**AC**

I affirm.

**Definitions**

**A patent,**( according to the WIPO)**, is**

(https://www.wipo.int/patents/en/faq\_patents.html)

A patent is an exclusive right granted for an invention. In other words, a patent is **an exclusive right to a product or a process** that generally provides a new way of doing something, or offers a new technical solution to a problem. To get a patent, technical information about the invention must be disclosed to the public in a patent application.

**HIV/AIDS related treatments include: Antiretroviral or ARV therapies, pre exposure prophylaxis, liposomal amphotericin , and combination medicines according to the CDC**

**For clarification: IP stands for intellectual property**

**C1: IP Limits Accessibility**

**The TRIPS agreement blocks access to HIV/AID treatments especially for developing countries Agniam ‘11**

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**‌**Despite the tremendous increase in access to ARVs, the still-glaringly disproportionate distribution of the mortality and morbidity burdens of AIDS between the poorer and industrialized regions of the world reinforces the “Life versus Profit” debate. **This discourse is important because it pitches profit by pharmaceutical corporations against access to essential medicines by vulnerable populations in developing and least developed countries.** Since AIDS is an incurable-but-treatable disease, the impediments to accessing ARVs by people living with HIV in poor countries are compelling factors that demand a re-assessment of the policy framework for emergent South-South cooperation.This framework would inevitably engage with and confront the normative architecture of global IP regimes, especially the TRIPS Agreement. **Although TRIPS-codified flexibilities have been pursued by a few developing countries, these measures, in the face of the high prevalence of HIV/AIDS among their populations, were either blocked or legally challenged by** some industrialized Member States of **the WTO**. It is not surprising, therefore, that within the first decade of the life of the TRIPS Agreement (1995-2005), initiatives such as the WTO Doha Ministerial Declaration on the TRIPS Agreement and Public Health and the WTO General Council Decision in 2003 emerged — all aimed at balancing the imperatives of intellectual property “rights” and access to life-saving pharmaceutical drugs. In the context of the Doha Declaration and the 2003 Decision, most scholars and commentators have rightly observed that difficult questions still linger on how and when to use TRIPS flexibilities on access to drugs and how to reconcile “conflicting” provisions of intellectual property and human rights treaties. In recent years, the “intellectual property versus access” debate seems to have shifted towards “innovation-plus-access”. This more holistic framework, championed and advocated by civil society and developing countries, is aimed at generating health-driven research and development that would strike a balance between promoting and protecting the right to access medicines, and the inventor’s “right” to profit.  This shift, which is captured in the Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property (GSPoA), adopted at the 2008 World Health Assembly, is being led by health authorities under the auspices of the World Health Organization (WHO). The success and sustainability of this framework, as observed by Ellen ‘t Hoen, will “depend on WHO’s forcefulness and resolve”. Given the history of WHO, which often favors non-binding (soft-law) governance instruments as opposed to legally-binding norms, it is open to debate whether WHO could be resolute enough to push the GSPoA framework to confront the normative architecture of the WTO in a way that satisfies public health and trade-economic-IP interests in a win-win scenario.

**IP protections prevent  development of generic drugs that can save the lives of the poor – the status quo secures the interests of multinationals.**

**Shah 10** (Anup: editor, health writer; "Pharmaceutical Corporations and Medical Research — Global Issues"; 10-2-2010; Global Issues; http://www.globalissues.org/article/52/pharmaceutical-corporations-and-medical-research; DT)

