### I affirm my value is justice, to each their due. We cannot have a just society if people who are marginalized are not treated equally.

### Structural violence is based on moral exclusion, which is fundamentally flawed because the exclusion is based on arbitrarily perceived differences.

**Contention 1  - Biopiracy**

**TRIPS cause monopolies and patents crops and agriculture  – Shiva ’06**

[Shiva, Vandana. “Profiteering from Death: TRIPS and Monopolies on Seeds and Medicines.” Revista Brasileira de Direito Internacional - RBDI, vol. 4, no. 4, 31 Dec. 2006, 10.5380/rbdi.v4i4.10421. Accessed 5 Apr. 2020]ZW

‌The Trade Related Intellectual Property Rights Agreement of WTO is the most far reaching in terms of creating corporate rights and corporate monopolies. During the Uruguay Round of the GATT, **the U**nited **S**tates **introduced its flawed patent system into the WTO, and thus imposed it on the rest of the world. US Corporations have admitted** that **they drafted and lobbied on behalf of TRIPs.** As a Monsanto spokesman said, “The industries and traders of world commerce have played simultaneously the role of patients, the diagnosticians, and prescribing physicians.” **TRIPs** not only made Intellectual Property Rights (IPR) laws global geographically, but also **removed ethical boundaries by including life forms and biodiversity into patentable subject matte**r. Living organisms and life forms that are self-creating were thus redefined as machines and artifacts made and invented by the patentee. Intellectual property rights and **patents** then **give the patent holder a monopolistic right to prevent others from making, using, or selling seeds. Seed saving by farmers has now been redefined from a sacred duty to a criminal offence of stealing “property”**. Article 27.3 (b) of the TRIPs agreement, which relates to patents on living resources, was basically pushed by the “Life Science” companies to establish themselves as Lords of Life. The chemical **companies** of the world **have bought up seed and biotech**nology **companies** and **reorganized themselves as Life Science corporations, claiming patents on genes, seeds, plants and animals.** Ciba Geigy and Sandoz have combined to form Novartis, Hoechst has joined with Rhone Poulenc to form Aventis; Zeneca has merged with Astia; Dupont has bought up Pioneer HiBred; and Monsanto now s Cargill Seeds, DeKalb, Calgene, Agracetus, Delta and Pine Land, Holden and Asgrow, Seminis. **Eighty percent of all genetically engineered seeds planted are Monsanto’s “intellectual property.**” And Monsanto owns broad species patents on cotton, mustard, soyabean – crops that were not “invented” or “created” by Monsanto but have been evolved over centuries of innovation by farmers of India and East Asia working in close partnership with biodiversity gifted by nature.

### AND, TRIPS have patented agricultural goods that are 70% of indigenous medicine -Shiva ‘06

[Shiva, Vandana. “Profiteering from Death: TRIPS and Monopolies on Seeds and Medicines.” Revista Brasileira de Direito Internacional - RBDI, vol. 4, no. 4, 31 Dec. 2006, 10.5380/rbdi.v4i4.10421. Accessed 5 Apr. 2020]ZW

there were only one or two cases of such false claims to invention on the basis of biopiracy, they could be called an error. However, biopiracy is an epidemic. N**eem, haldi, pepper, harar, bahera, amla, mustar, basmati, ginger, castor, jaramla, amaltas, karela and Jamun have all been patented.** **The problem is not,** as was made, **out to be in the case of turmeric, an error made by a patent clerk**. The problem is deep and systemic. And it calls for a systemic change, not case-by-case challenges. That is we demand a change in TRIPS and Patent Laws Some have suggested that biopiracy happens because Indian knowledge is not documented. That is far from true. **Indigenous knowledge in India has been systematically documented, and this in fact has made piracy easier**. And even the folk knowledge orally held by local communities deserves to be recognized as collective, cumulative innovation. The ignorance of such knowledge in the United States should not be allowed to treat piracy as invention. The potential costs of biopiracy to the Third World poor are very high since **two thirds of the people in the South depend on free access to biodiversity. for their livelihoods and needs**. Seventy percent of seed in India is saved or share farmers’ seed**; 70 percent of healing is based on indigenous medicine using local plants.** If a patent system that is supposed to reward inventiveness and creatively systematically reward piracy, if a patent system fails to honestly apply criteria of novelty and non-obviousness in the granting of patents related to indigenous knowledge, then the system is flawed, and it needs to change. It cannot be the basis of granting patents or establishing exclusive marketing rights. The problem of biopiracy is a result of Western-style IPR systems, not the absence of such IPR systems in India. Therefore, the implementation of TRIPs, which is based on the US style patent regimes, should be immediately stopped and its review started.

**AND, The commodification of agriculture risks future medicine and crops from being developed due to monoculture -Thompson ‘02**

Mushita, Andrew T., and Carol B. Thompson. “Patenting Biodiversity? Rejecting WTO/TRIPS in Southern Africa.” *Global Environmental Politics*, vol. 2, no. 1, 1 Feb. 2002, pp. 65–82, direct.mit.edu/glep/article/2/1/65/14146/Patenting-Biodiversity-Rejecting-WTO-TRIPS-in, 10.1162/152638002317261472. Accessed 9 Sept. 2021.(ZW).

