## 1

#### Interpretation: IP protections refer to copyright, trademarks, GI’s, patents, ID’s, and trade secrets

WTO No Date [World Trade Organization] [DS] [https://www.wto.org/english/tratop\_e/trips\_e/intel1\_e.htm]

(i) Copyright and rights related to copyright.back to top The rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films) are protected by copyright, for a minimum period of 50 years after the death of the author. Also protected through copyright and related (sometimes referred to as “neighbouring”) rights are the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations. The main social purpose of protection of copyright and related rights is to encourage and reward creative work. (ii) Industrial property.back to top Industrial property can usefully be divided into two main areas: One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguish the goods or services of one undertaking from those of other undertakings) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin). The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive. Other types of industrial property are protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets. The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities. A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing. The protection is usually given for a finite term (typically 20 years in the case of patents). While the basic social objectives of intellectual property protection are as outlined above, it should also be noted that the exclusive rights given are generally subject to a number of limitations and exceptions, aimed at fine-tuning the balance that has to be found between the legitimate interests of right holders and of users.

#### Violation – data exclusivity is a term several countries are trying to get protected by TRIPS – but it is fundamentally different from other IP protections

MSF May 2004 [Technical Brief, “Data exclusivity in international trade agreements: What consequences for access to medicines?”] [DS] [https://www.citizen.org/wp-content/uploads/dataexclusivitymay04.pdf]

“Data exclusivity” is a term covering measures some governments, especially the US, are seeking to include in bilateral and regional trade agreements. The implications of such measures need to be understood, because they could have far-reaching ramifications for access to medicines. Data exclusivity refers to a practice whereby, for a fixed period of time, drug regulatory authorities do not allow the registration files of an originator to be used to register a therapeutically equivalent generic version of that medicine. Data exclusivity is completely separate from patents. In fact, the strongest impact may be felt in a country where there is no patent for a medicine - if data exclusivity is granted this will provide a monopoly for a set period (e.g. five years). This short briefing paper outlines the consequences of data exclusivity for access to medicines and explains why countries are not obliged to agree to it. What kind of data are we talking about? “Data exclusivity” refers to test and other data that a pharmaceutical company must provide to a drug regulatory authority (DRA) in order to get first-time registration for any new medicine it wishes to market in a country. This test data is necessary to demonstrate the efficacy and safety of the drug. Registration - or marketing approval – by the DRA is needed before a medicine can be marketed in a country. When generic manufacturers later apply to register another version of an already-registered medicine, they only have to demonstrate that their product is therapeutically equivalent to the original. To fulfil the efficacy and safety requirements, the drug regulatory authority relies on the registration file of the original manufacturer. So what kind of exclusivity is it? In order to delay competition from generic manufacturers, multinational companies have been pushing hard to obtain exclusive rights over their test data. During this period of “data exclusivity”, the DRA is not authorised to rely on information in the originator dossier to approve/register generic versions of a medicine. This period of exclusivity may vary from five years in the US to eight-10 years in the EU and can be found in developed countries mostly in medicines legislation. Such legislation also exists in a limited number of developing countries. Practically, data exclusivity prevents DRAs from registering generic versions of a medicine during a limited period, unless the generic manufacturer independently carries out its own tests showing the safety and efficacy of the medicine. What are the consequences of data exclusivity for access to generic medicines? The biggest impact of data exclusivity is on medicines that are not patented in some countries, as a result of pre-TRIPS patent laws excluding pharmaceutical patents. This is the case of most antiretroviral medicines in Guatemala for instance1 , where generic manufacturers will now have to wait five years from the date of approval of the original medicine in Guatemala before obtaining registration of their own version of the medicine2 . In other words, even when a medicine is not protected by any patent, multinational pharmaceutical companies are assured a minimum period of monopoly in countries that provide data exclusivity. This is clearly going beyond the TRIPS Agreement (see further below). In other situations, where a medicine is protected by patents, data exclusivity may constitute a barrier to the use of compulsory licenses. If a generic manufacturer is granted a compulsory license to overcome the patent, it will not be able to make effective use of the license if it has to wait for the expiry of data exclusivity before it can get its generic version approved by DRA and put on the market. Therefore, countries will need to ensure that the use of compulsory licences are not restricted by data exclusivity. Data exclusivity is a means of impeding generic competition, and maintaining artificially high prices, thereby restricting access to medicines. Moreover, it could be considered unethical to require generic manufacturers to conduct their own safety and efficacy trials with proven effective compounds. Clinical trials could expose patients to sub-optimal treatment. Proof of therapeutic equivalence should be sufficient. 1 This is because Guatemala only introduced patent protection for pharmaceuticals in November 2000. Consequently, all medicines which were applied for patent protection before this date cannot be patented in Guatemala (except for new improved versions that meet the patentability criteria). See MSF report Drug patents under the spotlight – Sharing practical knowledge about pharmaceutical patents, May 2003. 2 In accordance with Decree 09-2003, and the recently signed Central America Free Trade Agreement (CAFTA) with the United States. What is the relationship between data exclusivity and patents? Patent application is made well before the application for drug registration, at the stage of basic research, but since patents now last for 20 years, they usually expire after the data exclusivity period. The schematic graph below illustrates the interference of patents and data exclusivity. basic preclinical clinical application drug research research research for registration approval end of 20-year patent 2-4 years 4-5 years 2-3 years start of 20-year patent 5-year data exclusivity Is data exclusivity another kind of intellectual property right? Compared to more traditional intellectual property rights such as patents and copyrights, data exclusivity is very unusual since it does not require any inventive activity for it to be granted. Data exclusivity protection is instead only based on the fact that an investment has been made by the originator in carrying out the necessary tests to demonstrate the safety and efficacy of their new medicine. Although the TRIPS Agreement now requires some protection for this sort of data, it does not require that exclusive rights be granted in the same way as patents or copyright.

#### Vote neg for limits and ground – data exclusivity does not require inventive activity, which skirts the innovation DA and access CP’s and makes advantage areas fundamentally different from other affs – it also opens the floodgate to any investment that has been made ever which explodes the topic and makes neg prep unfeasible.

#### Fairness – debate is a competitive activity that requires fairness for objective evaluation. Outweighs because it’s the only intrinsic part of debate – all other rules can be debated over but rely on some conception of fairness to be justified.

#### Drop the debater – deter future abuse and set better norms for debate.

#### Competing interps – [a] reasonability is arbitrary and encourages judge intervention since there’s no clear norm, [b] it creates a race to the top where we create the best possible norms for debate.

#### No RVIs – a] illogical, you don’t win for proving that you meet the burden of being fair, logic outweighs since it’s a prerequisite for evaluating any other argument, b] RVIs incentivize baiting theory and prepping it out which leads to maximally abusive practices c) incentivizes a collapse to all theory which destroys substantive education

## 2

#### Permissibility and presumption negate – a. the resolution indicates the affirmative is proactive, and permissibility would deny the existence of an obligation b. Statements are more often false than true because any part can be false. This means you negate if there is no offense because the resolution is probably false.

#### The neg burden is to prove that the aff won’t logically happen in the status quo, and the aff burden is to prove that it will.

