# SO21 – 1AC – GHI

## Framework

#### The standard is maximizing expected well-being

#### [1] Policy focus - Ethical policymaking requires calculation of consequences

Gvosdev 5 – Rhodes scholar, PhD from St. Antony’s College, executive editor of The National Interest (Nikolas, The Value(s) of Realism, SAIS Review 25.1, pmuse, AG)

As the name implies, realists focus on promoting policies that are achievable and sustainable. In turn, the morality of a foreign policy action is judged by its results, not by the intentions of its framers. A foreign policymaker must weigh the consequences of any course of action and assess the resources at hand to carry out the proposed task. As Lippmann warned, Without the controlling principle that the nation must maintain its objectives and its power in equilibrium, its purposes within its means and its means equal to its purposes, its commitments related to its resources and its resources adequate to its commitments, it is impossible to think at all about foreign affairs.8 Commenting on this maxim, Owen Harries, founding editor of The National Interest, noted, "This is a truth of which Americans—more apt to focus on ends rather than means when it comes to dealing with the rest of the world—need always to be reminded."9 In fact, Morgenthau noted that "there can be no political morality without prudence."10 This virtue of prudence—which Morgenthau identified as the cornerstone of realism—should not be confused with expediency. Rather, it takes as its starting point that it is more moral to fulfill one's commitments than to make "empty" promises, and to seek solutions that minimize harm and produce sustainable results. Morgenthau concluded: [End Page 18] Political realism does not require, nor does it condone, indifference to political ideals and moral principles, but it requires indeed a sharp distinction between the desirable and the possible, between what is desirable everywhere and at all times and what is possible under the concrete circumstances of time and place.11 This is why, prior to the outbreak of fighting in the former Yugoslavia, U.S. and European realists urged that Bosnia be decentralized and partitioned into ethnically based cantons as a way to head off a destructive civil war. Realists felt this would be the best course of action, especially after the country's first free and fair elections had brought nationalist candidates to power at the expense of those calling for inter-ethnic cooperation. They had concluded—correctly, as it turned out—that the United States and Western Europe would be unwilling to invest the blood and treasure that would be required to craft a unitary Bosnian state and give it the wherewithal to function. Indeed, at a diplomatic conference in Lisbon in March 1992, the various factions in Bosnia had, reluctantly, endorsed the broad outlines of such a settlement. For the purveyors of moralpolitik, this was unacceptable. After all, for this plan to work, populations on the "wrong side" of the line would have to be transferred and resettled. Such a plan struck directly at the heart of the concept of multi-ethnicity—that different ethnic and religious groups could find a common political identity and work in common institutions. When the United States signaled it would not accept such a settlement, the fragile consensus collapsed. The United States, of course, cannot be held responsible for the war; this lies squarely on the shoulders of Bosnia's political leaders. Yet Washington fell victim to what Jonathan Clarke called "faux Wilsonianism," the belief that "high-flown words matter more than rational calculation" in formulating effective policy, which led U.S. policymakers to dispense with the equation of "balancing commitments and resources."12 Indeed, as he notes, the Clinton administration had criticized peace plans calling for decentralized partition in Bosnia "with lofty rhetoric without proposing a practical alternative." The subsequent war led to the deaths of tens of thousands and left more than a million people homeless. After three years of war, the Dayton Accords—hailed as a triumph of American diplomacy—created a complicated arrangement by which the federal union of two ethnic units, the Muslim-Croat Federation, was itself federated to a Bosnian Serb republic. Today, Bosnia requires thousands of foreign troops to patrol its internal borders and billions of dollars in foreign aid to keep its government and economy functioning. Was the aim of U.S. policymakers, academics and journalists—creating a multi-ethnic democracy in Bosnia—not worth pursuing? No, not at all, and this is not what the argument suggests. But aspirations were not matched with capabilities. As a result of holding out for the "most moral" outcome and encouraging the Muslim-led government in Sarajevo to pursue maximalist aims rather than finding a workable compromise that could have avoided bloodshed and produced more stable conditions, the peoples of Bosnia suffered greatly. In the end, the final settlement was very close [End Page 19] to the one that realists had initially proposed—and the one that had also been roundly condemned on moral grounds.

#### [2] No moral intent/foresight distinction for states—it’s just avoiding responsibility.

David **Enoch 7** [The Faculty of Law, The Hebrew University, Mount Scopus Campus, Jerusalem], “INTENDING, FORESEEING, AND THE STATE,” Legal Theory, 13 (2007), 69–99, pg. 90-1, beckert

The general difficulty of the intending-foreseeing distinction here stemmed, you will recall, from the feeling that attempting to pick and choose among the foreseen consequences of one’s actions those one is more and those one is less responsible for looks more like the preparation of a defense than like a genuine attempt to determine what is to be done. Hiding behind the intending-foreseeing distinction seems like an attempt to evade responsibility, and so thinking about the distinction in terms of responsibility serves to reduce even further the plausibility of attributing to it intrinsic moral significance. This consideration—however weighty in general—seems to me very weighty when applied to state action and to the decisions of state officials. For perhaps it may be argued that individuals are not required to undertake a global perspective, one that equally takes into account all foreseen con- sequences of their actions. Perhaps, in other words, individuals are entitled to (roughly) settle for having a good will, and beyond that let chips fall where they may. But this is precisely what stateswomen and statesmen—and certainly states—are not entitled to settle for.44 In making policy decisions, it is precisely the global (or at least statewide, or nationwide, or something of this sort) perspective that must be undertaken. Perhaps, for instance, an individual doctor is entitled to give her patient a scarce drug without think- ing about tomorrow’s patients (I say “perhaps” because I am genuinely not sure about this), but surely when a state committee tries to formulate rules for the allocation of scarce medical drugs and treatments, it cannot hide behind the intending-foreseeing distinction, arguing that if it allows45 the doctor to give the drug to today’s patient, the death of tomorrow’s patient is merely foreseen and not intended. When making a policy-decision, this is clearly unacceptable. Or think about it this way (I follow Daryl Levinson here):46 perhaps restric- tions on the responsibility of individuals are justified because individuals are autonomous, because much of the value in their lives comes from personal pursuits and relationships that are possible only if their responsibility for what goes on in the (more impersonal) world is restricted. But none of this is true of states and governments. They have no special relationships and pursuits, no personal interests, no autonomous lives to lead in anything like the sense in which these ideas are plausible when applied to individuals persons. So there is no reason to restrict the responsibility of states in anything like the way the responsibility of individuals is arguably restricted.47 States and state officials have much more comprehensive responsibilities than individuals do. Hiding behind the intending-foreseeing distinction thus more clearly constitutes an evasion of responsibility in the case of the former. So the evading-responsibility worry has much more force against the intending-foreseeing distinction when applied to state action than elsewhere.

