### 1AC – framework – [short]

**I value morality.**

**The standard is minimizing material violence. [To clarify I defend utilitarianism].**

**Pleasure and pain are intrinsic value and disvalue**

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**Pleasure** is not only one of the three primary reward functions but it also **defines reward.** As homeostasis explains the functions of only a limited number of rewards, the principal reason why particular stimuli, objects, events, situations, and activities are rewarding may be due to pleasure. This applies first of all to sex and to the primary homeostatic rewards of food and liquid and extends to money, taste, beauty, social encounters and nonmaterial, internally set, and intrinsic rewards. Pleasure, as the primary effect of rewards, drives the prime reward functions of learning, approach behavior, and decision making and provides the **basis for hedonic theories** of reward function. We are attracted by most rewards and exert intense efforts to obtain them, just because they are enjoyable [10]. Pleasure is a passive reaction that derives from the experience or prediction of reward and may lead to a long-lasting state of happiness. The word happiness is difficult to define. In fact, just obtaining physical pleasure may not be enough. One key to happiness involves a network of good friends. However, it is not obvious how the higher forms of satisfaction and pleasure are related to an ice cream cone, or to your team winning a sporting event. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure [14]. Pleasure as a hallmark of reward is sufficient for defining a reward, but it may not be necessary. A reward may generate positive learning and approach behavior simply because it contains substances that are essential for body function. When we are hungry, we may eat bad and unpleasant meals. A monkey who receives hundreds of small drops of water every morning in the laboratory is unlikely to feel a rush of pleasure every time it gets the 0.1 ml. Nevertheless, with these precautions in mind, we may define any stimulus, object, event, activity, or situation that has the potential to produce pleasure as a reward. In the context of reward deficiency or for disorders of addiction, homeostasis pursues pharmacological treatments: drugs to treat drug addiction, obesity, and other compulsive behaviors. The theory of allostasis suggests broader approaches - such as re-expanding the range of possible pleasures and providing opportunities to expend effort in their pursuit. [15]. It is noteworthy, the first animal studies eliciting approach behavior by electrical brain stimulation interpreted their findings as a discovery of the brain’s pleasure centers [16] which were later partly associated with midbrain dopamine neurons [17–19] despite the notorious difficulties of identifying emotions in animals. Evolutionary theories of pleasure: The love connection BO:D Charles Darwin and other biological scientists that have examined the biological evolution and its basic principles found various mechanisms that steer behavior and biological development. Besides their theory on natural selection, it was particularly the sexual selection process that gained significance in the latter context over the last century, especially when it comes to the question of what makes us “what we are,” i.e., human. However, the capacity to sexually select and evolve is not at all a human accomplishment alone or a sign of our uniqueness; yet, we humans, as it seems, are ingenious in fooling ourselves and others–when we are in love or desperately search for it. It is well established that modern biological theory conjectures that **organisms are** the **result of evolutionary competition.** In fact, Richard Dawkins stresses gene survival and propagation as the basic mechanism of life [20]. Only genes that lead to the fittest phenotype will make it. It is noteworthy that the phenotype is selected based on behavior that maximizes gene propagation. To do so, the phenotype must survive and generate offspring, and be better at it than its competitors. Thus, the ultimate, distal function of rewards is to increase evolutionary fitness by ensuring the survival of the organism and reproduction. It is agreed that learning, approach, economic decisions, and positive emotions are the proximal functions through which phenotypes obtain other necessary nutrients for survival, mating, and care for offspring. Behavioral reward functions have evolved to help individuals to survive and propagate their genes. Apparently, people need to live well and long enough to reproduce. Most would agree that homo-sapiens do so by ingesting the substances that make their bodies function properly. For this reason, foods and drinks are rewards. Additional rewards, including those used for economic exchanges, ensure sufficient palatable food and drink supply. Mating and gene propagation is supported by powerful sexual attraction. Additional properties, like body form, augment the chance to mate and nourish and defend offspring and are therefore also rewards. Care for offspring until they can reproduce themselves helps gene propagation and is rewarding; otherwise, many believe mating is useless. According to David E Comings, as any small edge will ultimately result in evolutionary advantage [21], additional reward mechanisms like novelty seeking and exploration widen the spectrum of available rewards and thus enhance the chance for survival, reproduction, and ultimate gene propagation. These functions may help us to obtain the benefits of distant rewards that are determined by our own interests and not immediately available in the environment. Thus the distal reward function in gene propagation and evolutionary fitness defines the proximal reward functions that we see in everyday behavior. That is why foods, drinks, mates, and offspring are rewarding. There have been theories linking pleasure as a required component of health benefits salutogenesis, (salugenesis). In essence, under these terms, pleasure is described as a state or feeling of happiness and satisfaction resulting from an experience that one enjoys. Regarding pleasure, it is a double-edged sword, on the one hand, it promotes positive feelings (like mindfulness) and even better cognition, possibly through the release of dopamine [22]. But on the