## 1

#### Interpretation – topical affirmatives must only defend reduction of intellectual property rights for medicines.

#### Elimatne means

https://www.google.com/search?q=eliminate+deifnition&oq=eliminate+deifnition&aqs=chrome..69i57j0i13l3j0i13i30l6.1525j1j4&sourceid=chrome&ie=UTF-8

completely remove or get rid of (something).

#### Medicine is treatment for illness or injury

Cambridge Dictionary 21 [Cambridge Dictionary, 2021, <https://dictionary.cambridge.org/us/dictionary/english/medicine>] //Lex AKo

[treatment](https://dictionary.cambridge.org/us/dictionary/english/treatment) for [illness](https://dictionary.cambridge.org/us/dictionary/english/illness) or [injury](https://dictionary.cambridge.org/us/dictionary/english/injury), or the [study](https://dictionary.cambridge.org/us/dictionary/english/study) of this:

#### Violation – Data exclusivity are not IPP for medicine.

Thrasher 21 Thrasher, Rachel. “How Data Exclusivity Laws Impact Drug Prices:” *Global Development Policy Center Chart of the Week How Data Exclusivity Laws Impact Drug Prices Comments*, 25 May 2021, [www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data](http://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data)-exclusivity-laws-impact-drug-prices/. // Lex AKo

**Data exclusivity is a form of intellectual property protection that applies specifically to data from** pharmaceutical **clinical trials. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law.** Data exclusivity operates independently of patent protection and **can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection.** Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. **Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms**. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use,” it does not require exclusivity rules that block the registration of generic products.

#### Clinical trials are a study for medicine to then get protected, but not medicine themselves

Review [Institutional Review, "Clinical Trials," <https://www.phrma.org/policy-issues/Research-Development/Clinical-Trials>] //Lex AKo

A clinical trial is a carefully designed study which tests the benefits and risks of a specific medical treatment or intervention, such as a new drug or a behavior change (e.g., diet). Once researchers have completed a rigorous screening and preclinical testing process, the company files an Investigational New Drug (IND) application with the U.S. Food and Drug Administration (FDA). This application allows the investigational medicine to be tested in human volunteers in clinical trials.

#### Data exclusivity is not included in TRIPS, USPTO 21

[USPTO, Feb 11, 2021, "Trade related aspects of IP rights", No Publication, https://www.uspto.gov/ip-policy/patent-policy/trade-related-aspects-ip-rights, date accessed 9-16-2021] //Lex AT

TRIPS applies basic international trade principles to member states regarding intellectual property, including national treatment and most-favored-nation treatment. TRIPS establishes minimum standards for the availability, scope, and use of seven forms of intellectual property: copyrights, trademarks, geographical indications, industrial designs, patents, layout designs for integrated circuits, and undisclosed information (trade secrets). It spells out permissible limitations and exceptions in order to balance the interests of intellectual property with interests in other areas, such as public health and economic development. (For the complete text of the TRIPS Agreement, as well as an explanation of its provisions, see the WTO web site at [www.wto.org](http://www.wto.org/) .)

#### “Medicines” refers to patents

OxFam [Oxfam, No Date, "Intellectual property and access to medicine," No Publication, [https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/ //](https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/%20//) LEX JB]

**Intellectual property** (IP) has **different forms; in the case of access to medicines, we are talking about patents. Patents** are a public policy instrument **aimed at stimulating innovation**. By **providing** a monopoly **through a patent**—which **gives inventors an economic advantage**—governments seek to provide an incentive for R&D. At the same time, the public benefits from technological advancement.