#### [3] Ethical agnosticism means we should default towards preventing extinction as a meta-constraint on all ethical theories.

Nick **Bostrom 13** [Faculty of Philosophy & Oxford Martin School, Oxford], “Existential Risk Prevention as Global Priority”, Global Policy, Vol 4, Issue 1 (2013): 15-31, BE

**These reflections on moral uncertainty suggest an alternative, complementary way of looking at existential risk**; they also suggest a new way of thinking about the ideal of sustainability. Let me elaborate.¶ **Our present understanding of axiology might well be confused. We may not now know — at least not in concrete detail — what outcomes would count as a big win for humanity**; we might not even yet be able to imagine the best ends of our journey. **If we are indeed profoundly uncertain about our ultimate aims, then we should recognize that there is a great option value in preserving — and ideally improving — our ability to recognize value and to steer the future accordingly. Ensuring that there will be a future version of humanity with great powers and a propensity to use them wisely is plausibly the best way available to us to increase the probability that the future will contain a lot of value. To do this, we must prevent any existential catastrophe**.¶ We thus want to reach a state in which we have (*a*) far greater intelligence, knowledge, and sounder judgment than we currently do; (*b*) far greater ability to solve global-coordination problems; (*c*) far greater technological capabilities and physical resources; and such that (*d*) our values and preferences are not corrupted in the process of getting there (but rather, if possible, improved). Factors *b* and *c* expand the option set available to humanity. Factor *a* increases humanity's ability to predict the outcomes of the available options and understand what each outcome would entail in terms of the realization of human values. Factor *d*, finally, makes humanity more likely to want to realize human values.

### Plan

#### Plan Text: The member nations of the World Trade Organization ought to reduce intellectual property protectionsfor medicines.

## Contention 1 – Global Health Inequality (GHI)

### Subpoint A – Access to Medicine

#### IP protections allow developed countries to maintain extended monopolies in pharma, disproportionately hurting low-income countries

Baker et al 17 (Dean Baker is an American macroeconomist and co-founder, with Mark Weisbrot, of the Center for Economic and Policy Research in Washington, D.C. He is credited as one of the first economists to have identified the 2007–08 United States housing bubble., Arjun Jayadev is an Associate Professor of Economics at Azim Premji University and University of Massachusetts Boston., Joseph Stiglitz is an American economist, public policy analyst, and a professor at Columbia University. He is a recipient of the Nobel Memorial Prize in Economic Sciences and the John Bates Clark Medal.), “Innovation, Intellectual Property, and Development: A BETTER SET OF APPROACHES FOR THE 21st CENTURY”, July 2017, Azim Premji University & Columbia University, pg. 27-28, <https://www8.gsb.columbia.edu/faculty/jstiglitz/sites/jstiglitz/files/IP%20for%2021st%20Century%20-%20EN.pdf> NT

We have, thus far focused on how innovation may be better protected and incentivised in general. The IP regime as we noted in the introduction does not work very effectively in both developed and developing countries. In the former, several pathologies, such as the problems associated with patent thickets, patent trolls and evergreening are well documented. **High tech companies are often confronted with being unable to innovate without violating other companies’ intellectual property rights since innovation often requires the use of currently existing IP.** This leads to blocks (sometimes called a patent thicket), that delays and reduced IP because of the long and costly negotiations involved in obtaining the multiple permissions needed. Patent trolling, whereby innovators face suit from others who simply own IP to proft by licensing of litigation rather than undertaking production themselves is well known with particularly egregious cases. Estimates suggest that this cost the US roughly $30 billion a year (Bessen and Meurer, 2014). **Similarly, the process of evergreening, whereby companies extend their patent protection by inventing new follow-on patents that are closely linked but which allow for a longer period of monopoly than would otherwise be permitted, is an important impediment to competition, especially in the pharmaceutical industry.** 28 Our focus in this section is on the impact of the current IP regime on global development. Developing economies are, almost by definition, significantly distant from the global innovation and production frontier. While individual industries and firms can often be close to the frontier, the generalised adoption of latest generation technologies and the garnering of the positive externalities that often result from these is a key feature of advanced industrialised economies. What separates developing from developed countries is as much a gap in knowledge as a gap in resources. The artifcial scarcity created by IPR generates economic inefficiencies. One person’s access to knowledge does not detract from another’s. One country’s use of a new technology does not compromise the ability of the rest of the world to beneft from it. **The temporary monopoly conferred by IPR creates a market distortion, resulting in less access than is socially optimal.** At a time when learning is increasingly recognised as foundational to development, we should be skeptical of institutions that remove knowledge from the common pool without a clear justifcation (Stiglitz and Greenwald, 2014). From a development perspective, it is therefore necessary to evaluate whether IPR remains fit for the purpose, in the sense that it results in greater overall production of knowledge and the advancement of standards of living than would be achieved without it. There is an extensive literature that attempts to answer these questions. The evidence is uncertain at best and there are alternative mechanisms to protect intellectual effort, as noted before. In any case, from a development perspective, the inquiry must go further than this. First, the developing country needs to ask, what IPR (or more broadly, innovation system) best advances its own standard of living. **Stronger IPR may constitute a barrier to the ability of its firms catching up to the frontier, even if it enhances innovation within the country.** Because developing countries are engaged in catching up, the optimal IPR regime for them will in general differ from that for a more advanced economy. **Moreover, stronger IPR regimes will entail the transfer of more money in the form of royalty payments from developing to developed countries.** The benefits to developing countries from these increased payments (beyond the direct transfer of knowledge) are minimal, i.e. it is not likely that these payments will significantly affect either the amount or direction of research. **This is most apparent in the drug industry, where pharmaceutical company devote relatively little of their research budget towards the diseases that afflict developing countries, and the incremental returns that they receive from developing countries are sufficiently smaller that they are unlikely to affect significantly the overall pace of innovation.**