‌Using the utilitarian argument that patents provide incentive and rewards for innovations, the WTO gives entitlement to ownership. The exploitation of traditional knowledge systems, without due regard to the original innovators, is not new. What is new is that the WTO legalizes privatization of what has been “borrowed” from “natural” reserves. As Correa notes: “The creation of knowledge by indigenous/traditional farmer communities is characterized and compared to knowledge production in the “science” and “technology” systems. Intellectual property rights are currently applicable to downstream activities, while knowledge generated upstream is deemed to be in the public domain, despite its economic value.” 17 Plant breeding, however, cannot exist without access to many diverse varieties; it is a requirement. The so-called “raw materials” are germ plasm, and the narrow genetic composition of improved varieties makes them vulnerable to diseases so the breeder must return to the original parent strain for genetic variability for yet newer strains. However, in promoting adoption of new strains, there is constant danger that the original varieties may be lost, eliminating the essential resource for the new variety.18 **About 75 percent of active ingredients in pharmaceuticals come from plants in Southern countries. To give just one example from Africa, the rosy periwinkle of Madagascar provided two cancer drugs developed by Eli Lilly, which has reduced deaths from testicular cancer and childhood leukemia, making hundreds of millions of dollars for the corporation, and none for Madagascar.19 Today, Zimbabwe has over 50,000 registered traditional healers, using over 500 different types of plants for medicinal purposes.** **This traditional knowledge is so prized that medicinal plants are the objects of theft by pharmaceutical corporations.** Zimbabwe has taken more than one pharmaceutical corporation to court for patenting a local plant and the traditional knowledge of its use, without any reference to Zimbabwe, the source of the plant and the knowledge. The cost to take a corporation to court for stealing traditional knowledge is prohibitive for developing countries, estimated at US$0.5–1.0 million per case.20 Similarly, traditional cross-breeding of plants has provided seed and germ plasm to agribusiness, saving it millions of dollars. An Ethiopian crossbred barley in the 1950s saved the entire California crop from yellow dwarf virus, providing hundreds of millions of dollars to Californian agribusiness, but nothing for Ethiopia.21 A West African berry has a thaumatin plant protein which is 2000 times sweeter than sugar. The gene can already be inserted into fruits and if a sweetener is developed from the protein, it can be produced in genetically modified bacteria, eliminating the need for the berry itself. Not only will the original breeders of the berry not receive any benefit, but the genetically modified bacteria could run the world’s sugar cane and beet sugar producers out of business.22 In fact, under the WTO TRIPS law, if extended to plants as planned, the original innovators may be sued by the one who stole the plant if they dare to use their berries as sweeteners. Further, traditional farmers have been innovative breeders for centuries and they classify their seed. Mende farmers in Sierre Leone have long conducted ªeld trials to test new rice seeds for diverse soil types. In Rwanda farmers choose bean seeds that perform best in poor soils. In Zimbabwe and Mozambique, the consumers resist eating imported yellow maize, even in a drought, because they consider it cattle feed; their white maize varieties are bred for taste, not simply for yield. In Kenya it is said that the Bukusus people have a plant classiªcation system superior to that of Carl von Linnaeus. Traditional farmers in breeding and classifying plants have sustained biodiversity, which is the foundation for modern pharmaceuticals and food crops.23 The market for commercial seed is estimated at US$45 billion, and grow - ing. Only six corporations control the global commercial seed market: Monsanto, Dupont, Dow Elanco, Novartis, AgrEvo, and Zeneca. Investing in the future provided by creation of the WTO in 1995, Monsanto spent US$6 billion, from 1996–98, to take control of seed and biotechnology companies. Monsanto currently has a research and development (R&D) budget that is more than twice that of the entire worldwide network of public sector tropical research institutes.24 Biotechnology may prove to be the miracle technology of the 21st century, providing cures and prevention for HIV/AIDS or for devising new foods not yet imagined. However, it also poses many dangers, especially if owned and controlled by the very few. **Those criticizing the WTO are not criticizing biotech**nology. **They are criticizing the privatization of knowledge, the restriction of free sharing.**25 The argument here is that the **WTO legal regime will privatize biotech discoveries, make them available only if large profits are made—and can threaten biodiversity by promoting** (paying for, valuing) **monoculture.** Loss to biodiversity is not readily documented because no one knows how many plant species there are, and species become extinct in the process of evolution. The Green Revolution is perhaps the best example of how local diversity may give way to corporate monoculture. **In India, over 75 percent of total rice production uses less than 10 percent of the 30,000 varieties of rice available.** In Bangladesh, with 22 percent of the rice areas planted to modern varieties, 62 percent of those are from one maternal parent.26 **The current world food supply is highly vulnerable. Loss of diversity is loss of plant resource by which to improve varieties, either in the field or in the laboratory. Specialization threatens the genetic pool and increases instability of the ecological systems.** In Southern Africa professional plant breeders register their varieties and governments follow internationally recognized plant breeders’ rights. However, most of the registered plants are for cash crops. As of 1999, Zimbabwe has 31 genera or species protected, with 70 percent of the applications for cash crops.27 When one considers food crops, the majority of seed is saved and informally ex - changed, except for maize seed. Nongovernmental organizations (NGOs) are working with small farmers to increase their seed propagation and improve open pollinated varieties of grain and pulses.28 The serious question is—do improved varieties, whether by plant breeders or small farmers, have to be patented? If not patented, what are alternative means of protection of a nation’s indigenous plants? The goal of TRIPS of the WTO is to transform Southern Africa’s dual exchange—market place and on farm—into only market purchase. Southern Africa proposes alternatives which would protect plant resources and reward innovation, and not only that which occurs in a laboratory.