Ideologically, many **drug companies support the position of less government involvement, yet in the developing world in particular, diseases and illnesses affect the poorest the most who cannot afford expensive** (or even sometimes cheap) **treatments**. In the past decade or so, pharmaceutical companies have therefore also been criticized for ignoring this “market” because they can’t pay. [M]any people, most of them in tropical countries of the Third World, die of preventable, curable diseases.… Malaria, tuberculosis, acute lower-respiratory infections—in 1998, these claimed 6.1 million lives. People died because the drugs to treat those illnesses are nonexistent or are no longer effective. **They died because it doesn’t pay to keep them alive**. — Ken Silverstein, Millions for Viagra, Pennies for Diseases of the Poor, The Nation, July 19, 1999 Public announcements of drug donations to poor countries are often welcome, but sometimes the details reveal murkier intentions; some of the drugs are close to, or even past, their expiry date (and are expensive to dispose, adding more costs to recipient countries) for example. **Poorer countries encourage their drug companies to make cheaper generic alternatives to expensive branded ones or use other tools available at their disposal to help bring the price of medicines down to more affordable levels**. But **they face immense pressure from international institutions and multinational pharmaceutical corporations, even when generics and other options pursued are legitimate under international rules**. For these **multinationals**, **they’ve poured billions into some of these drugs and therefore want a patent system that will protect their investments for as long as possible. For the developing and poorer countries, as remote as these issues may seem, patents and intellectual property rights issues can mean life or death**. (For example, **at the end of the 1990s, the pharmaceutical industry lobbied the US government to threaten sanctions on South Africa for trying to produce generic drugs to fight** its growing **AIDS** problem. It took huge public outcry to get the case dropped some 2 years later.) The establishment of the World Trade Organization … imposed US style intellectual property rights around the world. These rights were intended to reduce access to generic medicines and they succeeded. Developing countries paid a high price for this agreement. But what have they received in return? **Drug companies spend more on advertising and marketing than on research, more on research on lifestyle drugs than on life saving drugs, and almost nothing on diseases that affect developing countries only. This is not surprising. Poor people cannot afford drugs, and drug companies make investments that yield the highest returns.** The chief executive of Novartis, a drug company with a history of social responsibility, said “We have no model which would [meet] the need for new drugs in a sustainable way … You can’t expect for profit organizations to do this on a large scale.” — Joseph Stiglitz (former World Bank Chief Economist and Nobel Prize winner for economics), Scrooge and intellectual property rights, British Medical Journal, December 23, 2006, Volume 333, pp. 1279-1280 These and many other issues are discussed further below.

**Patent protection increases costs beyond affordability; generic drugs are necessary to combat HIV/AIDS.**

**Chen 13** (contributing editor at In These Times and Dissent magazine, associate editor at CultureStrike; “Patents Against People How Drug Companies Price Patients out of Survival”, Dissent Magazine, 2013;<https://www.dissentmagazine.org/article/patents-against-people-how-drug-companies-price-patients-out-of-survival>

**The** purported **idea behind intellectual property protections** **is to create market incentives for innovation in the case of the pharmaceuticals industry**, guaranteeing a return on sales for drugs. The value proposition gets muddy when **humanitarian needs and market dynamics diverge—when malaria treatments for a rural village, for example, turn vastly less profit than the hot new anti-depressant**. Or when a drug’s price is derived almost entirely from the label on the box. **The generic drug sector** operates on a different tier of the market. With production driven in large part by India-based firms, it **still operates within a market-based system, but generics are exponentially more affordable for poor communities compared to the prices charged by dominant pharmaceutical brands. Cheap generics are the crux of global campaigns to expand HIV/AIDS treatment** and other medical solutions for patients **in poor countries**, supplying UNICEF and the U.S.-sponsored PEPFAR program. The medicine-related provisions of TRIPS, crystallized in the 2001 Doha Round of WTO talks, ensure some political flexibility for governments to circumvent patent protections on public health grounds. **The agreement exempts poorer countries from regular patent enforcement rules so that governments can expand access to affordable medicines by granting compulsory licenses to produce generics, which override foreign companies patents**. **For now, the poorest countries are generally exempted from the WTO’s major patent enforcement policies**, thanks to an interim grace period that allows governments to adjust their regulatory systems. Nonetheless, TRIPS sets the framework for future drug marketing and manufacturing in poor countries. Public health advocates, including World Health Organization (WHO) officials, contend that TRIPS and related free trade agreements containing various “TRIPS-plus” **provisions are designed to expand monopoly power and maximize profits, deepening the health gap between nations where new treatments are developed and poor regions where preventable scourges still flourish**. **The HIV/AIDS epidemic is one such “marketplace” for drugs**. **While movements have grown to expand treatment access, corporations have bulked up artificial barriers through intellectual property laws**. Today, 26 million people worldwide are still not getting proper treatment, and the WHO has recently pressed wealthy donor states for a major infusion of aid for treatment programs. Yet those same programs are sliding on a collision course with powerful pharmaceutical monopolies. Activists warn that existing TRIPS protections for access to basic anti-retrovirals will not cover newer, more advanced therapies, including “second-line” anti-retrovirals, which are deployed when patients develop drug resistance. **Other emerging disease threats may similarly intensify under the industry’s commercial barriers**. Health experts warn that **obstacles to treatment access for non-communicable diseases, such as diabetes and cancer** (which are spreading rapidly in the Global South but tend to attract less political attention than do infectious epidemics), **will engender the next crises in global medicine in poor countries**. Perhaps most insidiously, **new cutting-edge medical technologies, like genetic material, have already become new prospects for enrichment for multinationals**. Legal scholars have warned that **the system’s public interest protections do not adequately protect against abuse of gene patents**. A recent U.S. Supreme Court decision restricts but does not ban the commercial patenting of genetic material, which may complicate the regulatory scope of TRIPS.

