# Bronx dubs

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### Plan

#### **Plan Text: The member nations of the World Trade Organization ought to reduce data exclusivity intellectual property protections for medicines through TRIPs – Diependaele 17**

Diependaele, Lisa, et al. “Raising the Barriers to Access to Medicines in the Developing World - the Relentless Push for Data Exclusivity.” Developing World Bioethics, John Wiley and Sons Inc., Apr. 2017, [www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/](http://www.ncbi.nlm.nih.gov/pmc/articles/PMC5347964/). // LHP PS

**There seem to be few, if any, reasons left to accept data exclusivity in addition to the existing patent regime. Data exclusivity poses a considerable additional risk to the affordable access to medicines in developing countries.** In the absence of evidence that data exclusivity will support innovation and economic development, **there is no legitimate ground for developing countries to favour such a policy.** Moreover, **since current levels of revenue already generate copious profit margins for the pharmaceutical industry in US and EU markets, it is inequitable and highly problematic to require developing countries to implement data exclusivity**. For developed country markets, the key question remains whether society should pay the price for extended monopolies in return for merely ‘incremental’ innovations**. Even in the US and the EU, the implementation of data exclusivity, by undermining legitimate competition, seems incompatible with the long tradition of stringent competition and anti‐trust policies, which have always been vital components of the economic structure.** In its current form, **data exclusivity offers the pharmaceutical industry an ‘easy route’ to market exclusivity, without fear of challenges. Indeed, it seems that data exclusivity is meant to increase the (already significant) profitability of the pharmaceutical industry, rather than allowing them to have a legitimate demand fulfilled.**

**It’s topical and the aff solves – Data Exclusivity is a TRIPs Plus IP protection – 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/. // LHP AB

**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.

### Medicine Prices

#### Data exclusivity massively raises medicine prices.

#### **Statistically proven – multiple models agree that impacts are significant and consistent, range of empirical examples as well – Palmedo 21**

Palmedo, Michael. “Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports.” *Boston University Global Development Policy Center*, Apr. 2021,  [https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_048\_Palmedo\_FIN.pdf. //](http://www.bu.edu/gdp/files/2021/04/GEGI_WP__Bing_FIN.pdf.%20//) LHP AB

Michael Palmedo directs interdisciplinary research on intellectual property at American University (AU) Washington College of Law’s Program on Information Justice and Intellectual Property. His research focuses on the empirical evaluation of the impact of changes to patent and copyright laws. He recently completed the Shamnad Basheer IP/ Trade Fellowship at Texas A&M University, where he researched pharmaceutical industry influence into the U.S. government’s Special 301 Review.

Previous studies of **data exclusivity** have found that it **raises medicine prices and**/or **reduces access**. Data exclusivity requirements have **led to higher prices and $396 million additional expenses for Colombia’s public health system** (Cortés, et. al., 2012). **In the US, the price of one particular off-patent drug increased from nine cents to $4.85 per pill after data exclusivity** was applied (Kesselheim and Solomon, 2010). Two **studies of data exclusivity required by FTAs find a significant** impact – data exclusivity blocked **generic versions of off-patent medicines from the Guatemalan market** (Shaffer and Brenner, 2009) and **delayed the introduction of cheaper generics into the Jordanian market for 79 percent of medicines** (Malpani, 2009). Table 3 shows the **results of four regressions based on** the binary indicator of **data exclusivity**. **Each indicates that the relationship between data exclusivity and higher prices for pharmaceutical imports is statistically significant and robust to the inclusion of controls**. The coefficient on Year\*DataExclusivity is positive and significant in all specifications. The overall models fit the data well – all the right hand side variables have significant coefficients with the expected signs, the adjusted R-squared are all above 0.80 and the within-entity R-squareds range from 0.39 to 0.49. Column (1) shows the results with the overall time trend as a variable for the period 1996-2010. The **annual growth rate for pharmaceutical imports in countries without data exclusivity was 3.9 percent**, but the **corresponding growth rate in countries with data exclusivity was 7.6 percent**. Though the difference is small year to year, it compounds. **Over 15 years at these rates of growth, a price in a theoretical country without data exclusivity would increase 78 percent and the corresponding price in a theoretical country with data exclusivity would increase 200 percent**. GEGI@GDPCenter Pardee School of Global Studies/Boston University www.bu.edu/gdp 11 The control variables in this specification behave as expected. Logged GDP per capita in US dollars, taken from the World Bank, is positive, indicating the expected relationship between a country’s wealth and prices. Logged total kilograms is negative, supporting previous findings that larger pharmaceutical purchases are associated with lower prices (Helbe and Aizawa 2017).

#### Impacts:

#### 1] They directly push people into poverty

Hoban 10 Rose Hoban 9-13-2010 "High Cost of Medicine Pushes More People into Poverty" <https://www.voanews.com/science-health/high-cost-medicine-pushes-more-people-poverty> (spent more than six years as the health reporter for North Carolina Public Radio – WUNC, where she covered health care, state health policy, science and research with a focus on public health issues. She left to start North Carolina Health News after watching many of her professional peers leave or be laid off of their jobs, leaving NC with few people to cover this complicated and important topic. ALSO cites Laurens Niens who is a Health Researcher at Erasmus University Rotterdam)//Elmer

Health economist Laurens Niëns found that **drugs needed to treat chronic diseases could be considered unaffordable for many people in poor countries. Medicines can be expensive** and often make up a large portion of any family's health care budget. And the burden can be even greater for people in poor countries, where the **cost of vital medicines** can **push them into poverty**. **The problem is growing as more people around the world are diagnosed with chronic diseases such as high blood pressure and diabetes.** Being diagnosed with a chronic disease usually **compells patients to seek treatment for a prolonged period of time.** That **increases the eventual price tag for health**, says health economist Laurens Niëns at Erasmus University in the Netherlands. **Niëns examined medication pricing data from the World Health Organization** **and also looked at data from the World Bank on household income in many countries.** Using the data, he calculated how much people need to spend on necessities such as food, housing, education and medicines. "**The medicines we looked at are medicines for patients who suffer from asthma, diabetes, hypertension and we looked at an adult respiratory infection**," Niëns says. "Three conditions are for chronic diseases, which basically means that people need to procure those medicines each and every day." Niëns focused on the cost of medicine for those conditions. He found the **essential drugs could be considered unaffordable for many people in poor countries** - so much so that their cost often pushes people into abject poverty. "**The proportion of the population** that is living **below the poverty line, plus the people that are being pushed below the poverty line, can reach up to 80 percent in some countries for** some **medicines," Niëns says. He points out that generic medicines - which are more affordable than brand-name medications - are often** **not available in the marketplace**. And, according to Niëns, poor government policies can drive up the cost of medications. "For instance, a lot of governments actually tax medicines when they come into the country," he says. "[They] have no standard for the markups on medicines through the distribution chain. So often, governments think they pay a good price for the medicines when they procure them from the producer. However, before such a medicine reaches a patient, markups are sometimes up to 1,000 percent."

