# 1NC

#### Jim Oberweis, an influential Illinois senator and businessman famously stated, “I am a strong believer that intellectual property rights need to be protected.”

#### I negate the resolution resolved that: The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines.

### Fwrk

#### My value is morality as per the word ought in the resolution

#### My value criterion is maximizing expected wellbeing

#### Governments must aggregate because their policies benefit some and harm others. The only non-arbitrary way to prioritize is by helping the most amount of people. Actor-specificity comes first because different agents have different ethical obligations

Mack 4 [(Peter, MBBS, FRCS(Ed), FRCS (Glasg), PhD, MBA, MHlthEcon) “Utilitarian Ethics in Healthcare.” International Journal of the Computer, the Internet, and Management Vol. 12, No.3. 2004. Department of Surgery. Singapore General Hospital.] SJDI

Medicine is a costly science, but of greater concern to the health economist is that it is also a limitless art. Every medical advance created new needs that did not exist until the means of meeting them came into existence. Physicians are reputed to have an infinite capacity to do ever more things, and perform ever more expensive interventions for their patients so long as any of their patients’ health needs remain unfulfilled. The traditional stance of the physician is that each patient is an isolated universe. When confronted with a situation in which his duty involves a competition for scarce medications or treatments, he would plead the patient’s cause by all methods, short of deceit. However, when the physician’s decision involves more than just his own patient, or has some commitment to public health, other issues have to be considered. He then has to recognise that the unbridled advocacy of the patient may not square with what the economist perceives to be the most advantageous policy to society as a whole. Medical professionals characteristically deplore scarcities. Many of them are simply not prepared to modify their intransigent principle of unwavering duty to their patients’ individual interest. However, in decisions involving multiple patients, making available more medication, labour or expenses for one patient will mean leaving less for another. The physician is then compelled by his competing loyalties to enter into a decision mode of one versus many, where the underlying constraint is one of finiteness of the commodities. Although the medical treatment may be simple and inexpensive in many instances, there are situations such as in renal dialysis, where prioritisation of treatment poses a moral dilemma because some patients will be denied the treatment and perish. Ethics and economics share areas of overlap. They both deal with how people should behave, what policies the state should pursue and what obligations citizens owe to their governments. The centrality of the human person in both normative economics and normative ethics is pertinent to this discussion. Economics is the study of human action in the marketplace whereas ethics deals with the “rightness” or “wrongness” of human action in general. Both disciplines are rooted in human reason and human nature and the two disciplines intersect at the human person and the analysis of human action. From the economist’s perspective, ethics is identified with the investigation of rationally justifiable bases for resolving conflict among persons with divergent aims and who share a common world. Because of the scarcity of resources, one’s success is another person’s failure. Therefore ethics search for rationally justifiable standards for the resolution of interpersonal conflict. While the realities of human life have given rise to the concepts of property, justice and scarcity, the management of scarcity requires the exercise of choice, since having more of some goods means having less of others. Exercising choice in turn involves comparisons, and comparisons are based on principles. As ethicists, the meaning of these principles must be sought in the moral basis that implementing them would require. For instance, if the implementation of distributive justice in healthcare is founded on the basis of welfare-based principles, as opposed to say resource-based principles, it means that the health system is motivated by the idea that what is of primary moral importance is the level of welfare of the people. This means that all distributive questions should be settled according to which distribution maximises welfare. Utilitarianism is fundamentally welfarist in its philosophy. Application of the principle to healthcare requires a prior understanding of the welfarist theory as expounded by the economist. Conceptually, welfarist theory is built on four tenets: utility maximisation, consumer sovereignty, consequentialism and welfarism. Utility maximisation embodies the behavioural proposition that individuals choose rationally, but it does not address the morality of rational choice. Consumer sovereignty is the maxim that individuals are the best judge of their own welfare. Consequentialism holds that any action or choice must be judged exclusively in terms of outcomes. Welfarism is the proposition that the “goodness” of the resource allocation be judged solely on the welfare or utility levels in that situation. Taken together these four tenets require that a policy be judged solely in terms of the resulting utilities achieved by individuals as assessed by the individuals themselves. Issues of who receives the utility, the source of the utility and any non-utility aspects of the situation are ignored.