**Monoculture leads to a litany of impacts i.e. child hunger, disease, and even extinction -Grant ‘07**

**Grant, S. M. (2007). *The Importance of Biodiversity in Crop Sustainability: A Look at Monoculture. Journal of Hunger & Environmental Nutrition, 1(2), 101–109.* doi:10.1300/j477v01n02\_07 (ZW)**

**‌**Monoculture is presently associated with the move towards agricultural production for the market rather than consumption.10,19 Its strength, in theory, is that farmers, through production of mass quantities of a few crops that are in demand, can exploit all that this market can offer, without having to risk planting other varieties of crops that may not be in demand.9 Monoculture and the high-yielding varieties of cash crops released during the Green Revolution have been associated with the increased food production and productivity in South Asian regions during the past few decades. Monoculture has also been connected to the significant growth in the international food market and food assistance during the 1960s.13 Between 1970 and 1990, however, almost **half of the world’s less developed countries suffered a decline in** aggregate **food supply and more than a quarter suffered from an increase in child hunger.**19 In Africa and parts of Asia, **a reduction in traditional agricultural practices has resulted in an increase of food insecurity** at the household leve**l.**7,14,20 Subsistence farmers and near-subsistence farmers, many of whom previously supplemented their income by working for wealthier landowners, have seen their lands confiscated and their jobs replaced by pesticides, herbicides, and machines. These practices, implemented to grasp the opportunity provided by monoculture crops, were adopted by the large growers to eliminate the potential threat posed by trade unions and other farmers.9,14 The increased use of pesticides became unavoidable after traditional methods of mixed cropping, or intercropping, were replaced by **genetically uniform crops vulnerable to pests and disease.**5,14,21 **Adoption of monoculture** and its associated practices are also **linked to** an increase in the female work burdens and **higher incidence of malnutrition and morbidity**, when compared with practices in neighboring, less commercialized, regions. This significant relationship is observed in spite of an increased Gross National Product (GNP) and improved food security on a national level.7,20 The loss of dietary diversity has been widely recognized as a cause of vitamin A deficiency in developing countries. This loss of dietary diversity has also been linked to deficiency in other essential vitamins and minerals. Iron deficiency, for example, is estimated to affect onequarter of the world’s population.7 In rural areas of India, families have diets that are only sufficient in the cereal and grains category. In all regions of India, diets lack diversity in terms of fruits, green vegetables, and nuts with 8 to 30 percent of all families deficient in vitamin A.22 Dietary diversity is also becoming a major concern among the developed countries, as they are beginning to recognize that although their diets are rich in calories, they lack the diversity that is required to prevent a number of vitamin and mineral deficiencies.23,24 With the recent move towards environmental awareness in industrialized countries, those involved in food growth and distribution are recognizing that monoculture and its associated practices are not sustainable.25,26 Americans are looking for alternatives to the monoculture that has cultivated a surplus of corn fields and that is responsible for eliminating 80 percent of the over 7,000 apple varieties that were once available.10,2**7 Under a monocultural system, plants have to compete for nutrients at the same time, in the same proportion, and at the same depth. Plants under the monocultural system cannot help retrieve nutrients or water below their roots to benefit the rest of the crops in the field. Therefore, basic nutrients must be supplied artificially and abundantly for a nutritionally adequate yield.** If the supply of such nutrients is not sufficient, there is a decreased mineral content in foods cultivated in monoculture, which adds to consumers’ risk for mineral deficiencies.28 There has been longstanding concern that modern plant breeding and cultivation reduces genetic and/or species diversity. Such reduction has been linked to an increased vulnerability of crops to changes in pests and diseases and a decrease in their ability to respond to changes in climate and agricultural practices.5 Hurricanes in Central America have shown that traditional land management systems are more resilient in the face of natural disasters. In October, 1998, Hurricane Mitch devastated Honduras, Nicaragua, and Guatemala. Conventional farms using the industrial model of chemical-intensive monoculture had 60 to 80 percent more soil erosion, crop damage, and water loss, than those that practiced traditional methods such as crop mixing, biological pest control, and water conservation.15 For countries with little money for social safety nets, it is essential to give priority to this kind of resilience, protecting people from the loss of their livelihood.15,21 Definitions of productivity have been shifting. Recent studies have been measuring the overall farm productivity, rather than the yields of monocrops. Counting the benefits that diverse farm systems offer in terms of nutritional output and sustainability is being stressed.15 Diverse farm systems may not see the same yield levels that monocultured, high yield crops treated with fertilizers and pesticides can, if you compare crop to crop. Overall productivity, nevertheless, is much greater in the long term and the yield of the land increases significantly with less intensive, diverse cropping.15 The extensive cultivation of scientifically developed crop varieties has contributed immensely to the world’s food production.13 Yet, this practice has also led to “genetic erosion” and in turn has hindered efforts to further improve crop varieties.9 It is estimated that the introgression of new genes or the incorporation of new gene complexes into some breeding programs will be necessary to overcome the possible inability to further improve crops, to avoid genetic vulnerability to biotic stresses, and to widen crop adaptation to