**New treatments remain cost-intensive due to patents, blocking access to life-saving second and third line regimens -MSF ‘14**

“Generic Competition Pushing down HIV Drug Prices, but Patents Keep Newer Drugs Unaffordable.” Doctors without Borders - USA, 2013, www.doctorswithoutborders.org/what-we-do/news-stories/news/generic-competition-pushing-down-hiv-drug-prices-patents-keep-newer. Accessed 25 Aug. 2021.

The price of first- and second-line antiretrovirals (ARVs) to treat HIV are falling because of increased competition among generic producers, but **newer ARVs continue to be priced astronomically high,** according to the annual report Untangling the Web of ARV Price Reductions, released today by the international medical humanitarian organisation Médecins Sans Frontières (MSF) at the International AIDS Society conference in Kuala Lumpur. “It’s good news that the price of key HIV drugs continues to fall as more generic companies compete for the market, but the newer medicines are still priced far too high,” said Dr Jennifer Cohn, Medical Director at MSF’s Access Campaign. “MSF and other care providers need the newer treatments for people that have exhausted all other options, but patents keep them priced beyond reach. We also need to watch carefully as newer, better medicines reach the market in coming years, as these are the drugs that we’ll quickly be needing to roll out. The price question is far from resolved.” With the arrival of additional quality-assured sources in the past year, the ‘best possible’ price of a WHO-recommended one-pill-a-day first-line combination (tenofovir/lamivudine/efavirenz) has fallen 19% since last year (from $172 to $139 per person per year), with some countries able to achieve even lower prices in large volume orders. Likewise, as new generic competitors have emerged, the prices of two key medicines used in second-line treatment— atazanavir/ritonavir and lopinavir/ritonavir—have each fallen by 28% over the last year, with the most affordable second-line combination (zidovudine/lamivudine + atazanavir/ritonavir) now priced at $303 per year. This represents a 75% drop in the price of second-line treatment since 2006. However, today’s lowest second-line price is still more than double the cost of first-line treatment. But **for newer HIV medicines, including critical new classes of ARVs** such as integrase inhibitors, **generic competition is** mostly **blocked because of patents**. **As a result, these are much more expensive. The best possible price** of a possible salvage regimen **for people who have failed second-line treatment** (raltegravir + etravirine + darunavir + ritonavir) **is** $2,006 per year in the poorest countries—nearly **15 times the price of first-line treatment**. Countries that do not have access to these lowest available prices are paying many times more. For example, Thailand and Jamaica pay $4,760 and $6,570 respectively for the new drug darunavir alone; Paraguay pays $7,782 just for etravirine; and Armenia pays $13,213 just for raltegravir—just one of the three or four drugs that are needed for a full regimen. Securing the affordability of future medicines is also a priority. HIV experts highlight that **new potent and well-tolerated drugs** such as the integrase inhibitor dolutegravir **could in the future be used in improved first- or second-line, making affordable access to these newer drugs even more urgent.