#### The WTO has no jurisdiction over TRIPs, Francois

[Andre Francois, no date, "Spotlight on: TRIPS, TRIPS Plus, and Doha", Médecins Sans Frontières Access Campaign, https://msfaccess.org/spotlight-trips-trips-plus-and-doha, date accessed 10-16-2021] //Lex AT

Despite the Doha Declaration, in recent years, many developing countries have been coming under pressure to enact or implement even tougher or more restrictive conditions in their patent laws than are required by the TRIPS Agreement – these are known as ‘TRIPS plus’ provisions.  Countries are by no means obliged by international law to do this, but many, such as Brazil, China or Central American states have had no choice but to adopt these, as part of trade agreements with the United States or the European Union. These have a disastrous impact on access to medicines. Common examples of TRIPS plus provisions include extending the term of a patent longer than the twenty-year minimum, or introducing provisions that limit the use of compulsory licences or that restrict generic competition. One of these provisions is known as data exclusivity. This refers to exclusive rights, granted over the pharmaceutical test data submitted by companies to drug regulatory authorities for obtain market authorisation. It means that information concerning a drug’s safety and efficacy is kept confidential for a period of, say, five or ten years.

#### These cards prove theres no way for the aff to be enforced bc data exclusivity doenst exist in the WTO and they don’t have jurisdiciotn over it which is an indepdnet resolvability standard since judges need to eval debates.

#### Violation – they defend data exclusivity

#### Vote Neg –

#### 1] Limits – their model justifies defending ANY INTELLECTUAL PROPERTY PROTECTION outside of medicines from tertiary patents, provisional patents, design patents, and data exlcusitivyt which shifts an unfair prep burden to prep hundreds of affs compared to the generics that the AC has to answer

#### 2] Ground – in the context of data exclusivity all the literature is one sided bc its sucha niche area in the topic and the ground that negates is nonspecific and generic to innovation which allows the aff to delink out of all my positions.

#### 2] TVA – read the literature on the neg as a counterplan

#### Voters:

#### Fairness and education are voters – debate’s a game that needs rules to evaluate it and education gives us portable skills for life like research and thinking.

#### Precision o/w – anything else justifies the aff arbitrarily jettisoning words in the resolution at their whim which decks negative ground and preparation because the aff is no longer bounded by the resolution.

#### Drop the debater to deter future abuse since it’s the most severe form of punishment

#### No RVIs

#### 1] Skews neg strat since the 2AR can collapse for a persuasive 3min and I can never predict what they’ll say to preempt it

#### 2] Illogical – you shouldn’t win just cause you’re fair – it’s a litmus test for engaging in substance

#### 3] Topic ed – no RVI means we can go back to substance, but an RVI means the debate has to be resolved on the theory layer

#### 4] Chilling effect – new debaters will be scared to read theory because they’re scared of better debaters, which allows experienced debaters to get away with abuse

#### 5] Norming – I can’t concede the counterinterp if I realize I’m wrong which forces me to argue for bad norms

#### Use competing interps it creates a race to the top where we set the best norms, reaonsability is arbitrary and invites judge intervention

#### NC theory first –

#### a] I was only abusive because you were first and prevented me from creating a fair strat

#### b] Norming – more time

c] its your burden to be topical but all other shells are bidirectional

## 2

#### Intellectual property rights cannot be discriminated on the basis of field, or place of invention

WTO <https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm>, Article 27.1, Section 5 on patents, World trade Organization, WTO, Part II — Standards concerning the availability, scope and use of Intellectual Property Rights

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application. [(5)](https://www.wto.org/english/docs_e/legal_e/27-trips_04c_e.htm#fnt-5) Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

#### The WTO’s appellate body no longer exists to mediate disputes, without immediate buy in by states, and no mechanism to make disobedient states obey, the system collapses

Horton, 08/3, Lessons from Trump’s assault on the World Trade Organization, https://www.chathamhouse.org/2021/08/lessons-trumps-assault-world-trade-organization, Chatham House – International Affairs Think Tank, Communications Manager; Project Lead, Common Futures Conversations

The WTO is unique amongst international institutions because it has a powerful enforcement mechanism – the dispute settlement system. However, the fundamental vulnerability is that if powerful states like the US and others won’t participate in the system and be bound by its rules, they quickly risk becoming irrelevant. And that’s the situation we’re in right now with the appellate body crisis, where, without a functioning mechanism to ensure that WTO rules are enforced, the entire system of global trade rules risk collapsing. Ironically, the United States has been the leader of the liberal trading order for the past 70 years, but since Trump, it has become its leading saboteur.