new environments.18 In spite of impressive achievements in yield and disease resistance, concern about narrowing of the oat gene pool is warranted. Cultivar development in Canada since 1930 has been largely based on a genetic foundation of fewer than ten parental lines.18 This situation may also be true for the oat breeding programs in the United States, as most oat germplasms used for cultivar development before 1970 traced back to only seven varieties, which originated in Europe.18 Fu et al.18 confirmed the narrowness of the Canadian oat gene pool during analysis of data compiled on allelic diversity in 96 cultivars released from 1886 to 2001. The data revealed that the average number of alleles per cultivar was 1.29 for the 1930s, 1.27 for the 1940s, 0.92 for the 1950s, 0.60 for the 1960s, 0.53 for the 1970s, 0.62 for the 1980s and 0.64 for the 1990s. These results indicate that cultivars released before 1960 had more alleles than those released after 1960. Fu et al.18 reported that the reason the number of alleles increased from 1970 to 1980, was that a number of new alleles were added. These new varieties are attributed to modern selective breeding techniques.Over the past 30 years there has been an increase in the practice of monoculture and the use of growth fertilizer on Asian rice crops. This increase is attributed to the intense competition for survival among farmers unable to afford the high-yielding, pest-resistant “miracle seeds” introduced during the Green Revolution.9,14 The annual growth of fertilizer use on Asian rice has been up to 40 times faster than the growth of rice yields.14 Recently, however, rice farmers have been introduced to the practice of rice-fish farming, where the rice paddy can double as a fish-breeding ground. This cultivation alternative gives farmers access to fish protein without increasing their land holdings.9,15 The introduction of fish into the paddy fields has been shown to reduce the need for pesticides, increase the farm household income, and diversify agriculture production. Thus, it is believed that integrating farming systems can help farmers increase their farm incomes and enhance agricultural and rural development.9,29 Most farmers recognize that modern agricultural practices have contributed tremendously to the loss of traditional varieties from agroecosystems and that more sustainable alternatives exist. Many, however, feel that they are unable to adopt more sustainable growing techniques due to economic demands.15,29 In modern agricultural systems, farmers’ decisions are influenced to a large extent by market demand, changes in government policies, and other socioeconomic factors. Furthermore, considerations such as culture, religion, labor, technological skills, and dietary preferences also come into play.9,29 Zhu et al.9 reported great success among farmers who made use of mixed planting practices (intercropping) of traditional and hybrid rice varieties in Vietnam. Those who adopted these alternative methods recognized them as an ecologically sensitive approach to disease control, due to an apparent yield increase and decrease in fertilizer use. The data displayed that the number of traditional rice varieties in cultivation has increased dramatically, following the adoption of intercropping, and now includes some varieties that were formerly close to extinction. Among farmers, rare and endangered species have become more popular, where over the past decades farmers have reluctantly abandoned many of these varieties. This abandonment was based on their inability to grow them in monoculture, due to susceptibility to rice blast and other diseases.30 Conservation of crop diversity brings substantial economic benefits to farmers. Cultivation techniques associated with conservation, decrease the need for fertilizer, pesticides, and energy input, and produce high outputs.9,30 They also meet the demand of the market for some high quality and culturally important traditional rice varieties and improve agricultural ecosystems by significantly reducing pesticide use. Mixed planting of various combinations of crop species, such as wheat and fava beans, potato and maize, and oil rape and fava bean promise conservation and sustainability as well.9 Crop diversity management practices, however, are not a perfect solution to all of the world’s agricultural problems. It is not effective as a preventative measure for disease for which resistance is species nonspecific, for example.9 In addition, this method is easily adopted and popularized only in agricultural systems were manpower operation is still predominant. It would be difficult, at present, to apply the method in agricultural systems that employ industrial equipment.14 If crop diversity management proves to be practical for pest control, maintenance of high yields, and environmental protection, industrial equipment suitable for its application would have to be designed. An example of a circumstance where this has already been implemented would be the celery and leek intercropping system in Switzerland.9 It is recognized that a threat to the future survival of mankind is loss of biodiversity.3-5 Monoculture is a term that can be applied to any instance where a single practice**, species or behavior is favored by a population and exploited to the point where other practices, species or behaviors are at the risk of extinction**.2,6-9 Monoculture and its associated practices, therefore, run counter to biodiversity. Numerous ecological, agricultural, and economic studies have concluded that loss of variety and diversity makes a system vulnerable to its surrounding environment.4-5,12,14,18,21 Recent studies have also reported the negative repercussions of extensive pesticide and fertilizer use on the environment.9,14,29 Modern agriculture techniques and technologies are available to support more diverse and sustainable agriculture and only a select few have been presented in this short account. If we as a global community are to move towards a more resilient and viable agricultural economy, the following must be made a reality for future generations: A balance of power among the members of the food chain, open-mindedness to time-tested and new cultivation techniques, an appreciation of the natural diversity that exists, and recognition of ourselves as a small part of a larger ecosystem.

