peace%3a%20%20A%20Reader%20in%20Peace%20Studies, AD: 7/9/9)

The pursuit of positive peace nonetheless leads to certain agreed principles, one of which is a minimization of violence, not only the overt violence of war, but also what has been called “structural violence,” a condition that is typically built into many social and cultural institutions. A slave-holding society may be at “peace” in that it is not literally at war, but it is also rife with structural violence. Structural violence has the effects of denying people important rights such as economic opportunity, social and political equality, a sense of fulfillment and self-worth, and access to a healthy natural environment. When people starve to death, or even go hungry, a kind of violence is taking place. Similarly, when human beings suffer from diseases that are preventable, when they are denied a decent education, housing, an opportunity to play, to grow, to work, to raise a family, to express themselves freely, to organize peacefully, or to participate in their own governance, a kind of violence is occurring, even if bullets or clubs are not being used. Society visits violence on human rights and dignity when it forcibly stunts the optimum development of each human being, whether because of race, religion, sex, sexual preference, age, ideology, and so on. In short, structural violence is another way of identifying oppression, and positive peace would be a situation in which structural violence and oppression are minimized. In addition, social injustice is important not only in its contribution to structural violence, but also as a major contributor to war, often in unexpected ways. For many citizens of the United States and Europe, as well as privileged people worldwide, current lifestyles are fundamentally acceptable. Hence, peace for them has come to mean the continuation of things as they are, with the additional hope that overt violence will be prevented. For others – perhaps the majority of our planet – change of one sort or another is desired. And for a small minority, peace is something to fight for! A Central American peasant was quoted in the New York Times as saying “I am for peace, but not peace with hunger.” There is a long tradition suggesting that injustice is a primary cause of war. The French philosopher Denis Diderot, for example, was convinced that a world of justice and plenty would mean a world free of tyranny and war. Hence, in his 18th-century treatise, the *Encyclopedia,* Diderot sought to establish peace by disseminating all the world’s technical information, from bee-keeping to iron forging. And, of course, similar efforts continue today, although few advocates of economic and social development claim that the problem of violence can be solved simply by spreading knowledge or even by keeping everyone’s belly full.

## Contention 1

#### Contention 1 is 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 negative arguments – they are probably based on unfounded assumptions

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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.

#### 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.

#### Agriculture biotech innovation key to keep up with food demands – regulatory failures undermine U.S. agricultures, and result in increased global famines that risk instability

Redick 14, Thomas, JD (1985) from the University of Michigan and is chair of the American Bar Association Section on Environment, Energy & Resources (ABA-SEER) Committee on Agricultural Management, “The “Stacked” Pipeline of Biotech Specialty Crops and Regulatory/Market Barriers to Coexistence,” pg online @ <http://nabc.cals.cornell.edu/Publications/Reports/nabc_25/25_6_1_Redick.pdf>