Top of Form

Bottom of Form

#### Prefer:

#### 1] Text –

#### A] Ought is “used to express logical consequence” as defined by Merriam-Webster

(<http://www.merriam-webster.com/dictionary/ought>) //Massa

#### B] Oxford Dictionary defines ought as “used to indicate something that is probable.”

<https://en.oxforddictionaries.com/definition/ought> //Massa

#### 2] Debatability – a) it focuses debates on empirics about squo trends rather than irresolvable abstract principles that’ve been argued for

#### b) Prior Question to argumentation and key to education – It doesn't matter what you’re warranting, everything stems from logical reasoning.

**Muchika 18**, Celestine. “The Concept of Logic in Education.” Kenyaplex.com, 2018, [www.kenyaplex.com/resources/14317-the-concept-of-logic-in-education.aspx](http://www.kenyaplex.com/resources/14317-the-concept-of-logic-in-education.aspx). //Massa

**Logic refers to the philosophical study of correct reasoning**. It deals with principles of sound arguments. **On our daily basis, individuals engage in various forms of arguments where statements are made and conclusion drawn.** In most cases, wrong conclusions are arrived at involving wrong premises and undue generalizations. **Logic is therefore essential because it stipulates how arguments should be made and how fallacies can be detected in an argument and avoided.** Within logic, two forms of reasoning can be distinguished: \*Deductive reasoning \*Inductive reasoning **Deductive Reasoning** It involves reasoning from general to particular incidences. In this course, a conclusion is inferred or deduced from general statements (syllogism). Consider the following example; 1. All university students are immoral. 2 John is a university student. 3. Therefore John is immoral. The following reasoning has been expressed in syllogism form. The first two statements need to be stated before the third can follow. This type of reasoning **is prevalent in philosophy, religion and mathematics.** Inductive Reasoning Involves reasoning from general laws or conclusions being inferred from particular incidences. It is the reverse of deductive reasoning. In this type of reasoning, various incidences of a give specimen are observed over a given period of time. This type of reasoning is applicable with empirical sciences(The challenge of general ability) In modern philosophy, logic is expressed in two dimensions that is symbolic logic and analytic logic. Symbolic logic is applied in mathematics where symbols are used to explain a phenomenon. For example a+b=4 a=4-b Analytic logic is prevalently used by analytic philosophers who emphasize the logical analysis of language to arrive at a clear meaning of terms. Importance of **Logic 1. It helps us to reason correctly and avoid fallacies** (errors in reasoning) **2. It is** a **necessary** tool **for philosophical** and scientific **thinking. 3. Helps in conceptualizing educational policies** and realization of educational objectives. 4. It equips the teacher with the right reasoning and right language for curriculum content delivery. 5. Helps seek clarity and meaning of concepts and statements.

#### Moral Philosophy is negative education – allows students to justify and adopt repugnant beliefs.

**Posner 98** The Problematics of Moral and Legal Theory, Richard A. Posner [Chief Judge, United States Court of Appeals for the Seventh Circuit; University of Chicago Law School.], Harvard Law Review, Vol. 111, No. 7 (May, 1998), pp. 1637-1717//Massa

Third, **academic moralism cannot succeed** in its aim of improving human behavior, for a number of reasons: 1. Knowing the moral thing to do does not furnish a motivation for doing it; the motivation has to come from outside morality. 2. **The analytical tools employed in academic moralism - whether moral casuistry, or reasoning from the canonical texts of moral philosophy, or reflective equilibrium - are too feeble to override either narrow self-interest or moral intuitions**. As a result, academic moral- ism is helpless when moral intuitions clash or self-interest opposes them, and otiose when there is no such conflict. So "right answers" moral realism is hopeless, just like the metaphysical kind. And academic moralists have neither the rhetorical resources nor the detailed knowledge of social reality that might enable them to persuade with- out good methods of inquiry and analysis. 3. **There is so much disagreement** among academic moralists that **the reader can easily find a** persuasive **rationalization for his preferred course of conduct, whatever it is**. 4. The character of a modern academic career in philosophy is not conducive to moral innovation or insight. 5. Exposure to **moral philosophy may** actually **lead people to behave less morally by making them more adept at rationalization.**

#### 3] Neg definition choice – the aff should have defined ought in the 1ac because it was in the rez so it’s predictable contestation, by not doing so they have forfeited their right to read a new definition – kills 1NC strategy since I premised my engagement on a lack of your definition.

#### Now negate:

**Negate:**

#### 1] Inherency – either a) the aff is non-inherent and you vote neg on presumption or b) it is and it isn’t going to happen.

#### 2] Intellectual is defined as “possessing or showing intellect or mental compacity” (Dictionary.com) but property cant possess intellect so the resolutions incoherent

#### [3] member means “a body part or organ” (Marriam Webster) but a nation cannot have bodily organs so the resolutions incoherent

Nibs negate under comparative worlds – they prove that your world is one that is incoherent and can’t be evaluated in comparison to mine

## 3

#### Pharma innovation high now—monetary incentive is the biggest factor.

**Swagel 21** Phillip L. Swagel, Director of the Congressional budget office 4-xx-2021, "Research and Development in the Pharmaceutical Industry," Congressional Budget Office, <https://www.cbo.goc/publication/57126#_idTextAnchor020> SJ//DA

