# 1AC

### Framing

#### I value morality.

#### The standard is minimizing material violence.

**[1] Actor Spec— States must use util. Any other standard dooms the moral theory**

#### Goodin 90.

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

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

**[2]Pleasure and pain are the starting point for moral reasoning—they’re our most baseline desires and the only things that explain the intrinsic value of objects or actions**

#### Moen 16,

Ole Martin (PhD, Research Fellow in Philosophy at University of Oslo). "An Argument for Hedonism." Journal of Value Inquiry 50.2 (2016): 267 Let us start by observing, empirically, that **a widely shared judgment about intrinsic value** and disvalue **is that pleasure is intrinsically valuable and pain is intrinsically disvaluable**. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for **there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels**, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” **are** here **understood inclusively**, as encompassing anything hedonically positive and anything hedonically negative. 2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, **I might ask: “What for**?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. **The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good**. 3 As Aristotle observes: “**We never ask** [a man] **what** his **end is in being pleased, because we assume that pleasure is choice worthy in itself**.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that **if something is painful, we have a sufficient explanation of why it is bad**. If we are onto something in our everyday reasoning about values, it seems that **pleasure and pain are both places where we reach the end of the line in matters of value. Although pleasure and pain thus seem to be good candidates for intrinsic value and disvalue**, several objections have been raised against this suggestion: (1) that pleasure and pain have instrumental but not intrinsic value/disvalue; (2) that pleasure and pain gain their value/disvalue derivatively, in virtue of satisfying/frustrating our desires; (3) that there is a subset of pleasures that are not intrinsically valuable (so-called “evil pleasures”) and a subset of pains that are not intrinsically disvaluable (so-called “noble pains”), and (4) that pain asymbolia, masochism, and practices such as wiggling a loose tooth render it implausible that pain is intrinsically disvaluable. I shall argue that these objections fail. Though it is, of course, an open question whether other objections to P1 might be more successful, I shall assume that if (1)–(4) fail, we are justified in believing that P1 is true itself a paragon of freedom—there will always be some agents able to interfere substantially with one’s choices. The effective level of protection one enjoys, and hence one’s actual degree of freedom, will vary according to multiple factors: how powerful one is, how powerful individuals in one’s vicinity are, how frequent police patrols are, and so on. Now, we saw above that what makes a slave unfree on Pettit’s view is the fact that his master has the power to interfere arbitrarily with his choices; in other words, what makes the slave unfree is the power relation that obtains between his master and him. The difﬁculty is that, in light of the facts I just mentioned, there is no reason to think that this power relation will be unique. A similar relation could obtain between the master and someone other than the slave: absent perfect state control, the master may very well have enough power to interfere in the lives of countless individuals. Yet it would be wrong to infer that these individuals lack freedom in the way the slave does; if they lack anything, it seems to be security. A problematic power relation can also obtain between the slave and someone other than the master, since there may be citizens who are more powerful than the master and who can therefore interfere with the slave’s choices at their discretion. Once again, it would be wrong to infer that these individuals make the slave unfree in the same way that the master does. Something appears to be missing from Pettit’s view. If I live in a particularly nasty part of town, then it may turn out that, when all the relevant factors are taken into account, I am just as vulnerable to outside interference as are the slaves in the royal palace, yet it does not follow that our conditions are equivalent from the point of view of freedom. As a matter of fact, we may be equally vulnerable to outside interference, but as a matter of right, our standings could not be more different. I have legal recourse against anyone who interferes with my freedom; the recourse may not be very effective—presumably it is not, if my overall vulnerability to outside interference is comparable to that of a slave— but I still have full legal standing.68 By contrast, the slave lacks legal recourse against the interventions of one speciﬁc individual: his master. It is that fact, on a Kantian view—a fact about the legal relation in which a slave stands to his master—that sets slaves apart from freemen. The point may appear trivial, but it does get something right: whereas one cannot identify a power relation that obtains uniquely between a slave and his master, the legal relation between them is undeniably unique. A master’s right to interfere with respect to his slave does not extend to freemen, regardless of how vulnerable they might be as a matter of fact, and citizens other than the master do not have the right to order the slave around, regardless of how powerful they might be. This suggests that Kant is correct in thinking that the ideal of freedom is essentially linked to a person’s having full legal standing. More speciﬁcally, he is correct in holding that the importance of rights is not exhausted by their contribution to the level of protection that an individual enjoys, as it must be on an instrumental view like Pettit’s. Although it does matter that rights be enforced with reasonable effectiveness, the sheer fact that one has adequate legal rights is essential to one’s standing as a free citizen. In this respect, Kant stays faithful to the idea that freedom is primarily a matter of standing—a standing that the freeman has and that the slave lacks. Pettit himself frequently insists on the idea, but he fails to do it justice when he claims that freedom is simply a matter of being adequately (and reliably) shielded against the strength of others. As Kant recognizes, the standing of a free citizen is a more complex matter than that. One could perhaps worry that the idea of legal standing is something of a red herring here—that it must ultimately be reducible to a complex network of power relations and, hence, that the position I attribute to Kant differs only nominally from Pettit’s. That seems to me doubtful. Viewing legal standing as essential to freedom makes sense only if our conception of the former includes conceptions of what constitutes a fully adequate scheme of legal rights, appropriate legal recourse, justiﬁed punishment, and so on. Only if one believes that these notions all boil down to power relations will Kant’s position appear similar to Pettit’s. On any other view—and certainly that includes most views recently defended by philosophers—the notion of legal standing will outstrip the power relations that ground Pettit’s theory.