#### 2] High drug prices force patients to go underground for drugs.

Bryant 11 Clifton Bryant 2011 “The Routledge Handbook of Deviant Behaviour” (former professor of sociology at VA Tech)//Elmer // Recut LHP AB

Now, the field of medicine is able to achieve seemingly miraculous results, through organ transplantation, reviving patients who have been "clinically" dead, and curing supposedly "incurable diseases." Medical miracles are not cheap, however, and the costs of **medical care and** drugs **have risen (and** continue to rise**)** at a near-astronomical rate**.** Consequently, neither private medical insurance plans nor Medicare will now cover certain procedures, treatments, and medicines. In the future, with continuing reform of the US healthcare system, even fewer procedures, treatments, and medications might will be covered. Certainly, some medical treatment will be "rationed," and **particular categories of people (such as the elderly) may be systematically denied the coverage they need**. As a result of all this, medical**- and health-related** crime **and deviance** will inevitably rise. Medical insurance, Medicare, and Medicaid **fraud**, which is already prevalent today, **will increase exponentially**. Smugglers will "bootleg" ever more pharmaceuticals into the US, and a large, thriving, nationwide black market will develop for those who cannot afford to buy uncovered medications**.** More **medicines and diagnostic equipment will be stolen, and back- street medical procedures using such stolen equipment may well be offered for cash with no questions asked**. **Armed robberies of valuable pharmaceuticals from drug stores and super- markets will increase, too**. **Bribery to obtain insurance-uncovered or rationed medical care** (or, indeed, any kind of medical care where demand exceeds supply) will likely mushroom. **This is actually common in some countries around the world.** Counterfeiting expensive pharmaceuticals will be prevalent**, and medical frauds of all kinds will be very widespread**. Many of these frauds will be directed at the elderly population as it continues to increase in size. The elderly will be particularly vulnerable because they are most likely to be denied coverage for certain medical procedures or treatments. For instance, **private health insurance and Medicare will both refuse to cover a woman in her mid-80s for potentially life-saving heart-bypass surgery. As a result, she will be a prime candidate for victimization by medical fraud that offers her affordable, but bogus, treatment.** There is already a **thriving international black market in human organs** (Schepper-Hughes 2009). Kidneys are obtained from poor individuals in impoverished countries for relatively modest sums of money. This cash allows the donors to purchase luxuries, such as a small automobile, educate their children, or simply sustain their families for a few months. The organs are sometimes **transferred** quickly **to a hospital in the donor's own country** for transplant surgery. But on other occasions they are **transported to the US or another Western country**. In the US, obtaining an organ for transplantation in this fashion is illegal. Nevertheless, the practice will undoubtedly increase greatly in the future. Where medical care and medicines become exorbitantly expensive, cheaper ways to obtain them, even when these are illicit, will be sought. Where there are shortages of medical care or medicines, perhaps because of rationing, other means of obtaining them, even if deviant, will surely be employed. As the cost **and the difficulty** ofobtaining **medical care and** medicines increase, the implications for increased crime and deviance become almost limitless**.**

#### **Counterfeit drugs kill millions –**

Greenberger 20 Phyllis E. Greenberger 12-3-2020 "Counterfeit Medicines Kill People" <https://www.healthywomen.org/health-care-policy/counterfeit-medicines-kill-people/who-suffers-because-of-counterfeit-drugs> (HealthWomen’s Senior Vice President of Science & Health Policy)//Elmer // Recut LHP AB

**Over 1 million people die each year from fake drugs**. COVID-19 Have you ever had a hard time getting a prescription filled? Or maybe you've had to wrestle with your insurance provider to get them to pay for a medication vital for your health? Worse, maybe you're one of the 27.5 million uninsured Americans who find it difficult to get health care, let alone obtain the prescription drugs you may need. If you've had any of these experiences, then perhaps you've turned to the internet to buy medications that would require a prescription. While legal online pharmacies do exist, many **online pharmacies are fraudulent, selling counterfeit medications, and millions of people have fallen victim to these scammers**. Make no mistake: Counterfeit medicine is not real. The active ingredients that help you stay healthy may be missing or diluted to levels that are no longer potent. This **can be dangerous and even life-threatening**, as people rely on their medications to keep them well, and sometimes even alive. Many **counterfeit medicines aren't even drugs at all, but rather snake oil cures that make people sick — they may even contain dangerous ingredients such as heavy metals, highway paint or even rat poison**. The World Health Organization (**WHO) estimates that over 1 million people die each year from these substandard drugs**. It's estimated that more than 10% of all pharmaceuticals in the global supply chain are counterfeit in normal times, and during COVID-19, the increased use of telehealth and the appearance of fraudulent doctors has led to a surge in drug fraud. In October of this year, Peter Pitts, president of the Center for Medicine in the Public Interest, a nonpartisan research organization, said pharmaceutical fakery was a "spreading cancer." Counterfeiting is a major problem that requires the federal government to step up to slow — and eventually prevent — its spread. It's also vital that consumers know exactly what's at stake when taking these fake drugs. Who suffers because of counterfeit drugs? Expensive prescription medications and generic drugs in nearly every therapeutic class may be counterfeited. **Out of $4.3 billion worth of counterfeit medications seized between 2014 and 2016**, 35% were marked as antibiotics. Some of the other most common culprits in counterfeit medicine are used to "treat" HIV/AIDS, erectile dysfunction and weight loss. No matter what condition or disease the counterfeit medication is intending to treat, the outcome can be disastrous. Counterfeit medications **exacerbate other existing health crises**. The United States, for example, is in the midst of an **opioid epidemic that is killing 130 people per day**. As of 2018, counterfeit drugs containing **illegally** **imported fentanyl** (a powerful opioid) had contributed to this tragedy by causing deaths in 26 states. The U.S. Department of Justice found that, in at least one case, these counterfeit drugs had been sold through a fraudulent online pharmacy.

### Insulin

#### Data Exclusivity skyrockets insulin prices – **Palmedo 21**

Palmedo, Michael. “Evaluating the Impact of Data Exclusivity on the Price per Kilogram of Pharmaceutical Imports.” *Boston University Global Development Policy Center*, Apr. 2021,  [https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_048\_Palmedo\_FIN.pdf. //](http://www.bu.edu/gdp/files/2021/04/GEGI_WP__Bing_FIN.pdf.%20//) LHP AB

Michael Palmedo directs interdisciplinary research on intellectual property at American University (AU) Washington College of Law’s Program on Information Justice and Intellectual Property. His research focuses on the empirical evaluation of the impact of changes to patent and copyright laws. He recently completed the Shamnad Basheer IP/ Trade Fellowship at Texas A&M University, where he researched pharmaceutical industry influence into the U.S. government’s Special 301 Review.

This study’s pricing indicator is the **annual price per kilogram paid by each country for each sixdigit HS class of drug imports** from 1996 through 2010. This covers the period when most of the countries in my set adopted data exclusivity. During this time, Comtrade has data on imports of eight different classes of retail medicines classified at the 6-digit HS level, which are shown in Table 2. All of these are shipments of packaged medicines for human consumption, rather than active pharmaceutical ingredients or other unmixed pharmaceutical products, which fall under a different HS classification. **Table 2 also shows descriptive statistics for the price per kilogram in each of the HS classes in the dataset**. The mean varied significantly over the period from one class to the next, ranging from $29.70 for imports in HS 300450 (medicines containing vitamins) to $268.49 for those classified as HS 300439 (medicines containing certain types of hormones and antibiotics). There was also a lot of variation within each class, with the standard deviation exceeding the mean for half of the HS groups. Though skewed when taken as a whole and when disaggregated by HS class, the **data on price per kilogram logs normal**. Figure 2 compares the annual average price per kilogram paid by importing countries each year by countries with and without data exclusivity from 1996 to 2010. The price increased at a higher rate in the countries that had enacted data exclusivity. Average prices in each group tended to be similar until the early 2000s, and began to diverge after 2004. **Figure 3 compares the average price per kilogram separately for each HS classification**. While import price inflation was higher in countries with data exclusivity for all of the HS groups, the **difference was most pronounced in HS 300431** (medicines containing **insulin**) and HS 300439. The following section tests the significance of the difference in pharmaceutical import price inflation in countries with and without data exclusivity. GEGI@GDPCenter Pardee School of Global Studies/Boston University 8 www.bu.edu/gdp Figure 2. Average Price per Kilogram of Pharmaceutical Imports (USD) 0 40 80 120 160 200 1995 1997 1999 2001 2003 2005 2007 2009 2011 Data Exclusivity No Data Exclusivity Linear (Data Exclusivity) Linear (No Data Exclusivity) Table 2. HS Classifications and Descriptive Statistics HS Code Product Description Mean St. Dev. N 300410 Medicaments, containing penicillins, streptomycins or their derivatives 43.92 27.26 549 300420 Medicaments; containing antibiotics (other than penicillins, streptomycins or their derivatives) 86.74 119.20 515 300431 Medicaments; containing insulin 231.55 178.69 524 300432 Medicaments; containing corticosteroid hormones, their derivatives or structural analogues (but not containing antibiotics) 119.68 285.54 529 300439 Medicaments; containing hormones (but not insulin), adrenal cortex hormones or antibiotics 268.49 558.99 521 300440 Medicaments; containing alkaloids or their derivatives, containing ephedrine or its salts 107.45 148.18 524 300450 Medicaments; containing vitamins or their derivatives 29.70 46.38 543 300490 Medicaments; consisting of mixed or unmixed products n.e.c. in heading no. 3004 51.33 50.38 524