** “**Scaling up HIV treatment and sustaining people on treatment for life will depend on bringing the price of newer drugs down**,” said Arax Bozadjian, HIV Pharmacist at MSF’s Access Campaign. “Today, there are no quality-assured generic options for the large majority of the newer HIV drugs. Prices in middle-income countries are also a major concern. The terms of existing voluntary licence agreements aren’t good enough, most of them don’t have terms that are public-health oriented, and most middle-income countries are excluded, which limits these countries access to much-needed regimens.” **It was thanks to ‘patent oppositions’ in generics-producing India that the price of first- and second-line combinations were able to fall**, as additional generic producers entered the market. With newer HIV medicines increasingly being patented in countries with significant generic production capacity, like India, it will be critical for solutions to be identified to bring prices down. Patent applications should be opposed when they do not meet a country’s patentability requirements, as reaffirmed by the Indian Supreme Court’s decision against Novartis in April 2013. When patents prevent access, compulsory licences should be issued in the interest of public health. India issued its first compulsory licence in 2012 for a cancer drug that was deemed unaffordable, and similar moves should be taken to overcome unaffordable HIV drug prices. “In our clinic in Mumbai, **more and more patients need the newest expensive HIV drugs**, but we can’t afford these prices long-term, nor can the government,” said Leena Menghaney, Manager of MSF’s Access Campaign in India. “Countries need to tackle the problem of high drug prices head on, by making sure unwarranted patents are not granted, and by issuing compulsory licences when drugs are priced out of reach so that more affordable generic versions can be made.” A second report released today by MSF at the IAS conference, Putting HIV Treatment to the Test, looks at the price of HIV viral load tests. Viral load testing is the gold standard for HIV treatment monitoring in developed countries, as compared with either clinical or immunological (CD4) monitoring, it can more accurately and quickly detect when people are having problems adhering to their treatment and need additional counselling, or in fact are failing their treatment. WHO’s new treatment recommendations strongly recommend the use of regular viral load monitoring in developing countries. But price and complexity so far have hindered the roll out of these technologies in developing countries. “The goal of all HIV treatment programmes should be for ARVs to suppress the virus so people have ‘undetectable’ levels of virus in their blood,” said Dr. Cohn. “Viral load testing is the best way to keep people on their more affordable first-line combination of HIV drugs for as long as possible, and to switch only those people to newer drugs who really need it. With the price of second-line treatment coming down, **it’s** really **time to start** testing people’s viral load and **making sure people are on treatment that works for them, instead of waiting until** it’s too late and **they get sick again or die.”**

**Middle income countries are uniquely hard-hit by high prices and low global attention, risks increased spread and inaccessible treatment -MSF ‘15**

“As HIV Burden Overwhelmingly Shifts to ‘Middle-Income’ Countries, Access to Affordable Medicines Is under Threat | MSF.” Médecins sans Frontières (MSF) International, 2015, www.msf.org/hiv-burden-overwhelmingly-shifts-%E2%80%98middle-income%E2%80%99-countries-access-affordable-medicines-under-threat. Accessed 25 Aug. 2021.