### 1AC – Adv: Innovation

#### Innovation’s declining – increasing complexity, mediocre research and patents, and balkanization from university patents

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While Milton (1966, 15) assumed that research productivity per technical person increased at the same time as did costs – “[t]he augmentation by machines, for example, has increased the productivity of the average technical man-year to an unmeasured degree” – this turned out not to be the case. Rates of research and innovation productivity – investments, patents, papers and innovations per technical person as well as health, agricultural and other gains per paper and invention – declined even while investments increased. As Rescher (1978, 87) summarized, “the rapidly – indeed exponentially – increasing pace of effort-investment tends to mask the fact that the volume of high-quality returns per unit investment is apparently declining.” Earlier data regarding patent filings illustrated the problem of declining productivity. As early as 1936, Sanders (1936) concluded that, based on data between 1834 and 1934, while the number of patents per capita increased in the transition from an agricultural to an industrial economy, the rate of patenting seemed “to reach a constant level, or even show some drop” once industrialization took hold. Studies in the 1950s and 1960s refined Sanders's analysis by looking at patents against the number of technical workers rather than the entire population. Schmookler (1954) found that, despite an absolute increase in patent applications between 1870 and 1940, the number of patent applications per technical worker declined. Machlup (1962) found a similar decline between 1941 and 1958. Hausman et al. (1981) determined, based on patent and research and development data from 1968–1974, that firms suffered from a declining ability to translate their R&D investments into patents. Examining a variety of measures of productivity and innovation – GDP, education spending, as well as patents – Huebner (2005, 984) calculated that the US rate of innovation has been declining since 1916. Jones (2002, 220) noted that, despite the fraction of US STEM workers in the population increasing threefold (from 0.25 percent to 0.75 percent) between 1950 and 1993, “the growth rate of U.S. per capita GDP has been surprisingly stable.” Because infinitely increasing the number of STEM workers is unsustainable, he concluded, growth due to technology “must come to an end” (C. I. Jones 2002, 235). Total factor productivity (TFP) – the principal, if imperfect, measure of the pace of innovation and technical progress – peaked in 1940–1950 and has been steadily declining since, with a slight but short-lived increase between the mid 1990s and mid-2000s (Gordon 2016, 547; Griliches 1998; Field, 2006). Looking at similar data, Boniatu argued that “the U.S. economy seems to have reached its first threshold of mutation – and hence entered a phase of diminishing returns on innovation – in the thirties” (Bonaiuti, 2018, 1806). Bloom et al. (2020) conducted one of the most comprehensive studies documenting declining productivity since 1965. They compared economic outputs to investments made in research and development at both the macro and micro levels, and found the same phenomenon: research productivity was in systemic decline. At the macro scale, they measured economic output due to innovation in terms of TFP: “We find that research productivity for the aggregate U.S. economy has declined by a factor of 41 since the 1930s, an average decrease of more than 5% per year” (Bloom et al., 2020, 1105). At the micro level, whether measuring productivity in terms of yield rates for agricultural products, new drugs placed on the market, years of life saved from cancer or heart disease per publication or clinical trial, or chip density for computer chips, they uniformly found a drop. Lest one object that Bloom et al.’s findings only apply to older technologies, in which firms are plumbing the depths of a decreasing potential pool of innovations, Strumsky et al. (2010a, 503) examined new fields of technology, such as solar and wind technology, biotechnology and nanotechnology, where “simpler, basic discoveries can still routinely be made,” yet found a similar decline in productivity as in older fields. Based on their empirical analysis, they concluded that “in industrial economies there may no longer be increasing returns in newer sectors to offset diminishing returns in older ones” (Strumsky et al., 2010, 504). A recent study by Pammolli et al. (2020) suggests that the pharmaceutical industry has seen increased productivity since the early 2000s. This study used, however, a different measure of productivity than other studies in the field: attrition rates of drugs during clinical trials. While the authors found a drop in attrition rates, this may have been due to changes in the regulatory environment that relied increasingly on surrogate end-points5 of dubious value (Chen et al., 2020; Darrow et al., 2020) rather than on a real productivity gain. It is thus difficult to know whether their finding of increased productivity in the pharmaceutical industry is real or is simply a result of regulatory changes. 2.3. A divergence over patent data There is one notable exception in the empirical data on the productivity decline: from 1985 to 2013, the US went through a patent explosion. While patent applications per STEM worker were roughly stable between 1965 and 1985, domestic patent applications per STEM worker almost doubled (1.88)6 between 1985 and 2011. In a similar break with history, the number of domestic patent applications per research dollar more than doubled (2.13) between 1985 and 2013.7 This large upsurge in patenting led Gordon (2016, 567) to state that “[t]here is no debate about the frenetic pace of innovation activity, particularly in the spheres of digital technology, including robots and artificial intelligence.” There is, however, good reason to doubt this apparent frenetic pace of innovation between 1985 and 2013 (Gallini 2002). Kortum and Lerner (1999) argued that the patent upsurge was likely due to firms adopting better management or automation of the innovation process rather than increased innovation. Hall (2004) attributed the upsurge to strategic behavior by firms in complex product industries where products depend on multiple and broadly held patents. Rather than acquiring patents to protect key innovations, these players acquired large portfolios of patents “even those of dubious quality, that is, even those that they have no intention of enforcing” to attract venture capital to early-stage firms (Hall, 2004, 18). An empirical study by Danguy et al. (2014, 561) similarly concluded that strategy, rather than innovation, was driving global patent rate increases: “[T]he ‘global patent warming’ that is currently underway is essentially the result of the internationalization of patent applications and not a consequence of increased research productivity.” As the above summarizes, the patent explosion that began in the 1980s appears more due to a change in intellectual property management strategy than to effiency of the innovation system. Combined with the data on increasing costs and decreasing productivity, the evidence is strong that we are witnessing an innovation system that is growing less effective in creating wealth and social benefit. This decline has consequences, as I next examine: more risk adverse behavior that signals even greater future decline. 