Chart, scatter chart

Description automatically generated

#### The graph shows how insulin prices have hugely increased in a short span b/c of data exclusivity – will further increase with more exclusivity.

#### Insulin price gouging makes an essential medicine unaffordable – that causes diabetics to skip/ration doses, skimp on necessities, or die trying.

Barker 20 [Erin M Barker, Executive Editor at the Campbell Law Review with a JD, 2020, "When Market Forces Fail: The Case for Federal Regulation of Insulin Prices," Campbell Law Review, https://heinonline.org/HOL/P?h=hein.journals/camplr42&i=331]/Kankee

INTRODUCTION Today, a single vial of insulin can cost more than $250 in the United States, and most patients use between two and four vials each month.' Consequently, if a diabetic patient is without insurance, or if insurance does not cover a specific brand of insulin, that person could pay upwards of $500 to $1,000 per month out-of-pocket for an essential medication.2 These costs are astronomical and unacceptable-the federal government must step in to regulate pricing. On January 11, 1922, fourteen-year-old Leonard Thompson faced the end stages of a terminal illness: diabetes mellitus, otherwise known as type 1 diabetes.3 Thompson weighed only sixty-five pounds after living with diabetes for three years.' His attempt to control his diabetes with a starvation diet failed to keep him from slipping in and out of a diabetic coma.5 Desperate for any chance to save his son, Thompson's father agreed to let the hospital inject the boy with a recently-discovered drug-insulin.6 Thompson would be the first human subject to receive the injection,' and the results were nothing short of miraculous.' His blood sugar lowered to a normal level, and the glucose and ketones' present in his urine also lowered to a tolerable level.10 Four men discovered this "wonder drug"": Frederick Banting, Charles Best, James Collip, and John Macleod.12 Following Banting's and Best's initial publication of their results,13 the discovery of insulin and its successful application to human subjects landed on the covers of newspapers worldwide.14 Insulin provided life-saving treatment for people who previously faced a death sentence; the drug brought diabetic patients out of comas, allowing them to end their starvation diets and eat carbohydrates." For their discovery, Banting and Macleod won the 1923 Nobel Prize in Physiology or Medicine and split their winnings with Best and Collip.16 Banting, Best, and Collip acquired an American patent on insulin and its method of creation on January 23, 1923.17 When applying for their patent, the trio maintained that "their goal was not profit, but ensuring the speedy and safe availability of their discovery to the public.""8 They then sold their patent rights to the Board of Governors of the University of Toronto for $1.00 each.1 9 In a letter to the University's president, the trio wrote, "The patent would not be used for any other purpose than to prevent the taking out of a patent by other persons. When the details of the method of preparation are published anyone would be free to prepare the extract, but no one could secure a profitable monopoly."20 Banting, Best, and Collip stated a clear goal: their lifesaving invention was to remain available to all. That goal has failed. This Comment analyzes how federal regulation of insulin prices will correct failed market forces, leading to a stabilized market for the indispensable medication. Part I of this Comment will provide a brief overview of the current state of the insulin market in the United States. Part II of this Comment will explain economics-based justifications for adopting federal legislation to regulate the insulin market. It will also provide an overview of the types of regulatory schemes that the government could utilize in this market. Part III of this Comment will describe and critique legislation that two states-Nevada and Colorado-have already acted to regulate the cost of insulin and will then examine currently proposed federal legislation that aims to lower insulin prices. Lastly, Part IV of this Comment offers a solution: the addition of language to the proposed federal legislation, incentivizing competition and positively affecting market prices through the nationalization of patents. I. THE STATE OF THE INSULIN MARKET IN THE UNITED STATES TODAY A. Economic Impact ofRising Insulin Prices From 2002 to 2013, the cost of insulin nearly tripled.21 Then, from 2012 to 2016, the cost of insulin rose dramatically again, nearly doubling. 22 In the first month of 2019 alone, insulin manufacturers Sanofi and Novo Nordisk raised some of their insulin product prices as much as 4.9% and 5.2%, respectively. 23 As of 2017, diabetes treatment and complications cost the United States ("U.S.") more than $327 billion per year, making it the most expensive chronic illness in the country.24 This cost is a combination of $237 billion in direct medical costs, including $15 billion for insulin, and $90 billion in indirect costs. 25 The American Diabetes Association reports: While much of the cost of diabetes appears to fall on insurers (especially Medicare) and employers (in the form of reduced productivity at work, missed work days, and higher employer expenditures for health care), in reality such costs are passed along to all of society in the form of higher insurance premiums and taxes, reduced earnings, and reduced standard of living.26 Government insurance, including Medicare, Medicaid, and insurance through the military, provide for a majority (67.3%) of the cost of diabetes care in this country.27 Private insurance pays for 30.7%, and the uninsured pay for 2% of the cost of diabetes care. 28 Uninsured diabetics visit the doctor 60% less and receive 52% fewer prescriptions than insured diabetics, yet uninsured diabetics account for 168% more emergency department visits than insured diabetics.2 9 Accordingly, because of both the direct and indirect costs of diabetes care, it is not just diabetics who are paying-all of society shoulders the financial burden of the increasing cost of diabetes. 30 B. Social Impact ofRising Insulin Prices Rising insulin prices induce "negative health and financial burdens on the population." 3 1 Of the 30 million diabetic Americans, approximately 7.4 million require daily doses of insulin to survive.32 Rising insulin prices have forced some to cut back on or skip doses of insulin. 3 Others elect to forgo other necessities such as food or rent in order to afford insulin. 3 A 2018 study found that almost 26% of diabetics in the U.S. had rationed their insulin the previous year.35 Recently, poignant stories have emerged detailing the tragic societal consequences of these negative health and financial burdens, including deaths due to an inability to afford insulin. 6 One such story is that of Alec Smith, a twenty-six-year-old who died less than a month after his mother's health insurance plan removed him as a beneficiary.3 7 Smith, who worked a full-time job and earned more than minimum wage, could afford neither new insurance nor the monthly $1,000 out-of-pocket cost of his insulin. 38 Another story is that of Meaghan Carter, a forty-seven-year-old woman who died alone on her sofa on Christmas night because she could not afford insulin.3 9 Carter, a nurse, was between jobs.4 0 She planned to start a new nursing position with health insurance benefits only a week after her death.4 1 Carter's family found empty vials of insulin among Carter's nursing supplies in her home.42 According to Carter's sister-in-law Mindi Patterson, "[s]he had gauze, bandages and all her nursing supplies"-"plenty to take care of others but not enough to take care of herself." 4 3 The stories of Alec Smith and Meaghan Carter demonstrate that there is more than just money at stake here-people's lives are on the line because of insulin prices in the U.S. Almost a hundred years after the discovery of insulin, diabetics should not be forced to ration an essential drug or face death due to excessive costs. Banting, Best, and Collip's goal was to make insulin affordable for all," but that is not the case today. The current price of insulin in the U.S. is unacceptable and must be addressed. II. THE FEDERAL GOVERNMENT SHOULD REGULATE THE INSULIN MARKET BECAUSE OF THE FAILURE OF TYPICAL MARKET FORCES