**Removal of the G8 solves for biopiracy -Shiva ‘06**

[Shiva, Vandana. “Profiteering from Death: TRIPS and Monopolies on Seeds and Medicines.” Revista Brasileira de Direito Internacional - RBDI, vol. 4, no. 4, 31 Dec. 2006, 10.5380/rbdi.v4i4.10421] ZW

Monopolies on medicines and seeds are threatening the lives of millions. What is needed is a completion of the review of TRIPs and implementation of the Doha public health declaration. Article 27.3 (b), which allows the patents on seeds and plants, was to be reviewed in 1999 and by 2000, countries could amend the TRIPs agreement as a whole. However, the **G-8 has systematically blocked the review process**. In 2001, countries signed the Doha Declaration, which states, “The TRIPs agreement cam and should be interpreted and implemented in a manner supportive of WTO member’s right to protect public health and in particular to promote access to medicine for all.” **Yet, instead of promoting access to seed for all farmers and access to medicines for all, the G-8 is promoting access to monopoly markets for those pharmaceutical giants, which are also the seed biotechnology giants**. The priorities for the G-8 submitted as identified by the Personal Advisor to the Chancellor (Berlin, October 10, 2006) repeated refers to stronger IPR rights for corporations, and hence weaker rights to food and medicine for citizens. The note on priorities states, There is no mention of biopiracy. Product patents are, assumed to be a right and process patents are defined as “product piracy”. This is a trait support to corporate monopolies over seeds and medicines. Instead of making a commitment to the outstanding review of TRIPs, the G-8 priority is to create new agreements to enforce monopolies for corporations. “The ability of knowledge based societies to innovate is increasingly challenged by violations of intellectual property rights. In this context, the German G8 Presidency aims to bring the protection of innovation through international and domestic law onto the G8 agenda. Our particular attention goes to improving the implementation of intellectual property rights. However, we are primarily concerned with developing new initiatives within the G8 framework, for instance few international agreements that are necessary to solve problems with the implementation of existing national and international rules. In particular, we aim to initiate a structured dialogue with emerging countries about the protection of intellectual property. We assume that given the effort to develop their own technological innovations, these countries will also have a growing interest in improving the protection and implementation of intellectual property rights. India and China are resisting another international agreement, to force implementation of the biased TRIPS agreement which needs reform not implementation. This sounds like TRIPs plus. If **TRIPs has killed hundreds of thousands of farmers, by denying them seeds, and threatens to kill millions of people by denying them medicine**, how much more violence will a TRIPs plus, driven by the G-8, unleash on the poor of the world? Corporate intellectual property rights have become a threat to the survival of the poor. The G-8 cannot talk about achieving the Millennium Development Goals while **it promotes monopolies on seeds and medicines.** It cannot talk of a knowledge economy if it robs people of access to knowledge. And it cannot talk of equitable globalisation if **it denies the right to food and the right to health through monopolies in agriculture and medicine**. It cannot talk of a knowledge economy if it robs people of access to knowledge. And it cannot talk of equitable globalisation if it denies the right to food and the right to health through monopolies in agriculture and medicine.

**Drug prices are drastically lower after patent expiration, Schans ‘11**

“The Impact of Patent Expiry on Drug Prices: Insights from the Dutch Market.” *Journal of Market Access & Health Policy*, 2021, [www.tandfonline.com/doi/full/10.1080/20016689.2020.1849984](http://www.tandfonline.com/doi/full/10.1080/20016689.2020.1849984). Accessed 25 Aug. 2021.

‌This is the first study to investigate the impact of patent expiration on the drug prices for the Dutch market using two national databases including 250 drugs of which the patent expired. Four years after initial generic entry the median price ratio of these drugs was 0.59. However, the price decrease varied widely. Ranging from 0.08 to 0.81, depending on the revenue prior to patent expiration and the year of patent expiration. Additionally, it was shown that drug prices also decreased by 2.3% annually on average during the period of market exclusivity. The combination of the annual decrease during the market exclusive period with the impact of patent expiration indicates that **drug prices 48 months after patent expiration are 74% lower compared to initial market entry on average**. The results of **this** study **can** be used to **predict** the price developments and budget impact of **newly registered drugs** in the Netherlands, as well as those that are bound to face patent expiry **and generic entry** in the near future. This study can also be used to complement the Horizon scan, an initiative in the Netherlands to track all the innovative drugs that will come to the market as well as drugs that will have their patent expired in the near future [[8](https://www.tandfonline.com/doi/full/10.1080/20016689.2020.1849984)]. In particular, the outcomes of this study can be applied to estimate the cost-effectiveness of innovative drugs for pricing and reimbursement purposes. The data presented in this study enable the modelling of dynamic prices over the lifetime of a drug instead of the static price that is currently used in HTA and decision-making processes. Implementing price changes and possible generic substitution after patent expiry will retrieve a more reliable estimate of the cost-effectiveness of that drug in practice. **This is especially the case for** chronic diseases, as **drugs for chronic diseases [as they] are used during the patients’ entire life.**