2.4. Increasing risk adverse research and innovation behavior Starting in the 1950s, both firms and academic researchers narrowed the scope of their research and innovation efforts, preferring safer rather than more novel innovations (Strumsky et al., 2011). This occurred at approximately the same time as research and innovation costs ratcheted up, leading to the hypothesis that firms faced with increasing costs decided to reduce their risk by taking on less innovative research. Akcigit et al. (2013b, 4) reasoned that more high risk “ideas are costly to pursue, so inventors focus on reuse/refinements.” On the industrial front, Youn et al. (2015, 6) found that “the proportion of technological combinations (that is, inventions) that are ‘narrow’ began to increase and currently stands at about 50%.” Clancy (2017b) similarly found that “US patents have made increasingly less novel connections among technological constituents since the 1950s.” Similarly, Krieger et al. (2018, 4) documented “a decline in innovativeness of small molecule drugs over time” through their examination of investigational drug databases. Fojo et al. (2014, E7) attribute this decline to a desire to reduce the riskiness of earnings. They concluded that while a breakthrough, if successful, would lead to higher long-term earnings, if this “strategy is so risky that investors lose confidence and sell their shares,” they would suffer a drop in stock price. This complements the finding by Arora et al. (2015, 2, 5) that “large firms are withdrawing from investing in science internally and focusing more on development,” “leaving universities and small firms to generate new ideas.” On the academic side, Edwards et al. (2011) demonstrate how firms and researchers continued to explore the same limited set of research targets while ignoring most targets. For example, they found that 65% of 2009 publications focused on the same 10% of proteins as had been copiously studied between 1950 and 2002. As a result, they concluded that “[m]uch of the work that has emerged from exploring the human genome over the past ten years lies fallow” (Edwards et al., 2011, 165), a significant inefficiency in the system. Similarly, Stoeger et al. (2018, 7) found that “while biomedical research does focus on important genes, a disproportionally high amount of research effort concentrates on already well-studied genes.” Using machine learning techniques, they determined that this conservative selection of research targets meant that “even highly promising genes that could already be studied by current technologies remain ignored” (Stoeger et al., 2018, 10). On the other hand, Pammolli et al. (2020) document an increase in the novelty of pharmaceutical innovation based on two factors: the indication for the drug and its mechanism of action (i.e. its biological target). One possible explanation for this result is that declining regulatory standards reduced innovator risk, adjusting their cost-benefit analysis to support their pursuit of higher-risk research. Alternatively, lower regulatory standards may have led to higher cost medicines with no superior efficacy or safety replacing older, less expensive, medicines (Saluja et al., 2018). This would result in more expensive and less effective medicines entering the market, doing little to increase the efficiency of the innovation system. Go to: 3. Explanations for the decline The question left open from these observations is why, contrary to Milton's beliefs, research productivity has been declining. The literature offers three explanations for this decline: 1) with time, science becomes more costly, requiring greater investments to produce the same level of result; 2) science and science funding is skewing toward mediocrity, including through a misalignment of incentives for researchers and for firms; and 3) increasing reliance on early-stage, university, patenting has led to a balkanization of efforts. I examine each in turn. 3.1. Complexity in science Rescher (2014) has long argued that science is both more expensive and less productive because the questions we pose are increasingly complex. He reasoned that scientists solved the easy problems early on. As science progressed, the difficulty of extracting knowledge – with an increased need for technology, energy and staff – grew. He concluded that “the increasing resource requirement for digging into ever deeper layers of complexity is such that successive triumphs in our cognitive struggles with nature are only to be gained at an increasingly greater price” (Rescher 2014, 64). Weitzman (1998, 333) agreed, suggesting “that the ultimate limits to growth may lie not so much in our abilities to generate new ideas, as in our abilities to process to fruition an ever-increasing abundance of potentially fruitful ideas.” B. F. Jones (2009) examined one aspect of this complexity: the ability to absorb and deploy an ever-richer set of scientific knowledge. As science progressed and required greater knowledge, he hypothesized that scientists would deploy a combination of three strategies: 1) individual researchers would need to absorb more knowledge, delaying when they began their careers; 2) researchers would become more specialized; leading to 3) the need for larger teams. Using U.S. inventor data from 1975 to 1999, he found: “an upward trend in team size that is both general and steep”; an average increase of age of first invention of 0.66 years per decade across all fields; and a 6% increase in specialization per decade. Similarly, Levitt and Levitt (2017) found that the age of scientists winning their first grants from the National Institutes of Health increased from about 36 to 44 years between 1980 and 2011. It is certainly true that some new technologies, such as CRISPR-Cas9 (Doudna and Charpentier, 2014), greatly simplify research and require less expensive technology. Nevertheless, as discussed in 2.2, Strumsky et al. (2010a, 503) found decreasing rates of productivity in new fields generally, including in biotechnology, solar, wind and nanotechnology. Thus, while there are cost-saving new technologies – with even significant savings – the overall trend toward higher costs appears to hold. Following Rescher and others, the problem seems to lie more in the way we organize science and innovation – the institutions, models of organization, use of intellectual property rights, etc. – than the complexity of the questions researchers investigate. 