#### Reducing IP protection for insulin increases innovation – it stops redundant research and competition

Emily 20 [Emily Hanson, JD Candidate at the University of Georgia School of Law, 2020, “Economic Burdens of Life: Trade Secrecy and the Insulin Pricing Crisis in the United States,” Journal of Intellectual Property Law, https://digitalcommons.law.uga.edu/cgi/viewcontent.cgi?article=1457&context=jipl]/Kankee

The discussion above paints a grim picture. The abbreviated pathway to approval provided for under federal law has not achieved its goal of increasing competition and lowering prices in the insulin market. As progress stalls, many people with diabetes continue to struggle to pay for the medication they need as insulin prices continue to rise. It should be noted that some steps have been taken in 2019 by both corporations and governments to alleviate the insulin pricing crisis. For example, the three major insulin manufacturers, Eli Lilly, Sanofi, and Novo Nordisk, have each announced that they will lower the list prices of their insulin products.180 Furthermore, pharmacy benefits manager, Express Scripts, announced a price cap of twenty-five dollars per month for its members.181 Colorado recently passed legislation capping the price of insulin at $100 per month for insured patients.182 These efforts have one thing in common: they illustrate the fact that attention is increasingly being directed at this issue. The increase in attention, however, does not mean that the issue is solved. Unfortunately, all of the measures identified above are too limited in scope to serve as a complete solution to the problem. After all, Novo Nordisk or Express Scripts, for example, may decide tomorrow that the price guarantees they make today are no longer economically viable, which will leave diabetic patients in much the same place they are now. Many diabetics with health insurance in Colorado are seemingly out of immediate danger, but Colorado is home to only a very small percentage of all diabetics in the U.S.183 This is why legislation at the federal level is necessary to correct this issue for good. As discussed in section III(C) infra, trade secret is one of the three forms of intellectual property protection available to pharmaceutical innovators. In order for an innovation to qualify for this protection, it must: (1) confer economic benefit upon the holder, (2) not be generally known, and (3) be the object of reasonable steps by the holder to maintain its secrecy.184 Makers of pharmaceutical products, and biologic drugs in particular, avail themselves of trade secret protection quite liberally.185 Trade secret is particularly attractive for protecting the manufacturing processes for insulin and other biologics, which has a major impact on competition.186 Biologics like insulin differ considerably from chemical medications in terms of the difficulty of manufacturing them.187 Small-molecule chemical medications are relatively simple to describe scientifically,188 and a generic manufacturer can use any of a number of methods to synthesize the compound, all of which produce a result easily proven to be identical to the reference product.189 Insulin and other biologics, by contrast, have much more complex chemical structures.190 Small differences in the method of synthesis can lead to broad variation in the final result.191 This means that showing biosimilarity is very difficult unless the manufacturer uses the same method that the maker of the reference product used.192 Furthermore, the precise molecular identity of some biologic drugs is not known because the analytical techniques needed to make that determination do not yet exist.193 Crucially, to qualify for abbreviated approval under the Biosimilars Act, the maker of the biosimilar must make a product that not only is biosimilar, but can be shown to be biosimilar.194 Because trade secret protection can theoretically last indefinitely,195 makers of would-be biosimilar insulins may never have access to manufacturing process information, all but foreclosing the possibility of producing a follow-on insulin that the maker is able to prove is biosimilar to the reference.196 A claim that X is the same as Y is impossible to prove or disprove when Y’s identity is not known. A scaling back of trade secret protection for pharmaceuticals would ameliorate this problem. The Biosimilars Act does not require the maker of a reference product to disclose manufacturing information to any greater extent than is required under Hatch-Waxman, which means that it is unlikely to be successful in increasing competition in the insulin market now that insulin is within its scope.197 Insulin will likely continue to be more trouble than it is worth to biosimilar manufacturers. The Defend Trade Secrets Act of 2016 provides an extremely broad scope of the type of information that may be eligible for trade secret protection: [A]ll forms and types of financial, business, scientific, technical, economic, or engineering information, including patterns, plans, compilations, program devices, formulas, designs, prototypes, methods, techniques, processes, procedures, programs, or codes, whether tangible or intangible, and whether or how stored, compiled, or memorialized physically, electronically, graphically, photographically, or in writing.198 The breadth of the protection available under the DTSA means that makers of follow-on insulins will have an extremely difficult time showing that their products are biosimilar. Statutorily eliminating biologics manufacturing process information from trade secret eligibility (as an amendment to the Biosimilars Act, for example) would force pharmaceutical companies to choose among three alternatives. They could: (a) include process information in their patent application, (b) apply for separate patent protection for the process and the product, or (c) leave the process information with no protection at all. Acknowledging choice (c) to be in all likelihood the least popular of these, the net effect would be that the process by which biologics like insulin are manufactured would become part of the public omain once the patent expires, rather than remaining secret indefinitely as it does today. This change would naturally have downstream effects, both positive and negative. The first advantage would be that insulin and other biologics would become more attractive to makers of follow-on products. Armed with the knowledge needed to create a biosimilar without going through the costly process of additional research and development, follow-on firms could produce biosimilar insulins more cheaply. The second advantage would be that the growing fund of public knowledge about insulin and other biologics would facilitate greater innovation in the field over time.199 By keeping critical information about their discoveries secret, pharmaceutical companies prevent other companies, universities, and private research firms from benefitting from it.200 Trade secret law is often criticized for its tendency to cause redundancy and duplication of effort,201 and repetition of clinical trials to prove that a follow-on is biosimilar or interchangeable can cost hundreds of millions of dollars.202 A free flow of information about process in a field where process has a tremendous influence on the identity and quality of the final product203 would have substantial value to society.204 To that end, the third advantage to reducing trade secret protections would be a rebalancing of the public and private interests at stake in the market for insulin. The free-market approach to drugs and other medical products that operates in the U.S. presumes that the same forces at work in the markets for CocaCola and iPhones are at work in similar ways in the markets for insulin and other healthcare products.205 As discussed previously, the free-market approach has undoubted advantages,206 but the ethical implications of letting the market decide who can afford insulin and who cannot should not be ignored. A reduction of protection for an already immensely profitable industry207 would ease the burden on people who rely on insulin for survival. On the other hand, this approach does have drawbacks. For example, as with any limitation on intellectual property protection, there is the concern that this would decrease incentives to innovate.208 Insulin makers may decide to slow or halt development of costly new products if they fear that they will not be able to recoup their losses.209 However, this particular issue seems to be of less concern here than in other situations in which cutting edge biologics are not yet on the market. Insulin’s age and long history in the market will likely shield it from this negative effect because several safe and effective varieties already exist. Thus, while reducing trade secret protections for biologics may have the effect of making some drug manufacturers more reluctant to develop entirely new biologic drugs, it will likely have the opposite effect of improving competition for drugs that are already on the market. Furthermore, a compromise might be made to restrict the scaling-back of trade secret protection to insulin alone, rather than to all biologics. Using insulin as a sort of pilot for a broader scheme of reducing trade secret protections in the pharmaceutical industry would provide lawmakers and the public with some context for the effectiveness of such a scheme. A second potential drawback to this proposal is the possibility of a chilling effect on insulin production in general. Once information about manufacturing insulin enters the public domain, regulatory agencies like FDA will have the ability to set manufacturing standards accordingly.210 The more that is known about a substance, the easier it is to regulate.211 An increase in the minimum standard may raise production costs, thus deterring current producers from continuing to make insulin, and discouraging new firms from entering the insulin market in the first place. Trade secrecy has kept the barriers to entry high for competitors in the insulin market.212 There is no question that, in general, insulin and other biologics are more difficult and more expensive to produce than chemical medications.213 Thus, the U.S. is unlikely to see drastic price reductions for these products such as those that resulted from the enactment of Hatch-Waxman.214 However, the current situation is clearly untenable for patients, and a scaling back of trade secrecy in the insulin market would likely help facilitate price reduction. VI. CONCLUSION