‌At the International AIDS Society (IAS) Conference today, Médecins Sans Frontières (MSF) warned that **middle-income countries** (MICs), **which will be home to 70% of people living with HIV** by 2020, **face increasing threats to their ability to access affordable generic medicines**, which are crucial to countries’ ability to reach the global UNAIDS 90/90/90[1] targets.  “No one can deny the pivotal role that affordable antiretrovirals have played in putting 15 million people on HIV treatment, but as we look ahead to the next 15 million, we see that middle-income countries are increasingly constrained in accessing affordable generic medicines, and **this spells disaster for the global HIV response**,” said Dr. Peter Saranchuk, TB/HIV Advisor for MSF. The term ‘middle-income’ is an artificial classification that is not linked to public health realities on the ground – in fact, more than half of MSF’s medical programmes are in MICs, including India, Kenya, Lesotho, Myanmar and Swaziland. About 70% of the world’s poor live in MICs, and sixty percent of people with HIV live in these countries today. “Multiple threats on MICs are converging to form an unprecedented assault on access to medicines,” said Leena Menghaney, head of MSF’s Access Campaign in South Asia.  “Amongst other threats, some of the most acute come from **trading partners** – like the US and Japan – who **seek to impose intellectual property rules that will block access to generic medicines**; and from several donor agencies, including the Global Fund to Fight AIDS, Tuberculosis and Malaria, whose discriminatory policies are moving towards reducing funding for MICs at a time when global HIV targets call for increasing the pace of treatment scale-up.” Today, we see that the **pharmaceutical industry pricing strategies for antiretrovirals** (ARVs) and other medicines, including tiered pricing, voluntary licensing and donation programmes, **deliberately exclude middle-income countries**, and are almost entirely focused on excluding MICs **from accessing the lowest global prices available** to low-income countries.  This is particularly acute for third-line, or salvage regimens, which are priced out of reach for most countries.  For example, the raltegravir, etravirine, darunavir and ritonavir salvage regimen is available at the lowest global price for $1,854 per person per year (ppy), but middle-income countries often pay exponentially more:  for example, Myanmar pays $2,929 ppy and Ukraine pays $16,409 ppy.  **Second-line treatments, and some newer first-line treatments, are** also **priced out of reach.** Later this week, negotiators for the Trans-Pacific Partnership (TPP) agreement will meet in Hawaii to try to finalize terms for a trade pact that will encompass at least 40% of the world’s GDP.  One third of the 12 TPP countries are developing countries classified as middle-income economies who, if the deal is signed in its current form, would be forced to implement a range of new provisions that will lengthen, strengthen and expand patent and regulatory monopolies for medicines. For example, one proposed rule limits governments' ability to restrict pharmaceutical companies' efforts to pursue abusive ‘evergreening’ strategies to extend the life of pharmaceutical patents well beyond 20 years.  The effect is reduced ability to access affordable generic medicines. " Meanwhile, the Global Fund to Fight HIV/AIDS, Tuberculosis and Malaria’s ‘New Funding Model’ relies on a funding allocation formula based in part on income classifications, rather than public health needs. As a result, several MICs such as Ukraine and Vietnam have seen their funding reduced in the 2014-2016 funding period compared to previous years, limiting their ability to reach socially excluded groups. “To make matters worse, India - known as the pharmacy of the developing world for its role in producing affordable generic medicines - is facing its own set of pressures from the US, EU and other governments to roll back the country’s progressive patent laws in order to restrict generic competition, in favour of supporting the multinational pharmaceutical industry’s monopoly- and profit-driven business models,” said Menghaney. “**If these policies are allowed to continue, middle-income countries face nothing short of a calamity that poses a major threat to the global HIV response** and other health initiatives.”

**Stonewalling is preventing the treatment of hundreds of thousands with HIV related illness -MSF ‘19**

(Medecins Sans Frontieres, non-profit organization promoting public health globally, “Gilead fails to keep promise on access to lifesaving drug for people living with HIV”, June 27, 2019, https://www.msf.org/gilead-sciences-fails-expand-promised-access-lifesaving-drug-people-living-hiv)