other hand, pleasure simultaneously encourages addiction and other negative behaviors, i.e., motivational toxicity. It is a complex neurobiological phenomenon, relying on reward circuitry or limbic activity. It is important to realize that through the “Brain Reward Cascade” (BRC) endorphin and endogenous morphinergic mechanisms may play a role [23]. While natural rewards are essential for survival and appetitive motivation leading to beneficial biological behaviors like eating, sex, and reproduction, crucial social interactions seem to further facilitate the positive effects exerted by pleasurable experiences. Indeed, experimentation with addictive drugs is capable of directly acting on reward pathways and causing deterioration of these systems promoting hypodopaminergia [24]. Most would agree that pleasurable activities can stimulate personal growth and may help to induce healthy behavioral changes, including stress management [25]. The work of Esch and Stefano [26] concerning the link between compassion and love implicate the brain reward system, and pleasure induction suggests that social contact in general, i.e., love, attachment, and compassion, can be highly effective in stress reduction, survival, and overall health. Understanding the role of neurotransmission and pleasurable states both positive and negative have been adequately studied over many decades [26–37], but comparative anatomical and neurobiological function between animals and homo sapiens appear to be required and seem to be in an infancy stage. Finding happiness is different between apes and humans As stated earlier in this expert opinion one key to happiness involves a network of good friends [38]. However, it is not entirely clear exactly how the higher forms of satisfaction and pleasure are related to a sugar rush, winning a sports event or even sky diving, all of which augment dopamine release at the reward brain site. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure. Remarkably, there are pathways for ordinary liking and pleasure, which are limited in scope as described above in this commentary. However, there are **many brain regions**, often termed hot and cold spots, that significantly **modulate** (increase or decrease) our **pleasure or** even **produce the opposite** of pleasure— that is disgust and fear [39]. One specific region of the nucleus accumbens is organized like a computer keyboard, with particular stimulus triggers in rows— producing an increase and decrease of pleasure and disgust. Moreover, the cortex has unique roles in the cognitive evaluation of our feelings of pleasure [40]. Importantly, the interplay of these multiple triggers and the higher brain centers in the prefrontal cortex are very intricate and are just being uncovered. Desire and reward centers It is surprising that many different sources of pleasure activate the same circuits between the mesocorticolimbic regions (Figure 1). Reward and desire are two aspects pleasure induction and have a very widespread, large circuit. Some part of this circuit distinguishes between desire and dread. The so-called pleasure circuitry called “REWARD” involves a well-known dopamine pathway in the mesolimbic system that can influence both pleasure and motivation. In simplest terms, the well-established mesolimbic system is a dopamine circuit for reward. It starts in the ventral tegmental area (VTA) of the midbrain and travels to the nucleus accumbens (Figure 2). It is the cornerstone target to all addictions. The VTA is encompassed with neurons using glutamate, GABA, and dopamine. The nucleus accumbens (NAc) is located within the ventral striatum and is divided into two sub-regions—the motor and limbic regions associated with its core and shell, respectively. The NAc has spiny neurons that receive dopamine from the VTA and glutamate (a dopamine driver) from the hippocampus, amygdala and medial prefrontal cortex. Subsequently, the NAc projects GABA signals to an area termed the ventral pallidum (VP). The region is a relay station in the limbic loop of the basal ganglia, critical for motivation, behavior, emotions and the “Feel Good” response. This defined system of the brain is involved in all addictions –substance, and non –substance related. In 1995, our laboratory coined the term “Reward Deficiency Syndrome” (RDS) to describe genetic and epigenetic induced hypodopaminergia in the “Brain Reward Cascade” that contribute to addiction and compulsive behaviors [3,6,41]. Furthermore, ordinary “liking” of something, or pure pleasure, is represented by small regions mainly in the limbic system (old reptilian part of the brain). These may be part of larger neural circuits. In Latin, hedus is the term for “sweet”; and in Greek, hodone is the term for “pleasure.” Thus, the word Hedonic is now referring to various subcomponents of pleasure: some associated with purely sensory and others with more complex emotions involving morals, aesthetics, and social interactions. The capacity to have pleasure is part of being healthy and may even extend life, especially if linked to optimism as a dopaminergic response [42]. Psychiatric illness often includes symptoms of an abnormal inability to experience pleasure, referred to as anhedonia. A negative feeling state is called dysphoria, which can consist of many emotions such as pain, depression, anxiety, fear, and disgust. Previously many scientists used animal research to uncover the complex mechanisms of pleasure, liking, motivation and even emotions like panic and fear, as discussed above [43]. However, as a significant amount of related research about the specific brain regions of pleasure/reward circuitry has been derived from invasive studies of animals, these cannot be directly compared with subjective states experienced by humans. In an attempt to resolve the controversy regarding the causal contributions of mesolimbic dopamine systems to reward, we have previously evaluated the three-main competing explanatory categories: “liking,” “learning,” and “wanting” [3]. That is, dopamine may mediate (a) liking: the hedonic impact of reward, (b) learning: learned predictions about rewarding effects, or (c) wanting: the pursuit of rewards by attributing incentive salience to reward-related stimuli [44]. We have evaluated these hypotheses, especially as they relate to the RDS, and we find that the incentive