**Every year, the U.S. pharmaceutical industry develops a variety of new drugs that provide valuable medical benefits. Many of those drugs are expensive and contribute to rising health care costs for the private sector and the federal government. Policymakers have considered policies that would lower drug prices and reduce federal drug expenditures. Such policies would probably reduce the industry’s incentive to develop new drugs.** In this report, the Congressional Budget Office assesses trends in spending for drug research and development (R&D) and the introduction of new drugs. CBO also examines factors that determine how much drug companies spend on R&D: expected global revenues from a new drug; cost to develop a new drug; and federal policies that affect the demand for drug therapies, the supply of new drugs, or both. What Are Recent Trends in Pharmaceutical R&D and New Drug Approvals? T**he pharmaceutical industry devoted $83 billion to R&D expenditures in 2019. Those expenditures covered a variety of activities, including discovering and testing new drugs, developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. That amount is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation.** The share of revenues that drug companies devote to R&D has also grown: **On average, pharmaceutical companies spent about one-quarter of their revenues (net of expenses and buyer rebates) on R&D expenses** in 2019, which is **almost twice as large a share of revenues as they spent in 2000.** That revenue share is larger than that for other knowledge-based industries, such as semiconductors, technology hardware, and software. The number of new drugs approved each year has also grown over the past decade. On averace, the Food and Drug Administration (FDA) approved 38 new drugs per year from 2010 through 2019 (with a peak of 59 in 2018), which is 60 percent more than the yearly average over the previous decade. **Many of the drugs that have been approved in recent years are “specialty drugs.” Specialty drugs generally treat chronic, complex, or rare conditions, and they may also require special handling or monitoring of patients**. Many specialty drugs are biologics (large-molecule drugs based on living cell lines), **which are costly to develop, hard to imitate, and frequently have high prices.** Previously, most drugs were small-molecule drugs based on chemical compounds. Even while they were under patent, those drugs had lower prices than recent specialty drugs have. Information about the kinds of drugs in current clinical trials indicates that much of the industry’s innovative activity is focused on specialty drugs that would provide new cancer therapies and treatments for nervous-system disorders, such as Alzheimer’s disease and Parkinson’s disease. **What Factors Influence Spending for R&D?** Drug companies’ R&D spending decisions depend on three main factors: Anticipated lifetime global revenues from a new drug, **Expected costs to develop a new drug**, and Policies and programs that influence the supply of and demand for prescription drugs. Various considerations inform companies’ expectations about a drug’s revenue stream, including the anticipated prices it could command in different markets around the world and the expected global sales volume at those prices (given the number of people who might use the drug). The prices and sales volumes of existing drugs provide information about consumers’ and insurance plans’ willingness to pay for drug treatments. Importantly, when drug companies set the prices of a new drug, they do so to maximize future revenues net of manufacturing and distribution costs. A drug’s sunk R&D costs—that is, the costs already incurred in developing that drug—do not influence its price. **Developing new drugs is a costly and uncertain process, and many potential drugs never make it to market. Only about 12 percent of drugs entering clinical trials are ultimately approved for introduction by the FDA. In recent studies, estimates of the average R&D cost per new drug range from less than $1 billion to more than $2 billion per drug**. Those estimates include the costs of both laboratory research and clinical trials of successful new drugs as well as expenditures on drugs that do not make it past the laboratory-development stage, that enter clinical trials but fail in those trials or are withdrawn by the drugmaker for business reasons, or that are not approved by the FDA. Those estimates also include the company’s capital costs—the value of other forgone investments—incurred during the R&D process. Such costs can make up a substantial share of the average total cost of developing a new drug. The development process often takes a decade or more, and during that time the company does not receive a financial return on its investment in developing that drug. The federal government affects R&D decisions in three ways. First, it increases demand for prescription drugs, which encourages new drug development, by fully or partially subsidizing the purchase of prescription drugs through a variety of federal programs (including Medicare and Medicaid) and by providing tax preferences for employment-based health insurance. Second, the federal government increases the supply of new drugs. It funds basic biomedical research that provides a scientific foundation for the development of new drugs by private industry. Additionally, tax credits—both those available to all types of companies and those available to drug companies for developing treatmentscof uncommon diseases—provide incentives to invest in R&D. Similarly, deductions for R&D investment can be used to reduce tax liabilities immediately rather than over the life of that investment. Finally, the patent system and certain statutory provisions that delay FDA approval of generic drugs provide pharmaceutical companies with a period of market exclusivity, when competition is legally restricted. During that time, they can maintain higher prices on a patented product than they otherwise could, which makes new drugs more profitable and thereby increases drug companies’ incentives to invest in R&D. Third, some federal policies affect the number of new drugs by influencing both demand and supply. For example, federal recommendations for specific vaccines increase the demand for those vaccines and provide an incentive for drug companies to develop new ones. Additionally, federal regulatory policies that influence returns on drug R&D can bring about increases or decreases in both the supply of and demand for new drugs. Trends in R&D Spending and New Drug Development Private spending on pharmaceutical R&D and the approval of new drugs have both increased markedly in recent years, resuming a decades-long trend that was interrupted in 2008 as generic versions of some top-selling drugs became available and as the 2007–2009 recession occurred. **In particular, spending on drug R&D increased by nearly 50 percent between 2015 and 2019.** Many of the drugs approved in recent years are high-priced specialty drugs for relatively small numbers of potential patients. By contrast, the top-selling drugs of the 1990s were lower-cost drugs with large patient populations. R&D Spending R&D spending in the pharmaceutical industry covers a variety of activities, including the following: Invention, or research and discovery of new drugs; Development, or clinical testing, preparation and submission of applications for FDA approval, and design of production processes for new drugs; Incremental innovation, including the development of new dosages and delivery mechanisms for existing drugs and the testing of those drugs for additional indications; Product differentiation, or the clinical testing of a new drug against an existing rival drug to show that the new drug is superior; and Safety monitoring, or clinical trials (conducted after a drug has reached the market) that the FDA may require to detect side effects that may not have been observed in shorter trials when the drug was in development. In real terms**, private investment in drug R&D among member firms of the Pharmaceutical Research and Manufacturers of America (PhRMA), an industry trade association, was about $83 billion in 2019, up from about $5 billion in 1980 and $38 billion in 2000**.1 Although those spending totals do not include spending by many smaller drug companies that do not belong to PhRMA, the trend is broadly representative of R&D spending by the industry as a whole.2 A survey of all U.S. pharmaceutical R&D spending (including that of smaller firms) by the National Science Foundation (NSF) reveals similar trends.3 Although total R&D spending by all drug companies has trended upward, small and large firms generally focus on different R&D activities. **Small companies not in PhRMA devote a greater share of their research to developing and testing new drugs,** many of which are ultimately sold to larger firms (see Box 1). By contrast, a greater portion of the R&D spending of larger drug companies (including those in PhRMA) is devoted to conducting clinical trials, developing incremental “line extension” improvements (such as new dosages or delivery systems, or new combinations of two or more existing drugs), and conducting postapproval testing for safety-monitoring or marketing purposes.

#### DATA PROTECTION NECESSARY TO ENCOURAGE R AND D INVESTMENT AND GROWTH

Lybecker 14 Lybecker, Kristina (Associate Professor of Economics at Colorado College). "Essay: When Patents Aren't Enough: Why Biologics Necessitate Date Exclusivity Protection." William Mitchell Law Review 40.4 (2014): 7.

Data exclusivity protection is vital to the development of future biologics and the preservation of the incentives needed to encourage investment in the R&D that makes these drugs a reality. As described above, recent studies estimate that the pre-approval cost of developing a biologic approaches $1.2 billion and that the time needed to recover the pre-approval R&D costs is between 12.9 and 16.2 years.26 The remaining effective patent life provides innovators with their only opportunity to appropriate the returns on their investments. The profitability of this limited period determines whether or not future investments will be made. Undermining the future of this technology with weakened intellectual property protection for the limited cost savings anticipated through biosimilar competition is undeniably short sighted. The incentives to invest in biologic vaccines and therapies must be preserved with twelve years of data exclusivity. Accordingly, the current negotiations surrounding the TPP Trade Agreement include provisions for twelve years of data exclusivity for biologics. The TTP Trade Agreement is presently under negotiation by the United States and eleven other countries: Australia, Brunei Darussalam, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Vietnam.27 The agreement will promote trade and investment among member countries as well as encourage economic growth and development, innovation, and job creation. Given the importance and size of the economies of the participating nations and their share of global trade, the TPP Trade Agreement is among the most significant of recent trade agreements. Specifically, the eleven other TPP countries have a combined population of 482 million and generate close to fifteen percent of global trade.28 In combination, the current TPP countries represent the largest U.S. market for exports of goods and services. In 2012, TPP countries consumed forty-five percent of exported U.S. goods.29 The agreement seeks to eliminate all trade tariffs; promote free trade; and comprehensively addresses trade in goods and services, rules of origin, trade remedies, nontariff barriers to trade, intellectual property, competition policy, and government procurement policy. The negotiations are ongoing, but a number of sticking points have greatly slowed their progress. Specific issues include policies surrounding investment, the environment and climate change, e-commerce, public procurement, agricultural export subsidies, and intellectual property rights. For the biopharmaceutical industry, a global standard of protection is essential to ensure the innovator firm receives a return on its investment, as well as for ensuring the safety and efficacy of these medicines. Moreover, trade and IP protection enhance growth, and growth furthers access to medicines. A 2006 United Nations Industrial Development Organization report studied the role of intellectual property rights in technology transfer and economic growth in advanced nations, concluding that evidence suggests that strengthening intellectual property rights raises growth, in part due to increased innovation and technology diffusion. In addition, for middle-income countries, data indicate that stronger intellectual property rights regimes facilitate both domestic innovation and technology diffusion through foreign patenting and international trade, which can positively impact growth.30 A 2012 study further supports these conclusions, finding that “patent protection enhances innovation and economic growth, in countries where the capacity to conduct innovative [R&D] exists.”31 Intellectual property rights encourage growth, and growth enhances access. History supports this argument as well. The strength of these linkages is evident in the recent experiences of China, India, and Brazil. In the ten-year period between 1995 and 2005, these three nations doubled or nearly doubled their Patent Rights Index rating.32 Significantly, in the same period both biotechnology patenting and technology transfer, as captured by Foreign Direct Investment, increased substantially.33 These studies all point to the importance of encouraging innovation, supporting intellectual property protection, and including data exclusivity protections for development and growth.