### Framework

#### Pain and pleasure are intrinsically valuable – to justify beyond that runs into moral incoherence. Moen 16,

Moen 16 [Ole Martin Moen, Research Fellow in Philosophy at University of Oslo “An Argument for Hedonism” Journal of Value Inquiry (Springer), 50 (2) 2016: 267–281] SJDI // RCT by JPark

Let us start by observing, empirically, that a widely shared judgment about intrinsic value and disvalue is that pleasure is intrinsically valuable and pain is intrinsically disvaluable. On virtually any proposed list of intrinsic values and disvalues (we will look at some of them below), pleasure is included among the intrinsic values and pain among the intrinsic disvalues. This inclusion makes intuitive sense, moreover, for there is something undeniably good about the way pleasure feels and something undeniably bad about the way pain feels, and neither the goodness of pleasure nor the badness of pain seems to be exhausted by the further effects that these experiences might have. “Pleasure” and “pain” are here understood inclusively, as encompassing anything hedonically positive and anything hedonically negative.2 The special value statuses of pleasure and pain are manifested in how we treat these experiences in our everyday reasoning about values. If you tell me that you are heading for the convenience store, I might ask: “What for?” This is a reasonable question, for when you go to the convenience store you usually do so, not merely for the sake of going to the convenience store, but for the sake of achieving something further that you deem to be valuable. You might answer, for example: “To buy soda.” This answer makes sense, for soda is a nice thing and you can get it at the convenience store. I might further inquire, however: “What is buying the soda good for?” This further question can also be a reasonable one, for it need not be obvious why you want the soda. You might answer: “Well, I want it for the pleasure of drinking it.” If I then proceed by asking “But what is the pleasure of drinking the soda good for?” the discussion is likely to reach an awkward end. The reason is that the pleasure is not good for anything further; it is simply that for which going to the convenience store and buying the soda is good.3 As Aristotle observes: “We never ask [a man] what his end is in being pleased, because we assume that pleasure is choice worthy in itself.”4 Presumably, a similar story can be told in the case of pains, for if someone says “This is painful!” we never respond by asking: “And why is that a problem?” We take for granted that if something is painful, we have a sufficient explanation of why it is bad. If we are onto something in our everyday reasoning about values, it seems that pleasure and pain are both places where we reach the end of the line in matters of value.

#### Thus, the standard is maximizing expected well-being. It’s hedonistic act util.

### Method

#### The role of the ballot should be a critical pedagogy of hope centering around formulating concrete alternatives to existing conditions. Amsler

Amsler, Sarah S. 2007 “Pedagogy against “dis-utopia”: From conscientization to the education of desire.”

In other words, **critical pedagogy is often assumed to be an inherent source of hope because it disrupts and denounces the illusion of historical fate** and liberates emergent utopian impulses through which self-determination is announced (da Veiga Coutinho 1974: 11). **But** critical educators are now asking **what relevance this understanding of pedagogy might have in a society where desires for individual transcendence and social change are or appear to be absent, devalued or denied. What are the possible consequences of conscientization in conditions where exposing complex power relations and dominant social forces emboldens fatalistic emotions rather than transforming them into hope; where, to paraphrase a well-worn theory, we see through ideologies and yet still buy into them?** Or as Henry Giroux more poignantly asks – and here what appears as hyperbole must be understood in the context of contemporary American political culture and the moral indignities of Abu Ghraib – ‘**what resources and visions does hope offer…when most attempts to interrupt the operations of an incipient fascism appear to fuel a growing cynicism rather than promote widespread individual and collective acts of resistance?’** (Giroux 2002: 38) What become of efforts to democratize knowledge when consuming publics democratically demand authoritarian teaching, or when self-realization is defined as the skilful adaptation to an existing order of things? In such circumstances, **‘critical hope’ becomes a paradoxical problematic rather than an assumed outcome of critical education**. **If the need or desire for personal transcendence or social change is not taken for granted as pre-existing or immanent, then the object of critical pedagogy must either be to create them, or to create the conditions for their emergence**. The aim of educating against the ideological forces of post-modern capitalism is therefore neither simply to recognize the social world, nor to create conditions of emancipatory communication. Instead, it is to produce the value orientations that make both of these activities meaningful in the first place. Hence, **the new movement in critical pedagogy prioritizes the ideational production of ‘critical hope’ as a motivational basis for transformative social action prior to and outside of concrete political or economic struggle, rather than beginning from it. Institutionalized critical education has become a project less in the service of particular political struggles and more an attempt to resist the closure, privatization, apathy, and psycho-emotional ‘coldness’ that is presumed to abort political struggle at its immediate roots of subjective experience.** Writing in defence of higher education as a key site of cultural resistance, **Giroux argued that critical pedagogy is no longer simply a matter of ‘raising consciousness’ about the possibilities for realistic opposition, but a question of educating people to believe that these possibilities are worthwhile in the first place** (1997: 28). This type of educational practice moves beyond cognitive rationality and towards the psychological, emotional and ethical experiences through which it is mediated. **The question here is not only what makes it possible for people to rationally formulate alternatives to existing conditions, but also what makes it possible for them to want to do so**. This reflects a turn away from the duality of ‘reason and freedom’ towards a more complex theory of social agency that includes its ‘morethan-rational’ and ‘less-than-rational’ dimensions (or in other words, the ‘pretheoretical’ and ‘extramundane’ elements) of human action, as well as the social and emotional foundations of inter-subjective ethics (Ahmed 2004; Anderson 2006; Anderson and Harrison 2006). In other words, contemporary critical educators are trying to produce through pedagogy a condition which, according to Honneth, is presumed to have been lost in the mid-twentieth century and yet which critical theory requires for its own justification: an innate, essential and indomitable need for personal and social transformation. This presents a familiar dilemma: ‘how can we imagine these new concepts even arising here and now in living beings if the entire society is against such an emergence of new needs?’ (Marcuse 1970: 76). Or, in the words of C. Wright Mills, we seem to have two choices when theorizing need and desire. On the one hand, he wrote, ‘if we take the simple democratic view that what men [sic] are interested in is all that concerns us, then we are accepting the values that have been inculcated, often accidentally and often deliberately’. On the other hand, ‘if we take the dogmatic view that what is to men’s interests, whether they are interested in it or not, is all that need concern us morally, then we run the risk of violating democratic values’ (Mills 1959: 194). In his habitually accessible way, Mills expressed the stubborn tension between socially constituted need asit-appears or is experienced, on the one hand, and universal norms of need that may be abstracted from or alien to lived experience, on the other. **It is this unhappy no-choice between the reification of immediate particular experience and the authoritarian imposition of abstract generality that critical theory must aim to transcend.**

**Activists must learn to speak the language of TRIPS to avoid big ideas sliding back into the status quo – Halbert 05:**

Halbert, Debora. “Globalization (2005).” Globalized Resistance to Intellectual Property, 2005, globalization.icaap.org/content/v5.2/halbert.html. // LHP PS