Biotech Benefits and the Upcoming Pipeline It is now clear that agricultural biotechnology has provided benefits both to human health and to the environment. This continues to be clear, despite what activists say, since growers are using fewer chemicals such as pesticides. Some of the major US-based environmental groups are starting to get behind agricultural biotechnology. In a speech to a European audience in 2012, the vice president of the Worldwide Fund for Nature (WWF-US) in the United States said, “I’m convinced that modern genetic technology could help get better yields from local and regional crops in Africa and South-East Asia” (McEwan, 2012) We have improved food safety through use of biotech corn. Iowa State University has done excellent research showing that mycotoxin formation is reduced in certain Bt-corn varieties. It is unhealthy to eat known carcinogens. If other nations struggling to cope with mycotoxin-related effects (cancer, birth defects, etc.), simply by approving planting of Bt corn those nations would reduce those effects and bring health benefits through biotechnology. (Murillo-Williams and Munkvold, 2008). Moreover, time has trumped the early concerns expressed by Al Gore about biotech crops exacerbating over-supply; we know now that the world has become too needy to be cavalier in dismissing innovation in agricultural biotechnology. With people around the world asking for more and more corn, soy and other foods at reasonable prices, and rioting to overthrow their governments, we know that yields actually matter. While many factors were contributory, the recent violent protests in North Africa and the Middle East coincided with sudden peaks in global food prices. Researchers suggest that a given food- price threshold may exist, above which protests become likely (Lagi et al., 2011). With such social unrest making the world an increasingly unstable place, we do not have the luxury of tinkering with the highly productive US agricultural system that makes food for the world without risking serious negative impacts overseas. The pipeline for biotech crops is becoming more interesting with each innovation in plant breeding. Genes are being silenced with no “plant pest” DNA to regulate or test for, making regulation more complex. Such new plant-breeding methods involve: • RNA-interference. • Oligo-RNA etc—Cibus, Keygene, etc. • Public-academic breeding coming on fast? • USDA does not see a plant pest, EPA sees resistance issues, etc. The pipeline of biotech commodity crops promises new approaches to food and agriculture, and, finally, direct consumer benefits, not just improved production traits (e.g. herbicide and pest resistance) enabling more-efficient production. These include: • Improved consumer health (high oleic, omega-3 soy, etc.) • Stress-tolerant cultivars, possibly N2 -fixing corn • Environmental impact management—lower GHG emissions • Feeds to reduce feedlot waste (by manipulating genes for phytase to increase efficiency of consumption of phosphates) • More crop from a drop—drought-tolerance in time for climate-disrupted agriculture. Although some proposed innovations may prove to be mere pipedreams, people are working on N2 fixation in corn with symbiotic microorganisms and also making corn photosynthesis work for soy (i.e. “C4 soy”) (Buchanan et al., 2010). There will be more room for public and academic breeding tools in the smaller specialized sector of agriculture. All of this innovation has environmental and economic benefits. This has led the World Wildlife Fund, Environmental Defense Council, and even the Natural Resources Defense Council to start talking about technology neutrality vis-à-vis biotech crops. Opposition to GMOs keeps coming and coming, however. The recently withdrawn French Séralini study, which showed tumors in rats, serves to demonstrate the commitment of certain researchers to bend scientific rules to achieve anti-GMO results. Although the study was badly flawed, it has caused governments to say, “Well, that’s peer-reviewed science. Let’s ban it and make nations stop exporting it to us.” While the high cost of regulatory compliance has led to oligopoly power with a “concentration” in the biotech-seed marketplace, the coming decade may see more new players entering the marketplace (e.g. Okanagan Specialty Crops with its Arctic® Apple2, and J.R. Simplot with its “Innate®” potato1).

#### Doing the affirmative ensures that companies can no longer hoard patents and kill innovation. Reducing IPP has that big of an impact.

**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.

## Contention 2

#### Contention 2 is Global Health Inequality

#### The WTO’s Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) causes massive global health inequality

K. M. Gopakumar 15, legal advisor and senior researcher with the Third World Network, “Twenty years of TRIPS agreement and access to medicine: a development perspective,” Indian Journal of International Law 55, 367–404 2015, <https://link.springer.com/article/10.1007%2Fs40901-016-0022-7>