#### Extinction comes first under any framework- millions dying outweighs any other impact

### C1: Disease Innovation

#### Studies currently show that IPR has been effective in pharmaceutical innovations that help with diseases. The only incentive for companies to researches new drugs is reduced competition which the affirmative destroys. The huge risk that goes into developing a drug would otherwise not make its innovation worthwhile.

Will Rinehart, Director of Technology and Innovation Policy at the American Action Forum 14, Director of Technology and Innovation Policy at the American Action Forum, 7-29-2014, "Intellectual Property Underpinnings of Pharmaceutical Innovation: A Primer," https://www.americanactionforum.org/research/intellectual-property-underpinnings-of-pharmaceutical-innovation-a-primer/

Being that it is an exclusive right to a piece of knowledge, patents are often considered to be a kind of monopoly. Criticism has been heaped upon patents in exactly the way one would expect given this definition. The creation of intellectual property rights creates an allowable exclusivity. Yet, it should be immediately apparent that patents do not automatically confer a monopoly over an industry. For example, a pharmaceutical company that invents a new and improved cancer medicine is still in competition with alternatives from other companies, which ultimately acts as a constraint on their ability to charge prices above a competitive level. Commercial success is tied to more than just an innovative idea; superior marketing, management, positioning, and other factors are likely to be more important than the patent itself. Moreover, individuals and companies will seek multiple solutions to the same problem, whether that might be in new commercial arrangements or products. By limiting a particular avenue for competitors, patents have the potential effect of promoting further innovation by encouraging others to develop new products. PATENTS IN PHARMACEUTICALS The medical field presents a strong case for patents, and because of its unique features, allows for a better understanding of the current tensions in other areas of patent policy. The medical field has a lone inventor myth, which is exemplified in the belief of the cure for cancer. The truth is that there is unlikely to be any sole cure, but rather through research and applied innovation, effective methods and treatments for dealing with these diseases will be found. Of course, this means that the entire endeavor will be expensive. As with any piece of property, the bounds of intellectual property must be set, which is where we first encounter the variance that can exist between industries under patent protection. Compared to software patents where there is far less clarity in breadth of patents, medical patents tend to be more discreet in their delineation. It is relatively clear what constitutes a new drug and what does not. Pharmaceutical companies also differ from other industries in their cost structure, including the time and resources needed to bring an innovation to market. Both the research phase and the regulatory approval process are costly and time intensive. Biopharmaceutical discovery has benefited from a remarkable shift in research and technology. Even in the last 10 years, the methods to innovation have been revolutionized, spurred on by better understandings of genetic relationships. Take for example, Gleevec, a treatment for chronic myeloid leukemia. Before the drug was introduced, less than a third of those diagnosed with chronic myeloid leukemia were alive five years later, but after it became available that figure jumped to 90 percent. The method of research responsible for its development was extremely innovative and as such the total development was costly. Gleevec and the drugs that followed it are part of a new breed of drugs that are far more complex than their predecessors. Even with biopharmaceutical innovations, estimates place the average cost of bringing a successful new drug to market at around $1.2 billion. After compounds are screened for use to treat a condition, only about 1 out of the 6 that make it to clinical trials will eventually obtain FDA approval. The table below shows that total industry research and development (R&D) has increased in recent years. The marginal cost of another pill is often miniscule compared to the initial investment cost. Prices for generic drugs are substantially lower than the original brand because these new firms don’t have to amortize the initial R&D costs over a drugs patent life. Additionally, pharmaceutical firms face high risks in their ventures as well as high costs of entry compared to other industries. Clinical trials provide an example of the costs to develop a market ready drug. As the Tufts Group has shown, the average length of a clinical trial increased by 70 percent from 1999 to 2005. In that same time period, the average number of routine procedures per trial increased by 65 percent. To add to that, the average clinical trial staff work burden increased by 67 percent. To top it all off, enrollment criteria and trial protocols resulted in 21 percent fewer volunteers being admitted into trials and 30 percent more enrollees dropping out before completion of the tests. Overall, the regulatory process of drug approval levies a heavy risk for manufacturers and innovators. For every one drug that passes through the regulatory approval process, manufacturers usually assess 5,000-10,000 substances. This is a time consuming and expensive process where innovators hope to see a return on their investment over the long-term. The FDA aims to strike a balance between access to life-saving treatments and assuring the public with standards of safety in all pharmaceuticals. The final step in pending drug approval usually involves hundreds to thousands of participants in a blind study of the drug. This part of the process now represents about 40 percent of pharmaceutical companies’ R&D expenditures. However, this often-cited statistic actually understates the amount spent. R&D expenditures include all pharmaceutical candidates that a company tests—including hundreds that never reach this trial stage. An analysis conducted by the Manhattan Institute found that for the drugs that are actually approved, these clinical trials typically represent 90 percent or more of the cost of developing an individual drug all the way from laboratory to pharmacy. CONCLUSION Medical treatments are among the best cases where intellectual property law has gotten things right. Patents are an important way to ensure that the benefits of research are captured by the creator. Solving the 21st Century’s problems will require complex solutions that will only come about because of intense research and development. Patents ensure that this research takes place. Even though some have criticized aspects of the patent regime, the system itself still serves as a testament to and an enabler of American innovation.