3.2. Mediocrity and misalignment Tainter proposed a second reason for decreasing productivity in the face of increasing costs: that research trends toward mediocre, middle of the road, and non-disruptive science and away from high-risk, breakthrough explorations. Tainter's argument, building on that of de Solla de Solla Price, 1986, 92), was that the average scientist today is of a lesser quality than that of yesterday due to the greater expansion in the number of researchers (Tainter, 1988). Indeed, between 1950 and 1993, C. I. Jones (2002, 220) found that the fraction of STEM researchers in the US tripled. While Tainter argues that this extra mass of researchers dilutes the effect of extraordinary scientists, there is no evidence to support this and seems to buy into a biased understanding of assessing quality (Kaatz et al., 2016; Wang et al., 2017). It further ignores the reality that the era of the lone scientist has given way to team science (B. Uzzi et al., 2013). Mediocrity comes in various guises, however. To render the concept more objective, and thus tractable, we can interpret mediocrity to mean a trend toward average, rather than exceptional, creativity. The literature on creativity and its component parts has grown over the decades (Amabile, 1983). In particular, Lee et al. (2015) identified two aspects of creativity that apply to scientific outputs: impact and novelty. A decline in research impact may help explain the cost and productivity problem. As Lee et al. (2015, 695) noted, impact is “realized through a social process interacting with the community and is therefore ultimately an ex post and subjective judgment” of the value of research. With this in mind, we can ask whether the incentives (and discentives) universities and firms establish to encourage teams to innovate lead to less productive outcomes. Specifically, do these incentives lead teams to expend ever more resources to obtain fewer innovations or innovations that offer ever lower productivity gains in health, the environment or the economy? Assessing real impact – the effect of a journal publication or innovation on changing real world outcomes – is difficult so both universities and firms measure something else: impact factor for universities and patent applications for firms. Neither captures impact fully, setting up perverse incentives. Universities and funding councils generally assess academic impact through citation analysis (McKiernan et al., 2019), not on the basis of the direct impact an artifact has on health or the economy. Because of the assumption that the more a paper is cited, the more important and, hence, novel it is, universities and funding councils only peripherally assess real impact. Wang et al. (2017, 1417) find, however, that the assumption that impact measures novelty is wrong. They conclude that more novel papers are actually less likely to be published in high Impact Factor journals – journals with a high average number of citations. They attribute this conclusion, in part, to the fact that novel papers take longer – more than 5 years – to achieve a high number of citations. As Journal Impact Factor is calculated on the basis of citations to articles published in that journal over only the previous two years (Garfield, 1999), the calculation ignores the higher long-term impact of novel articles. Given the two-year window for assessing impact, journals focus on publishing papers that generate short-term impact as they obtain no advantage from a paper with only a long-term impact. At the same time, academic researchers focus on publishing papers that generate short-term citations, even at the expense of novelty. Given how much weight peer review committees place on Journal Impact Factor, Wang et al. (2017, 1425) argue that there is a bias against novelty that applies “not only to funding decisions but to science policy more generally.” Because of this bias, “competitive selection procedures encourage relatively safe projects, which exploit existing knowledge, at the expense of novel projects that explore untested approaches” (Wang et al., 2017, 1416). Bhattacharya and Packalen (2020b, 17) concur, arguing that “[p]eer reviewers—a conservative lot if there ever was one—abet this tendency since grant applicants can credibly reassure them the proposed work is likely to produce visible, if marginal, successes.” Both Rzhetsky et al. (2015, 14,572) and Packalen and Bhattacharya (2018) give empirical support to this argument. Analysing millions of biomedical papers over a 30-year period, Rzhetsky et al. found that most researchers pursue conservative, low-risk, strategies, focusing on well-known molecules and “rarely wander far across the knowledge network or bridge disconnected chemicals.” This is exacerbated by the scarcity of funding opportunities that encourage risk-taking (Azoulay et al., 2011). Industry also leans towards lower impact research. In the pharmaceutical field, Fojo et al. (2014, E9) argue that “the rapidly rising cost of cancer therapies, the regulations governing their adoption by public and private insurers, and the increasing economic risk of drug development have had the unintended consequence of stifling progress by diverting enormous amounts of time, money, and other resources toward therapeutic indications that are arguably marginal.” More broadly, Strumsky et al. (2011) found that commercially-oriented researchers increasingly turn toward exploiting existing knowledge to generate small improvements rather than undertake riskier research that would expand product development in new directions. They speculate that researchers do so “[u]nder pressure to generate patents in copious amounts” (Strumsky et al., 2011, 8). This was particularly true during the patent explosion that started around 1985, discussed earlier at 2.3. Feldman (2018) documents that, between 2005 and 2015, pharmaceutical firms focused more on protecting past drugs through additional patents than on discovering new medicines. Due to strategic uses of patent law, “there is a complete undermining of the system for pharmaceutical innovation as the repeated addition of protections, one after another, pushes competition further into the future, threatening innovation in the process” (Feldman, 2018, 639). For both industry and universities, the incentives they provide to encourage impact actually decrease novelty and have little to do with real world impact. There is thus a deep misalignment between incentives and innovation, leading to lower novelty. 