# 1AC – Innovation and Inequality

### Case

**Pharmaceutical innovation is *declining***

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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

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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.

#### Err aff – offensive patents are more likely to be used than defensive patents

Gubby 19 (Helen Gubby, Is the Patent System a Barrier to Inclusive Prosperity? The Biomedical Perspective, Wiley Online Library, 06 September 2019, <https://onlinelibrary.wiley.com/doi/full/10.1111/1758-5899.12730)//ww> pbj

Patent system manipulation The patent system has become the context in which many innovations reach society. Patented inventions are everywhere: from everyday kitchen items like coffee machines and cleaning products to inventions that have a significant global impact, such as advances in medicinal drugs, systems to purify water and increasing the harvest from crops. In return for disclosing the information necessary for others ‘skilled in the art’ to make the invention, inventors of new and useful products and processes are rewarded with a monopoly, usually for 20 years. The patent is the legal instrument that protects that monopoly. The ideology behind the development of the patent system was to create a win-win situation: increased prosperity for inventors as they could make use of their market monopoly position to establish their reputation, recover research costs and make a profit, and increased prosperity and welfare for society which could benefit from these new inventions. But does the patent system deliver a win-win result? The patent application must describe how to make the invention and this information is published during the patent application process. Typically applicants will keep this information to the absolute minimum necessary in order to obtain the patent. Patenting only selected aspects of an invention can obscure the overall configuration of the invention. The use by corporations of patents as strategic tools has further undermined the original goals of the patent system and skewered the patent bargain in favour of the inventor. Biomedical innovations are vital to healthcare: they should not be controlled by private companies through patent monopolies. 1 The patent monopoly The monopoly awarded to the patentee gives the patent holder the right to exclude all others from making, using, selling, offering to sell, keeping the product or importing anything covered by the patent claims in all countries where patent protection has been granted. In general, this exclusionary right persists (if renewal fees are paid) until the expiration of the patent protection period. This yields the patent owner significant power. Even Adam Smith, who considered most exclusive privileges to be detrimental to society, did not consider this to be the case with respect to patent monopolies. These, Smith considered, ‘are harmless enough’: For if the legislature should appoint pecuniary rewards for the inventors of new machines, etc., they would hardly ever be so precisely proportioned to the merit of the invention as this is. For here, if the invention be good and such as is profitable to mankind, he will probably make a fortune by it; but if it be of no value he also will reap no benefit. (Smith, 1762-3, p. 83) This too was Jeremy Bentham's justification of the patent system: the utilitarian ground of efficiency. An exclusive privilege, Bentham argued, is ‘of all rewards the best proportioned’ (Bentham, 1843, p. 71). If the invention were not useful there would be no reward; if it was useful then the reward would be proportionate to its utility. 2 The distortion of the patent system: the patent as a strategic tool As the economy has largely shifted from industrial manufacturing to high-tech, life science and information processing industries, intellectual property has become more and more important. Corporations have become increasingly aware of the potential of the patent, not just as a shield to protect against imitation, but as a strategic tool to block competition and dominate markets. Patents have come to have a broader strategic function in which innovation may only play a small part. Although many patents do not produce any income: ‘In terms of strategy, though, the patent can be much more valuable’ (Macdonald, 2004, p. 143). Patent strategy is directly related to the business context. The Carnegie Mellon Survey of the US manufacturing sector in 1994 revealed that firms often used patents as strategic tools, rather than as simply a means of protecting an invention from wrongful imitation (Cohen et al., 2000). In their examination of motives to patent, Blind et al. (2009) recognised that, although protection from imitation was still the most important factor, ‘the importance of the strategic motives to patent are confirmed’ (Blind et al., 2006, p. 671). Patent strategies The decision to patent has become in part uncoupled from the original core purpose of the patent: to protect an invention from unfair imitation by other market participants. Larger firms, with the capital assets to pay for the cost of patenting, use their patent portfolios strategically. Patents have become useful as bargaining chips; they provide