#### Innovation checks future disease – extinction

Engelhardt 8 [H. Tristram. Innovation and the pharmaceutical industry: critical reflections on the virtues of profit. M & M Scrivener Press, 2008 (doctorate in philosophy (University of Texas at Austin), M.D. (Tulane University), professor of philosophy (Rice University), and professor emeritus at Baylor College of Medicine)] Recut Justin

Many are suspicious of, or indeed jealous of, the good fortune of others. Even when profit is gained in the market without fraud and with the consent of all buying and selling goods and services, there is a sense on the part of some that something is wrong if considerable profit is secured. There is even a sense that good fortune in the market, especially if it is very good fortune, is unfair. One might think of such rhetorically disparaging terms as "wind-fall profits". There is also a suspicion of the pursuit of profit because it is often embraced not just because of the material benefits it sought, but because of the hierarchical satisfaction of being more affluent than others. The pursuit of profit in the pharmaceutical and medical-device industries is tor many in particular morally dubious because it is acquired from those who have the bad fortune to be diseased or disabled. Although the suspicion of profit is not well-founded, this suspicion is a major moral and public-policy challenge. Profit in the market for the pharmaceutical and medical-device industries is to be celebrated. This is the case, in that if one is of the view (1) that the presence of additional resources for research and development spurs innovation in the development of pharmaceuticals and med-ical devices (i.e., if one is of the view that the allure of profit is one of the most effective ways not only to acquire resources but productively to direct human energies in their use), (2) that given the limits of altruism and of the willingness of persons to be taxed, the possibility of profits is necessary to secure such resources, (3) that the allure of profits also tends to enhance the creative use of available resources in the pursuit of phar-maceutical and medical-device innovation, and (4) if one judges it to be the case that such innovation is both necessary to maintain the human species in an ever-changing and always dangerous environment in which new microbial and other threats may at any time emerge to threaten human well-being, if not survival (i.e., that such innovation is necessary to prevent increases in morbidity and mortality risks), as well as (5) in order generally to decrease morbidity and mortality risks in the future, it then follows (6) that one should be concerned regarding any policies that decrease the amount of resources and energies available to encourage such innovation. One should indeed be of the view that the possibilities for profit, all things being equal, should be highest in the pharmaceutical and medical-device industries. Yet, there is a suspicion regarding the pursuit of profit in medicine and especially in the pharmaceutical and medical-device industries.

#### Pharma spills-over – has cascading global impacts that are necessary for human survival.

NAS 8 National Academy of Sciences 12-3-2008 “The Role of the Life Sciences in Transforming America's Future Summary of a Workshop” //Re-cut by Elmer

Fostering Industries to Counter Global Problems The life sciences have applications in areas that range far beyond human health. Life-science based approaches could **contribute to advances in** many industries, from energy production and pollution remediation, to clean manufacturing and the production of new biologically inspired materials. In fact, biological systems could provide the basis for new products, services and industries that we cannot yet imagine. Microbes are already producing biofuels and could, through further research, provide a major component of future energy supplies. Marine and terrestrial organisms extract carbon dioxide from the atmosphere, which suggests that biological systems could be used to help manage climate change. Study of the complex systems encountered in biology is decade, it is really just the beginning.” Advances in the underlying science of plant and animal breeding have been just as dramatic as the advances in genetic can put down a band of fertilizer, come back six months later, and plant seeds exactly on that row, reducing the need for fertilizer, pesticides, and other agricultural inputs. Fraley said that the global agricultural system needs to adopt the goal of doubling the current yield of **crops while reducing key inputs like pesticides, fertilizers, and water** by one third. “It is more important than putting a man on the moon,” he said. Doubling agricultural yields would “change the world.” Another billion people will join the middle class over the next decade just in India and China as economies continue to grow. And all people need and deserve secure access to food supplies. Continued progress will require both basic and applied research, The evolution of life “put earth under new management,” Collins said. Understanding the future state of the planet will require understanding the biological systems that have shaped the planet. Many of these biological systems are found in the oceans, which cover 70 percent of the earth’s surface and have a crucial impact on weather, climate, and the composition of the atmosphere. In the past decade, new tools have become available to explore the microbial processes that drive the **chemistry of the oceans**, observed David Kingsbury, Chief Program Officer for Science at the Gordon and Betty Moore Foundation. These technologies have revealed that a large proportion of the planet’s genetic diversity resides in the oceans. In addition, many organisms in the oceans readily exchange genes, creating evolutionary forces that can have global effects. The oceans are currently under great stress, Kingsbury pointed out. Nutrient runoff from agriculture is helping to create huge and expanding “dead zones” where oxygen levels are too low to sustain life. Toxic algal blooms are occurring with higher frequency in areas where they have not been seen in the past. Exploitation of ocean resources is disrupting ecological balances that have formed over many millions of years. Human-induced changes in the chemistry of the atmosphere are changing the chemistry of the oceans, with potentially catastrophic consequences. “If we are not careful, we are not going to have a sustainable planet to live on,” said Kingsbury. Only by understanding the basic biological processes at work in the oceans can humans live sustainably on earth.

## 4

#### The appeal to util makes debate unsafe, since the logic of “the end justifies the means” can justify *any* reprehensible action.

Anderson Anderson, Kerby. [National Director of Probe Ministries International] “Utilitarianism: The Greatest Good for the Greatest Number.” *Probe*, 2004**. RP**

One problem with utilitarianism is that its leads to an ‘end justifies the means’ mentality. If any worthwhile end can justify the means to attain it, a true ethical foundation is lost. But we all know that the end does not justify the means. If that were so,then Hitler could justify the Holocaust because the end was to purify the human race. Stalin could justify his slaughter of millions because he was trying to achieve a communist utopia. The end never justifies the means. The means must justify themselves. A particular act cannot be judged as good simply because it may lead to a good consequence. The means must be judged by some objective and consistent standard of morality. Second, utilitarianism cannot protect the rights of minorities if the goal is the greatest good for the greatest number. Americans in the eighteenth century could justify slavery on the basis that it provided a good consequence for a majority of Americans. Certainly the majority benefited from cheap slave labor even though the lives of black slaves were much worse. A third problem with utilitarianism is predicting the consequences. If morality is based on results, then we would have to have omniscience in order to accurately predict the consequence of any action. But at best we can only guess at the future, and often these educated guesses are wrong. A fourth problem with utilitarianism is that consequences themselves must be judged. When results occur, we must still ask whether they are good or bad results. [Further][,] [u]tilitarianism provides no objective and consistent foundation to judge results because results are the mechanism used to judge the action itself. Inviolability is intrinsically valuable.