The two decades of TRIPS show clearly that the compulsory product patent regime succeeded in increasing the monopoly of pharmaceutical TNCS in new medicine market. The product patent regime has put curbs on the availability of generic versions of new medicines. The failure of patent system resulted in the call for fresh look at the role of patent and public policy. Two economists argue that ‘‘…public policy should aim to decrease patent monopolies gradually but surely, and ultimate goal should be the abolition of patents.’’107 Another academic notes: ‘‘Even pharmaceutical and biotech companies usually do not need more than about a decade of monopoly power to encourage their very large investments in new drugs.’’108 There is an urgent need to interrogate the international IP regime in general and patent protection for pharmaceuticals in particular, which does not reflect the health and development needs of people, especially those living in developing countries. The Declaration on Patent Protection: Regulatory Sovereignty under TRIPS released in 2014, an initiative of the Max Plank Institute for Innovation and Competition on the occasion of the 20th anniversary of the TRIPS notes four major developments that require accommodating the law to changed circumstances. First, the ‘historically unprecedented numbers of patents filings and grants’ create problems such as backlogs at patent offices, patent thickets, market entry barriers and increased litigation that ultimately generate impediments to research and commercialisation. The result is rising costs of monitoring patents and legal uncertainty, limiting the economic freedom of market participants, which in turn affects consumer welfare and distorts competition. Thus ‘the overall social benefits of innovation are reduced while an imbalance emerges between those able to cope with the resulting insecurities and related costs, such as multinational enterprises with their own patent departments, and those who cannot, such as small and medium sized enterprises or individual inventors.’109 Second, the new technologies like biotechnology, business methods and computer science as well as standard setting, strategic patenting and non-practising entities all affect the functioning of the patent system as a regulatory institution. Third, the role of patents in corporate management has undergone a change from a defensive means to protect research and development outcomes to become strategic assets to influence the conditions of competition. Fourth, the industrialised countries have tilted the balance in the patent regime towards right holders by reducing the burden for the patent applicants such as expanded scope of patentability, lower eligibility standards and reduced fees, as well as extending the rights of patent owners such as longer term of patent, harsher sanctions, strengthened ways for private and public enforcement. Therefore, the Declaration states: ‘the patent system faces increasing friction with ancillary public policy goals, such as protecting the environment, preserving biodiversity or ensuring affordable access to medicines.’110 Against this background there is an urgent need to review the TRIPS patent regime, especially the compulsory product patent protection. The Agreement itself contains provisions to review its implementation. Article 71.1 of the TRIPS Agreement provides mandatory review of the implementation of this Agreement after the expiration of the transitional period referred to in paragraph 2 of Article 65. Hence this review was to initiate in 2010. According to Art.71.1: The Council shall, having regard to the experience gained in its implementation, review it two years after that date, and at identical intervals thereafter. The Council may also undertake reviews in the light of any relevant new developments, which might warrant modification or amendment of this Agreement. There is a fear that the review may result in an opposite result if developed countries use the opportunity of review to push for TRIPS plus amendments using the second sentence of Article 71.1. However, Para 19 of the Doha Ministerial Declaration clearly defines the mandate of the review. It states, ‘‘The Council may also undertake reviews in the light of any relevant new developments, which might warrant modification or amendment of this Agreement.’’111 However, so far no WTO Member State submitted any proposal in this regard. It is important for developing countries to propose amendment of the compulsory product patent protection in the light of experiences under 20 years of TRIPS Patent Regime. Echoing the same sentiment, the UNDP-appointed Global Commission on HIV and the Law observed the ‘TRIPS has failed to encourage and reward the kind of innovation that makes more effective pharmaceutical products available to the poor, including for neglected diseases. Countries must, therefore, develop, agree and invest in new systems that genuinely serve this purpose, prioritising the most promising approaches including a new pharmaceutical R&D treaty and the promotion of open source discovery.’112 Further, the Commission recommended that: The UN Secretary-General must convene a neutral, high-level body to review and assess proposals and recommend a new intellectual property regime for pharmaceutical products. Such a regime should be consistent with international human rights law and public health requirements, while safeguarding the justifiable rights of inventors. Such a body should include representation from the High Commissioner on Human Rights, WHO, WTO, UNDP, UNAIDS and WIPO, as well as the Special Rapporteur on the Right to Health, key technical agencies and experts, and private sector and civil society representatives, including people living with HIV. This re-evaluation, based on human rights, should take into account and build on efforts underway at WHO, such as its Global Strategy and Plan of Action on Public Health, Innovation, and Intellectual Property and the work of its Consultative Expert Working Group. Pending this review, the WTO Members must suspend TRIPS as it relates to essential pharmaceutical products for low- and middle-income countries.113 As part of the implementation of the recommendation UN SecretaryGeneral has established a 16-member High Level Panel on Access to Medicines. This Panel is to review and assess various proposals and make recommendation to ‘‘remedy the policy incoherence between international human rights law and trade rules in the context of access and health technologies.’’114 It is expected to look at a new IP regime, which can ensure both access and innovation as recommended by the Global Commission on HIV/AIDS. The incoherence between trade law and human rights law cannot be addressed by using flexibilities in the TRIPS Agreement. As long as an international obligation to provide product patent protection for pharmaceutical inventions exists, the above-mentioned incoherence is also to exist. Therefore, it is important to restructure the TRIPS and TRIPS plus IP regime, which not only prevent the access to affordable medicine, but also failed to deliver access to R&D needs of developing countries. There is a need to provide enough policy space for countries to design their patent laws, especially to fulfill their human right obligations on right to health and right to science. Scrapping of the compulsory product patent protection under the TRIPS Agreement is critical to serve this purpose.

#### GHI affects half the world, and worsens economic inequality causing cyclical poverty

Mamiko Yoshizu et al. 17, Communications Officer at the WHO, Simeon Bennett, Communications Officer at the WHO, Tomoko Hirai, Communications Officer at the World Bank, Gregory Härtl, Spokesperson at the WHO, World Bank and WHO: Half the world lacks access to essential health services, 100 million still pushed into extreme poverty because of health expenses,” December 13th, 2017, https://www.who.int/news/item/13-12-2017-world-bank-and-who-half-the-world-lacks-access-to-essential-health-services-100-million-still-pushed-into-extreme-poverty-because-of-health-expenses