leverage. Large patent portfolios are a means to get access to important co-operations or cross-licensing arrangements (Blind et al., 2009, p. 431). Yet while building the portfolio requires enormous legal costs, it contributes little to research incentives. Furthermore, these portfolios can be used not just to oblige competitors to take licences, but also the terms of these licences can restrict competitors to certain areas of technology (Barton, 2000). Larger firms can afford to play the ‘wrap around’ strategy. Instead of applying for a single patent to cover an invention, other patents are filed around the main patent. These related patents lock down the discrete features of an invention. The tactic hinders entry to the market. Competitors will be put to time, effort and cost to fight their way through all the relevant patents covering the technology. Furthermore, the chance that the competitor's invention may infringe one of the many claims in one of the many patents is high. Not only can damages be awarded for infringement, but also an injunction. Injunctions prevent the party accused of infringement from producing any products that require the use of the technology covered by the infringed patent and all infringing products are removed from the market. Patents may be used simply to block competitors. Using a patent as a blocking strategy is common practice (Neuhäusler, 2012). Defensive blocking is used to protect a firm's own freedom to operate: it does not want to be shut out by the patents of its rivals. An offensive blocking strategy is where patents are filed to cover products or processes that the firm does not intend to practice itself, but which could be viable alternatives to competitors. By patenting all conceivable alternatives, research by competitors that might threaten their own technological lead can be thwarted. As in general a patentee is under no obligation to license out its technology to another, the strategy can deter market entry or new product launch. This offensive blocking of competitors by means of patents, ‘is clearly a case of the patent system being used for purposes other than for which it was originally intended’ (Blind, 2009, p. 436). However, both defensive and offensive blocking should be a policy concern, as they can reduce economic efficiency. Defensive patenting increases cost to firms without necessarily producing any benefit and offensive patenting can reduce technological progress and increase consumer costs by reducing competition (Thumm, 2004, p. 533). Using data from a large-scale survey of patent applications, Torrisi discovered that a substantial share of patents remained unused and a substantial number of patent applications were filed to block other patents. There were institutional differences; there were more unused patents in Japan and the EU than in the USA. Although cautious to make generalisations about unused patents, as some unused patents are there to ensure freedom to operate or simply because of management inefficiency, Torrisi et al. did conclude that: ‘[o]ur results highlight that there might be substantial benefits that patent owners draw from being able to keep patent rights unused. These would have to be balanced against possible harm imposed on other economic agents’ (Torrisi et al., 2016; , p. 1384). These strategies show a disconnect with the original purpose of the patent system. Patent strategies impact on innovation, and this in turn impacts on society. Concern was already expressed quite forcibly some years ago by Turner: Surely when the framers of the [US] Constitution empowered Congress to grant monopolies to ‘promote the progress of science and the useful arts’, they did not envision the beneficiaries of this grant would use it to bury new technologies to protect market share or capital investments. (Turner, 1998, p.209) Administrative failures Patent offices have been struggling to cope with the increasing number of patent applications: in 2017, more than 3 million patent applications were filed worldwide (WIPO, 2018). This influx has resulted in substantial application backlogs, with an increasingly long time between the patent filing and the patent grant: five years is not unusual. Complaints of poor quality control have been made concerning the US Patent and Trademark Office as well as the European Patent Office (Abbott, 2004; Mabey, 2010). The WIPO recognised a consistent upward trend in patent filings is putting patent offices under enormous pressure (WIPO, 2017, p. 13). Why are these administrative failings dangerous from a societal perspective? Patents grant a monopoly that can impact innovative processes for 20 years or more. Patents have been granted that should not have been granted. When an overly broad patent is granted, this can block further innovation by others. Broad patents may mean that access to vital research is not available because the results of that research are covered by patent claims. In particular, broad basic patents on fundamental research can block and deter follow-on research. The incentive to innovate is reduced (Barton, 2000; Henry and Stiglitz, 2010).1 Back in 1966, the societal implication of overly broad grants was expressed clearly by the US Supreme Court when it rejected a broad claim covering a group of chemicals: ‘Such a patent may confer power to block off whole areas of scientific development without compensating benefits to the public.’2 3 The exclusionary effects of patent system manipulation: the biomedical sector Biotechnical inventions have a fundamental impact on healthcare, with applications in medical diagnosis, research tools and pharmaceutical drugs. Knowledge has become a very valuable asset. Its commercialisation opens up lucrative business opportunities. The strategic use of patents in the biomedical sector is intended to protect those business interests. However, those patent strategies have societal repercussions. Intellectual property rights and biomedical research A common argument is that there is a distinction between fundamental research and the application of that research; fundamental research should remain in the public domain, while applications can be the province of patents. That is a misguided distinction. As Eisenberg and Nelson point out, the conventional view that basic research is a public enterprise while applied technology is a private enterprise conducted in the hope of earning profits, ignores the ways in which basic science and applied technology can frequently overlap: public and private interest may then conflict (Eisenberg and Nelson, 2002). Fundamental research can become proprietary. A patent should only give protection to an invention. According to US law, this invention must be ‘useful’ (35 US Code, Section 101) and the European Patent Convention 1973 (EPC) requires that an invention is capable of ‘industrial application’ (Art. 52, EPC). Patent law therefore mandates that there must be a practical application. Consequently, a patent does not extend to a discovery, the terrain of fundamental research, as this is explicitly excluded from patentability. The line between ‘discovery’ and ‘invention’ has, however, become exceedingly thin, if non-existent, with respect to molecular technology. The current position with regard to genes and DNA sequences in effect marks a departure from the traditional doctrine that excluded discoveries from patentability. Genes are not new products; they exist in nature and therefore cannot be invented. Yet today, genes and gene sequences are patented as inventions, being regarded as ‘products’. Even if a use of the gene or sequence is speculative, if a use is plausible at the time the patent is filed the utility requirement is fulfilled. The EPC was amended to be brought into line with the terms of the European Directive on the legal protection of biotechnological inventions. This Directive states: An element isolated from the human body or otherwise produced by means of a technical process, including the sequence or partial sequence of a gene, may constitute a patentable invention, even if the structure of that element is identical to that of a natural element.3 Taking an apparently different track, in 2013 the US Supreme Court stated that the mere act of isolating a gene from its surrounding genetic material was not an act of invention. The court did accept synthetic cDNA as patentable, as this was created in the laboratory.4 Scientists have voiced concern that what is often patented has not so much been produced but rather discovered, and is human genetic information rather than an invention (see for a summary of some of these arguments Bergel, 2015). These developments in patent law have created a very real danger: researchers could be barred from accessing fundamental research, which in turn could hinder new knowledge and further innovation. Back in 1998, Heller and Eisenberg warned policy makers to be alert: more upstream rights could block downstream innovation. In this way, the private ownership of biomedical research could lead to fewer useful products for improving human health (Heller and Eisenberg, 1998). If genes and DNA sequences are patent protected, then the patent owner has the right to exclude all others from using that technology. This breach of the discovery/invention distinction is symptomatic of the expansion of patentable subject matter at a global level, extending property claims deep into biology and limiting the scope for accessible treatment and future research (David and Halbert, 2017). The danger of private ownership of fundamental research became apparent with the commencement of the Human Genome Project in the 1990s. The project turned into a struggle between publically funded scientists and private companies. Publically funded scientists worked hard to ensure that all their research would remain in the public domain and therefore published all their findings to prevent patent applications blocking access to research. Their attempts were not always successful. For example, one day before Mike Stratton was due to publish his paper on cancer genes in the journal Nature in 1995, the private company Myriad Genetics applied for a patent on BRCA1 and BRCA2, which were associated with breast cancer. The patents allowed it to charge for tests at a cost of $2,500 per patient. Licences for the use of its simpler tests for breast cancer by other labs cost several hundred dollars per patient, a cost that, given the nature of the American healthcare system, meant the test was not available for all female patients in the USA. By 2015, Myriad