3.3. Balkanization through university intellectual property The economics literature is frustratingly in no better position today than it was in the 1950s to answer the question of whether patents increase or decrease overall innovation (William, 2017; Gallini, 2017; Sampat and Williams, 2018; Hall, 2019). Further, there is evidence that, while intellectual property and economic growth are correlated, the direction of causation may be from growth to higher levels of intellectual property protection, mediated by politics, rather than from intellectual property to growth (Morin and Gold, 2014; Gold et al., 2019). We do know that certain industries have constructed themselves around the availability of patents and hence incumbents remain dependent on them (Hall and Harhoff, 2012; Galasso and Schankerman, 2015). These industries include the chemical, pharmaceutical and biopharmaceutical industries. We also know that the availability of patents shapes the fields and nature of innovation, even if their effect on overall levels of innovation is uncertain (Moser, 2013). We have increasing evidence concerning the effect of university-held patents on innovation, although the literature is not yet conclusive. On the positive side, there are certainly technologies that emerged from universities through patenting into socially valuable innovations (Hockstad et al., 2017; Allard et al., 2018; Reinhart, 2020). Some of these relied on patents as a key instrument used to attain those benefits (Bremer et al., 2009). Further, Walsh et al. (2003) point out, using interview data, that broadly licensed university biotechnology research tools – such as PCR and recombinant DNA methods – impose relatively small extra costs and delays. On the negative side, university patents impose a number of transaction costs, whether through decreased freedom-to-operate (Gaessler et al., 2019) or through increased university patenting – documented by Bremer et al. (2009) – that entails not only the direct costs of obtaining a patent but accompanying litigation and negotiation costs. One must also be mindful that the benefits of university patenting are tempered by three factors. First, as Williams (2010) demonstrated, increased costs of accessing knowledge decreases the level of follow-on use of that knowledge. Second, the fact that universities used patents as a mechanism to transfer inventions to the private sector does not imply that the private sector could not have obtained the inventions through other mechanisms as efficienly. For example, a firm working in concert with a non-patenting university could develop and patent its own invention based on the collaboration. This is what occurred when Celgene acquired a patent over a drug directly building on previous unpatented research done in collaboration with the Structural Genomics Consortium (“The Ontario Institute for Cancer Research and the Structural Genomics Consortium Develop and Give Away New Drug-like Molecule to Help Crowd-Source Cancer Research” n.d.). Beyond this, universities have under-explored alternative intellectual property regimes – such as regulatory data protection – that provide fewer restrictions on use of the invention than do patents. Third we do not – and may never truly – know the quantity of university-originated innovations that would have come about but never materialized because of lack of freedom to operate, the threat of patent litigation from universities or their licensees (Gold and Carbone, 2010), restrictive licensing, or delays caused by negotiations over patents. Thus, one needs to temper assertions that the absence of university patents “would inevitably slow the development and reduce the availability of new treatments and vaccines” (Reinhart, 2020) with the reality that the empirical literature is mixed at best. Still, it is quite plausible that, in the absence of university patents, certain technologies would either be delayed or (less plausibly) never developed. On the other hand, the empirical literature also suggests that in the presence of those patents, other technologies are likely delayed or never developed. It is thus unsurprising that the literature suggests that the move to university-owned and controlled patents, accelerated, in part, through the 1980 Bayh-Dole Act (Mowery et al., 2001), did not demonstrably achieve either of the two overarching goals of the practice: to increase the level of innovation in the economy and to increase revenue gains for universities (Eisenberg and Cook-Deegan, 2018; Ouellette and Tutt, 2020; Corredoira et al., 2019). There are several reasons put forward to explain why a university patenting strategy has not had the desired results, including decreased downstream development and upstream duplication (Egelie et al., 2019), increased difficulty and delays in establishing contractual relationships with university technology transfer offices (Dahlborg et al., 2017; Hertzfeld et al., 2006; Kira R. Fabrizio, 2006), lack of university expertise and market knowledge (Swamidass and Vulasa, 2009), delayed dissemination and uptake of results (Williams, 2013; Fabrizio, 2009; Kira, 2006; West, 2006), perverse university incentive structures (Ouellette and Tutt, 2020; Eisenberg and Cook-Deegan, 2018) and the use of university patents to sue firms that have developed products without the aid of university patents (Eisenberg and Cook-Deegan, 2018, 82; Rooksby, 2011). Other forms of intellectual property rights, notably trade secrets (Williams, 2013; Gallini, 2017; Sampat and Williams, 2018) and university contractual relations (Walsh et al., 2005) also reduce the subsequent use of knowledge. Secrecy leads to data silos that hamper further research, especially when combined with privacy and informed consent rules (Rai, 2017). Negotiations over intellectual property rights with universities create complexity and thus either delay or result in the failure to reach a deal (Hertzfeld et al., 2006; Kira R. Fabrizio, 2006). In summary, the argument in favor of Bayh-Dole is mixed at best. There exist reasons to believe that not only do university-held patents, but other forms of intellectual property such as trade secrets, increase the costs of both current research efforts – through delay in establishing research collaborations – and future research. Whatever benefits that may arise from university patenting are likely outweighted by the balkanization of knowledge that they create. 3.4. Summary While none of the three explanations explored above – increased complexity, misaligned incentives, and knowledge silos protected by intellectual property – may alone explain the increasing inefficiency of the innovation system to create wealth and attain socially beneficial innovations, together they threaten the logic of the status quo approach to innovation policy. In the short-term, governments can only maintain current levels of innovation through increasingly large injections of resources. Meanwhile, at the individual and firm level, actors continue to move away from risk, toward less radical and less productive innovation. Consumers, patients and firms seeking productivity gains through innovation will see declining benefit from them both in terms of quality of life and economic growth. Measures of innovation based on patents and impact factors may rise, but these are illusions caused by strategic behavior rather than increased productivity. With declining economic productivity and declining rates of socially beneficial innovations, at some point governments may no longer be willing to fund research and development. With firms increasingly unwilling to fund the development of the basic knowledge to spur innovation, the result could very well be a further, steeper, decline in the efficiency of the innovation system.