The themes found in the counter-globalization movement are not new, however new avenues for expressing these concerns have emerged. For example, resistance to the monetary policies of the 1970s foreshadows today’s critique of the WTO and the TRIPS agreement. An international environmental movement is not new, but concern over patents, biotechnology, seed ownership, and traditional knowledge have added a new dimension. Movements focused on human rights, social justice, and decolonization at the international level are not new, but issues of biopiracy, access to patented medication, and biocolonialism emerging from the TRIPS agreement are a new twist. While not the only common concern shared by these diverse groups, intellectual property has become a crosscutting issue and part of a new language of resistance through which to address the problems of globalization. The crosscutting nature of intellectual property brings together activists working at the local, national and international levels with NGOs, National governments, and the United Nations. Ultimately, these issues are then turned back upon international intellectual property agreements and create an atmosphere where new agreements or changes to already existing agreements will be met with increasing demands for public access and accountability. New social movements and grassroots organizations have also emerged around the idea of intellectual property itself (Story, 2002: 125; Drahos, 2002: 174). Drahos suggests webs of dialogue are emerging and connecting otherwise disparate groups. Nationally and internationally the process of intellectual property standard-setting is becoming caught up in webs of dialogue, webs in which an increasing number of non-state actors and non-business actors participate (175). Chapman argues that human rights organizations have entered this web of dialogue to raise concern about the consistency of human rights with intellectual property rights (2002). While these “webs” lack of a clear center, groups fighting distinct causes (access to seeds in India, access to AIDS medication in South Africa, control of traditional knowledge in Australia or Hawai’i) are thematically linked together by the underlying legal system of intellectual property. Rosemary Coombe also identifies the way resistance to intellectual property issues are forming. Strategic alliances are being forged between Indigenous NGOs, North-South alliances of farmers’ and peasants’ groups, traditional healers’ associations, environmental NGOs, development institutions and activists whose primary commitments are to maintaining food security, as well as to religious organizations who maintain an opposition to the patenting of lifeforms on spiritual grounds. These new coalitions form the core of a new and vibrant political movement organized around growing opposition to existing intellectual property laws, the way patent and plant breeder’s protections are granted, the practices of rights granting bodies in the industrialized world and an insistence upon recognition of alternative values – other than creation of incentives for the further development, proliferation, and circulation of commodities – to those currently given primacy in discussions of intellectual property (2001: 275-276). Organizations within this loosely defined sphere have begun to develop a global language of resistance designed to unite people living around the world to fight for greater equity and social justice. Conflict emerges because the language of social justice encoded in the international human rights arena is not easily translated into the language of trade and economics (Chapman: 867). The disconnect between the language spoken by grassroots organizations and the language of policy and law is of concern to some theorists who argue that at the international level the professionalization and westernization of “social movement” groups has silenced the voices of grassroots organizations in the global south (Batliwala: 396-398). In fact, the ability to speak the language of policy making becomes a key point of entry into the international system as Batliwala notes, Government authorities often collude and reinforce the exclusion of direct stakeholders by inviting the elite NGOs into policy-making processes, rather than the loud, militant, and difficult to control grassroots groups who do not speak the same bureaucratic language that elite social advocates have learned (398). These concerns are well founded and important to consider. Daniel Mato argues, for example, that Indigenous groups must learn to speak the language of Western diplomacy in order to be heard while at the same time retaining some sense of “authenticity (2000).” It is of concern that the voices heard in negotiating rooms emerge almost exclusively from the global north and from those who can speak the language of law and economics, who control access to “public space (Batliwala: 397).” However, I seek to conceptualize the problem somewhat differently. Both a critique of the current system and methods for working outside the system are necessary to long term social change. There is a need for those with training to translate legal documents into common terms and also a need to express grassroots concerns about the TRIPS agreement in terms of the law. Phrases that enter the conversation between legal scholars have no meaning to those outside the legal discourse (parallel imports, compulsory licensing, exhaustion, sui generis protection, etc). Thus, a translation in both directions is necessary. However, grassroots movements, transnational social movements, and NGOs go beyond a critique of the present by creating a vision of a different and alternative future. These visions of the future must exist outside the existing international paradigm if they are to offer an alternative to the status quo. I will divide the resistance to TRIPS into two prongs. The first prong is an imminent critique of TRIPS – one that does not wish to see the agreement thrown away, but is one where the agreement is changed to better represent interests that were initially excluded. This critique emerges from the work of legal scholars and activists who voice their concerns in the language of international law and offer remedies that can be sought within the TRIPS agreement and the framework of existing international law. The second prong is the resistance developed by transnational social movements working with local activists outside the legal discourse of TRIPS. This resistance is the articulation of an alternative to the current processes of globalization. This future vision is wrapped into the larger social protest of counter-globalization and places its focus on envisioning a better and different world. In the following two sections I will take up these prongs, beginning with a description of the immanent critique of TRIPS. CRITIQUE OF THE LANGUAGE OF TRIPS **Assuming that states wish to retain legitimacy in the face of social protest, the concerns of activists must be translated into a language understood by states and their negotiators. Street theatre and non-violent protest suggest that problems exist, but the gap between the language of activism and the language of trade agreements is so wide that conversation is difficult, if not impossible between these two spheres. The work of legal scholars, and activist groups who can speak the language of the law and who grasp the construction of the TRIPS agreement, have been especially important in translating social protest into potential changes to the TRIPS agreement.** For example, Martin Khor suggests that, “As the imbalances and problems generated by TRIPS become more obvious, there is mounting public demand for change. The range of demands include the following: More time, flexibility and freedom to choose options for developing countries in the implementation of the agreement. Restraint by developed countries and their corporations from taking action against developing countries; A review and revision of TRIPS to remove its problematic aspects and to enable the implementation of its positive aspects (such as provisions on technology transfer) The removal of TRIPS altogether from the WTO (2002: 202).” Issues like the ones outlined here come from the network of non-state and non-business actors described by Drahos who have grave concerns regarding TRIPS. In order to be taken seriously, their specific concerns are not framed as a call to eliminate TRIPS, but instead as a way of reinterpreting the agreement. While the original negotiating powers behind TRIPS may reject these suggestions, future negotiations over the TRIPS agreement will have to take many of these concerns into consideration. One important insight that has emerged from this dialogue is that flexibility already exists within TRIPS, it must now be utilized to help those who have yet to benefit from the system (Correa, 2002: 52; Love, 2002: 74). It is important to remember that concerned policy makers and legal scholars began articulating a critique of TRIPS almost from the inception of the agreement. Legal scholars and NGO groups already within the WTO system did not need the pressure of external social movements to critique the TRIPS agreement, and immanent legal critiques emerged independently from the counter-globalization efforts. Legal scholars and other groups interested in the immanent critique of TRIPS, especially those already within the TRIPS/WTO world, are in a unique position to translate the concerns of grassroots movements into the language of international treaty making. The future potential transformation of TRIPS into an agreement that meets the needs of the global south rests to a large degree on those who can translate the concerns percolating within civil society into the language of international agreements. I will draw upon three examples to illustrate the importance of this type of work. First, the work of Daniel Gervais serves as an example of translating concerns voiced within global civil society into a language that may be acceptable to the TRIPS agreement. Some of Gervais’ work focuses upon traditional knowledge and its protection within TRIPS. By developing a “Declaration of Traditional Knowledge and Trade” within the appropriate legal language, the work of Professor Gervais serves as a bridge between two distinct paradigms of thinking – one existing outside the structure of TRIPS, the other within the negotiating process (2004). While it remains important for groups focused on fighting for the preservation of traditional knowledge to articulate their concerns outside the language of copyright and patent law, and perhaps help transform the discourse from outside, it also seems important to make the agreement reflect the type of social justice we wish to see. For example, Caren Irr describes the development of a “people’s rights” perspective that would take cultural identity as a starting point and offer a critique to the economic framework of intellectual property (2003: 15). A second