was worth over $3bn (Pollock, 2018, p. 64). The leading patent offices, those in the USA, Europe and Japan, have granted thousands of patents claiming human DNA. Patent thickets have already emerged, with many of the sequences claimed in patents overlapping. For example, a gene with 15 exons could have a separate patent on each exon; there could be a claim on the complete sequence, as well as a claim on the promoter sequence. One illustration of the complexity of these overlapping patents is the difficulties encountered by researchers from the PATH foundation when they were trying to develop a malaria vaccine: they had to negotiate research use for the 39 different patents involved (Thomas et al., 2002). Thomas also points to the dangers of broad patents grants: ‘Furthermore, because the majority of patents covering DNA sequences are what are termed per se claims, the applicant, in making the first claim, gains the right to all uses, including those that are as yet undiscovered’ and ‘[a]n excessively broad patent that contains claims to all conceivable diagnostic tests creates a monopoly, such that there is little incentive to develop improved tests’ (Thomas et al., 2002, pp. 1186–1187). Some commentators are not convinced that patent monopolies have hindered follow-up research. Clark states that there is a lack of evidence that intellectual property protection measures have had a significant negative impact on academic biomedical research: ‘In the face of no empirical evidence, the myth that patents inhibit biomedical research, publication and dissemination of knowledge is promulgated’ (Clark, 2011, pp. 79–80). Caulfield et al. (2006), while acknowledging that there have been good reasons for concern, like Clark concludes ‘the feared problems have not widely manifested’. However, Caulfield et al.'s research does point to one important exception: gene patents that cover a diagnostic test. Patent owners have asserted exclusivity or licence terms ‘widely viewed as inappropriate’ (Caulfield et al., 2006;, pp. 1892–1893). The assertion of ‘no empirical evidence’ is certainly too strong. Examples of problematic access to fundamental technology do bubble to the surface. One such example is the position regarding zinc-finger proteins (ZFPs), which can bind almost all DNA sequences. The ZFP patent portfolio has been dominated by one firm in particular: Sangamo. Researchers found that Sangamo was highly selective in its choice of collaborators. Academic scientists therefore often took the risk of using the technology without a licence, hoping that Sangamo would not sue academics. However, even this did not solve the problem. The patents did not disclose all the necessary information. Vital knowledge remained in the Sangamo database and design rule set. Without this proprietary information scientists could not practice the claimed invention: ‘More complete patent disclosure might also have obviated the need to generate various open science alternatives to the Sangamo platform’ (Chandrasekharan et al., 2009). These examples should not be dismissed as ‘anecdotes’; they are important. They indicate that access by academics to fundamental research can be hampered. Nor do we know how many innovative start-ups or small firms have been hindered by blocking patents, too expensive licences, restrictive licence terms or threats of being sued for patent infringement. An assessment of the situation cannot be made simply by looking at litigated cases: litigated cases are always the tip of the iceberg. The pharmaceutical industry Pharma companies stress that medicinal drugs take years of research and development. The venture is also far from risk free: the drug may be a failure either because clinical trials fail, so approval is not given, or because it is not a commercial success. Based on a study at the Tufts Center, it has been estimated that the time needed for the development of a new drug, from initial stages through to approval, takes on average 11.8 years and will cost in the range of $802 million to $1.8 billion (DiMasi et al., 2003; Barazza, 2014). It is these costs, the industry argues, that justify the high price of the drugs. In a critique of the methodology used by the Tufts Center to explain a cost of $802 million, and the lack of public access to the data used for the study, Light and Warburton argue that such estimates should be treated with scepticism; these are ‘mythical costs’ to try to justify the high prices of drugs (Light and Warburton, 2011). What is clear is that if the drug survives the patent process and the authorisation process, and turns out to be a blockbuster, huge profits can be reaped. For example, the Danish company Lundbeck grew rapidly in the 1990s primarily because of its anti-depression drug, Citalopram. Citalopram alone accounted for around 80 per cent of the company's sales by the end of the twentieth century, with large sales figures for Europe and the USA at that time bringing in kr. 720 million.5 Similarly, Losec, a medicine for stomach ulcers, was so successful that it is estimated to have brought in between $15–30 billion for AstraZeneca, making AstraZeneca one of the largest global pharmaceutical companies (Granstrand and Tietze, 2014). Many pharmaceutical companies have not been reticent to exert