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

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

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

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

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

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

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

#### That fuels monopolies stifling innovation.

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

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

#### 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.

#### Four 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] Pharma is key to biotech

Garth JS Cooper 6, independent medical scientist at the University of Auckland, “Fates Intertwined,” March 2006, <https://library.wur.nl/WebQuery/file/cogem/cogem_t4505194e_001.pdf>

Biotechnology and pharmaceuticals are inextricably intertwined. Although biotech companies often rely upon the resources of larger pharma companies, the converse is also true. Among other things, biotechs require funding, validation, and access to expertise and markets. Big pharma continues to need ideas and products, and places to outsource risk. The pharmaceutical industry faces uncertainties driven by falling innovation 1,2, its relevance to reducing the global burden of disease , and the equity of access to its products3. If biotechs are not embraced by pharma—they cannot be copied —then as competitors they will increasingly come to dominate the industrial nexus. The issues of both industries need to be addressed together. Apart, biotech and pharma will continue to struggle with the self-determining issues that they currently confront. Working together, the fabric of these industries will be transformed and the world of human therapeutics will flourish.

#### Biotech collapse wrecks the economy

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

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

#### Economic decline causes global war---the current confluence of tech disruption, nationalism, polarization, and declining multilat make escalation likely

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The next economic crisis is closer than you think. But what you should really worry about is what comes after: in the current social, political, and technological landscape, a prolonged economic crisis, combined with rising income inequality, could well escalate into a major global military conflict. The 2008-09 global financial crisis almost bankrupted governments and caused systemic collapse. Policymakers managed to pull the global economy back from the brink, using massive monetary stimulus, including quantitative easing and near-zero (or even negative) interest rates. But monetary stimulus is like an adrenaline shot to jump-start an arrested heart; it can revive the patient, but it does nothing to cure the disease. Treating a sick economy requires structural reforms, which can cover everything from financial and labor markets to tax systems, fertility patterns, and education policies. Policymakers have utterly failed to pursue such reforms, despite promising to do so. Instead, they have remained preoccupied with politics. From Italy to Germany, forming and sustaining governments now seems to take more time than actual governing. And Greece, for example, has relied on money from international creditors to keep its head (barely) above water, rather than genuinely reforming its pension system or improving its business environment. The lack of structural reform has meant that the unprecedented excess liquidity that central banks injected into their economies was not allocated to its most efficient uses. Instead, it raised global asset prices to levels even higher than those prevailing before 2008. In the United States, housing prices are now 8% higher than they were at the peak of the property bubble in 2006, according to the property website Zillow. The price-to-earnings (CAPE) ratio, which measures whether stock-market prices are within a reasonable range, is now higher than it was both in 2008 and at the start of the Great Depression in 1929. As monetary tightening reveals the vulnerabilities in the real economy, the collapse of asset-price bubbles will trigger another economic crisis – one that could be even more severe than the last, because we have built up a tolerance to our strongest macroeconomic medications. A decade of regular adrenaline shots, in the form of ultra-low interest rates and unconventional monetary policies, has severely depleted their power to stabilize and stimulate the economy. If history is any guide, the consequences of this mistake could extend far beyond the economy. According to Harvard’s Benjamin Friedman, prolonged periods of economic distress have been characterized also by public antipathy toward minority groups or foreign countries – attitudes that can help to fuel unrest, terrorism, or even war. For example, during the Great Depression, US President Herbert Hoover signed the 1930 Smoot-Hawley Tariff Act, intended to protect American workers and farmers from foreign competition. In the subsequent five years, global trade shrank by two-thirds. Within a decade, World War II had begun. To be sure, WWII, like World War I, was caused by a multitude of factors; there is no standard path to war. But there is reason to believe that high levels of inequality can play a significant role in stoking conflict. According to research by the economist Thomas Piketty, a spike in income inequality is often followed by a great crisis. Income inequality then declines for a while, before rising again, until a new peak – and a new disaster. Though causality has yet to be proven, given the limited number of data points, this correlation should not be taken lightly, especially with wealth and income inequality at historically high levels. This is all the more worrying in view of the numerous other factors stoking social unrest and diplomatic tension, including technological disruption, a record-breaking migration crisis, anxiety over globalization, political polarization, and rising nationalism. All are symptoms of failed policies that could turn out to be trigger points for a future crisis. Voters have good reason to be frustrated, but the emotionally appealing populists to whom they are increasingly giving their support are offering ill-advised solutions that will only make matters worse. For example, despite the world’s unprecedented interconnectedness, multilateralism is increasingly being eschewed, as countries – most notably, Donald Trump’s US – pursue unilateral, isolationist policies. Meanwhile, proxy wars are raging in Syria and Yemen. Against this background, we must take seriously the possibility that the next economic crisis could lead to a large-scale military confrontation. By the logic of the political scientist Samuel Huntington , considering such a scenario could help us avoid it, because it would force us to take action. In this case, the key will be for policymakers to pursue the structural reforms that they have long promised, while replacing finger-pointing and antagonism with a sensible and respectful global dialogue. The alternative may well be global conflagration.