Pharmaceutical corporation Gilead Sciences has failed to deliver on promises to make an important drug available to people suffering from a life-threatening [HIV](https://www.msf.org/hivaids)-related infection, said Médecins Sans Frontières (MSF). Nearly one year ago, Gilead announced its ‘access initiative’ promising lower prices for **liposomal amphotericin** B (L-AmB) in 116 developing countries, but to date, the drug largely **remains inaccessible**. Gilead has registered the drug in only six of the 116 countries, and even where it is registered, the drug is unavailable at an affordable price, for MSF and others. Just over a year ago**, the drug was recommended** by the World Health Organization (WHO) **as the preferred treatment** over a suboptimal, more toxic treatment (AmB deoxycholate), as the safety benefits and fewer side effects associated with L-AmB could improve treatment outcomes and management in low-resource settings where most cases **of cryptococcal meningitis** occur. WHO, however, recognised that high prices and a lack of registration of L-AmB created major barriers to people [accessing this drug](https://www.msf.org/access-medicines) in developing countries. Although Gilead publicised their pledge to reduce the price of the drug to a ‘no-profit’ price of US$16.25 per vial in September 2018, L-AmB continues to be priced out of reach in many developing countries. For example, in South Africa, the drug is priced as high as $200 per vial (at least $4,200 per full treatment course). In India, it is priced at $45 per vial (nearly $1,000 per full treatment course). Gilead has a monopoly on L-AmB. **Although this medicine is no longer under patent, the corporation has refused to license its technology and manufacturing methods to potential generic manufacturers, thereby delaying** the **availability** of less expensive products. “We are alarmed to see that **people living with HIV** in India today **continue to suffer** from cryptococcal meningitis just as they did during the height of the global AIDS epidemic nearly two decades ago, **even though effective prevention and treatment** for the infection **exists,**” said Dr Amit Harshana, MSF Medical Coordinator in India. “It’s unacceptable that people are still dying because the tools to prevent, treat and cure cryptococcal meningitis are not available where people who have this infection live.” “Due to Gilead’s inaction to make this drug widely accessible, we are forced to buy the drug on the private market and will have to continue to do so, at nearly three times the price the corporation announced last year,” Dr Harshana said. **Cryptococcal meningitis kills more than 180,000 people every year, 75 per cent of whom live in sub-Saharan Africa.** **It especially affects people living with HIV** whose immune systems are severely suppressed, leaving them vulnerable to such deadly opportunistic infections. MSF treats the infection in all its HIV programmes, including in the Democratic Republic of Congo, India, Malawi, Myanmar and South Africa.

**9.8 million people aren’t accessing treatment -UNAIDS ‘21**

UNAIDS. *2018 GLOBAL HIV STATISTICS*. , 2020.

**37.7 million** [30.2 million–45.1 million] **people globally were living with HIV in 2020.** 1.5 million [1.0 million–2.0 million] people became newly infected with HIV in 2020. **680 000** [480 000–1.0 million] **people died from AIDS-related illnesses** in 2020. **27.5 million** [26.5 million–27.7 million] **people were accessing antiretroviral therapy** in 2020. 79.3 million [55.9 million–110 million] people have become infected with HIV since the start of the epidemic. 36.3 million [27.2 million–47.8 million] people have

**Left untreated, HIV/AIDS mortality rates skyrocket -Gilroy ‘20**

“What Is the Prognosis of Untreated HIV Infection?” *Medscape.com*, 26 June 2021, www.medscape.com/answers/211316-6065/what-is-the-prognosis-of-untreated-hiv-infection. Accessed 25 Aug. 2021.