their monopoly position to ensure market dominance and satisfy their investors. However, with some exceptions, a patent expires after 20 years. When the patent expires, the market for the drug opens up to generic drug companies. These generic drug manufacturers have not had to sustain the costs in development of the original brand manufacturers. This means that they can sell generic medicines considerably cheaper: on average 25% lower than the price of the brand drugs at the time of generic entry and 40% lower two years after entry. The share of the market by generic companies after two years is estimated at 45% (European Commission, 2009: paragraph 1560). It is not surprising, given the huge profits that a blockbuster drug can make for a company, that pharma companies will look to manipulate the patent system to prolong their market dominance. The brand name drug companies have various strategies they can employ. They can wrap many patents around the original patent, resulting in patent clusters. Patents are filed for certain specific aspects of a single product, such as dosing, delivery systems and combinations. For example, depending on the medicine, the medicine may come with a proprietary inhaler or injector that is integrated into the product. Yet these combinations will be patented separately. Consequently, even after all the patents on the medicine expire, the remaining patents on the associated device, or parts of the device, can be sufficient to prevent generic entry (Beall et al., 2016). The ‘evergreening’ strategy is a form of blocking mainly used in the pharmaceutical industry. As the patent system allows improvements and additions to be patented, inventions that are really just slight modifications of the old drug are patented. These secondary patents, usually filed just before the patent on the original drug expires and competition can start, each gain 20 years protection. The weaker patents are an attempt to prolong the patent protection of the original, much stronger patent. Although from the technical perspective only minor improvements may be involved, from an economic perspective these can be significant as patents for incremental improvement processes can be filed almost continually. Building and maintaining a patent network of new medical applications, improvements and substitutions is an effective evergreening strategy, also cutting down possibilities for ‘invent around’ attempts (Granstrand and Tietze, 2014). As Dwivedi et al. (2010, p. 324) notes: ‘While most of these evergreening strategies conform to the letter of the law, very often they seem to undermine the spirit in which patent laws were created’. Even when generic products do enter the market, patients will not always opt for the cheaper drug. Why? What should not be underestimated is the scope and intensity of the marketing campaigns of the brand name companies. Their aim is to ensure that patients switch to the second generation product by convincing them that the newer version is worth the extra money. Strategies include convincing marketing authorisation and pricing and reimbursement bodies, as well as doctors, that the generic product is less safe, less effective or of inferior quality (European Commission, 2009). Another major strategy used by brand name companies is the so-called ‘pay-for-delay’ practice. This practice was one of the concerns that prompted the European Commission to launch its enquiry into the pharmaceutical industry in 2008. In a ‘pay-for-delay’ agreement, a generic manufacturer agrees to delay entry to the market in exchange for a value transfer. Instead of the claimant brand name company demanding damages from the generic company for infringement of its existing secondary patents, in reverse payment settlements the one accused of infringement is the one receiving payment. The generic company is basically paid simply to keep out of the patent owner's market, often also agreeing not to challenge the validity of the claimant's (secondary) patents. The parties can reach a settlement by in effect sharing part of the monopoly profit, the consequence being that prices are kept high (Choi et al., 2014). Following the sector enquiry, the European Commission issued a number of decisions against brand name companies and those generic companies that had entered into agreements with them. In 2013, Lundbeck and four generic firms were fined €145 million, a decision confirmed by the General Court of the European Union in 2016: the agreement was per se illegal being a violation of EU competition law. Other pharma companies fined included Johnson & Johnson, Novartis and Servier. The Final Report by the European Commission observed: ‘The additional costs caused by delays to generic entry can be very significant for the public health budgets and ultimately the consumer.’ (European Commission, 2009, p. 1558). These ‘pay-for-delay’ agreements have also been challenged in the USA. The Federal Trade Commission (FTC) was of the opinion that these agreements were infringements of competition law and that ‘[a]lthough both the brand name companies and generic firms are better off with such settlements, consumers lose the possibility of earlier generic entry’.6 In the lawsuit the FTC brought against Actavis for agreeing to delay bringing its version of Solvay's AndroGel to market, the US Supreme Court did not categorise the agreement as per se illegal. It mandated that a ‘rule of reason’ approach should be used, reviewing such settlements on a case by case basis.7 The FTC has remained committed to scrutinising pay-for-delay agreements. The monopoly position has made it possible for pharma companies to charge high prices for their medicines. At times this has caused public outrage, particularly when the price of a drug rose considerably from one day to another. For example, the price of tablets containing the drug Daraprim, when acquired by Turing Pharmaceuticals, rose from $13.50 a tablet to $750 a tablet overnight, bringing the cost of treatment per annum for some patients to thousands of dollars. Cycloserine increased in price from $500 for 30 pills to $10,800 for 30 pills after it was acquired by Rodelis Therapeutics (Pollack, 2015). The high price of some medications has caused concern in Europe too. Governments struggle in their negotiations with pharma companies. In the Netherlands, the government has expressed its dissatisfaction with the current situation in a report. One of the problems highlighted in this report is the patent monopoly: Another important cause of high prices is the extensive protection manufacturers obtain on their patents. This process was originally intended to stimulate innovation, but is currently used by the industry to maintain a monopoly – and thereby a high price - on new medications for as long as possible. This has a significant impact on society: The way the pharmaceutical market works has led to innovation and new medicines which are extremely valuable for patients. But those patients, and in fact all Dutch people who pay insurance premiums, find themselves at a disadvantage because pharmaceutical companies have a monopoly when it comes to new medicines. Therefore, we need to seek a healthy balance between rewarding innovation and the affordability of medicinal care. (Ministry of Public Health, Welfare and Sport, the Netherlands, 2016: pp. 4, 13) The price of medicines has become a matter of critical importance even for wealthier countries. The pharmaceutical industry and developing countries However, perhaps the largest group of patients excluded from the potential benefits of biomedical research are those in developing countries. Exclusion can originate in the very choice of which drugs pharma companies decide to develop. Their research tends to be market orientated. By the end of the twentieth century, only about one per cent of newly developed drugs were for tropical diseases, such as African sleeping sickness, dengue fever and leishmaniosis (Maurer et al., 2004). Companies aim to make a profit and satisfy shareholders. It is therefore not surprising that expensive R&D will be more geared up to the types of illnesses prevalent in developed countries, as these countries have more capital resources to pay the price for these drugs. As Stiglitz (2006: p. 1279) observed: ‘Poor people cannot afford drugs, and drug companies make investments that yield the highest returns’. Not only does the choice of which drug is developed significantly impact on developing countries: the imposition of stringent requirements for intellectual property protection under the TRIPS agreement is also a factor in access to treatment. This was made explicit in the World Bank report: Nothing is more controversial in TRIPS. It is conceivable that patent protection will increase incentives for R&D into treatments for diseases of particular concern to poor countries. However because purchasing power is so limited in the poorest countries, there is little reason to expect a significant boost in such R&D. Accordingly, many developing countries see little potential benefit from introducing patents. In contrast, potential costs could be significant. (World Bank, 2001, p. 137) The Doha Declaration on the TRIPS Agreement in 2001 did confirm the right of countries to use compulsory licences to gain access to medicines. By issuing a compulsory licence, the government gives permission to a third party to produce the patented product or process without the consent of the patent owner. The drug so produced is much cheaper than the brand name drug at the monopoly price. This right has already been exercised on various occasions, for example by the South African authorities in 2003 in order to create more general access to AIDS medicines. Does compulsory licensing therefore deal with any negative impact of TRIPS for developing countries, given that TRIPS hindered the use of cheaper, domestic generic versions of brand name patented drugs? Compulsory licensing is not without undesirable side effects. It has the potential to reduce incentives for pharma companies to innovate, and for tensions between the government authorising the compulsory licences and the governments of the patentees, which can have both political and economic implications (Flynn et al., 2009; Reichman, 2009). There have been indications that the USA is not entirely at ease when states order compulsory licensing of American pharmaceuticals (Nagan et al., 2017). Compulsory licensing may be an instrument to alleviate the strictures of the patent system to some extent, but it is not the entire solution.