#### **Innovating new drugs that deal with disease is crucial to humanity’s well being – history shows that pandemics, from smallpox to influenza to COVID, we should always be finding new drugs**

Dennis Pamlin & Stuart Armstrong, Executive Project Managers of Global Risks 15, Dennis Pamlin, Executive Project Manager Global Risks, Global Challenges Foundation, and Stuart Armstrong, James Martin Research Fellow, Future of Humanity Institute, Oxford Martin School, University of Oxford, February 2015, “Global Challenges: 12 Risks that threaten human civilization: The case for a new risk category,” Global Challenges Foundation, p.30-93, https://api.globalchallenges.org/static/wp-content/uploads/12-Risks-with-infinite-impact.pdf

4 Global A pandemic (from Greek πᾶν, pan, “all”, and δῆμος demos, “people”) is an epidemic of infectious disease that has spread through human populations across a large region; for instance several continents, or even worldwide. Here only worldwide events are included. A widespread endemic disease that is stable in terms of how many people become sick from it is not a pandemic. 260 84 Global Challenges – Twelve risks that threaten human civilisation – The case for a new category of risks 3.1 Current risks 3.1.4.1 Expected impact disaggregation 3.1.4.2 Probability Influenza subtypes266 Infectious diseases have been one of the greatest causes of mortality in history. Unlike many other global challenges pandemics have happened recently, as we can see where reasonably good data exist. Plotting historic epidemic fatalities on a log scale reveals that these tend to follow a power law with a small exponent: many plagues have been found to follow a power law with exponent 0.26.261 These kinds of power laws are heavy-tailed262 to a significant degree.263 In consequence most of the fatalities are accounted for by the top few events.264 If this law holds for future pandemics as well,265 then the majority of people who will die from epidemics will likely die from the single largest pandemic. Most epidemic fatalities follow a power law, with some extreme events – such as the Black Death and Spanish Flu – being even more deadly.267 There are other grounds for suspecting that such a highimpact epidemic will have a greater probability than usually assumed. All the features of an extremely devastating disease already exist in nature: essentially incurable (Ebola268), nearly always fatal (rabies269), extremely infectious (common cold270), and long incubation periods (HIV271). If a pathogen were to emerge that somehow combined these features (and influenza has demonstrated antigenic shift, the ability to combine features from different viruses272), its death toll would be extreme. Many relevant features of the world have changed considerably, making past comparisons problematic. The modern world has better sanitation and medical research, as well as national and supra-national institutions dedicated to combating diseases. Private insurers are also interested in modelling pandemic risks.273 Set against this is the fact that modern transport and dense human population allow infections to spread much more rapidly274, and there is the potential for urban slums to serve as breeding grounds for disease.275 Unlike events such as nuclear wars, pandemics would not damage the world’s infrastructure, and initial survivors would likely be resistant to the infection. And there would probably be survivors, if only in isolated locations. Hence the risk of a civilisation collapse would come from the ripple effect of the fatalities and the policy responses. These would include political and agricultural disruption as well as economic dislocation and damage to the world’s trade network (including the food trade). Extinction risk is only possible if the aftermath of the epidemic fragments and diminishes human society to the extent that recovery becomes impossible277 before humanity succumbs to other risks (such as climate change or further pandemics). Five important factors in estimating the probabilities and impacts of the challenge: 1. What the true probability distribution for pandemics is, especially at the tail. 2. The capacity of modern international health systems to deal with an extreme pandemic. 3. How fast medical research can proceed in an emergency. 4. How mobility of goods and people, as well as population density, will affect pandemic transmission. 5. Whether humans can develop novel and effective anti-pandemic solutions.