#### Patents and market exclusivity are vital to big pharma monopolies, preventing generics from entering the market and allowing heavily marked-up prices

Kesselheim et al 16 (Aaron S. Kesselheim, MD, JD, MPH, Program On Regulation, Therapeutics, And Law (PORTAL), Division of Pharmacoepidemiology and Pharmacoeconomics, Department of Medicine, Brigham and Women’s Hospital and Harvard Medical School. Jerry Avorn, Professor of Medicine at Harvard Medical School and Chief of the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women’s Hospital. Ameet Sarpatwari is an Assistant Professor of Medicine at Harvard Medical School and the Assistant Director of the Program On Regulation, Therapeutics, And Law (PORTAL) within the Division of Pharmacoepidemiology and Pharmacoeconomics at Brigham and Women's Hospital.), “The High Cost of Prescription Drugs in the United States Origins and Prospects for Reform”, Journal of the American Medical Association, 8-23-16, <https://jamanetwork.com/journals/jama/article-abstract/2545691> NT

The most important factor that allows manufacturers to set high drug prices for brand-name drugs is market exclusivity,28 which arises from 2 forms of legal protection against competition. Together, these factors generate government-granted monopoly rights for a defined period. Initial regulatory exclusivity is awarded at FDA approval. **New small-molecule drug products automatically earn a guaranteed period of 5 to 7 years before a generic competitor can be sold, 29 and new biologic drugs are protected from competition for 12 years**.30 The second type of market protection is patent-related exclusivity because manufacturers can receive patents lasting 20 years or more for their inventions.31 The US Patent and Trademark Office issues this intellectual property right—originally written into the US Constitution to encourage innovation—for inventions that are “novel,” “useful,” and “non-obvious.”32 Although regulatory exclusivities often set a lower-bound duration for market exclusivity, the actual length of such exclusivity is most commonly dictated by patent time. Because initial patents protecting the active ingredient are usually obtained when a drug is first synthesized, and the clinical trial and FDA review process usually takes on average 6 to 8 years, only half of the patent period may be left by the drug approval date.33However, a company can apply to have this period extended by up to 5 years to account for the time spent during regulatory review and half the time in clinical trials (“patent term restoration”), to a maximum of 14 years.34 In addition, sponsors can also earn 6 more months of market exclusivity by testing their products in children,35 an incentive earned by more than 200 drugs since legislation created the pediatric exclusivity program in 1997.36 Overall, the median length of post approval market exclusivity is 12.5 years for widely used drugs (interquartile range, 8.5- 14.8 years) and 14.5 years for highly innovative, first-in-class drugs (interquartile range, 13.3-15.8 years).37,38 During that exclusivity period, the availability of treatment alternatives might be expected to exert pressure to reduce the price of a drug.39 For example, approximately a year after Gilead introduced sofosbuvir, AbbVie received approval for a 4-drug, direct acting, antiviral regimen that achieved similar clinical response rates against the hepatitis C virus, leading some payers to negotiate sofosbuvir discounts of more than 40%.40 In practice, however, competition between 2 or more brand name manufacturers selling drugs in the same class does not usually result in substantial price reductions.41 For example, of the 8 cholesterol-lowering statins that the FDA has approved, 2 have until recently remained patented: rosuvastatin (Crestor) and pitavastatin (Livalo). Despite the similar performance of these drugs in decreasing low-density lipoprotein cholesterol to other off-patent statins,42 the price of rosuvastatin increased 91% between 2007 and 2012, from $112 to $214 per prescription.43 During the same time, the price of the comparably effective atorvastatin decreased from $127 to $26 per prescription owing to the expiration of its patent protection in 2011.44 Similar effects have been observed for other drug classes.45 One factor that undermines competition among treatment alternatives is the separate roles of patients, prescribers, and payers: physicians write prescriptions, pharmacists sell medications, and patients or their insurers pay for them.46 This separation has traditionally insulated physicians from knowing about drug prices or considering those prices in their clinical decisionmaking47 and can similarly remove many patients with good drug coverage from considering the price of the medications they “purchase.” **The only form of competition that consistently and substantially decreases prescription drug prices occurs with the availability of generic drugs, which emerge after the monopoly period ends.** With FDA approval, these products can be substituted for bioequivalent brand-name drugs by the pharmacist under state drug product selection laws. In states with less restrictive drug product selection laws, **generic products comprise up to 90% of a drug’s sales** within a year after full generic entry.48 Drug prices decline to approximately 55% of brand-name drug prices with 2 generic manufacturers making the product, 33% with 5 manufacturers, and 13% with 15 manufacturers.49 In 2012, the US Government Accountability Office estimated that generic drugs accounted for approximately 86% of all filled prescriptions and saved the US health care system $1 trillion during the previous decade.50 **Entry of generic drugs into the market, however, is often delayed. For pharmaceutical manufacturers, “product life-cycle management” involves preventing generic competition and maintaining high prices by extending a drug’s market exclusivity.** This can be achieved by obtaining additional patents on other aspects of a drug, including its coating, salt moiety, formulation,51 and method of administration.52,53 In an example of this strategy, the manufacturer of the proton-pump inhibitor omeprazole (Prilosec) received an additional patent on the drug’s S-isomer, despite the absence of any compelling pharmacologic difference. This led to the creation of esomeprazole (Nexium) as a newly branded product that was sold for $4 a pill, a 600% markup over the over-the-counter version of omeprazole.54 Because permissive US Patent and Trademark Office standards for novelty or usefulness make it relatively easy to patent many nontherapeutic aspects of a drug, companies can strategically patent small changes and try to influence prescribers and patients to transition from one linked product to the next, sometimes discontinuing production of older versions of the drug. For their part, generic manufacturers have engaged in litigation with brand-name manufacturers that could lead to the patents being invalidated, but these suits are frequently settled.55 Historically, brand-name manufacturers have offered substantial financial inducements as part of these settlements to generic manufacturers to delay or even abort generic introduction.48 Settlements involving large cash transfers are called “pay for delay”; for example, in a patent challenge case related to the antibiotic ciprofloxacin (Cipro), the potential generic manufacturer received upfront and quarterly payments totaling $398 million as part of the settlement and agreed to wait until patent expiration to market its product.56