#### 3 impacts:

#### [1] 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.

#### [2] Ag biotech innovation key to keep up with food demands – regulatory failures undermine U.S. ag, 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).

#### Food shortage cause extinction

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Weapons of Mass Destruction Detonating just 50–100 out of the global arsenal of nearly 15,000 nuclear weapons would suffice to end civilisation in a nuclear winter, causing worldwide famine and economic collapse affecting even distant nations, as we saw in the previous chapter in the section dealing with South Asia. Eight nations now have the power to terminate civilisation should they desire to do so – and two have the power to extinguish the human species. According to the nuclear monitoring group Ploughshares, this arsenal is distributed as follows: – Russia, 6600 warheads (2500 classified as ‘retired’) – America, 6450 warheads (2550 classified as ‘retired’) – France, 300 warheads – China, 270 warheads – UK, 215 warheads – Pakistan, 130 warheads – India, 120 warheads – Israel, 80 warheads – North Korea, 15–20 warheads.11 Although actual numbers of warheads have continued to fall from its peak of 70,000 weapons in the mid 1980s, scientists argue the danger of nuclear conflict in fact increased in the first two decades of the twenty-first century. This was due to the modernisation of existing stockpiles, the adoption of dangerous new technologies such as robot delivery systems, hypersonic missiles, artificial intelligence and electronic warfare, and the continuing leakage of nuclear materials and knowhow to nonnuclear nations and potential terrorist organisations. In early 2018 the hands of the ‘Doomsday Clock’, maintained by the Bulletin of the Atomic Scientists, were re-set at two minutes to midnight, the highest risk to humanity that it has ever shown since the clock was introduced in 1953. This was due not only to the state of the world’s nuclear arsenal, but also to irresponsible language by world leaders, the growing use of social media to destabilise rival regimes, and to the rising threat of uncontrolled climate change (see below).12 In an historic moment on 17 July 2017, 122 nations voted in the UN for the first time ever in favour of a treaty banning all nuclear weapons. This called for comprehensive prohibition of “a full range of nuclear-weapon-related activities, such as undertaking to develop, test, produce, manufacture, acquire, possess or stockpile nuclear weapons or other nuclear explosive devices, as well as the use or threat of use of these weapons.”13 However, 71 other countries – including all the nuclear states – either opposed the ban, abstained or declined to vote. The Treaty vote was nonetheless interpreted by some as a promising first step towards abolishing the nuclear nightmare that hangs over the entire human species. In contrast, 192 countries had signed up to the Chemical Weapons Convention to ban the use of chemical weapons, and 180 to the Biological Weapons Convention. As of 2018, 96 per cent of previous world stocks of chemical weapons had been destroyed – but their continued use in the Syrian conflict and in alleged assassination attempts by Russia indicated the world remains at risk.14 As things stand, the only entities that can afford to own nuclear weapons are nations – and if humanity is to be wiped out, it will most likely be as a result of an atomic conflict between nations. It follows from this that, if the world is to be made safe from such a fate it will need to get rid of nations as a structure of human self-organisation and replace them with wiser, less aggressive forms of self-governance. After all, the nation state really only began in the early nineteenth century and is by no means a permanent feature of self-governance, any more than monarchies, feudal systems or priest states. Although many people still tend to assume it is. Between them, nations have butchered more than 200 million people in the past 150 years and it is increasingly clear the world would be a far safer, more peaceable place without either nations or nationalism. The question is what to replace them with. Although there may at first glance appear to be no close linkage between weapons of mass destruction and food, in the twentyfirst century with world resources of food, land and water under growing stress, nothing can be ruled out. Indeed, chemical weapons have frequently been deployed in the Syrian civil war, which had drought, agricultural failure and hunger among its early drivers. And nuclear conflict remains a distinct possibility in South Asia and the Middle East, especially, as these regions are already stressed in terms of food, land and water, and their nuclear firepower or access to nuclear materials is multiplying. It remains an open question whether panicking regimes in Russia, the USA or even France would be ruthless enough to deploy atomic weapons in an attempt to quell invasion by tens of millions of desperate refugees, fleeing famine and climate chaos in their own homelands – but the possibility ought not to be ignored. That nuclear war is at least a possible outcome of food and climate crises was first flagged in the report The Age of Consequences by Kurt Campbell and the US-based Centre for Strategic and International Studies, which stated ‘it is clear that even nuclear war cannot be excluded as a political consequence of global warming’. 15 Food insecurity is therefore a driver in the preconditions for the use of nuclear weapons, whether limited or unlimited. A global famine is a likely outcome of limited use of nuclear weapons by any country or countries – and would be unavoidable in the event of an unlimited nuclear war between America and Russia, making it unwinnable for either. And that, as the mute hands of the ‘Doomsday Clock’ so eloquently admonish, is also the most likely scenario for the premature termination of the human species. Such a grim scenario can be alleviated by two measures: the voluntary banning by the whole of humanity of nuclear weapons, their technology, materials and stocks – and by a global effort to secure food against future insecurity by diverting the funds now wasted on nuclear armaments into building the sustainable food and water systems of the future (see Chapters 8 and 9). Climate Change The effects of food and war on climate change as it is presently predicted to occur were described in Chapter 3: in brief, the stable climate in which agriculture arose over the past 6000 years is now becoming increasingly unstable as a result of the billions of tonnes of carbon that humans are injecting into the atmosphere and oceans, forming a colossal heat engine to drive more frequent, violent weather. This in turn impairs food production in regions of the world already facing severe stresses from population growth and resource depletion. Military analysts describe climate change as a ‘threat multiplier’, augmenting the tensions, conflict and instability which already exist. In reality it is a feedback loop, in which worsening climate conditions cause greater food insecurity, which is met by measures (like increased land clearing and use of fossil fuels and chemicals), which in turn worsen climate conditions, which worsen food security, which cause wars, which inflict more eco-damage... Two degrees (2 C) of global warming – described as the danger point for humanity – are predicted to occur well before 2050 because of our collective failure to curb our carbon emissions.16

#### [3] Monopolies powered by patent law cause 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.