At least half of the world’s population cannot obtain essential health services, according to a new report from the World Bank and WHO. And each year, large numbers of households are being pushed into poverty because they must pay for health care out of their own pockets. Currently, 800 million people spend at least 10 percent of their household budgets on health expenses for themselves, a sick child or other family member. For almost 100 million people these expenses are high enough to push them into extreme poverty, forcing them to survive on just $1.90 or less a day. The findings, released today in Tracking Universal Health Coverage: 2017 Global Monitoring Report, have been simultaneously published in Lancet Global Health. "It is completely unacceptable that half the world still lacks coverage for the most essential health services," said Dr Tedros Adhanom Ghebreyesus, Director-General of WHO. "And it is unnecessary. A solution exists: universal health coverage (UHC) allows everyone to obtain the health services they need, when and where they need them, without facing financial hardship." "The report makes clear that if we are serious – not just about better health outcomes, but also about ending poverty – we must urgently scale up our efforts on universal health coverage," said World Bank Group President Dr. Jim Yong Kim. "Investments in health, and more generally investments in people, are critical to build human capital and enable sustainable and inclusive economic growth. But the system is broken: we need a fundamental shift in the way we mobilize resources for health and human capital, especially at the country level. We are working on many fronts to help countries spend more and more effectively on people, and increase their progress towards universal health coverage." There is some good news: The report shows that the 21st century has seen an increase in the number of people able to obtain some key health services, such as immunization and family planning, as well as antiretroviral treatment for HIV and insecticide-treated bed nets to prevent malaria. In addition, fewer people are now being tipped into extreme poverty than at the turn of the century. Progress, however, is very uneven. There are wide gaps in the availability of services in Sub-Saharan Africa and Southern Asia. In other regions, basic health care services such as family planning and infant immunization are becoming more available, but lack of financial protection means increasing financial distress for families as they pay for these services out of their own pockets. This is even a challenge in more affluent regions such as Eastern Asia, Latin America and Europe, where a growing number of people are spending at least 10 percent of their household budgets on out-of-pocket health expenses. Inequalities in health services are seen not just between, but also within countries: national averages can mask low levels of health service coverage in disadvantaged population groups. For example, only 17 percent of mothers and children in the poorest fifth of households in low- and lower-middle income countries received at least six of seven basic maternal and child health interventions, compared to 74 percent for the wealthiest fifth of households. The report is a key point of discussion at the global Universal Health Coverage Forum 2017, currently taking place in Tokyo, Japan. Convened by the Government of Japan, a leading supporter of UHC domestically and globally, the Forum is cosponsored by the Japan International Cooperation Agency (JICA), UHC2030, the leading global movement advocating for UHC, UNICEF, the World Bank, and WHO. Japanese Prime Minister Shinzo Abe, UN Secretary-General Antonio Guterres, World Bank President Kim, WHO Director-General Tedros and UNICEF Executive Director Anthony Lake will all be in attendance, in addition to heads of state and ministers from over 30 countries. "Past experiences taught us that designing a robust health financing mechanism that protects each individual vulnerable person from financial hardship, as well as developing health care facilities and a workforce including doctors to provide necessary health services wherever people live, are critically important in achieving 'Health for All,'" said Mr. Katsunobu Kato, Minister of Health, Labour and Welfare, Japan. "I firmly believe that these early-stage investments for UHC by the whole government were an important enabling factor in Japan’s rapid economic development later on." The Forum is the culmination of events in over 100 countries, which began on Dec. 12—Universal Health Coverage Day—to highlight the growing global momentum on UHC. It seeks to showcase the strong high-level political commitment to UHC at global and country levels, highlight the experiences of countries that have been pathfinders on UHC progress, and add to the knowledge base on how to strengthen health systems and effectively promote UHC. The main high-level sessions of the Forum take place tomorrow, Dec. 14, and will also feature an all-day “innovation showcase,” highlighting innovations driving progress in health systems around the world, and a celebratory public event in the evening. A commitment to action, called the Tokyo Declaration on Universal Health Coverage, will be released during the Forum’s closing ceremony. "Without health care, how can children reach their full potential? And without a healthy, productive population, how can societies realize their aspirations?" said UNICEF Executive Director Anthony Lake. "Universal health coverage can help level the playing field for children today, in turn helping them break intergenerational cycles of poverty and poor health tomorrow." Building on the G7 Ise-Shima Summit and the TICAD VI in 2016, both of which stress the need for UHC, the Forum in Tokyo is seen as a milestone for accelerating progress towards the target of UHC by 2030, a key part of the Sustainable Development Goals. Countries will then gear up for the next global moment: a high-level meeting of the UN General Assembly on UHC in 2019.

#### Bad practices stunt competition by preventing other companies from entering the market and increasing drug prices. The affirmative solves by reducing IPP, we reduce the impact of TRIPS and help create more affordable medicine for people in need.

**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."