‌**The prognosis in patients with untreated HIV infection is** poor, with **an overall mortality rate of more than 90%. The average time from infection to death is 8-10 years,** although individual variability ranges from less than 1 year to long-term nonprogression. Many variables have been implicated in HIV's rate of progression, including CCR5-delta32 heterozygosity, mental health, [84] concomitant drug or alcohol abuse, superinfection with another HIV strain, nutrition, and age. There is less evidence that treatment of HIV-2 infection slows progression, and certain antiretroviral medications (specifically the non-nucleoside–analogue reverse-transcriptase inhibitors) are not effective against HIV-2. The HIV-1 viral-load assays are much less reliable at quantifying HIV-2, if they work at all. HIV-2 viral load assays have been developed, but none has been approved by the US Food and Drug Administration except as blood donor–screening tools. **Once infection has progressed to AIDS, the survival period is usually less than 2 years in untreated patients**. Persons in whom the infection does not progress long-term may not develop AIDS for 15 years or longer, although many still exhibit laboratory evidence of CD4 T-cell decline or dysfunction. [85, 86, 87, 88] The appropriate use of combination **antiretroviral therapies and prophylaxis** for opportunistic infections **dramatically improves survival and greatly decreases the risk of secondary** opportunistic **infection**s. [89, 90, 91] The risk of AIDS-associated lymphoma is not altered by antiviral therapy and, as such, has grown in prevalence among overall AIDS-defining conditions. Sackoff et al found that between 1999 and 2004, the HIV-related mortality rate in New York City decreased each year by approximately 50 deaths per 10,000 people with AIDS. The rate of non–HIV-related deaths also showed a decline, more modest but consistent, with about 7.5 fewer deaths per 10,000 people with AIDS per year. [90] Importantly, many researchers have consistently shown that the primary risk factor for infection affects mortality. For example, the mortality rate among intravenous drug users tends to be higher, whether related to HIV disease or non-HIV disease.Overall, with the increasing use of antiretroviral therapy and the introduction of better antiviral regimens, survival with HIV infection has increased over time, although it is not yet equivalent to that in uninfected individuals. (See the image below.

**Thus, I affirm that the people ought to take control of HIV/AIDS related treatments from member states of the World Trade Organization through patent expiration.**

**Solvency**

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

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

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

**Framework**

#### Structural violence is based on moral exclusion, which is fundamentally flawed because exclusion is not based on dessert but rather on arbitrarily perceived differences.

#### Winter and Leighton 01 - Deborah DuNann Winter (professor of psychology at Whitman College) and Dana C. Leighton (Assistant Professor of Psychology at Texas A&M University), “Peace, conflict, and violence: Peace psychology in the 21st century,” Pg. 4-5, 2001

#### Finally, to recognize the operation of structural violence forces us to ask questions about how and why we tolerate it, questions which often have painful answers for the privileged elite who unconsciously support it. A final question of this section is how and why we allow ourselves to be so oblivious to structural violence. Susan Opotow offers an intriguing set of answers, in her article Social Injustice. She argues that our normal perceptual cognitive processes divide people into in-groups and out-groups. Those outside our group lie outside our scope of justice. Injustice that would be instantaneously confronted if it occurred to someone we love or know is barely noticed if it occurs to strangers or those who are invisible or irrelevant. We do not seem to be able to open our minds and our hearts to everyone, so we draw conceptual lines between those who are in and out of our moral circle. Those who fall outside are morally excluded, and become either invisible, or demeaned in some way so that we do not have to acknowledge the injustice they suffer. Moral exclusion is a human failing, but Opotow argues convincingly that it is an outcome of everyday social cognition. To reduce its nefarious effects, we must be vigilant in noticing and listening to oppressed, invisible, outsiders. Inclusionary thinking can be fostered by relationships, communication, and appreciation of diversity. Like Opotow, all the authors in this section point out that structural violence is not inevitable if we become aware of its operation, and build systematic ways to mitigate its effects. Learning about structural violence may be discouraging, overwhelming, or maddening, but these papers encourage us to step beyond guilt and anger, and begin to think about how to reduce structural violence. All the authors in this section note that the same structures (such as global communication and normal social cognition) which feed structural violence, can also be used to empower citizens to reduce it. In the long run, reducing structural violence by reclaiming neighborhoods, demanding social jus- tice and living wages, providing prenatal care, alleviating sexism, and celebrating local cultures, will be our most surefooted path to building lasting peace.