#### A major country operating outside WTO consensus wrecks global trade norms

Bacchus 20 [James Bacchus, member of the Herbert A. Stiefel Center for Trade Policy Studies, the Distinguished University Professor of Global Affairs and director of the Center for Global Economic and Environmental Opportunity at the University of Central Florida, 12-16-2020, "An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines," Cato Institute, [https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines]/Kankee](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines%5d/Kankee)

In a sign of their increasing frustration with global efforts to ensure that all people everywhere will have access to COVID-19 vaccines, several developing countries have asked other members of the World Trade Organization (WTO) to join them in a sweeping waiver of the intellectual property (IP) rights relating to those vaccines. Their waiver request raises anew the recurring debate within the WTO over the right balance between the protection of IP rights and access in poorer countries to urgently needed medicines. But the last thing the WTO needs is another debate over perceived trade obstacles to public health. Unless WTO members reach a consensus, the multilateral trading system may be further complicated by a delay like that in resolving the two‐​decades‐​old dispute between developed and developing countries over the compulsory licensing and generic distribution of HIV/AIDS drugs. A new and contentious “North‐​South” political struggle definitely would not be in the interest of the developed countries, the developing countries, the pharmaceutical companies, or the WTO. Certainly it would not be in the interest of the victims and potential victims of COVID-19. Background In early October 2020, India and South Africa asked the members of the WTO to waive protections in WTO rules for patents, copyrights, industrial designs, and undisclosed information (trade secrets) in relation to the “prevention, containment or treatment of COVID-19 … until widespread vaccination is in place globally, and the majority of the world’s population has developed immunity.”1 India and South Africa want to give all WTO members freedom to refuse to grant or enforce patents and other IP rights relating to COVID-19 vaccines, drugs, diagnostics, and other technologies for the duration of the pandemic. In requesting the waiver, India and South Africa have argued that “an effective response to the COVID-19 pandemic requires rapid access to affordable medical products including diagnostic kits, medical masks, other personal protective equipment and ventilators, as well as vaccines and medicines for the prevention and treatment of patients in dire need.” They have said that “as new diagnostics, therapeutics and vaccines for COVID-19 are developed, there are significant concerns, how these will be made available promptly, in sufficient quantities and at affordable prices to meet global demand.”2 Later in October, the members of the WTO failed to muster the required consensus to move forward with the proposed waiver. The European Union, the United States, the United Kingdom, and other developed countries opposed the waiver request.3 One WTO delegate, from the United Kingdom, described it as “an extreme measure to address an unproven problem.”4 A spokesperson for the European Union explained, “There is no evidence that intellectual property rights are a genuine barrier for accessibility of COVID‐​19‐​related medicines and technologies.”5 In the absence of a consensus, WTO members have decided to postpone further discussion of the proposed waiver until early 2021. Balancing IP Rights and Access to Medicines Not New to WTO This waiver controversy comes nearly two decades after the end of the long battle in the multilateral trading system over access to HIV/AIDS drugs. At the height of the HIV/AIDS crisis at the turn of the century, numerous countries, including especially those from sub‐​Saharan Africa, could not afford the high‐​priced HIV/AIDS drugs patented by pharmaceutical companies in developed countries. Having spent billions of dollars on developing the drugs, the patent holders resisted lowering their prices. The credibility of the companies, the countries that supported them, and the WTO itself were all damaged by an extended controversy over whether patent rights should take precedence over providing affordable medicines for people afflicted by a lethal disease. Article 8 of the WTO Agreement on the Trade‐​Related Aspects of Intellectual Property Rights (the TRIPS Agreement) provides that WTO members “may, in formulating or amending their laws and regulations, adopt measures necessary to protect public health … provided that such measures are consistent with the provisions of this Agreement.” In similar vein, Article 7 of the TRIPS Agreement provides that the “protection and enforcement of intellectual property rights” shall be “in a manner conducive to social and economic welfare.”6 It can be maintained that these two WTO IP rules are significantly capacious to include any reasonable health measures that a WTO member may take during a health emergency, such as a pandemic. Yet there was doubt among the members during the HIV/AIDS crisis about the precise reach of these provisions. As Jennifer Hillman of the Council on Foreign Relations observed, ordinarily the “inherent tension between the protection of intellectual property and the need to make and distribute affordable medicines” is “resolved through licensing, which allows a patent holder to permit others to make or trade the protected product—usually at a price and with some supervision from the patent holder to ensure control.”7 But, in public health emergencies, it may be impossible to obtain a license. In such cases, “compulsory licenses” can be issued to local manufacturers, authorizing them to make patented products or use patented processes even though they do not have the permission of the patent holders.8