**Contention 2 - Innovation**

### failing clinical trials, drug prices, econ recovery and more are swamping invest now

Langley 4/21 [(Kare, reporter for The Wall Street Journal in New York, where she primarily covers the U.S. stock market), “Biotech Stocks Fall Out of Favor After Disappointing Trial Results, Big Rally “, WSJ, 4/21/2021, https://www.wsj.com/amp/articles/biotech-stocks-fall-out-of-favor-after-disappointing-trial-results-big-rally-11619016330]

Shares of Sarepta Therapeutics Inc., Amicus Therapeutics Inc. and Frequency Therapeutics Inc. are among the recent losers for biotech investors, having lost more than half their value so far this year. “It’s felt like a kitchen sink in terms of the number of factors weighing on biotech sentiment in the near term,” said Andy Acker, who manages the Janus Henderson Global Life Sciences Fund. Among those are **disappointing clinical trials, concern about the possibility of renewed focus on drug prices** in Washington **and the recent rotation into economically sensitive stocks.** Biotech shares enjoyed a powerful rally last year. The Nasdaq biotech gauge soared 26% in 2020 on excitement about the potential for Covid-19 treatments and vaccines as well as a broader rally in shares of companies that can perform when the economy is struggling. The S&P 500, meanwhile, gained 16% last year, and the Nasdaq Composite surged 44%. Rapid gains or losses in share prices following clinical-trial results or regulatory decisions are a feature of **biotech investing,** but a smattering of **negative news has damped enthusiasm** in recent months. Shares of Sarepta Therapeutics plunged 51% on Jan. 8 after mixed results from a study of a drug targeting a form of muscular dystrophy. The shares are now down 58% for the year. Amicus Therapeutics shares dropped 33% on Feb. 12 after trial results for its treatment of a rare disorder called Pompe disease disappointed investors. And shares of Frequency Therapeutics plunged 78% on March 23 after the company found its lead drug aimed at treating sensorineural hearing loss didn’t lead to any hearing benefit when given in a four-dose schedule. Those stocks are down 57% and 72%, respectively, this year. Also weighing on sentiment**: The F**ederal **T**rade **C**ommission **has indicated it is preparing to take a harder line on drug-company mergers, which are a source of potential value for investors** in small biotech shops. The commission in March said it would reconsider its approach to scrutinizing deals that could harm competition. “Biotech can be driven by mergers,’ said Jeremie Capron, director of research at ROBO Global, a research and investment-advisory firm. “A change at the FTC, it reduces the probability of a favorable outcome in terms of an acquisition.” Analysts will also be keeping an eye on any efforts in Washington to reduce drug prices. Some **investors are betting against companies in the industry.** Biotech stocks accounted for five of the 10 most-shorted stocks on U.S. exchanges at the end of March, according to S&P Global Market Intelligence. Short interest in Esperion Therapeutics Inc.stood at 34% of shares outstanding as of March 31, followed by Clovis Oncology Inc. at 31% and Inovio Pharmaceuticals Inc. at 26%, an S&P analysis showed. As Covid-19 vaccines reach more people and the economy picks up, investors have favored shares of banks, energy producers and other companies that tend to do well in a strong economy. They have been less interested in stocks that hold out the prospect of innovation-driven growth in fields like technology and biotech. Expectations of a strong recovery have also been seen in the bond market, where falling prices lifted the yield on the benchmark 10-year U.S. Treasury note to 1.566% on Wednesday from 0.913% at the end of last year. As yields climb, borrowing costs for businesses also rise. That often lands hard on biotech companies, where hefty bills for research and development can arrive long before revenue.

### IP stifles innovation with unnecessary expenses and IP violations. University of Notre Dame 19

 [(University of Notre Dame, One of America’s leading undergraduate teaching institutions, Notre Dame also has been at the forefront in research and scholarship.) “Intellectual Property Rights: The Good, The Bad, and China” University of Notre Dame, Law and Entrepreneurship, 2/25/19. <http://sites.nd.edu/entrepreneurlaw/2019/02/25/intellectual-property-rights-the-good-the-bad-and-china/>] **¶**