**Vote them down – this abhorrent discourse promotes terrible ideologies in the debate space.**

#### Discourse in round comes first – educators must take a stance against oppression in the activity – we can’t separate the flow from our performance.

**Vincent:** – (Christopher [Debate Coach, former college NDT debater] “Re-Conceptualizing Our Performances: Accountability In Lincoln Douglas Debate”

Charles Mills argues that “the moral concerns of African Americans have centered on the assertion of their personhood, a personhood that could generally be taken for granted by whites, so that blacks have had to see these theories from a location outside their purview.” For example, I witnessed a round at a tournament this season where a debater ran a utilitarianism disadvantage. His opponent argued that this discourse was racist because it ignores the way in which a utilitarian calculus has distorted communities of color by ignoring the wars and violence already occurring in those communities. In the next speech, the debater stood up, conceded it was racist, and argued that it was the reason he was not going for it and moved on, and still won the debate. This is problematic because it demonstrates exactly what Mill’s argument is. For the black debater this argument is a question of his or her personhood within the debate space and the white debater was not held accountable for the words that are said. Again for debaters of color, their performance is always attached to their body which is why it is important that the performance be viewed in relation to the speech act. **Whites are allowed to take for granted the impact their words have on the bodies in the space. They take for granted this notion of personhood and ignore the concerns of those who do not matter divorced from the flow.** It is never a question of “should we make arguments divorced from our ideologies,” it is a question of is it even possible. It is my argument that our performances, regardless of what justification we provide, are always a reflection of the ideologies we hold. Why should a black debater have to use a utilitarian calculus just to win a round, when that same discourse justifies violence in the community they go back home to? **Our performances and our decisions in the round, reflect the beliefs that we hold when we go back to our communities. As a community we must re-conceptualize this distinction the performance by the body and of the body by re-evaluating the role of the speech and the speech act**. It is no longer enough for judges to vote off of the flow anymore. **Students of color are being held to a higher threshold to better articulate why racism is bad**, which is the problem in a space that we deem to be educational. It is here where I shift my focus to a solution. **Debaters must be held accountable for the words they say in the round. We should no longer evaluate the speech. Instead we must begin to evaluate the speech act itself. Debaters must be held accountable for more than winning the debate. They must be held accountable for the implications of that speech**. As educators and adjudicators in the debate space we also have an ethical obligation to foster an atmosphere of education. **It is not enough for judges to offer predispositions suggesting that they do not endorse racist, sexist, homophobic discourse, or justify why they do not hold that belief, and still offer a rational reason why they voted for it. Judges have become complacent in voting on the discourse,** if the other debater does not provide a clear enough role of the ballot framing, or does not articulate well enough why the racist discourse should be rejected. Judges must be willing to foster a learning atmosphere by holding debaters accountable for what they say in the round. **They must be willing to vote against a debater if they endorse racist discourse.** They must be willing to disrupt the process of the flow for the purpose of embracing that teachable moment. The speech must be connected to the speech act. **We must view the entire debate as a performance of the body, instead of the argument solely on the flow**. Likewise, judges must be held accountable for what they vote for in the debate space. If a judge is comfortable enough to vote for discourse that is racist, sexist, or homophobic, they must also be prepared to defend their actions. We as a community do not live in a vacuum and do not live isolated from the larger society. That means that judges must defend their actions to the debaters, their coaches, and to the other judges in the room if it is a panel. Students of color should not have the burden of articulating why racist discourse must be rejected, but should have the assurance that the educator with the ballot will protect them in those moments. **Until we re-conceptualize the speech and the speech act, and until judges are comfortable enough to vote down debaters for a performance that perpetuates violence in the debate space, debaters and coaches alike will remain complacent in their privilege**. As educators we must begin to shift the paradigm and be comfortable doing this. As a community we should stop looking at ourselves as isolated in a vacuum and recognize that the discourse and knowledge we produce in debate has real implications for how we think when we leave this space. Our performances must be viewed as of the body instead of just by it. As long as we continue to operate in a world where our performances are merely by bodies, we will continue to foster a climate of hostility and violence towards students of color, and in turn destroy the transformative potential this community could have.

#### Additionally:

#### [1] Reversibility: once oppressive rhetoric is used it cannot be taken back

#### [2] Norm setting: we are part of a larger debate community with extensive norms – letting bad discourse be rampant kills the community

**There isn’t a perf con – we critique the framing that you use not the impacts and engaging in the system is different than endorsing the system**

## 5

#### Interpretation: If debaters disclose full text, they must not post the full text of the cards in the cite box, but must upload an open source document with the full text of their cards. To clarify, you don’t have to disclose highlighting or underlining, you just need an open source document with minimally the full, un-underlined text of cards

#### B. Violation: screenshots

Text

Description automatically generated

#### C. Standards

#### 1. Pre-round prep: prep becomes atrocious when you don’t make your tags bold and just throw up massive amounts of text on the wiki page which makes it nearly impossible to locate certain arguments.

#### Discourages tricks—you can just hide a bunch of blippy arguments in your massive amounts of useless text which is prevented if tags are easy to sort out and you’re more up front about your arguments.

#### Their model is awful because it’s extremely difficult to determine when a position stops and starts.

#### Also key for disability inclusion because people with dyslexia struggle to read through long blocks of text—outweighs accessibility is a multiplier for their impacts

#### Key to education since we aren’t able to engage your arguments properly since you’ve intentionally made your wiki page a mess.

#### 2. NDCA rules: see the screenshot – checks reasonability and counterinterp planks since its predictable /Users/ishanbhatt/Desktop/Screen Shot 2017-09-09 at 9.03.39 PM.png

## Case

#### The aff misdiagnoses the issue.

Andreassen 15 [Tom; Ph.D-candidate at the Programme for Applied Ethics at the Norwegian University of Science and Technology, Trondheim; "Patent funded access to medicines," Developing world bioethics; 2015; 15.3: 152-161.] Justin

Other local factors than price also need to be taken into consideration. Many hold that inflated drug prices are not the problem at all. Pharmaceutical industry attorney Philip Grubb, speaking of AIDS medicine, thus holds that:

In fact, patents are not the problem. Not only are there no patents for most of these AIDS drugs in most African countries, there are also no patents in any countries for most of the drugs on the WHO Essential Drugs List – so why then are these essential drugs not readily available to patients in poor countries? The answer is simply lack of money to buy even cheap medicines, and lack of social and medical infrastructure to deliver them. The terrible truth is that if AIDS could be cured by a glass of clean water, there would still be millions who would have no access to the cure. Unfortunately, patents and the ‘greedy’ pharmaceutical companies make a much easier target than the miserly rich country governments and the corrupt poor country governments who together make up the real problem.35

The infrastructure problem pointed out by Grubbs gives no argument to the effect that high prices are not an issue. Rather it highlights that solutions to the access problem must address these other factors as well, and not ignore them. Mechanisms for strengthening health infrastructure need to be included in a viable effort to improve access to drugs.