### C2: Safety

#### While it may sound like a good idea to reduce ITP in a vaccum, the alternative is actually much worse. Because people can build off of previous innovated drugs without patents, they can make counterfeit drugs that aren’t safe. However, because they offer them at a cheaper price, many are willing to buy them.

Tavares, an experience patent attorney focused on medical drugs 9/28 [Inês D. Tavares (Trademark and Patent Attorney at Inventa International focusing on the African continent. “Worldwide: Counterfeiting Of Fake Drugs In Africa: Current Situation, Causes And Countermeasures”. Mondaq. 28 September 2020. Accessed 8/8/21. <https://www.mondaq.com/nigeria/trademark/988968/counterfeiting-of-fake-drugs-in-africa-current-situation-causes-and-countermeasures> //Xu]

Although stopping counterfeiting is proven to be an extremely difficult challenge in Africa, several countries, along with the help of World Health Organization and other Institutions have been joining the fight. The WHO is assisting countries in developing the expertise needed to regulate drugs. One of the most important measures is the effective drug registration. Drug registration, also known as marketing authorization and product licensing, allows a country to evaluate if a specific pharmaceutical is safe for consumers to use. Through marketing licensing authorities can also assure that the manufacturing, the storage as well as the distribution of a pharmaceutical was righteously made and cared for without putting at risk the product efficiency and most importantly safety. The incursion of Anti-Counterfeiting Acts in the jurisdictions is of extreme importance to give Authorities the necessary mandate to combat counterfeiting by means of carrying out the adequate and necessary actions that will address the issue directly. A strategy that has been put in place in Tanzania and Ghana, for instance, is to instead of shutting out illegal vendors, invest in training, regulating and licensing them. Furthermore, different countries are investing in awareness campaigns to educate locals to the dangers of consuming fake pharmaceuticals. By educating the consumers they are making people more alert to the signs. Pharmaceutical red flags include, but are not limited to the following: they almost always have a cheaper price tag, they can have a different packaging or the packaging can be altered from the original, the location where the drugs are being sold is usually not reliable and trustworthy. Of course, it can be difficult, at times, to set the original product from the fake product apart. The best indicatory is usually the price point of the fake drug, being set much lower than the first generation good and the problem aggravates when the underground markets take advantage of the loopholes existing in the pharmaceutical distributing systems to channel their counterfeited drugs into the hospital, pharmacies and other distributors, which is one big reason for the education and training of consumers and health workers who are often unable to detected fake products from first generation goods. Countries like Kenya, Ghana and Nigeria have also implemented mobile telephone based consumer verification into their regulations. This system allows consumers to be protected, empowering them against fraudulent products. African countries working together is crucial, regional coordination can help control the problem at customs and at safeguarding borders. Nigeria and Cameroon had signed a cooperation agreement and compromise to sharing experiences and technical expertise to combat the problem. More recently, the Presidents of the Democratic Republic of Congo, Niger, Senegal, Togo, Uganda, Ghana and Gambia signed the Lomé initiative, dated of January 2020, a binding agreement to criminalize trafficking of falsified medicines. The Lomé initiative tackles soft spots such as the lack of regulation and weak healthcare systems. Several African countries are now trying to implement a set of measures at customs such as enabling the interception of contraband (illegal drugs as well as weapons), conduct baggage, cargo and mail inspections to travellers, protect businesses against illegal trade malpractice and enforce import and export restrictions and even prohibitions. However, and although countries are making more efforts into fighting the pharmaceutical counterfeiting problematic, the matter is extremely complex. It involves dangerous lobbies and the work of organized crime, corruption and bribery. All of these are not easy to dismantle. Several previously mentioned factors such as extreme poverty, the uneducated level of the people and lack of an effective and responsive Healthcare System aggravates the predicament. More often than not, consumers have no other alternative than to resort to drug outlets. We have to join efforts worldwide to combat fake medicine markets to thrive in Africa and other areas and Intellectual Property has an enormous role in the fight. More and more regulations are being put in place and a larger number of officials are being trained at customs to be able to detect and identify counterfeited goods, either pharmaceutical or not. Counterfeiting is a global pandemic with tragic consequences and it is crucial for countries and other institutions governmental and non-governmental to join forces and keep fighting to end the problem thus save millions of lives and jobs each year.