#### Big pharma monopolies are detrimental to developing countries – patent law and TRIPS both decrease access to medicine

Ahmediani and Nikfar 16 (Saeed Ahmadiani and Shekoufeh Nikfar both work in the Department of Pharmacoeconomics and Pharmaceutical Administration at Tehran University of Medical Sciences), “Challenges of access to medicine and the responsibility of pharmaceutical companies: a legal perspective”, 5-4-16, DARU Journal of Pharmaceutical Sciences, pg. 2-3, DOI 10.1186/s40199-016-0151-z, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4855755/> NT

Huge part of barriers in access to medicine returns to patent law and its consequences. Although patent law generally has been used for centuries [2], the manifestation of TRIPS agreement in 1994 turned it to a new form of challenge. This agreement force the World Trade Organization (WTO) members to take action for protecting intellectual property rights, which entails that any patented product should be produced, imported, sold or used under permission of the patent owner [3]. This includes medicine, thus the production of each medicine is initiated with a period of monopoly in the market with the highest possible price. In this period there will be no low price generic drugs in the market after signing the agreement by one state (for those drugs which are still under patent), and hence, patients should provide the expensive branded medicine either out of pocket or by using their insurance. **The problem will rise up when it comes to a developing country where population not only have lower economic status, but also lower health status and higher needs to medicine**. According to WHO, life expectancy in developed countries was 1.7 fold higher than developing countries in 2002, showing a 32-years gap in life expectancy between these societies [4]. Also, data shows that infectious diseases such as TB have a negative relationship with GDP per capita of the country [5] (also see Fig 1). These health measures make it obvious that in developing countries there is a higher need to medical technologies which many of them are under patent. At the same time, health insurance coverage is usually poor in these countries and patients often have to pay for the branded medicine out of their own pockets. Evidence shows that the lower the national income is, the higher the out of pocket share of health spending will be [6]. **With higher needs and lower economic ability, providing branded medicine will result in a large load of expenditure for states, catastrophic expenditures for patients [7] and increase of mortality and/or morbidity because of low access to medicine** (see Fig 2). Moreover, if any TRIPS member produce or provide an under patent product, the company can sue the member state and ask for a fine compensating the market loss. This was the case for South Africa in late 90s, when giant pharmaceutical companies such as GlaxoSmithKline filed a lawsuit to the Pretoria High Court against the South African government because of importation of generic anti-retroviral medicine- for treating HIV/AIDS endemic situation [8]. The Pharmaceutical Association was using this law to save their presence in the pharmaceutical market of South Africa. However, there were millions of people suffering from HIV/AIDS while could not afford the original brand medicine and the South African state was trying to find a way to guarantee their health. After three years of clashes, the court overruled the patent law in the case and recognized the right to health as a basic human right for the South African patients. Consequently big pharma companies withdrew the lawsuit and started negotiations for dropping the price of original brand to come into the South Africa market [9]. Although this was a happy-ending experience, no country can be sure that the court will give the right to the member state again and hence, in many cases the government prefer to import the branded medicine from the beginning, even if it is not affordable for a part of population. The TRIPS agreement is not the end of story. Less than a decade after the first TRIPS agreement, United States started to make bilateral trade agreements with other TRIPS members to expand and deepen the TRIPS agreement. **These agreements (generally known as TRIPS-plus) decrease the flexibilities which were anticipated for some exceptional situations- particularly for developing countries- and increase the duration of patents in some cases.** Until now, there are 20 countries that accepted such an agreement with US [10], which surprisingly 80 % of them are developing countries. If we consider the economic power of United States and its role in pharmaceutical industry, then it is not hard to guess about the effect of these agreements on the access to medicine in the subjected developing countries. Besides the patent law and TRIPS-plus agreements, there is always a bias towards maintenance medicine- the controlling medicine for chronic conditions. Pharmaceutical companies have a substantial desire in developing drugs which are focused on disease areas within the developed world, such as chronic diseases and cancer treatments, not only because of high prevalence, but also because these drugs are often used in long term, which means a long term costumer for the company, particularly if one can take the advantage of patent. As an instance, a new anti-hypertensive medicine not only has more costumers, also most of the costumers have to use the medicine until the end of their lives, let’s say 10–15 years in average. On the other side, giant pharmaceutical companies are less interested in modern anti-parasites, antibiotics and other medicines related to acute conditions, while these medicines are more needed in developing countries and this bias cause a lower access to medicine- and a lower health in result- in these low income areas. The mentioned bias also can be seen against “rare diseases” (i.e., diseases with prevalence less than 1/2000), even if they might be chronic. This inattentiveness to some specific diseases forms when the disease is rare or restricted to some particular areas and population, hence pharmaceutical companies find no incentive to invest on research and development of new medicine specified for a limited population, specifically when there is a large possibility that the state does not have the ability to pay for the medicine and the company should provide it underprice. To see it evidently, from over 1500 drugs which have been approved during 1975–2004, only about 1 % of them were related to the diseases which are known as neglected [11], while over 10 % of global burden of disease is caused by these diseases [12]. This is also reflected in 10/90 phenomena: only 10 % of R&D expenditures is related to problems of 90 % of world population [13]. These facts clearly show an insufficient attention from pharmaceutical companies to this field of health needs. According to WHO, already over one billion people are affected by neglected tropical diseases [14], which may considerably decrease both the life expectancy and quality of life. By considering the higher rate of these diseases in low income countries, it is to say that this situation can cause a huge discrimination between high and low income societies, not only in terms of health, but also economically as a consequence of low health level. All these modern structures, from patents and TRIPS-plus agreements to bias in pharma industry, cause a decrease or imbalance in access to medicine, and hence an inequity in health between and within the communities, which can be considered as a breach of human rights as will be explained further.