#### [3] 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 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 Those 2 C of warming portend bad things for any food system that depends on the weather – but just how bad cannot easily be forecast as both the climate state and the response of the global food system are governed by human behaviour, which is fairly unpredictable. Current estimates suggest crop losses of the order of 20–50 per cent at the very time we are trying to raise food output by 50–70 per cent. What can be confidently predicted, however, is that there will be an increase in both the frequency and scale of harvest failures and agricultural disease outbreaks around the world as we approach the mid century – and that beyond 2 C of warming it will become very hard indeed to maintain a stable outdoors, agriculture-based system to meet an anticipated doubling in world demand for food by the 2060s. The ‘worst case’ risk of this, as previously outlined, would be ten billion people having to subsist on enough food to feed only four billion. That, however, is by no means the worst case of the climate story. There are ominous signs that humans have already unleashed planetary forces over which we have absolutely no control – and that these, should they become large enough, will take charge of the Earth’s climate engine and drive it into a superheated condition of +9–10 C or even higher. Today, more people are aware that global warming may lead to complete melting of all glaciers and the polar ice-caps, thereby raising sea levels by 65 metres and inundating almost all of the world’s seaboard cities, fertile river deltas and coastal plains.17 This would clearly have a devastating effect on coastal food production. However, this process will probably take several centuries, allowing populations ample time to relocate inland. That sea levels previously rose by a similar quantum at the end of the last Ice Age, flooding part of Australia, severing Britain from Europe and America from Asia, is proof enough that such events occur as a regular part of the Earth’s warming and chilling cycles. The great existential threat to humanity lies in vast stores of frozen methane gas (CH4) locked into the soils of the tundra regions of Canada and Siberia, in colossal deposits of frozen methane on the continental seabed surrounding the Arctic Ocean, and in massive stores of methane submerged in peat deposits and swamps in places such as the Amazon and the wet tropical forests of Southeast Asia and Africa. Methane is a gas with 20–70 times the climate-forcing power of carbon dioxide. These deposits are the accumulation of the slow decomposition of planet and animal matter in the Earth’s sediments over several hundred million years – they are identical in origin to the gas bubbles that surface when we stir the bed of a pond or lake. The actual volume of these methane deposits is still being assessed by science. Recent estimates suggest: • seabed deposits – between 500–2500 billion tonnes of frozen carbon;18 • tundra deposits – potentially emitting 180–420 million tonnes of carbon a year by 2100; and • tropical peat swamps – could emit 480–870 million tonnes of carbon a year by 2100.19 That carbon released from peat swamps, tundra and possibly the oceans can have a catastrophic effect on the Earth’s climate is foreshadowed by an event known as the Palaeocene–Eocene Thermal Maximum (PETM), which took place some 55 million years ago, when Earth took a sudden fever and its temperature rocketed upwards by +5–9 C. This ‘heat spike’ caused a lesser extinction event involving widespread loss of ocean life and a smaller toll of land animals.20 However, the heating occurred over a much longer period – 100–200,000 years, compared with human-driven heating (50–100 years) – and is thought to have been mainly caused by the drying out and burning of tropical peat swamps as the climate warmed. However, the volume of carbon which caused this sharp planetary heat spike in the past is estimated to be barely a tenth of that released by humanity today.21 Today, human activity in clearing rainforests, draining swamps and burning the world’s forests to open them up for farming and food production is releasing vast amounts of methane and CO2. Explosion craters have been reported across Canada and Siberia as frozen methane deposits well up and erupt with the melting of the tundra. And scientists from Sweden, Russia, Canada and America have reported methane bubbling from the seabed of the Arctic Ocean, though not yet in massive volumes. The risk in all this is that, by warming the planet by only 1–2 C, we have set in train natural processes that we are powerless to control, setting ourselves on an inescapable trajectory to a Hothouse Earth, 5–10 C or more above today’s levels. Although it is hard to estimate, some scientists are of the view that fewer than one billion humans would survive such an event22 – in other words, nine people out of every ten may perish in the cycle of famines, wars, heatwaves and pandemic diseases which global overheating would entail. This underlies the deadly urgency of ceasing to burn all fossil fuels, locking up as much carbon as possible and re-stabilising the Earth’s climate. In that, food production can and will play a central role. Poisoned Planet ‘Earth, and all life on it, are being saturated with man-made chemicals in an event unlike anything which has occurred in all four billion years of our planet’s story. Each moment of our lives, from conception unto death, we are exposed to thousands of substances, some deadly in even tiny doses and most of them unknown in their effects on our health and wellbeing or upon the natural world. These enter our bodies with every breath, each meal or drink, the clothes we wear, the products with which we adorn ourselves, our homes, workplaces, cars and furniture, the things we encounter every day. There is no escaping them. Ours is a poisoned planet, its whole system infused with the substances humans deliberately or inadvertently produce in the course of extracting, making, using, burning or discarding the many marvellous products on which modern life depends. This explosion in chemical use and release has all happened so rapidly that most people are blissfully unaware of its true magnitude and extent, or of the dangers it now poses to us all as well as to future generations for centuries to come.’ This is a summation of the chemical crisis facing all of humanity, as well as all life on Earth, which I wrote in Surviving the 21st Century, and which is based on the extensive scientific research reported in Poisoned Planet.23 It is a crisis with profound impact for everyone. According to the medical journal The Lancet, nine million people – one in six – die every year from chemical pollution of their air, water, food and living environment.24 A further 40 million die from the so-called noncommunicable or ‘lifestyle’ diseases (NCDs), cancer, heart disease, diabetes and lung disease, which are mostly diet-related.25 Food production, as we have seen, is deeply implicated in the chemical deluge. However, it is also an existential threat to human health, both in terms of infectious disease and the new ‘lifestyle’ diseases. No-one to my knowledge has compiled an accurate assessment of the total chemical effusion of humanity or presented a realistic impression of its true scale. Box 6.1 represents my own best estimate, drawn from various reliable sources. From this it can easily be seen that the scale of humanity’s chemical assault on ourselves and on the planet is many times the scale of our climate assault – yet this issue commands nowhere near the political or scientific priority that it should. It is arguably the most under-rated, under-investigated and poorly understood of all the existential threats to humanity. The poisoning of the Earth by human activities has grave implications for the health and safety of the global food chain and its eight billion consumers. It is not only the use of chemicals in food production that is of concern, but also the contamination of water, soils and livestock by industrial pollutants from other sources, such as mining or manufacturing. It is also the disruption of vital services such as pollination by insects of a [[BOX 6.1 OMITTED]] third of the world’s food crops and 90 per cent of wild plants.26 It is the contamination of up to three quarters of the world fish catch with microscopic plastic particles and clothing microfibres made by the petrochemical industry.27 The ending of this flood of poisons is a prerequisite for a safe, healthy and sustainable global food supply in future. And, since government regulation has largely failed to stem the worldwide flood, the task now falls to consumers – to choose foods which have been produced by safe methods and shun foods produced by unsafe methods. That is the only way that the food industry can be encouraged (and penalised) into doing the right thing by humanity and the planet: by consumers rewarding it for producing clean food and punishing it for toxic food. Otherwise it will continue to pollute as profitably as it can. It follows that the urgent global education of consumers about which foods are safe and which are toxic is also a pre-requisite. Food Security Our demand for food is set to double by the 2060s – potentially the decade of ‘peak people’, the moment in history when the irresistible human population surge may top out at around 10 billion. However, as we have seen, many of the resources needed to supply it agriculturally could halve and the climate for the growing of food outdoors become far more hostile. Why food insecurity is an existential threat to humanity should, by now, be abundantly clear from the earlier chapters of this book: present systems are unsustainable and, as they fail, will pose risks both to civilization and, should these spiral into nuclear conflict, to the future of the human species. The important thing to note in this chapter is that food insecurity plays into many, if not all, of the other existential threats facing humanity. The food sector’s role in extinction, resource scarcity, global toxicity and potential nuclear war has already been explained. Its role in the suppression of conflict is discussed in the next chapter. Its role in securing the future of the megacities, and of a largely urbanised humanity, is covered in Chapter 8. And its role in sustaining humanity through the peak in population and into a sustainable world beyond is covered in Chapter 9.