#### High drug prices leads to use of substandard drugs which cause antimicrobial resistance, WBG 17

World Bank Group, March 2017, “DRUG-RESISTANT INFECTIONS A Threat to Our Economic Future”, <https://documents1.worldbank.org/curated/en/323311493396993758/pdf/final-report.pdf> //Lex AT

Even as there is overuse and misuse of antimicrobials, some poor populations still lack access to effective medicines. For example, one million children are estimated to die each year from untreated pneumonia and sepsis, which can be effectively managed with antibiotics (Laxminarayan et al. 2016). Weak health care systems, AMR, and the penetration of many countries’ antimicrobials markets by substandard and counterfeit drugs— these conditions all contribute to low access to effective antimicrobials. Relatively high prices of the more powerful, later-generation, antimicrobial drugs are also a factor. The development and marketing of these drugs occurred since the first-line, relatively inexpensive antimicrobials lost their effectiveness because of AMR. High drug prices then squeeze the finite health care budgets of governments, charities, and households, resulting in diminished access to treatment, especially for the poor and vulnerable. In addition to the effect on individual health outcomes, shrinking access to effective antimicrobials hinders progress toward universal health coverage (UHC), a pillar of the Sustainable Development Goals for 2030.4 We will discuss the potential development impacts of AMR extensively in Part II. In Part IV, we will show how country action to promote UHC can simultaneously enable more effective AMR control.

#### That kills 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

**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.

### Case

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

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

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

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

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

#### Data exclusivity is necessary to ensure effective clinical research

Bing 21 Dr. Han Bing (senior research fellow at the Institute of World Economics and Politics of Chinese Academy of Social Sciences). “TRIPS-plus Rules in International Trade Agreements and Access to Medicines: Chinese Perspectives and Practices.” Global Development Policy Center, Global Economic Governance Iniative. GEGI Working Paper 049, April 2021. JDN. https://www.bu.edu/gdp/files/2021/04/GEGI\_WP\_\_Bing\_FIN.pdf