#### Pharma patents are rewarding failure and benefit the least innovative parts of the industry

Feldman 8/8/21 (Robin Feldman’s work focuses on the role of intellectual property law in technology and innovation; drug patents, pricing, and health care law; and artificial intelligence and data. She is the Arthur J. Goldberg Distinguished Professor of Law, the Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the UC Hastings Center for Innovation (C4i).), “Our patent system is broken. And it could be stifling innovation.”, The Washington Post, <https://www.washingtonpost.com/outlook/2021/08/08/our-patent-system-is-broken-it-could-be-stifling-innovation/> NT

Incentivizing failure is particularly problematic in light of a historic shift in the pharmaceutical industry over the past decade. Faced with stagnating research results, the industry has shifted to outsourcing innovation. Specifically, the majority of innovation in the pharmaceutical industry comes from academia or from small life-science companies. Large pharmaceutical companies then shepherd the drugs through the FDA approval process and into production. And so, **at the end of the day, the big companies — the ones arguing for compensation for failure through hefty patent returns — are not the ones taking the greatest risks for drug development.** Rather, they are gaming the patent system: maintaining high prices and keeping competitors out with patent protections. Consider Gilead’s hepatitis C cure, Sovaldi. The company more than recouped what it paid for the drug in the first year of sales alone. And after five years, the company reaped in excess of $58 billion dollars from sales of the drug, more than five times what it paid to acquire the drug from the start-up that took the initial risk and engaged in the innovation. Or consider Merck’s immunotherapy drug, Keytruda. In 2020 alone, the drug’s sales topped $14 billion, with no signs of flagging. Forbes estimates that the value of Keytruda is $200 billion — a far cry from the $300 million the company paid to acquire it. And Keytruda’s boatload of patents insulates the company’s pricing scheme from competition. Yet the true innovator — that is, the company that took the research risk — isn’t the one reaping the lion’s share of the reward. Rather, the bulk of the patent reward is going to the company that walked the last mile. Examples such as these show how **modern pharmaceutical markets allow large companies to be over-rewarded while innovators are under-rewarded.** If society actually wanted a patent system that compensates for failure, the dollars would go to those who make the investment in the research and take the risk of failure — the inventors. None of that is happening here. Instead, by passing so little of the profit to those who perform the successful research, the system dilutes the incentive for research. **We are not just incentivizing failure, we are sending those dollars to the least inventive part of the innovation chain.** In short, incentivizing failure is as counterproductive as the phrase sounds. Why would we want a patent system in which the less efficient person — the one who fails more along the way — gets a larger reward? Unless we recognize that problem, the nation may find itself sliding quietly into an approach that undermines the contours of the patent system from time immemorial, hampering our ability to innovate in crucial areas.

### Subpoint B – Climate Change

#### Removing patents for drugs removes the incentive for pharma companies to merge by removing the common threat of patent cliffs, which solves innovation and increases drug research

Feldman 4/6/21 (Robin Feldman’s work focuses on the role of intellectual property law in technology and innovation; drug patents, pricing, and health care law; and artificial intelligence and data. She is the Arthur J. Goldberg Distinguished Professor of Law, the Albert Abramson ’54 Distinguished Professor of Law Chair, and Director of the UC Hastings Center for Innovation (C4i).), “Drug companies keep merging. Why that’s bad for consumers and innovation.”, The Washington Post, <https://www.washingtonpost.com/outlook/2021/04/06/drug-companies-keep-merging-why-thats-bad-consumers-innovation/> NT

The Federal Trade Commission’s acting chairwoman, Rebecca Kelly Slaughter, recently announced that the agency would collaborate with regulators in Canada and the European Union to review its guidelines for evaluating drug company mergers. This move may signal more active policing of consolidation in the pharmaceutical industry. For prescription drug users and society at large, this is a welcome — and long overdue — change, one with the potential to spur innovation and offer more treatment options to Americans. **In the past few decades, three waves of mergers have substantially increased concentration in the pharmaceutical industry.** The first wave occurred from approximately 1988 to 1991, with the second following between approximately 1996 and 2002. The third began in 2010 and remains ongoing. The result of these merger waves has been a dramatically consolidated industry. In 1987, the combined market share of the eight largest drug companies stood at a relatively low 36 percent. By the conclusion of the first merger wave, it had grown to 42 percent; by 2012, in the wake of the second merger wave, the ratio had climbed to 53 percent. All told, between 1995 and 2015, the 60 leading pharmaceutical companies merged to only 10. **As a result, now only a handful of manufacturers are responsible for sourcing the vast majority of prescription drugs: Just four companies, for example, produced more than 50 percent of all generic drugs in 2017.** This dramatic consolidation has remade the pharmaceutical industry. Before 1988, a robust cohort of drug manufacturers often competed across multiple therapeutic areas. This competition encouraged exploring different possible approaches for treating the same disease state as well as treatments for a wider range of health concerns, **increasing the potential for innovations that might improve lives**. Although this marketplace was better for innovation, drug companies were drawn to merging because of the lure of increased market power, improved synergies, larger economies of scale and more diverse product portfolios. Abrupt changes to the environment surrounding the pharmaceutical industry also encouraged consolidation. In the late 1980s, widespread deregulation at both the state and federal level may have facilitated an uptick in mergers, particularly as companies with expiring drug patents sought to make up for their revenue losses by acquiring other profitable drugs. The second merger wave beginning around 1996 can be traced in part to another external shock, as globalization spurred firms to join forces to reach more potential markets. **Similar to the first merger wave, “patent cliffs,” in which many of a company’s drugs were set to lose their lucrative patent monopoly around the same time, also helped push firms to combine forces.** But the newly consolidated pharmaceutical industry actually stifled innovation. In the period following merger waves one and two, the industry generated fewer new molecular entities each year compared to pre-merger levels. Merged drug companies also spent proportionally less on research than their non-merged competitors.