#### [4] 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.

### 1AC – Solvency

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

#### Feldman, 19

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

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

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

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

#### Ventures, 20

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

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

**Limiting evergreening causes decreased prices and increased innovation**

#### Stanbrook, 13

 (Matthew B. Stanbrook, MD PhD, 8-6-2013, accessed on 8-23-2021, PubMed Central (PMC), "Limiting “evergreening” for a better balance of drug innovation incentives", https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3735737/)WWPP

The global pharmaceutical industry’s most important new development this year may have taken place in the courtroom rather than in a laboratory. In April 2013, India’s Supreme Court denied a patent on a new version of the drug imatinib (used primarily in the treatment of certain forms of leukemia) to its manufacturer Novartis, arguing that it was not different enough from the previous version.1,2 This unprecedented decision will likely preserve the availability of much cheaper generic versions of imatinib and other drugs, not only for India but also for the many developing nations India supplies with affordable pharmaceuticals. Lessons may be taken from this in other countries, particularly in affluent nations like Canada. At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “me too” drugs, and demonstration that the resulting incremental benefits in efficacy and safety are clinically meaningful is often lacking. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive sufficient incentives to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their drug-development resources away from innovation. Current patent legislation may not be optimal for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve denying future patents for modifications that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the extensive patent litigation that contributes to the high prices of generic drugs in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.