### AT NONADHERENCE -> EXTINCTION

#### Turn

#### 1] Low prices cause AMR.

Babu and Suma 6 [Babu, Varsha, and C. Suma. "Antibiotic pricing: when cheaper may not be better." Clinical infectious diseases 43.8 (2006): 1085-1086. (Government Primary Health Center)] Elmer

To The Editor—Antibiotics in India have always been cheaper in absolute terms thanks to weak patent laws that have been in effect until recently. Because a direct translation of drug prices from US dollars to Indian rupees (INR) would have rendered most new antibiotics inaccessible to the vast majority of Indians, such patent violations were subtly encouraged. Even despite this, we were caught unaware when pharmaceutical representatives approached our primary care center in rural India, claiming that a 5-day course of levofloxacin would henceforth cost the patient ∼INR 20 (<$0.50). Reluctant to accept such a statement at face value, we consulted the CIMS Updated Prescriber's Handbook [1], a popular index of pharmaceutical drugs available in India. Here, we discovered that a 5-day course of oral levofloxacin (500 mg once daily) cost anywhere from INR 19.5 to INR 475 ($0.50–$10.50), with most companies pricing their brand at <$1 for a full course. The same course in the United States would cost >$100. Intrigued, we did some more research and came up with the following results. The cheapest 5-day courses of first-line antibiotics, such as oral amoxicillin (500 mg thrice daily) or oral erythromycin (500 mg 4 times daily), cost INR 45 ($1) and INR 90 ($2), respectively. On the other hand, the cost of a 3-day course of oral azithromycin (500 mg daily) was one-half that of a course of erythromycin. Despite the obvious price advantage to the patients, we find this trend troubling. **Lower prices** often **lead to wider prescription of a given drug**, especially in resource-limited settings. **If** second-line **antibiotics**—such as levofloxacin and azithromycin—**are made available at lower prices** than first-line antibiotics, **there is a high probability of their overuse and subsequent development of resistance**. In the face of **very low costs of medication**, patients are unlikely to complain of escalating medical expenses. The issue assumes more gravity when one considers the fact that levofloxacin is an important second-line drug for the treatment of tuberculosis [2]. Its widespread use in the community **is likely to lead to emergence of resistance** **among** **mycobacteria** **and** delayed diagnosis of **tuberculosis** [3]—an occurrence that India, with its large population of tuberculosis-affected patients, cannot afford. We believe we have encountered a situation where **low prices of antibiotics are likely to cause more harm than good**. In the post World Trade Organization treaty scenario, governments in resource-limited countries should use their privileges of essential drug control to ensure that the costs of first-line antibiotics remain lower than those of second-line drugs. Such a government-instituted ladder in antibiotic pricing is essential to prevent the misuse of antibiotics in the community and to ensure that antibiotic resistance is kept at low levels.

#### 2] Reverse causal statistics confirm the aff increases AMR.

Horowitz and Moehring 04 [John and Brian; Department of Economics, Ball State University, Business Economist; “How property rights and patents a¡ect antibiotic resistance,” Economics of Pharmaceuticals, <https://sci-hub.se/10.1002/hec.851>] Justin

How property rights and patents a¡ect antibiotic resistance Bacterial resistance to antibiotics has prevented humanity’s dreams of eliminating several diseases [1]. Antibiotic resistance also causes otherwise easily treatable diseases to become difficult or impossible to suppress. The Forum on Emerging Infections of the US Institute of Health found that ‘Antibiotic-resistant bacteria generate a minimum of $4 billion to $5 billion in costs to US society and individuals yearly . . . ’[2]. Previous authors have pointed out that antibiotic use creates both negative and positive externalities [3–7]. Antibiotic use creates a positive externality because antibiotic use can improve public health by preventing patients from becoming carriers of a disease and thus less likely to infect others (‘herd immunity’). Antibiotic use creates a negative externality because antibiotic use by one patient may generate resistant bacteria, that can infect others. Efficient antibiotic treatment implies that the antibiotic is used until the additional benefit (marginal value of treatment+improved public health) is equal to the additional costs incurred (costs of treatment+increased resistance). If each individual user of the antibiotic were bearing all the costs and receiving all the benefits of their antibiotic use, there would be no external effects, and antibiotic use would be efficient. Excessive antibiotic use arises because the user does not bear the cost of increased antibiotic resistance in the future [8]. When antibiotic use creates negative externalities, then (1) regulations, (2) taxation, and (3) tradeable permits can be used to reduce antibiotic use and reduce antibiotic resistance [6,9]. There has been little discussion of how property rights and patents can reduce antibiotic resistance. This article has three purposes. This article explains: (1) how a lack of property rights can cause excessive antibiotic use, (2) how patents create property rights and reduce excessive antibiotic use assuming there is little cross-resistance,a and (3) how a monopsonistic buyer can solve the property rights problem and decrease antibiotic resistance (but, in practice often increase resistance). The negative externality from antibiotic use is analogous to over-fishing in open-access fisheries. Open-access exists where property rights are not well defined and fishermen do not bear the full costs of their fishing efforts. A fisherman who leaves a fish, in the open fishery, to grow larger is unlikely to catch the fish in the future and thus will not receive future benefits from abstinence. An individual who is unable to capture future benefits will keep the fish creating inefficiently large current fishing efforts. Similarly, an individual who is unable to capture future benefits of a non-resistant bacterial strain (susceptible to a specific antibiotic treatment) will in the present use that antibiotic excessively. A model of antibiotic resistanceb Assume that j represents a particular antibiotic such as penicillin or streptomycin. The demand (D) for antibiotic j is represented by Pt=abQt where Pt is the price of an antibiotic treatment in time period t, a is the maximum price that people are willing to pay for the first antibiotic treatment, b is the slope of the demand curve, and Qt is the number of antibiotic treatments in time period t. c,d Antibiotic use reduces the risk of infection to other people. For simplicity, we assume the marginal external benefit (MEBt) is constant. The marginal social benefit is found by vertically adding MEBt to the demand curve. In other words, the marginal social benefit equals Pt \* =abQt+MEBt=D+MEBt. However, purchasers of the antibiotic are unlikely to benefit from the marginal external benefit to others from using the antibiotic. Since buyers are likely to ignore MEBt, there is an argument for the use of a public health system or other mechanism that subsidizes antibiotic use.e The marginal revenue faced by the supplier of antibiotic j is MRt= a2bQt. If there exists a public health system or other mechanism to account for the MEBt, the marginal revenue is MRt \* =a2bQt+MEBt. In Figure 1, the horizontal axis denotes the number of treatments of antibiotic j used to treat bacterial infections and the height of the demand curve (D) shows how much people are willing to pay for one more antibiotic treatment. MC depicts the marginal cost of antibiotic treatment, it includes the marginal cost of producing each additional unit of the antibiotic, the cost of visiting a doctor to get a prescription, and any discomfort from the use of the antibiotic.f The MC is assumed to be upward sloping. If the antibiotic treatment is stopped before all the bacteria are killed, use of the antibiotic in the current period causes more resistant bacteria in the future. P1 n¼1 an=ð1 þ rÞ n @Rtþn=@Qt measures the present value of the additional cost of increased resistance. @Rtþn=@Qt measures how a marginal increment in current antibiotic use increases the number of resistant bacteria in period t+n. t indicates the current time period and n is the number of time periods in the future that the resistance problem is being measured. Future resistance problems are discounted using the present value formula 1/(1+r) n where r is the interest rate at which future resistance is discounted into current dollars. The higher the interest rate, the less people are concerned about future resistance problems. In other words, the higher the interest rate, the lower the current value of the negative externality caused by future antibiotic resistance.