#### The pharma industry exacerbates climate change, with big pharma causing significantly more carbon emissions than even the automotive industry

Belkhir 4/19/21 (Dr. Lotfi Belkhir, tenure track Associate Professor, Walter G. Booth School of Engineering Practice, and Class of 1962 Mechanical Engineering Endowed Chair in Eco-Entrepreneurship. Dr. Belkhir is a visionary and results-driven academic and business practitioner. He is a researcher, teacher, inventor and entrepreneurial leader with 17 years of distinguished industrial experience in sustainable and innovation-powered business creation and economic growth. Dr. Belkhir is an expert and thought-leader in the field of Total Sustainable Management, Eco entrepreneurship, digital convergence and its socio-environmental impact. Possesses proven leadership skills in research and development, IP protection, business development, finance, strategic planning, and general management. He possesses strong and successful international experience and alliances, public speaking, and relationship building. Multicultural, and fluent in English, French and Arabic, Dr. Belkhir earned his Ph.D. in condensed matter physics from SUNY and MBA in Management of Technology, Walden University.), “How big pharma contributes to climate change”, Global News, first published 6-1-19 and updated 4-19-21, <https://globalnews.ca/news/5330863/climate-change-pharmaceutical-companies/> NT

Rarely does mention of the pharmaceutical industry conjure up images of smokestacks, pollution and environmental damage. **Yet our recent study found the global pharmaceutical industry is not only a significant contributor to global warming, but it is also dirtier than the global automotive production sector**. It was a surprise to find how little attention researchers have paid to the industry’s greenhouse gas emissions. Only two other studies had some relevance: one looked at the environmental impact of the U.S. health-care system and the other at the pollution (mostly water) discharged by drug manufacturers. Our study was the first to assess the carbon footprint of the pharma sector. More polluting More than 200 companies represent the global pharmaceutical market, yet only 25 consistently reported their direct and indirect greenhouse gas emissions in the past five years. Of those, only 15 reported their emissions since 2012. One immediate and striking result is that the pharmaceutical sector is far from green. We assessed the sector’s emissions for each one million dollars of revenue in 2015. Larger businesses will always generate more emissions than smaller ones; in order to do a fair comparison, we evaluated emissions intensity. We found it was 48.55 tonnes of CO2e (carbon dioxide equivalent) per million dollars. That’s about 55 per cent greater than the automotive sector at 31.4 tonnes of CO2e/$M for that same year. We restricted our analysis to the direct emissions generated by the companies’ operations and to the indirect emissions generated by the electricity purchased by these companies from their respective utilities companies. The total global emissions of the pharma sector amount to about 52 megatonnes of CO2e in 2015, more than the 46.4 megatonnes of CO2e generated by the automotive sector in the same year. The value of the pharma market, however, is smaller than the automotive market. By our calculations, the pharma market is 28 per cent smaller yet 13 per cent more polluting than the automotive sector. Extreme variability We also found emissions intensity varied greatly within the pharmaceutical sector. For example, the emissions intensity of Eli Lilly (77.3 tonnes of CO2e/$M) was 5.5 times greater than Roche (14 tonnes CO2e/$M) in 2015, and Procter & Gamble’s CO2 emissions were five times greater than Johnson & Johnson, even though the two companies generated the same level of revenue and sell similar lines of products. **Energy use, including heating, ventilation and air conditioning, in the manufacturing facilities of pharmaceutical companies produces large amounts of greenhouse gas emissions**. We found outliers, too. The German company Bayer AG reported emissions of 9.7 megatonnes of CO2e and revenues of US$51.4 billion, yielding an emission intensity of 189 tonnes CO2e/$M. This intensity level is more than four times greater than the overall pharmaceutical sector. In trying to explain this incredibly large deviation, we found that Bayer’s revenues derive from pharmaceutical products, medical equipment and agricultural commodities. While Bayer reports its financial revenues separately for each division, it lumps together the emissions from all the divisions. The company also reports and tracks its emission intensity in terms of tonnes of CO2e produced for each tonne of manufactured goods, whether fertilizer or Aspirin, for example. This level of opacity makes it not only impossible to assess the true environmental performance of these kinds of companies. It also raises questions about the sincerity of these companies’ strategies and actions in reducing their contribution to climate change. Climate compliance We also estimated how much the pharmaceutical sector would have to reduce its emissions to comply with the reduction targets in the Paris Agreement. **We found that by 2025, the overall pharma sector would need to reduce its emissions intensity by about 59 per cent from 2015 levels**. While this is clearly a far cry from their current levels, it is interesting to note that some of the 15 largest companies are already operating at that level, namely Amgen Inc., Johnson & Johnson and Roche Holding AG.

#### Warming causes extinction, mass inequality and guarantees every other impact—only the plan can reduce emissions

Spratt and Dunplop 19, David Spratt [Research Director for Breakthrough National Centre for Climate Restoration, Melbourne, and co-author of Climate Code Red: The case for emergency action] & Ian Dunlop [member of the Club of Rome. Formerly an international oil, gas and coal industry executive, chairman of the Australian Coal Association, chief executive of the Australian Institute of Company Directors, and chair of the Australian Greenhouse Office Experts Group on Emissions Trading 1998-2000], “Existential climate-related security risk: A scenario approach,” Breakthrough - National Centre for Climate Restoration, May 2019, pg. 8-10, beckert. Brackets in original text