example comes from the Gene Campaign who worked in conjunction with farmers in India to resist legislation that would favor plant breeders over farmers. Through the work of the Gene Campaign, and other civil society groups, farmers’ rights, specifically their rights to sell seeds and to be paid for the use of their seed varieties, were added to the legislation (Sahai 2002: 214). Over a seven-year period, the Gene Campaign worked to ensure that farmers’ rights are protected in domestic legislation and not relegated to the language of “exemptions” under the law (Ibid). Because the goal was to ensure adequate protection in domestic legislation, it was important that the groups be able to translate their concerns into legal language. The Gene Campaign considered the final result a success. When combined together, local activists and transnational groups made an impact on issues related to intellectual property and moved the debate towards one that better protected the public. **A final example that highlights the combined efforts of a transnational movement with legal actors that can impact the interpretation of the TRIPS agreement comes from the on-going battle to access AIDS medication throughout the globe, but specifically in South Africa. A network of groups worked together to raise awareness of the problem and develop a language that would create solutions. Oxfam, Medecins Sans Frontieres (MSF), Health Action International (HAI), Consumer Project on Technology (CPT), South Centre, Third World Network, and the Quaker United Nations Office, ACT-UP Philadelphia, the Health GAP Coalition, and WHO worked on different aspects of the problem (Mayne, 2002: 246). The actions ranged from civil disobedience and social protest to letter writing and conferences. The movement spanned the globe and focused upon the hypocritical words of the Clinton administration and condemned the current interpretation of the TRIPS agreement. While there remains substantial work to do, these organizations brought the issue of access to medication to Doha and were successful in gaining a “new” interpretation of TRIPS through the Doha Declaration. I say a “new” interpretation, but many have argued that flexibility already exists within the TRIPS agreement, it was simply a matter of replacing the interpretation used by the U.S. with the more accurate interpretation already within the TRIPS agreement. The Doha Declaration embodied the concerns of activists within the language of international agreements. As Ruth Mayne points out, this network of organizations was able to shift the TRIPS agenda towards a more health-focused one. The actors in this specific battle go beyond social movement organizations and include NGOs and trade negotiators from the developing world, an interesting alliance (Mayne: 253).** Mayne identifies the key components that led to a successful campaign to provide access to treatment: To date, the NGO campaign has been effective because it combined: strong public campaigning messages and actions based on powerful human illustrations that helped generate public outrage an high media coverage across TV, radio and print; global and cross-sectoral alliances of NGOs that supported and built on strong national campaigns, and shared analysis through the Internet; a growing alliance between developing countries and NGOs at the WTO; partially successful attempts to find supporters among rich countries; informed insider face-to-face lobbying at the highest level based on plausible analysis and evidence; and the strategic targeting of companies and governments at different times. Nevertheless, there is still much to be done in the battle for cheap medicine, adequate healthcare and reform of global patent rules (257). **These strategic options are key to the ongoing struggle to revise the TRIPS agreement to accommodate the concerns of the public at large. Transnational actors along with legal scholars play a key role in the process by translating the larger concerns of social protest into language that can be included into legislation and international agreements.** However, an equally important aspect of transnational social movements surrounding issues of globalization is their ability to move beyond the legal language of TRIPS and to articulate a different type of globalization altogether. This function of social movements will be addressed in the next section. ANOTHER WORLD IS POSSIBLE **Activists working outside the legal discourse translate the abstract language of copyright and patents into a language understood by the general public. They do this by focusing on real harms such as the lack of medicine, the appropriation of traditional knowledge, the biopiracy of materials so that people throughout the world realize that this otherwise impenetrable document has real impacts on their lives. Organizations interested in intellectual property are growing in number. Millions throughout the world have been mobilized around intellectual property issues. Organizations in the developed world connect with those in the developing world and lobby their respective governments on issues related to intellectual property, social justice, and a democratic global civil society. By developing pressure from below, concerns are raised that democratically elected governments cannot ignore, or at least must pay lip service to. Given their position as outsiders, activists have gone beyond seeking potential remedies within legalistic language or minor repairs to the foundational documents. Part of the strength of the globalization movement is the articulation of another world. At the global level there is emerging a discourse of resistance under the Zapatista slogan another world is possible. This resistance is articulating a different globalized world based on social justice and democratic opportunities, not neo-liberal trade policies.** The World Social Forum is one example of this globalizing resistance. It operates as a unifying space for transnational actors under the banner of “another world is possible.” In January 2004, the 4 th annual WSF meeting was held in Mumbai, India where over 100,000 attended the meetings with 80,000 representatives from different nations (Thekaekara 2004; Baird 2004). The event originated as an alternative to the World Economic Forum held in Davos Switzerland, the annual event for international business elite to discuss world economic policy. The World Social Forum, by contrast, brings thousands of people from around the globe to meet and discuss the impact of globalization on their everyday lives (Morberg, 2003). The 2005 World Social Forum was held January 26-31 in Porto Alegre, Brazil with the same results. The World Social Forum is one example of new public spaces created to deal with issues of globalization and issues of intellectual property. **What transnational social movements along the globalization front bring to the table is an articulation of a different way to globalize. The critique they offer of current intellectual property and globalization efforts is important, but the articulation of alternatives is equally important and remains distinctly outside the law. Ultimately, whether the critique produces changes to the TRIPS agreement or an alternative paradigm for understanding world trade, the perspectives of global actors that contradict those who negotiated the original TRIPS agreement cannot be ignored.** THE FUTURE: TO REINTERPRET OR RETREAT? Despite global social protest, it must also be recognized that many do not see the problems with TRIPS as overprotection, but as underprotection. In fact, before the agreement even took affect, the United States had announced that TRIPS was “both inadequate and their implementation framework too long and too lax (Umoren, 1995). Any effort to redefine TRIPS along the lines of human rights and the public interest will be met with resistance on the part of intellectual property interests. In the on-going process of development, then, there must be vigilant watchdogs over the language and application of TRIPS and any future negotiation done at the international level. Some might argue that changes to the TRIPS agreement do not challenge the structure of the agreement, but merely accommodate and diffuse social protest. Thus, while many work to change the agreement and feel it can become a document that protects interests in both the north and the south, others wish to see the entire structure dismantled. This debate will continue into the future. It is possible that the evolution of the document may result in a balance achieved between the global south and the global north. However, the evidence suggests that if the global south were to gain more ground, the developed world, especially the United States, will ignore TRIPS and seek harsher punishments and wider intellectual property rights outside the TRIPS framework. Either way, a question of legitimacy remains. For the United States the agreement does not go far enough. For the global south and many working in civil society groups, it goes too far. As increasing protest regarding the scope of protection emerges, the potential is there to transform TRIPS into a document that can articulate claims about equal protection and social justice. However, in making these claims, more powerful states may opt out of the regime in favor of bilateral negotiations. TRIPS is not alone on the world scene, however. There may also be a role for the World Intellectual Property Organization (WIPO) to play in the future. WIPO has become interested in the access to knowledge issue and will hold meetings to discuss access to knowledge, an issue that is part of what is being called the “development agenda.” The development agenda emerged from the Doha WTO talks and endorses changes advocated by developing countries, NGOs, and civil society groups from around the world. These groups seek to grow a movement around development issues, especially centered on the work of WIPO and the WTO. In April, talks were held in Geneva to help plan the development agenda issues to be taken up by WIPO in June. Issues to be discussed range from traditional knowledge to open source. There is hope that as demands of access to knowledge grow, these demands can serve as a unifying theme bringing players from the north and the south together to reformat international agreements on issues concerning intellectual property rights. **To the degree that a global civil society is emerging, it is emerging around issues of democracy and social justice at the international level and is built upon resistance to a tightly controlled international regime that benefits the few at the expense of the many. Of course, while much happens at the level of ideas, until these ideas are translated into social structures that can more fairly benefit all it will be easy to slide back into the status quo. While it may never be the case that we can create another world, the past ten years can teach us that we can still try to make the world we live in a better one.**