Safeguarding a company’s intellectual property (IP) can be crucial to developing and maintaining a successful business. In a New York Times Magazine article “Z-Burger Case Shows Value of Trademark Protection,” Payam Tabibian, the original owner and creator of the successful Z-Burger fast-food chain, was able to protect his creation precisely because he had registered his trademarks at the outset of creating his business. IP rights not only help preserve an entrepreneur’s business, however, they are also crucial for encouraging innovation, protecting small businesses, and helping to establish brand trust and awareness. Additionally, IP rights can assist in securing secondary revenue streams and can also be used as leverage if an entrepreneur is in possession of a valuable patent they want to use as collateral when financing their startup. Although the United States has relatively strong IP rights, the legal landscape may not protect all IP equally. As Forbes article In Today’s Market, Do Patents Even Matter? points out, a patent does not protect your IP rights from being infringed upon; it simply provides the patent holder a means of legal recourse in the event they are infringed. Even if an entrepreneur decides to sue, most litigation lasts between three to five years and costs millions. Novice entrepreneurs and small startups are not financially equipped to fight in the IP battles that routinely occur between heavy-hitters such as Apple and Samsung. Another issue is larger firms using the **IP laws to register patents and then never actually use them, consequently stifling innovation.To make matters worse, around 97% of all patents never even recoup the costs of filing, making them an unnecessary expense in many circumstances.** Regardless of the argument whether IP rights are essential for new businesses and entrepreneurs, the facts illustrate that they nevertheless play a vital role in America’s economy. An article in The Economist, America Can’t Control the Global Flow of Ideas, underscores how the desire among businesses for strong IP laws is high because so much is at stake, with American businesses deriving 80% of their market value from intangible assets and own half of the world’s IP. These same businesses rely on selling their products across borders where IP protection is not nearly as a secure, specifically in China. The White House itself published a report accusing China of IP violations, which included accusations of “outright theft and forced transfer of IP to joint-venture partners in China.” As cited in a Forbes article, Feeding the Fire of Genius: Intellectual Property And America’s High-Tech Future, the United States Trade Representative stated that “Chinese theft of American IP currently costs between $225 billion and $600 billion annually.” With China being listed as “the world’s principal IP infringer,” startups and large firms alike are advocating for the Trump administration to tighten its grip over China’s unfair trade practices regarding IP. Whether the current administration will be able to successfully curtail such trade violations is still up for debate, with entrepreneurs **waiting on the sidelines hoping that the legal system will prevail in protecting their IP rights.**

### IP is worse for innovation— it favors developed countries and prevents innovation through imitation or innovation in places outside the wealthy nations, Chao and Mody 15 [(Tiffany E, Department of Surgery, Massachusetts General Hospital, Boston, Massachusetts, USA) (Gita N, Program in Global Surgery and Social Change, Harvard Medical School, Boston, Massachusetts, USA) “The impact of intellectual property regulation on global medical technology innovation,” BMJ Journals, 3/5/15. <https://innovations.bmj.com/content/1/2/49>] ¶

Technology innovation has the potential to expand equitable healthcare to underserved populations in global health. At the same time, device **patents and their legislation can be barriers to innovation for developing countries.** For example, the WHO has developed a ‘Compendium of innovative health technologies for low-resource settings’.1 Most of these technologies are inexpensive to develop, inexpensive to manufacture and relatively easy to use. Nevertheless, the WHO clearly states that inclusion in their Compendium does not necessarily mean “the use of the technologies is…in accordance with the national laws and regulations of any country, including…patent laws.” Of course, it would be a challenge to innovate in the absence of legislation on trademark laws and trade secrets. Since the profitability of devices depends on leveraging existing pathways for device development, manufacturing and distribution, intellectual property (IP) protection is a major aspect of commercialisation of technologies. Certainly investors in new start-ups look for IP protection as a high priority. Regulation of IP, therefore, is necessary to stimulate invention and new technologies. However, for technologies in low-resource settings, IP protection has historically been sparse. The World Intellectual Property Organisation reports that in 2012, high-income countries shared 64.5% of the world's total number of patents, while lower-middle-income countries held only 2.9%, with low-income countries owning only 0.4%.2 **This disparity clearly demonstrates limited IP support for frugal innovation emerging from developing countries.** Ironically, inventors in low-resource settings are presented with an abundance of important clinical needs and fewer established infrastructure constraints, so that there is a vast untapped potential for innovations to originate in these settings and move to the more developed world (known as reverse innovation).3 Inventors of healthcare devices for the developing world have varying interest in pursuing patent protection of their devices.i High cost, time and logistics are oft-cited reasons for not pursuing patents. Factors influencing the cost include not just the expense of filing (which can be thousands of dollars) but also fees for legal counsel and maintenance of the patent. These costs are a barrier in their own right, and they can also lead to increases in the price of the end product, which can be significant in a highly cost-sensitive market. An additional barrier is limited knowledge of complicated international patent laws with inadequate access to qualified IP lawyers. In cases where out-of-country universities are involved in patenting the technologies, the bureaucracy involved in dealing with the technology transfer office and their inexperience in executing foreign filings is a barrier (though there are counterexamples of very significant university partnerships in developing bottom-of-the-pyramid technologies). Another major reason for limited IP protection of technology for low-resource settings is the spirit behind the innovation in the first place; inventors designing for low-resource settings are often interested in keeping their device design open source, to maximise spread and impact. Also, consumers of the technologies are highly focused on affordability. Prosecution of infringement of IP laws in low-resource settings is limited, and violating IP laws is a pragmatic way for ‘copycats’ to reduce their investment costs in research and development, and quickly sell products, getting healthcare technology to those who need it. Most countries do operate under patent laws compliant with the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement, a framework that requires IP laws to resemble those of developed areas. This agreement applies to all WTO member countries. Therefore, unless a developing country wishes to withdraw from the WTO, its IP laws are required to resemble those in the USA or Europe, leaving little flexibility to tailor to local needs.4 This means that international **IP laws are often in the economic interests of developed countries rather than in the innovation interests of other countries.**5 As a result of these issues, the most prevalent strategy among global health technologies has often been to **develop without regard for IP protection.** A major advantage of this approach is that it **can allow for open-source innovation,** permitting technological learning through imitation. This approach can also eliminate the many costs of foreign protection or patent enforcement, allowing for a frugal approach to the initial development of the technology itself. Furthermore, this approach is most in line with the collaborative spirit of global health innovation. Nevertheless, there do exist some opportunities for frugal approaches to IP. Simplified legislation or pro bono opportunities for counsel allow an effective system of justice for inventors to take full advantage of legislation to promote innovation.6 Grants and other forms of non-dilutive funding enable inventors to develop global health technologies without being overly concerned about licensing or investment opportunities. Some potential legislative changes also could be made, such as creation of public–private partnerships that could facilitate government-funded research to be protected and disseminated at affordable cost in such countries.7 Other existing exemptions in international agreements could be implemented, including research exemptions for experimental uses of IP or government imposed non-exclusive or compulsory licensing.8 While there remains potential for more imaginative IP legislation in developing countries, original technologies continue to be developed in these settings. On the international stage, forums such as the WHO Global Forum on Medical Devices highlight emerging technologies that “impact the continuum of care ranging from screening to diagnosis, treatment and rehabilitation under the Universal Health Coverage Strategy.”9 These platforms demonstrate that despite the hurdles faced by developing economies in capturing the benefits of IP laws, global health technologies can be and will continue to be developed outside of these limitations.