2020–2030: Policy-makers fail to act on evidence that the current ​Paris Agreement path — in which global human-caused greenhouse emissions do not peak until 2030 — will lock in at least 3°C of warming. The case for a global, climate-emergency mobilisation of labour and resources to build a zero-emission economy and carbon drawdown in order to have a realistic chance of keeping warming well below 2°C is politely ignored. As projected by Xu and Ramanathan, by 2030 carbon dioxide levels have reached 437 parts per million — which is unprecedented in the last 20 million years — and warming reaches 1.6°C.18 2030–2050: Emissions peak in 2030, and start to fall consistent with an 80 percent reduction in fossil-fuel energy intensity by 2100 compared to 2010 energy intensity. This leads to warming of 2.4°C by 2050, consistent with the Xu and Ramanathan “baseline-fast” scenario.19 However, another 0.6°C of warming occurs — taking the total to 3°C by 2050 — due to the activation of a number of carbon-cycle feedbacks and higher levels of ice albedo and cloud feedbacks than current models assume. [It should be noted that this is far from an extreme scenario: the low-probability, high-impact warming (five percent probability) can exceed 3.5–4°C by 2050 in the Xu and Ramanathan scheme.] 2050: By 2050, there is broad scientific acceptance that system tipping-points for the West Antarctic Ice Sheet and a sea-ice-free Arctic summer were passed well before 1.5°C of warming, for the Greenland Ice Sheet well before 2°C, and for widespread permafrost loss and large-scale Amazon drought and dieback by 2.5°C. The “hothouse Earth” scenario has been realised, and Earth is headed for another degree or more of warming, especially since human greenhouse emissions are still significant.20 While sea levels have risen 0.5 metres by 2050, the increase may be 2–3 metres by 2100, and it is understood from historical analogues that seas may eventually rise by more than 25 metres. Thirty-five percent of the global land area, and 55 percent of the global population, are subject to more than 20 days a year of lethal heat conditions, beyond the threshold of human survivability. The destabilisation of the Jet Stream has very significantly affected the intensity and geographical distribution of the Asian and West African monsoons and, together with the further slowing of the Gulf Stream, is impinging on life support systems in Europe. North America suffers from devastating weather extremes including wildfires, heatwaves, drought and inundation. The summer monsoons in China have failed, and water flows into the great rivers of Asia are severely reduced by the loss of more than one-third of the Himalayan ice sheet. Glacial loss reaches 70 percent in the Andes, and rainfall in Mexico and central America falls by half. Semi-permanent El Nino conditions prevail. Aridification emerges over more than 30 percent of the world’s land surface. Desertification is severe in southern Africa, the southern Mediterranean, west Asia, the Middle East, inland Australia and across the south-western United States. Impacts: A number of ecosystems collapse, including coral reef systems, the Amazon rainforest and in the Arctic. Some poorer nations and regions, which lack capacity to provide artificially-cooled environments for their populations, become unviable. Deadly heat conditions persist for more than 100 days per year in West Africa, tropical South America, the Middle East and South-East Asia, contributing to more than a billion people being displaced from the tropical zone. Water availability decreases sharply in the most affected regions at lower latitudes (dry tropics and subtropics), affecting about two billion people worldwide. Agriculture becomes nonviable in the dry subtropics. Most regions in the world see a significant drop in food production and increasing numbers of extreme weather events, including heat waves, floods and storms. Food production is inadequate to feed the global population and food prices skyrocket, as a consequence of a one-fifth decline in crop yields, a decline in the nutrition content of food crops, a catastrophic decline in insect populations, desertification, monsoon failure and chronic water shortages, and conditions too hot for human habitation in significant food-growing regions. The lower reaches of the agriculturally-important river deltas such as the Mekong, Ganges and Nile are inundated, and significant sectors of some of the world’s most populous cities — including Chennai, Mumbai, Jakarta, Guangzhou, Tianjin, Hong Kong, Ho Chi Minh City, Shanghai, Lagos, Bangkok and Manila — are abandoned. Some small islands become uninhabitable. Ten percent of Bangladesh is inundated, displacing 15 million people. Even for 2°C of warming, more than a billion people may need to be relocated and In high-end scenarios, the scale of destruction is beyond our capacity to model, with a high likelihood of human civilisation coming to an end.21 National security consequences: For pragmatic reasons associated with providing only a sketch of this scenario, we take the conclusion of the ​Age of Consequences ‘Severe’ 3°C scenario developed by a group of senior US national-security figures in 2007 as appropriate for our scenario too: Massive nonlinear events in the global environment give rise to ​massive nonlinear societal events.​ In this scenario, nations around the world will be ​overwhelmed by the scale of change and pernicious challenges, such as pandemic disease. The internal cohesion of nations will be under great stress, including in the United States, both as a result of a dramatic rise in migration and changes in agricultural patterns and water availability. The flooding of coastal communities around the world, especially in the Netherlands, the United States, South Asia, and China, has the potential to challenge regional and even national identities.​ Armed conflict between nations over resources, such as the Nile and its tributaries, is likely and nuclear war is possible. The social consequences range from increased religious fervor to ​outright chaos.​ In this scenario, climate change provokes ​a permanent shift in the relationship of humankind to nature​’.22 (emphasis added) DISCUSSION This scenario provides a glimpse into a world of “outright chaos” on a path to the end of human civilisation and modern society as we have known it, in which the challenges to global security are simply overwhelming and political panic becomes the norm. Yet the world is currently completely unprepared to envisage, and even less deal with, the consequences of catastrophic climate change.23 What can be done to avoid such a probable but catastrophic future? It is clear from our preliminary scenario that dramatic action is required this decade if the “hothouse Earth” scenario is to be avoided. To reduce this risk and protect human civilisation, a massive global mobilisation of resources is needed in the coming decade to build a zero-emissions industrial system and set in train the restoration of a safe climate. This would be akin in scale to the World War II emergency mobilisation. There is an increasing awareness that such a response is now necessary. Prof. Kevin Anderson makes the case for a Marshall Plan-style construction of zero-carbon-dioxide energy supply and major electrification to build a zero-carbon industrial strategy by “a shift in productive capacity of society akin to that in World War II”.24 Others have warned that “only a drastic, economy-wide makeover within the next decade, consistent with limiting warming to 1.5°C”, would avoid the transition of the Earth System to the Pliocene-like conditions that prevailed 3-3.3 million years ago, when temperatures were ~3°C and sea levels 25 metres higher.25 It should be noted here that the 1.5° goal is not safe for a number of Earth System elements, including Arctic sea-ice, West Antarctica and coral reefs.