#### WTO cred solves nuclear war – allows an off-track for nuclear weapons.

Hamann 09 [(Georgia Hamann is a J.D. Candidate, Vanderbilt University Law School, “Replacing Slingshots with Swords: Implications of the Antigua-Gambling 22.6 Panel Report for Developing Countries and the World Trading System,” 2009.] TDI

**Voluntary compliance with WTO rules** and procedures is of the utmost importance **to the international trading system**.'0 0 Given the increasingly globalized market, the coming years will see an increase in the importance of the WTO **as a cohesive force and arbiter of disputes that likely will become more frequent and injurious**. **01' The work of the WTO cannot be overstated in a nuclear-armed world,** as the body continues to promote respect and even amity among nations with opposing philosophical goals or modes of governance. 10 2 Demagogues in the Unites States may decry the rise of China as a geopolitical threat, 0 3 and extremists in Russia may play dangerous games of brinksmanship with other great powers, **but trade keeps politicians' fingers off "the button**. ' 10 4 **The WTO offers an astounding rate of compliance** for an organization with no standing army and no real power to enforce its decisions, suggesting that governments recognize the value of maintaining the international construct of the WTO. 105 **In order to promote voluntary compliance, the WTO must maintain a high level of credibility**. 106 Nations must perceive the WTO as the most reasonable option for dispute resolution or fear that the WTO wields enough influence to enforce sanctions. 10 7 The arbitrators charged with performing the substantive work of the WTO by negotiating, compromising, and issuing judgments are keenly aware of the responsibility they have to uphold the organization's credibility. 108

Extinction ow on magnitude kills everyone in the world and is irresversible

## 4

#### CP Text: The member nations of the World Trade Organization should strengthen data exclusivity protections for CAR-T therapy and reduce protections for all other medicines as outlined in the 1AC.

#### Data exlcusivity is uniquely key to CAR-T--high market value and competitiveness means infringement cases devastate companies, Haley 20

[James F Haley, May 6, 2020, "Patent issues in CAR-T technology", No Publication, https://www.iam-media.com/litigation/patent-issues-in-car-t-technology, date accessed 10-14-2021] //Lex AT

A recent patent infringement action in the United States has also demonstrated the value of CAR-T patents. A California jury found that Gilead’s Yescarta infringed Juno Therapeutics’ patent directed to a CAR-encoding polynucleotide. The jury awarded Juno $752 million, based, in part, on Gilead’s representation to the US Securities and Exchange Commission (SEC) that Yescarta was worth an estimated $6.2 billion, which the judge enhanced to over $1.1 billion for willful infringement. In view of the increasingly crowded CAR-T field and the commercial value of CAR-T products and patents, innovators, follow-on developers and late entrants in the CAR-T field should develop early on a sound patent strategy and thoroughly vet their products and processes for any freedom-to-operate issues. Further, any patent strategy relating to the identification of a new disease-associated biomarker or neoantigen should include a CAR-T patent strategy during the early stages of product research and development.