Diagram

Description automatically generated

an converts the increase in antibiotic resistance into dollar terms. The larger an, the higher the cost of an increase in resistance. An increase in an might be caused by the current knowledge that there are few new antibiotics in the pipeline of the drug companies. Existing evidence indicates that the volume of antibiotic exposure is the key determinate in causing antibiotic resistance [11–13].g Resistance to some antibiotics has persisted years after usage has ceased or been substantially reduced. Twenty percent of Enterobacteriaceae were resistant to streptomycin approximately 25 years after streptomycin use was greatly reduced [14]. Likewise, when sulphonamide prescriptions decreased from 320 000 prescriptions per year in 1991 to 7000 in 1999, resistance fell from 46% in 1991 to 40% in 1999 [15]. Cross-resistance is probably one of the main reasons that resistance continues after ceasing or reducing antibiotic use.h Chiew et al. [14] found that of their isolates that were resistant to streptomycin, 86% were also cross-resistant to spectinomycin. Enne et al. [15] also conclude that their results suggest that cross-resistance is important. These results are different from a Finnish study where resistance of group A streptococci which were resistant to erythromycin fell quickly when erythromycin was reduced [16]. This may be because in Finland, erythromycin resistance had emerged recently and the strains were not crossresistant [15]. When there is cross-resistance, use of antibiotic x creates a negative externality by reducing the effectiveness of antibiotic j. People buy antibiotics to reduce and eliminate bacterial infections. If usage of antibiotic x reduces the effectiveness of antibiotic j, then using antibiotic x reduces the demand for antibiotic j. In other words, when there is cross-resistance between antibiotic x and j, usage of antibiotic x causes a decrease in demand for antibiotic j. Efficient antibiotic consumption implies that the antibiotic is used until the additional benefit (‘cure’+improved public health) is equal to the additional costs incurred (marginal costs of treatment+increased resistance). In Figure 1, the efficient quantity of the antibiotic is Qt \* where both the external benefit and external cost are taken into account. Since antibiotic resistance reduces the value of the antibiotic, suppliers of patented antibiotics have an incentive to take into account antibiotic resistance. However, unless there is some mechanism to incorporate external benefits such as subsidies or a public health system, suppliers do not have an incentive to take into account external benefits. To maximize profits, the suppliers will produce where marginal revenue (not including the external benefit) equals the marginal cost (including the external cost). In Figure 1, assuming no public health demand and no cross-resistance, Qt M of antibiotic j will be used which is less than the efficient quantity Qt \* . Extended patents reduce antibiotic resistance Ineffective antibiotics are most likely when there is open-access. In the case of antibiotics, open-access occurs when anyone can produce, sell, and use the antibiotic. In other words, no patents or licenses govern the production of the antibiotic and it is sold over the counter. Under these circumstances, producers would be unwilling to incur any cost to enhance the future efficacy of an antibiotic that had no property rights attached to it and thus was subject to open-access. The 14-year delay (1928– 1942) between the discovery and the production of penicillin may be attributed to the lack of property rights (patent protection) [1, p. 32–51]. Streptomycin and sulpha drugs got to market much faster partly because Merck and Company and I.G. Farben were secretive until they developed a patentable production process and financially benefitted from their discoveries. The classic case of open-access is a fishery. Any fisherman leaving a fish in the water to grow larger is unlikely to catch it in the future. This leads fishermen to act as if they were unconcerned about future fish stocks and catch too many immature fish. A prominent reason for open-access in antibiotics is expired patents. This causes the price of antibiotic j to decrease and the quantity used to increase. This is depicted in Figure 1. When there is openaccess, since producers have no private future benefits to discount, the industry’s equilibrium output and price is where D=MC. Quantity is now Qt c and price is Pt c . There is no economic profit at Qt c because total revenue (TR) equals total costs (TC).i With open-access, pharmaceutical companies have less incentive to research and develop new antibiotics. Antibiotic resistance can be reduced by extending the duration of the patent on antibiotic j. Patents give the owners an incentive to protect the value of antibiotics by curtailing their usage. However, near the end of patent protection, pharmaceutical firms may have an incentive to overuse antibiotics to capture profits which will not be accessible in the future. Another end period problem, is that effectively using old antibiotics may forestall resistance to newer antibiotics. Unfortunately, once a drug goes off patent there is little financial incentive to study new areas of use. One way to ameliorate this end period problem is to extend the effective life of antibiotic patents.j Optimal antibiotic use is achieved by establishing an owner with incentives to consider the effect of contemporary use on future antibiotic resistance. Permanent patents would prevent inefficiently accelerated use of the antibiotic near the termination of the patent. In other words, prolonging the patent period would reduce the incentives to excessively discount future resistance. A result of an extended patent system is that there will be more infections in the current time period. The cost of this increment in contemporary infections, however, is less than the value of future infections which will be treatable because of fewer resistant bacteria. The pharmaceutical company would establish a reservation price on the antibiotic equal to the discounted expected future value of a future treatment. Only current consumers who value their treatment less than this discounted future price will refrain from purchasing the antibiotic.

#### Dispute settlement will take at least 6 ½ years – circumvention.

* Process takes 5 years and the 18 months to get a report

Patnaik 21 [Priti; 3/12/21; Founding Editor, Geneva Health Files; “Could Vaccine Nationalism Spur Disputes At The WTO; TRIPS Waiver Talks Update,” Geneva Health Files, <https://genevahealthfiles.substack.com/p/could-vaccine-nationalism-spur-disputes>] Justin

