**I value morality.**

**The standard is maximizing expected well being**

**[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

**Pharmaceutical innovation is *declining***

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

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

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

Richards et al 20[ Kevin T. Richards, Coordinator is a Legislative Attorney Kevin J. Hickey is a Legislative Attorney Erin H. Ward is a Legislative Attorney Drug Pricing and Pharmaceutical Patenting

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.

#### 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.

#### [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

Julian Cribb 19, Author, journalist, editor and science communicator, principal of Julian Cribb & Associates who provide specialist consultancy in the communication of science, agriculture, food, mining, energy and the environment, more than thirty awards for journalism. 10/03/2019. “6 - Food as an Existential Risk.” Food or War, 1st ed., Cambridge University Press. DOI.org (Crossref), doi:10.1017/9781108690126.

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.

### 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."

#### Decreasing patents doesn’t stifle innovation, but increases it through collaboration between companies – empirics

Laurie Garrett 5/21 [Laurie Garrett is a columnist at Foreign Policy, a former senior fellow for global health at the Council on Foreign Relations, and a Pulitzer Prize-winning science. MAY 7, 2021, "Stopping Drug Patents Has Stopped Pandemics Before," Foreign Policy, https://foreignpolicy.com/2021/05/07/stopping-drug-patents-pandemics-coronavirus-hiv-aids/]//anop

U.S. President Joe Biden’s waiver of patent protections for U.S.-made COVID-19 drugs and vaccines is a historic milestone and a moral imperative. It is also an overdue acknowledgement of recent experiences. Contrary to prognostications from the pharmaceutical sector that side-stepping the Trade-Related Aspects of Intellectual Property Rights (TRIPS) component of the World Trade Organization (WTO) will mark the death knell of the drug industry, the world’s response to HIV/AIDS long ago demonstrated that patents stymie accessible treatment, cost lives, and offer little bona fide enhancement of innovation. There are challenges that lie ahead—but harm to pharmaceutical companies or future patients who will rely on their productivity do not count among them. 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A battle unfolded, pitting a reluctant—even obstinate—pharmaceutical industry against AIDS activists, physicians, and political leaders from developing countries. In 2002, former U.S. President Bill Clinton intervened, using his bully pulpit in consultation with a team of academic experts convened by his philanthropic foundation to contrive a tech-transfer scheme that had Western pharmaceutical companies provide their patented drug formulas to Indian generic manufacturing companies, ultimately bringing down annual treatment costs from nearly $10,000 to less than $100. Far from bringing chaos to the pharmaceutical industry and stifling innovation, the Clinton Foundation’s maneuver around the strict enforcement of intellectual property laws ushered in a dramatic era of HIV drug invention that improved the antiviral power of treatment, lowered drug side effects, developed new drug forms that are now taken to prevent infection, increased options for pediatric care, and greatly improved the methods for which HIV positive individuals could take their life-sparing treatments. Despite the loss of guaranteed patent protection and pressure to transfer technology to, primarily, Indian pharmaceutical companies, wealthy nations’ drug companies have profited and continue to innovate on the HIV/AIDS front. You can support Foreign Policy by becoming a subscriber. SUBSCRIBE TODAY Of the multiple COVID-19 vaccines currently in use, the most promising—the mRNA and adenovirus vector products—all arose from government-funded research, mostly based in academic research centers. AstraZeneca’s vaccine, for example, grew out of the United Kingdom’s government-back research and development at Oxford University. The Moderna and Pfizer mRNA vaccines grew out of years of National Institutes of Health-funded research in the United States and with predecessor Ebola vaccines in the Democratic Republic of the Congo, Guinea, Sierra Leone, and Liberia. China’s vaccine built on years of military immunization work. And thanks to Operation Warp Speed, many companies involved in the vaccine chain of production have benefited with a total of $18 billion of U.S. government subsidies. The speed and scale of COVID-19 vaccine production in the United States is largely thanks to the country’s taxpayers. This week, Pfizer reported earning $3.5 billion in profits during the first quarter of this year from its COVID-19 vaccine. Moderna earned the first profits the fledgling company has ever seen—$1.73 billion—and projects nearly $20 billion in earnings this year. Despite setbacks, both the AstraZeneca and Johnson & Johnson adenovirus vector vaccines are making handy profits, projected to each garner multiple billions of dollars this year. Even Sinopharm from China and Gamaleya from Russia expect to reap ample profits in 2021, both in cash and diplomacy, as they sell vaccines directly to key governments. The Novavax company, which makes a not-yet-approved protein vaccine, expects massive earnings in late 2021. 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Although waiving TRIPS requirements on COVID-19 vaccines is a spectacular, historic gesture, would-be generic makers worldwide will soon discover their efforts are stymied not by patents but for want of Avanti Polar Lipids’ liposome ingredients, Flexsafe RM special bags to hold liquid vaccines in bulk, phosphate-buffered saline solution, Distearoylphosphatidylcholine for liposome-making, 5’ cap for mRNA made by TriLink BioTechnologies, RNA polymerases—the list goes on, and on, and on. As the number of would-be vaccine makers grows, so will demand for thousands of such items, putting pressure on companies that are, in many cases, mom-and-pop operations. Worse, pressure on supplies critical for COVID-19 vaccine making is already resulting in a production loss of vital medicines for other diseases. Oxygen, after all, is ubiquitous, unpatented, free to all—unless it is needed in pure form, in a pressurized tank, or for ventilation use by a critically ill COVID-19 patient in Pune, India. 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### Underview

#### 1AR theory –

#### A. AFF gets it because otherwise the neg can engage in infinite abuse, making debate impossible.

#### B. Drop the debater – the short 1AR irreparably skewed from abuse on substance and time investment on theory.

#### C. No RVIs – the 6-minute 2nr can collapse to a short shell and get away with infinite 1nc abuse via sheer brute force and time spent on theory.

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#### 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.