salience or “wanting” hypothesis of dopaminergic functioning is supported by a majority of the scientific evidence. Various neuroimaging studies have shown that anticipated behaviors such as sex and gaming, delicious foods and drugs of abuse all affect brain regions associated with reward networks, and may not be unidirectional. Drugs of abuse enhance dopamine signaling which sensitizes mesolimbic brain mechanisms that apparently evolved explicitly to attribute incentive salience to various rewards [45]. Addictive substances are voluntarily self-administered, and they enhance (directly or indirectly) dopaminergic synaptic function in the NAc. This activation of the brain reward networks (producing the ecstatic “high” that users seek). Although these circuits were initially thought to encode a set point of hedonic tone, it is now being considered to be far more complicated in function, also encoding attention, reward expectancy, disconfirmation of reward expectancy, and incentive motivation [46]. The argument about addiction as a disease may be confused with a predisposition to substance and nonsubstance rewards relative to the extreme effect of drugs of abuse on brain neurochemistry. The former sets up an individual to be at high risk through both genetic polymorphisms in reward genes as well as harmful epigenetic insult. Some Psychologists, even with all the data, still infer that addiction is not a disease [47]. Elevated stress levels, together with polymorphisms (genetic variations) of various dopaminergic genes and the genes related to other neurotransmitters (and their genetic variants), and may have an additive effect on vulnerability to various addictions [48]. In this regard, Vanyukov, et al. [48] suggested based on review that whereas the gateway hypothesis does not specify mechanistic connections between “stages,” and does not extend to the risks for addictions the concept of common liability to addictions may be more parsimonious. The latter theory is grounded in genetic theory and supported by data identifying common sources of variation in the risk for specific addictions (e.g., RDS). This commonality has identifiable neurobiological substrate and plausible evolutionary explanations. Over many years the controversy of dopamine involvement in especially “pleasure” has led to confusion concerning separating motivation from actual pleasure (wanting versus liking) [49]. We take the position that animal studies cannot provide real clinical information as described by self-reports in humans. As mentioned earlier and in the abstract, on November 23rd, 2017, evidence for our concerns was discovered [50] In essence, although nonhuman primate brains are similar to our own, the disparity between other primates and those of human cognitive abilities tells us that surface similarity is not the whole story. Sousa et al. [50] small case found various differentially expressed genes, to associate with pleasure related systems. Furthermore, the dopaminergic interneurons located in the human neocortex were absent from the neocortex of nonhuman African apes. Such differences in neuronal transcriptional programs may underlie a variety of neurodevelopmental disorders. In simpler terms, the system controls the production of dopamine, a chemical messenger that plays a significant role in pleasure and rewards. The senior author, Dr. Nenad Sestan from Yale, stated: “Humans have evolved a dopamine system that is different than the one in chimpanzees.” This may explain why the behavior of humans is so unique from that of non-human primates, even though our brains are so surprisingly similar, Sestan said: “It might also shed light on why people are vulnerable to mental disorders such as autism (possibly even addiction).” Remarkably, this research finding emerged from an extensive, multicenter collaboration to compare the brains across several species. These researchers examined 247 specimens of neural tissue from six humans, five chimpanzees, and five macaque monkeys. Moreover, these investigators analyzed which genes were turned on or off in 16 regions of the brain. While the differences among species were subtle, **there was** a **remarkable contrast in** the **neocortices**, specifically in an area of the brain that is much more developed in humans than in chimpanzees. In fact, these researchers found that a gene called tyrosine hydroxylase (TH) for the enzyme, responsible for the production of dopamine, was expressed in the neocortex of humans, but not chimpanzees. As discussed earlier, dopamine is best known for its essential role within the brain’s reward system; the very system that responds to everything from sex, to gambling, to food, and to addictive drugs. However, dopamine also assists in regulating emotional responses, memory, and movement. Notably, abnormal dopamine levels have been linked to disorders including Parkinson’s, schizophrenia and spectrum disorders such as autism and addiction or RDS. Nora Volkow, the director of NIDA, pointed out that one alluring possibility is that the neurotransmitter dopamine plays a substantial role in humans’ ability to pursue various rewards that are perhaps months or even years away in the future. This same idea has been suggested by Dr. Robert Sapolsky, a professor of biology and neurology at Stanford University. Dr. Sapolsky cited evidence that dopamine levels rise dramatically in humans when we anticipate potential rewards that are uncertain and even far off in our futures, such as retirement or even the possible alterlife. This may explain what often motivates people to work for things that have no apparent short-term benefit [51]. In similar work, Volkow and Bale [52] proposed a model in which dopamine can favor NOW processes through phasic signaling in reward circuits or LATER processes through tonic signaling in control circuits. Specifically, they suggest that through its modulation of the orbitofrontal cortex, which processes salience attribution, dopamine also enables shilting from NOW to LATER, while its modulation of the insula, which processes interoceptive information, influences the probability of selecting NOW versus LATER actions based on an individual’s physiological state. This hypothesis further supports the concept that disruptions along these circuits contribute to diverse pathologies, including obesity and addiction or RDS.