**TRIPS decreases innovation especially for developing countries and creates monopolies Andrioti ‘18**

Andrioti, Athina, et al. The Right to Health and Pharmaceutical Companies in Developing Countries: Access to Medicines. , 2018.

‌The initial argument in favor of the adoption of the TRIPS Agreement and the provision of pharmaceutical patent protection was the avoidance of free riders and thus the promotion of innovation. However, doubt can be cast as to whether meaningful innovation is actually promoted through patents. Although patent protection may indeed incentivize R&D of - at least some - medicines through protecting innovators’ rights, there are some methods used by the pharmaceutical industry within the current patent system that give rise to certain concerns regarding the extent to which current R&D priorities and innovation are meaningful from a right-to-health perspective. To that extent it is argued that ‘Patents are increasingly used as strategict assets to influence the conditions of competition rather than as a defensive means to protect research and development outcomes’.86 Firstly, pharmaceutical companies are driven by their for-profit nature and seek to benefit as much as possible from the monopoly that is provided by the TRIPS Agreement. They delay the generic competition through ‘evergreening’ of patents that ‘refers to the practice of obtaining new patents on a patented medicine by making minor changes to it’ before the patent period of the initial medicine expires.87 This leads to what Donald Light and Joel Lexchin refer to as ‘the real innovation crisis’ which ‘stems from current incentives that reward companies for developing large numbers of new drugs with few clinical advantages over existing ones’.88 A study by Robin Feldman published in 2018 supports this argument, showing that ‘78% of the drugs associated with new patents in the FDA’s records were not new to the market, but existing drugs’, a percentage which is estimated to increase to 80% in the following years.89 Another issue that is related to the concern over whether the existing incentives for innovation are compatible with the right to health, is connected to the ‘neglected diseases’ and the amount of R&D efforts directed towards markets where the purchasing power is limited, namely developing countries. Lee C Moerman and A.L van der Laan define ‘neglected diseases’ as ‘a group of diseases that attract little or no research and development, and in some cases, a cessation of manufacture of drugs or vaccine’ and they categorize such diseases into two groups: diseases for which ‘effective treatment is not available’ at all and ‘diseases which have treatments but for reasons of access and affordability are not available’ in developing countries.90 According to the WHO Commission Report on Intellectual Property Rights, Innovation and Public Health, ‘Poverty affects purchasing power, and the inability of poor people to pay reduces effective demand, which in turn affects the degree of interest of for-profit companies.’91 Thus, it is very likely that the monopolies provided by the TRIPS Agreement will drive R&D towards diseases that are more likely to generate profit rather than towards diseases which are prevalent in developing countries, where people have the highest needs for such R&D. On this basis it seems then that ‘The argument that intellectual property rights are a tortured solution to providing a social good, but alas necessary, does not work for those poor who may die because of the TRIPS regime.

### Decline of medical innovation risks extinction

**Sachs** 8/17/**14**—Professor of Sustainable Development, Health Policy and Management @ Columbia University [Jeffrey D. Sachs (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.**