#### Thus, the ROB is to vote for the debater with the best strategy to overcome structural violence.

#### Medicine and society are historically exclusionary towards HIV/AIDS patients. That requires an investigation into reducing barriers for those afflicted with the disease. OHCHR ‘19

#### OHCHR. “HIV/AIDS and Human Rights.” Ohchr.org, 2019. https://www.ohchr.org/en/issues/hiv/pages/hivindex.aspx.

#### Human rights are inextricably linked with the spread and impact of HIV on individuals and communities around the world. A lack of respect for human rights fuels the spread and exacerbates the impact of the disease, while at the same time HIV undermines progress in the realisation of human rights. This link is apparent in the disproportionate incidence and spread of the disease among certain groups which, depending on the nature of the epidemic and the prevailing social, legal and economic conditions, include women and children, and particularly those living in poverty. It is also apparent in the fact that the overwhelming burden of the epidemic today is borne by developing countries, where the disease threatens to reverse vital achievements in human development. AIDS and poverty are now mutually reinforcing negative forces in many developing countries. The relationship between HIV/AIDS and human rights is highlighted in three areas: Increased vulnerability: Certain groups are more vulnerable to contracting the HIV virus because they are unable to realize their civil, political, economic, social and cultural rights. For example, individuals who are denied the right to freedom of association and access to information may be precluded from discussing issues related to HIV, participating in AIDS service organizations and self-help groups, and taking other preventive measures to protect themselves from HIV infection. Women, and particularly young women, are more vulnerable to infection if they lack of access to information, education and services necessary to ensure sexual and reproductive health and prevention of infection. The unequal status of women in the community also means that their capacity to negotiate in the context of sexual activity is severely undermined. People living in poverty often are unable to access HIV care and treatment, including antiretrovirals and other medications for opportunistic infections. Discrimination and stigma: The rights of people living with HIV often are violated because of their presumed or known HIV status, causing them to suffer both the burden of the disease and the consequential loss of other rights. Stigmatisation and discrimination may obstruct their access to treatment and may affect their employment, housing and other rights. This, in turn, contributes to the vulnerability of others to infection, since HIV-related stigma and discrimination discourages individuals infected with and affected by HIV from contacting health and social services. The result is that those most needing information, education and counselling will not benefit even where such services are available. Impedes an effective response: Strategies to address the epidemic are hampered in an environment where human rights are not respected. For example, discrimination against and stigmatization of vulnerable groups such as injecting drug users, sex workers, and men who have sex with men drives these communities underground. This inhibits the ability to reach these populations with prevention efforts, and thus increases their vulnerability to HIV. Likewise, the failure to provide access to education and information about HIV, or treatment, and care and support services further fuels the AIDS epidemic. These elements are essential components of an effective response to AIDS, which is hampered if these rights are not respected.

#### The affirmative is not the state. Calling for reform and ending of mass violence does not endorse the state. Newman ‘10

**(Newman, Saul. Reader in Political Theory at Goldsmiths, U of London, Theory & Event Volume 13, Issue 2)**

**There are two aspects that I would like to address here. Firstly, the notion of demand: making certain demands on the state – say for higher wages, equal rights for excluded groups, to not go to war, or an end to draconian policing – is one of the basic strategies of social movements and radical groups. Making such demands does not necessarily mean working within the state or reaffirming its legitimacy. On the contrary, demands are made from a position outside the political order, and they often exceed the question of the implementation of this or that specific measure. They implicitly call into question the legitimacy and even the sovereignty of the state by highlighting fundamental inconsistencies between, for instance, a formal constitutional order which guarantees certain rights and equalities, and state practices which in reality violate and deny them.**

**Underview**

1AR Theory – a] the aff gets it because otherwise the 1NC could engage in unchecked, infinite abuse which outweighs anything else, b] it’s drop the debater because the 2AR is too short to win a shell AND substance so theory can only check abuse for the aff if it’s a win condition, c] no neg RVI because otherwise they could dump in the 2nr for 6 minutes and get away with anything by sheer brute force, d) competing interps because you have 6 minutes to respond to my 1ar arguments so you should have to prove a better model e) Aff theory first – it’s a much larger strategic loss because 1min is ¼ of the 1AR vs 1/7 of the 1NC which means there’s more abuse if I’m devoting a larger fraction of time.