#### Emperics prove data exclusivity is key, Boustany 18

Charles Boustany (physician and former congressman). “Americans Fund Most of the World’s Drug Research. Here’s How Trump Can End That.” Fortune. 9 August 2018. JDN. https://fortune.com/2018/08/09/trump‑drugs‑prices‑pharmaceutical‑research/

Complicating the situation, many nations have relatively weak intellectual property pro‑ tections, which enable generic drug makers to copy and sell innovators’ drug designs just a few years after those designs have been released. Consider biologics, a cutting‑edge class of drugs made from living organisms. These treatments hold great promise for treating diseases like cancer, multiple sclerosis, and Alzheimer’s. But they’re extremely difficult, time‑consuming, and expensive to make. To encourage researchers to develop these treatments, the U.S. grants innovators 12 years of biologic data protection. During this period, rival firms are forbidden to use the innovator’s clinical trial data to create knockoff products. The protection period effectively gives innovators time to recoup their development costs and earn a profit. In contrast, Canada only provides eight years of biologic data protection. Mexico pro‑ vides no data protection at all unless innovators undergo a substantial legal process. That means Mexican drug firms can immediately start using innovators’ data to test the effectiveness of knockoff “biosimilars,” so long as the original biologic is sold in Mexico. If U.S. companies earned more revenue from foreign nations, then the American com‑ panies could spend more on R&D. This ultimately would result in new treatments and inject more competition into the U.S. drug market, leading to lower prices for American patients.

#### CAR-T technology solves cancer but R&D is key, Fernandez 21

[[CLARA RODRÍGUEZ FERNÁNDEZ](https://www.labiotech.eu/author/clara/), 10-11-2021, "A Cure for Cancer? How CAR-T Cell Therapy is Revolutionizing Oncology", Labiotech.eu, https://www.labiotech.eu/in-depth/car-t-therapy-cancer-review/, date accessed 10-14-2021] //Lex AT

CAR-T clinical trials have shown huge remission rates, of up to [93%](https://ashpublications.org/bloodadvances/article/4/10/2325/456149/Efficacy-and-safety-of-anti-CD19-CAR-T-cell), in severe forms of blood cancer. This is particularly impressive considering most CAR-T clinical trials recruit cancer patients that have not responded to many if not all other available treatments. These results have fed the expectations of patients and investors alike, but it’s important to remember that the therapy can also have flaws. André Choulika, CEO of French CAR-T developer Cellectis, put it bluntly: “I’m just trying to be realistic, CAR-T is not the miracle cure for cancer.” Indeed, CAR-T cells have in fact been linked to severe and even lethal side effects, such as neurotoxicity and cytokine release syndrome. Over the years, several companies have reported deaths in late-stage clinical trials with CAR-T therapies. This has made many realize that the technology might not be as perfect as originally expected. Many of these deaths were reported in trials testing CAR-T therapies against the CD19 antigen found in immune B cells — the most studied target in the CAR-T field. Four of the five CAR-T therapies currently on the market target CD19 to treat several forms of cancers affecting B cells, such as lymphoma and leukemia. “The initial furor and excitement of CAR-T have led to extensive and rapid clinical development in the CD19 target space,” explained David Gilham, Chief Scientific Officer at Belgian CAR-T company Celyad. “Research is busy catching up at the moment, in particular concerning toxicity. The lack of good preclinical models hampers this work, but with clinical samples available, ongoing investigations are now closer to identifying the underlying mechanisms and further refining the approach.”