#### The plan solves - WTO is crucial to global equity and reduce poverty

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Recurrent deadlocks have plagued the Doha negotiations since their launch in 2001, damaging the credibility of the organization that oversees this unfortunate negotiation process. The WTO’s Ministerial Conference in Nairobi in 2015, which coincided with the 20th anniversary of the WTO’s founding, should have been a moment for celebration. Instead, it turned out to be an embarrassment: for the first time the Ministerial Declaration reflected not consensus but fundamental division over whether even to reaffirm the Doha mandates, which had sought to launch an ambitious round of multilateral trade liberalization with a close eye on development issues. At its Ministerial Conference in Buenos Aires, in 2017, the WTO sank to a new low: this conference was unprecedented in its failure to even produce a Ministerial Declaration. The WTO seems to be whimpering its way to an inglorious end. And if the global trading mechanism does indeed collapse, the consequences will be adverse for all parties, but especially so for the poorest of the world. PUNISHING DEVELOPING COUNTRIES AND THE POOREST PEOPLE In 2010, the Millennium Development Goals reached one of its targets, of cutting extreme poverty by half. The most important factor that contributed to this achievement was economic growth in many developing countries, especially China and India. Although such growth was fueled by several factors, one critical driver was international trade. Extensive research shows that the countries and regions that harnessed the opportunities afforded by low tariffs and open markets did particularly well, aided as they were by a reliable system of enforceable trade rules—all negotiated, monitored, and implemented under the auspices of the WTO. Still, between 600 million and 700 million people currently live under $1.90 per day and are concentrated in middle-income and lower-income developing countries. For instance, 4.5 percent of Brazilians live below the extreme poverty line, six percent do in India, and 34 and 42 percent do in Afghanistan and Nigeria. Much work still has to be done to address the concerns of the poor worldwide, and a minimal step toward this would be to ensure continued market access for developing countries and to maintain the predictability of tariff and non-tariff barriers. If the WTO collapses, rich countries would easily be able to crank up tariffs against poorer countries, while introducing many other protectionist measures to discourage imports. Developing countries, which have experienced growth through exports, and have adapted their production chains to export markets, would be hit hard. A decline in their exports would directly affect their producers and workers in the affected industries, resulting in losses for poor people who can least afford such losses. The costs, moreover, would go beyond the immediate job losses and price hikes in basic goods. The first fundamental benefit that poor countries derive from the WTO is that they get a relatively level playing field for negotiating with more powerful countries. Outside the WTO, in bilateral and regional settings, it is much easier to coerce countries into accepting harsh terms in a trade deal, such as through stringent environmental and labor standards that they would find virtually impossible to meet. In contrast, the institutional setting of the WTO offers developing countries some indispensable advantages. Formally, all members in the WTO have one vote each (very different from voting procedures at the UN Security Council and the International Monetary Fund). This is a powerful equalization tool, which is rendered all the more potent by the fact that consensus-based decision-making allows even the smallest and weakest player de jure veto power. Informally, having an audience within the institution, and a range of partners to work with, enables poor countries to form coalitions with like-minded states. Some powerful coalitions have emerged over the years, which have allowed poor and middle-income countries to band together (sometimes also with developed countries) to punch considerably above their weight in the Doha negotiations. One example is the G-33. It began as a coalition of 33 developing countries including China, India, Indonesia, Nigeria, Pakistan, and others, but now comprises 47 members and has managed to resist calls for greater market opening for agricultural products in developing economies. The G-20, a coalition led by Brazil, China, and India at the time of its founding, which now includes 23 developing countries, has demanded more ambitious market opening for agricultural products in developed country markets. Without the WTO, developing countries would have neither the institutional rules to protect them nor the support of coalitions to enhance their bargaining power. The second important benefit that developing countries derive from the WTO is its Dispute Settlement Mechanism (DSM), which allows members to take another member “to court” over violating trade rules. In the event a judgment is made, the WTO can then authorize retaliatory measures against the responding party. Even though there are several deterrents that might make poor countries reluctant to make use of this facility (including the fact that bringing a dispute against a rich country requires extensive technical and legal know-how, and low-income countries sometimes lack the resources and capacity to initiate a case), the figures show considerable learning and growing effectiveness on their part. While the United States and the European Union have been the most avid users of the DSM (they have brought 115 and 97 cases, respectively, since 1995), many large developing countries have also frequently lodged complaints. China, for example, has brought 15 cases; India, 23; and Brazil, 31. Nor should one assume that the DSM has been the stomping ground of only developed countries and rising powers. David has sometimes taken on Goliath. Ecuador, for example, filed a complaint against U.S. action against its shrimp exports in 2005, and won, despite the extreme asymmetry of power. Allow the WTO to wither away and the world returns to a system of unchecked power politics. The costs, moreover, would not necessarily be limited to the “global South” and its poorest people. FROM WIN-WIN TO LOSE-LOSE Even if a WTO collapse would strike the poorest nations the hardest, rich countries will not escape its impact, as the resulting protectionism would greatly hurt poor consumers in developed economies. They would lose access to cheap and competitive imports from developing countries, including essential items such as fruits and vegetables, garments, footwear, and other items on which the average person spends a large proportion of his or her disposable income. The impact of increased tariffs on employment, however, would be, at best, mixed. Any gains would be restricted to specific sectors. For instance, a tariff increase on steel imports may see job increases in that particular industry—although tariffs would not save the job losses that have occurred due to technological innovation—but many other U.S. industries that rely on steel imports, such as producers of cars or electrical machinery, would see their production costs rise. This, in turn, would negatively affect their domestic and international competitiveness, profit margins, and their ability to hire and pay wages. Further, it is unlikely that other countries will accept such treatment sitting down. Retaliatory action could potentially go considerably beyond the steel and steel-consuming sector. China is the second-largest market for agricultural exports from the United States; if China increased trade barriers against soybeans, coarse grains, meat products, and cotton, it could hurt U.S. jobs across several sectors. Of course, such measures by China would be welfare-reducing for its own consumers too, who benefit from these key and competitive U.S. imports. Almost all parties would thus end up in an entirely unnecessary and sad lose-lose situation. In sum, a trade war would be a lose-lose for all, but particularly the poorest in developed and rising powers.