#### Successful revolutions have never asked for a complete clean break--the only way to make radical change is through a process of finding a target and building a movement. – Malm 21:

Malm, Andreas. “We Must Nationalise Total.” Versobooks.com, 2021, https://www.versobooks.com/blogs/5168-we-must-nationalise-total.

Clearly, the situation is not the same. Our political world is completely different. That said, the First World War can be seen as the catastrophe that really began the twentieth century. Governments throughout the world, particularly in Europe, were prepared to send millions of soldiers to die on the battlefield without a valid reason. Individuals such as Vladimir Ilyich Ulyanov, known as Lenin, and Rosa Luxemburg, then asserted that if we wanted to stop this catastrophe, we had to depose its artisans and transform the war into a political crisis. That is how the situation today is analogous. **We are faced with a chronic emergency which will continue for the long term and worsen on many fronts because we have ruling classes that maintain the driving forces of this ecological crisis. Our political task is** precisely that which Lenin and Rosa Luxemburg had to confront: **how to transform these moments of crisis, such as the pandemic, into political crises that shatter the driving forces behind these problems.** *You quote Lenin when he said that ‘to temporise in insurrection is death…It is impossible to save anything now by half-measures.’ There is no place here for reformism. Where do you situate yourself between the three classic branches of political transformation, i.e. reformism, revolutionary reformism and revolution?* If I understand you correctly, I would say **that I situate myself rather on the side of revolutionary reformism, because I do not think that the left or the climate movement should demand today the complete abolition of capitalism, should seek to make a clean slate. To start with, no revolution of that kind ever succeeded. Lenin himself did not demand such a thing, the Bolshevik slogan was peace, bread and land**. Those were the key demands that fuelled their revolutionary project. **The left has spent around two centuries trying to abolish capitalism, so far without success, and it finds itself today, throughout the world, in a state of unprecedented weakness. To imagine that we could pass from our dreadful present weakness to the total abolition of capitalism tomorrow is for me completely unrealistic. Besides, we have to act extremely rapidly given the timescale of the climate crisis, and we cannot give ourselves tasks that are impossible to accomplish in this short space of time. But it is precisely because the timescale is so short and the change needed so colossal that we have to attack the very powerful interests at the heart of the capitalist economy**. **Take Total for example – the largest French private company – which continues to grow in the Arctic or in East Africa by constructing what will soon be the longest oil pipeline in the world.****[[1]](https://www.versobooks.com/blogs/5168-we-must-nationalise-total" \l "_edn1" \o ") That must stop. We cannot have companies of this type, which profit from the expansion of fossil fuel production. These companies must be closed and transformed into something completely different. Those are the kinds of ‘reform’ I would like to see: nationalise Total, immediately end completely its production of oil and gas, and transform it into a company devoted to the capture and sequestration of atmospheric CO2, for example**. **To achieve this, we need a different kind of French state, acting in response to massive popular pressures. And if this reform were brought about, would it also open up a process of reorganisation of French society? I don’t know. But these are fundamental demands, concrete ones, that we have to formulate. At the stage of the conflict where we are at present, therefore, it is not a matter of saying that we have to get rid of the capitalist system from one day to the next, but certainly to formulate extremely basic and necessary demands** – in this case to take control of oil and gas companies, and then see where we go from there. *Perhaps the most difficult change concerns our way of life, the goods we produce, the way in which we consume… Fossil energies are one thing, but there is also the extraction of metal to make cars or buses, natural resources to build homes, etc. The idea of sobriety and sharing goes against the desire produced by society to live like the upper classes. How do we convince the population?* Two things. **On a strategic level, it is logical to be a bit down to earth in the sense that, to start a process of radical transformation of society, you have to begin somewhere and identify an enemy – or a force – that is actually at the centre of the disorder and must be defeated. And once you have achieved this, you move on to the following steps. So, to concentrate on the oil and gas companies doesn’t mean that everything is perfect with solar or wind energy, electric cars, etc., but that this is what is imperative strategically**. Now, I also think that we can envisage a transition towards a society without fossil fuels, which will improve people’s quality of life and is not just a question of sacrifice. Certain sacrifices will have to be accepted, of course, such as aviation as we know it, and by the richest people first of all. But ordinary workers will also have to accept certain sacrifices – the overconsumption of meat, for example. It is possible to explain to people in a sufficiently convincing way that they have much to gain from such a transition: working less, not seeing their job suddenly offshored to China, etc. *Many currents in the ecological movement are inspired by anarchism, and have a pretty hostile attitude towards the state, seeing it as centralising, concerned to develop its power and its economy, fundamentally anti-democratic… What is your position towards the state?* **In my ideal world, power would be decentralised. But we are at the opposite extreme from an ideal situation, and we are heading closer towards nightmare and dystopia. To wait for another form of state would therefore be both crazy and criminal. The only way to escape from the impasse, I believe, is a centralised power capable of braking the forces of destruction.** Take the recent legal case where The Hague tribunal decided that Shell has to reduce its CO2 emissions by 45 per cent by 2030. Of course, we don’t know if this will be carried out. **But, in principle, what this suggests is that you can have a state apparatus ordering an oil and gas company to change its practices, and perhaps, in the end, to cease its activities completely. I can see no other institution than the state, in our societies, able to take and apply such a decision. That is not something that can be carried out by neighbourhood committees or a federation of councils – unless this establishes itself as a new state.** Concerning this case at The Hague, it is interesting to the extent that it reveals that therex is a branch of our state apparatus, the judicial branch, which is sensitive to the pressure of the climate movement. **We must not stop exerting pressure on the various branches of the state apparatus, even if we do not like the state. We are in a crisis, and we must use all the forces available to us.** *You are one of the few intellectuals to think on both a strategic and a tactical level, with the ideas you develop in* How to Blow Up a Pipeline*. How do you combine the two things?* Certain methods would do us a lot of harm at this stage – for example, if some climate activists started to adopt armed struggle. But that apart, **we need the greatest possible diversity of tactics, including legal cases, various kinds of lobbying, parliamentary efforts, electoral campaigns, street occupations, and mass blockades of lignite mines, as Ende Gelände have been doing in Germany.****[[2]](https://www.versobooks.com/blogs/5168-we-must-nationalise-total" \l "_edn2" \o ") Mass civil disobedience, of course, but also the destruction of property and sabotage.** The projects to expand the extraction of fossil fuel that are currently under way throughout the world really deserve to be destroyed. If people in Uganda or Tanganyika destroyed the pipelines there tomorrow, I don’t see how you could condemn this. Throughout human history, what destruction of property would be more legitimate than that? The great paradox is that this has not yet happened on a large scale. *That’s what you call the ‘Lanchester enigma’, after the essayist John Lanchester who in 2007 expressed his surprise that climate activists had not yet committed acts of terrorism, given the scale of the catastrophe, and the ease with which one could sabotage a gas station or vandalise an SUV…* It’s just crazy that ‘business as usual’ continues with everything we know today, given that 30 million people have had to flee their homes just in the last year because of natural catastrophes bound up with extreme meteorological phenomena – consequences of global heating. That reminds me of the recent novel by Kim Stanley Robinson, *The Ministry for the Future*. He imagines a very convincing transition in the form of a kind of best-case scenario for the coming decades, involving a plethora of movements and tactics. **Sabotage and destruction of property play a key role. But there are also existing state institutions operating under the aegis of the United Nations, and a multitude of local initiatives… I believe that this is the best way of thinking the transition: a turbulent and disorderly process, acting on different levels, with recourse to various tactics. If French people launched a campaign against Total, that could very easily include forms of destruction of property, and that could increase the pressure.**