Hi, From the view on the street in Geneva, pandemic policy-making is unmistakably being shaped at the World Trade Organization, riding on the momentum generated when Director-General Ngozi took office earlier this month. After speaking on her first day at work at the General Council meeting earlier this month, her interventions on addressing the trade aspects of fighting the pandemic have been swift. She also spoke at the COVID-19 Vaccines Manufacturing Summit earlier this week. Alongside the political discussions on the TRIPS waiver, a few countries have come together asking her direct intervention to alleviate production shortages of vaccines by engaging with the industry. We bring all this for you, and more in this edition. In our story this week, we explore the possibility of whether vaccine nationalism can result in disputes at the WTO. The opinion on this divided. However, we would not be surprised if commercial and political interests eventually far outweigh the public health implications of such potential disputes. We also bring you a brief update on the TRIPS waiver discussions at the TRIPS Council meeting at WTO from earlier this week. Seasoned watchers believe that the waiver might just be able to get a critical mass of support. Stay tuned, it is going to get interesting and not pretty. Vacuous statements on solidarity that we have witnessed from political leaders might finally translate into some real meaning in the coming weeks and months. Read these stories collectively. One leads to the other. It has been interesting to report on the pandemic with issues simultaneously straddling these different worlds of health and trade. In other news from us, happy to share that Geneva Health Files participated in this report on how the institutions of International Geneva responded to policy-making for the pandemic. (“Covid-19: Que Fait La Genève Internationale? by Annick Chevillot) Finally, we continue to be encouraged by the steadily growing numbers of our supporters. We are making it work because of you. Thank you. Do spread the word around and let your tribe grow! Please note that we are making an exception and will make this exclusive edition public after a few days, to accommodate regular readers who are in the process of making a transition into paid subscriptions. Thank you for understanding. Until next week! Best, Priti Write to us: patnaik.reporting@gmail.com or genevahealthfiles@protonmail.com; Follow us on Twitter: @filesgeneva 1. Story of the week WILL VACCINE NATIONALISM LEAD TO WTO DISPUTES? Experts believe that the solution to vaccine nationalism is not filing disputes, but negotiations. But lawyers anticipate disputes even if filed simply for political leverage. Vaccine nationalism, a condition that has flourished during COVID-19, is loosely understood as the tendency of countries to hoard vaccines. But protectionist trade practices of hoarding medical supplies began as soon as the pandemic hit. This is now taking a serious turn with export restriction measures adopted by some countries. This could lead to a real possibility of countries taking the legal route to file disputes at the WTO, even if only for political leverage, experts say. Geneva Health Files spoke to legal experts, lawyers and delegations of some countries for this story. Will rising protectionism to address the pandemic relate to a rash of WTO disputes? Yes and no, depending on who you speak to. Earlier this week, Ngozi Okonjo-Iweala, WTO DG, said that 59 members and 7 observers, had some pandemic-related export restrictions or licensing requirements in place at the end of February, primarily for personal protective equipment. She pointed out that these figures were lower than the 91 countries that had brought in such measures over the past year. Image Credit: Photo by Anete Lusina from Pexels EU-AUSTRALIA When EU announced measures for export authorization earlier this year, amidst prevailing conditions of scarcity of vaccines production, it was met with near-ubiquitous criticism. Our interest was piqued when Italy decided to block export of AstraZeneca vaccine doses to Australia. It is understood that Australia had discussed these concerns with DG Ngozi. It was reported that Australia intended to work with other countries including Canada, Japan, Norway and New Zealand, “to pressure European officials in Brussels as a group.” We reached out to the Australian Permanent Mission to the WTO in Geneva, to find out if the country had plans to file a dispute. In response to our question on whether there has been any formal consideration at this stage to file a WTO dispute against the EU, a spokesperson of the mission answered in the negative. “Australia intends to work cooperatively with like-minded states, including the EU, to deliver vaccines as a global good. Our view is that vaccines should not be subject to restrictive trade measures,” the spokesperson told Geneva Health Files. We were also told that Australia’s Minister for Trade, Dan Tehan had spoken to the EU Trade Commissioner Valdis Dombrovkis on Australia’s approach. The spokesperson also confirmed that the minister had spoken to the WTO DG on the matter. Does this mean we will witness no disputes as a result of protectionist measures during the pandemic, will countries opt for negotiation over a litigious route to address vaccine shortages? WILL DISPUTES ARISE? One Geneva-based trade source on the condition of anonymity said, “The way the EU was excoriated at the [WTO] General Council meeting (earlier this month), in response to its trade restriction measures, shows that this issue will not go away anytime soon. There is a real possibility of members filing disputes.” (One diplomatic source called discussions at the General Council meeting last week as “a slaughterhouse”) The view on whether members will rush in to file disputes is divided – not the least because of what it means to go through the dispute settlement process at the WTO in the midst of a pandemic. For one, there is the issue of time constraints. Disputes at the WTO can take long. This is apart from the current crisis facing the international trade court – WTO’s Appellate Body which is not currently functional. Disputes around the pandemic will need to be resolved quickly to have any impact. It could take up to 18 months to get a panel report in the WTO disputes settlement system. So experts feel that WTO disputes system may not be suitable for these kinds of urgent challenges. While it is too soon to dismiss the possibility of trade disputes, experts believe that the way to address competition for medical products during the pandemic will be through negotiation. Experts point to the 2001 dispute brought by the U.S. against Brazil, during the AIDS crisis, which ended up as mutually agreed solution. (See DS199: Brazil — Measures Affecting Patent Protection). The dispute involved Brazil’s local working requirements in its industrial property law. Joost Pauwelyn, Professor of International Law, who also heads the department at The Graduate Institute in Geneva, believes that the focus is and should be on finding solutions, practical ways to address concerns, not litigation. Last year, Pauwelyn analysed the legal framework of export restrictions at the EU and WTO level. (See Export Restrictions in Times of Pandemic: Options and Limits under International Trade Agreements) "There is no GATT/WTO ruling that addresses the issue (of the use of export restrictions in the health area) directly. The IP-related disputes that arose during the AIDS crisis were negotiated. It was dealt with at the political level (TRIPS council, General Council etc.) and ultimately via a waiver and TRIPS treaty amendment, not in the dispute settlement system," Pauwelyn says. Asked whether the crisis in the Appellate Body will dissuade countries from filing disputes, Pauwelyn says, “WTO dispute settlement is currently broken given the option to block panel outcomes to a non-existent Appellate Body. In addition, the process takes about 4-5 years, but under this status quo, it means that by the time the case is settled, the world may already be facing the next pandemic so to speak. So in practical terms, filing a dispute could be a non-starter.”

#### The WTO can’t enforce the aff- causes circumvention.

Lamp 19 [Nicholas; Assistant Professor of Law at Queen’s University; “What Just Happened at the WTO? Everything You Need to Know, Brink News,” 12/16/19; <https://www.brinknews.com/what-just-happened-at-the-wto-everything-you-need-to-know/>] Justin

Nicolas Lamp: For the first time since the establishment of the WTO in 1995, the Appellate Body cannot accept any new appeals, and that has knock-on effects on the whole global trade dispute settlement system. When a member appeals a WTO panel report, it goes to the Appellate Body, but if there is no Appellate Body, it means that that panel report will not become binding and will not attain legal force.

The absence of the Appellate Body means that members can now effectively block the dispute settlement proceedings by what has been called appealing panel reports “into the void.”

The WTO panels will continue to function as normal. When a panel issues a report, it will normally be automatically adopted — unless it is appealed. And so, even though the panel is working, the respondent in a dispute now has the option of blocking the adoption of the panel’s report. It can, thereby, shield itself from the legal consequences of a report that finds that the member has acted inconsistently with its WTO obligations.

#### Recent evidence confirms

Hillman and Tippett 21 [Jennifer A; Senior fellow for trade and international political economy; Alex; Research associate for international economics, at the Council on Foreign Relations; “Europe and the Prospects for WTO Reform,” CFR; 3/10/21; <https://www.cfr.org/blog/europe-and-prospects-wto-reform>] Justin

The WTO has been in the clutches of a slow-moving crisis for years. At its heart are a series of disputes about the role of the WTO’s Appellate Body, the final arbiter in the WTO’s Dispute Settlement System. Today, the Appellate Body sits empty, severely undermining the capacity of the WTO to resolve trade disputes.

Since the start of the Trump administration, the United States has refused to appoint any new members to the body, effectively allowing countries to avoid compliance with WTO rulings. The primary driver of this drastic action has been American frustration at perceived judicial overreach. U.S. policymakers, starting with the George W. Bush administration, have repeatedly voiced their displeasure with Appellate Body decisions, contending that certain decisions have reached beyond the text of existing WTO agreements.