#### Contagious Cancer is a major and legitimate threat AND causes extinction.

Johnson 16 [George Johnson, columnist and science journalist for the New York Times, M.A. in Journalism and Public Affairs, American University, 2-22-2016, "Scientists Ponder the Prospect of Contagious Cancer (Published 2016)," The New York Times, <https://www.nytimes.com/2016/02/23/science/scientists-ponder-the-prospect-of-contagious-cancer.html?mcubz=0>] Elmer

For all its peculiar horror, cancer comes with a saving grace. If nothing else can stop a tumor’s mad evolution, the cancer ultimately dies with its host. Everything the malignant cells have learned about outwitting the patient’s defenses — and those of the oncologists — is erased. The next case of cancer, in another victim, must start anew. Imagine if instead, cancer cells had the ability to press on to another body. A cancer like that would have the power to metastasize not just from organ to organ, but from person to person, evolving deadly new skills along the way. While there is no sign of an imminent threat, several recent papers suggest that the eventual emergence of a contagious human cancer is in the realm of medical possibility. This would not be a disease, like cervical cancer, that is set off by the spread of viruses, but rather one in which cancer cells actually travel from one person to another and thrive in their new location. So far this is known to have happened only under the most unusual circumstances. A 19-year-old laboratory worker who pricked herself with a syringe of colon cancer cells developed a tumor in her hand. A surgeon acquired a cancer from his patient after accidentally cutting himself during an operation. There are also cases of malignant cells being transferred from one person to another through an organ transplant or from a woman to her fetus. On each of these occasions, the malignancy went no further. The only known cancers that continue to move from body to body, evading the immune system, have been found in other animals. In laboratory experiments, for instance, cancer cells have been transferred by mosquitoes from one hamster to another. And so far, three kinds of contagious cancers have been discovered in the wild — in dogs, Tasmanian devils and, most recently, in soft shell clams. The oldest known example is a cancer that spreads between dogs during sexual intercourse — not as a side effect of a viral or bacterial infection, but rather through direct conveyance of cancer cells. The state of the research is described in a review, “The Cancer Which Survived,” published last year by Andrea Strakova and Elizabeth P. Murchison of the University of Cambridge. The condition, canine transmissible venereal tumor disease, is believed to have sprung into existence 11,000 years ago — as a single cell in a single dog — and has been circulating ever since. (Why did this happen in dogs and not, say, cats? Perhaps because of what the authors demurely call the dogs’ “long-lasting coital tie” — the half an hour or so that a male and female are locked in intercourse, tearing genital tissues and providing the cancer cells with a leisurely crossing.) Normally a cancer evolves in a single body over the course of years or decades, accumulating the mutations that drive it to power. But to have survived for millenniums, researchers have proposed, canine cancer cells may have developed mechanisms — like those in healthy cells — to repair and stabilize their own malignant genomes. Early on, cancer cells typically flourish by disabling DNA repair and ramping up the mutational frenzy. Somewhere along the way, the age-old canine cells may have reinvented the device to extend their own longevity. There is also speculation that this cancer may have learned to somehow modify canine sexual behavior in ways that promote the disease’s spread and survival. The second kind of contagious cancer was discovered in the mid-1990s in Tasmanian devils, which spread malignant cells as they try to tear off one another’s faces. Though it may be hard to sympathize, devil facial tumor disease threatens the creatures with extinction. With so few examples, transmissible cancer has been easy to dismiss as an aberration. But in December, scientists at the Universities of Tasmania and Cambridge reported in Proceedings of the National Academy of Sciences that Tasmanian devils are passing around another kind of cancer — genetically distinct from the first. It’s weird enough that one such cancer would arise in the species. What are the chances that there would be two? One theory is that the animals are unusually vulnerable. Driven so close to extinction — by climate change, perhaps, or human predators — the species is lacking in genetic diversity. The cells of another devil injected through a vicious wound may seem so familiar that they are ignored by the recipient’s immune system. If some of the cells carry the mutations for the facial cancer, they might be free to flourish and develop into a new tumor. But the scientists also proposed a more disturbing explanation: that the emergence of contagious cancer may not be so rare after all. “The possibility,” they wrote, “warrants further investigation of the risk that such diseases could arise in humans.” Cancer has probably existed ever since our first multicellular ancestors appeared on Earth hundreds of millions of years ago. The life spans of even the longest-lived animals may be just too brief for cancers to easily evolve the ability to leap to another body. Otherwise, contagious cancer would be everywhere.