**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.

**Extinction comes first under any framework.**

**Pummer 15** [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now, whatever general moral view we adopt: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war. How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world. According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here. If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people. Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But ***that is a huge mistake.*** Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; ***it is not the view that the latter don’t matter***. Even John Rawls wrote, “All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.” ***Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good***, from an impartial point of view. They’d thus imply very strong reasons to reduce existential risk, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk. It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being. To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk. Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. ***We should also take into account moral uncertainty.*** What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts? I’ve just argued that there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree. But even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one (and 10% sure that one of these other ones is correct), they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk. Perhaps most disturbingly still, even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world. Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. It is enough for my claim that there is moral agreement in the relevant sense if, at least given certain empirical claims about what future lives would most likely be like, ***all minimally plausible moral views would converge on the conclusion that we should try to save the world***. While there are some non-crazy views that place significantly greater moral weight on avoiding suffering than on promoting happiness, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless seem to be fairly implausible views. And even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve. Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast. We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period. Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.” (From chapter 36 of On What Matters)

### 1AC – Adv – Innovation

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

Gold 21, E Richard. [E. Richard Gold is a CIGI senior fellow and a James McGill Professor with McGill University’s Faculty of Law and was the founding director of the Centre for Intellectual Property Policy. “The fall of the innovation empire and its possible rise through open science.” Research policy vol. 50,5 (2021): 104226. doi:10.1016/j.respol.2021.104226]//anop

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

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

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

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

#### That fuels monopolies stifling innovation.

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

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

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

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

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

#### Four impacts:

#### [1] Only pharma innovation solves global pandemics that risk extinction

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

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

#### [2] Pharma is key to biotech

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

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

#### Biotech collapse wrecks the economy

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

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

#### 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.

### Underview

#### [1] 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.

#### [2] AFF RVIs —

#### A. Skew – there’s no 2AC to develop carded offense and the 1AR has to over-cover since the 6 minute 2NR is devastating which encourages them to under-develop T in the NC and over-develop in the NR – need the RVI to develop good, in-depth T offense

#### B. Reciprocity – T is a unique avenue to the ballot that the aff can’t access – makes T structurally unfair without the RVI.