Undisclosed test or other data refer to the data obtained in the entire medicine development process to demonstrate the medicine’s safety, efficacy and quality. The medicines and healthcare products regulatory agencies in various countries analyze and evaluate whether to approve the marketing of a new medicine based on such data. Since it is obtained from scientific studies, undisclosed test or other data are unable to satisfy the requirements of patent grant and cannot be protected by patent rights. However, the cost of obtaining marketing approval is expensive and the first registrant needs to be significant to overcome the negative price effects of competition from pharmaceutical manufacturers that free ride on the initial registrant’s marketing approval. Therefore, it is argued that, without a period of monopoly, the new drug developers will have no incentive to “conduct the costly clinical research and trials necessary to obtain marketing approval” (Chow and Lee 2018). Given its importance to the pharmaceutical industry, the United States is a strong proponent of adding such a provision in the TRIPS Agreement (Chow and Lee 2018). However, since the TRIPS Agreement was formally implemented 25 years ago, WTO members had not yet unified their opinions on the application of this provision. The United States, the European Union, and some members argue that, taking into account the considerable amount of efforts and costs for generating the necessary data, unless permitted by the originator, undisclosed test or other data should be granted exclusive rights against disclosure for a specific period of time (UNCTAD & ICTSD 2013, 613-615). During the period, government agencies shall not only protect such data against disclosure, but also prevent generic drug manufacturers from relying upon the data to obtain marketing approval. Developing countries such as Argentina, Brazil, India, and Thailand provide a non-exclusive protection on undisclosed test or other data, that is, such data are protected against unfair commercial use, but not granted exclusive rights, which allows government agencies to rely on such data to approve the marketing of generic medicines (UNCTAD & ICTSD 2013, 615-616). Developing countries believe that if the US and European practices were adopted, the marketing of generic medicines would be delayed, thereby unreasonably restricting the public access to medicines (UNCTAD & ICTSD 2013, 621). Prior to accession to the WTO in 2001, there were no data exclusivity provisions in China. After joining the WTO, China has assumed the obligation to protect such data in compliance with the TRIPS Agreement. Unlike most WTO members, as a condition for accession to the WTO, China agreed to provide data exclusivity protection for a period of six years (Feng 2010). Included in the Part V “Trade-Related Intellectual Property System” of the Report of the Working Party on the Accession of China (World Trade Organization 2001), China reiterated the content of and added what is not stipulated in Article 39(3) of the TRIPS Agreement. That is, during the period of six years, China does not allow approval of marketing for generic medicines, in order to provide exclusive protection for undisclosed test or other data of new chemical entities (World Trade Organization 2001, 284). Moreover, such protection is independent of patent protection, which means such data are protected whether a medicine is granted patent or not. The period of six years exclusive protection for undisclosed test or other data is longer than the period of 5 years of protection in the US and a number of bilateral free trade agreements.

#### Data exclusivity key to innovation and economic growth---plan collapses growth.

**IFPMA 11** (International Federation of Pharmaceutical Manufactures & Associations, July 2011 xx-xx-xxxx, " Data Exclusivity: Encouraging Development of New Medicines", <https://www.ifpma.org/wp-content/uploads/2016/01/IFPMA_2011_Data_Exclusivity__En_Web.pdf>) // CH

The Role of Data Exclusivity in Economic Growth, Investments and improvement of Health Care Systems **Data exclusivity** can be a **key consideration in** the business decision to introduce new innovative drugs into a market. The **incentive provided by exclusivity periods is well recognized**, particularly for pediatric and orphan drugs. **Exclusivity periods** based on data developed in conjunction with study of these specific uses **is a highly appropriate tool for providing the incentives to investigate previously “neglected diseases”** areas.

In addition, when an innovative medicine is introduced into the national health care system, doctors, nurses, hospitals and pharmacies must be educated. This is usually done by the innovator having developed all the scientific information necessary for approval of the medicine. The innovator closely monitors reports on treatment results and ensures patient safety by incorporating data in its local product registration, launch and education program.

By **providing** a **means for the innovator to potentially recoup the costs involved in conducting** any locally required **clinical tests** for marketing approval and the significant costs of introducing a new product to the market, **countries which offer data exclusivity are encouraging businesses to move their product, investment and potential manufacturing to their markets earlier**. If other companies could immediately use these data to obtain their own marketing authorization, thus competing with the innovator, there would be less incentive for the innovator to invest in that market or to conduct the necessary trials.

**Data exclusivity can** also **enhance technology transfer and can stimulate generic drug production or medicines for specific or unmet needs**. By providing an incentive to introduce new innovative medicines to a market, **data exclusivity can result in greater access to new innovative medicines and spur the introduction of generic medicines** once the exclusivity period ends. Data exclusivity is **a tool that recognizes and rewards the time, effort, and economic investments made by the innovator** in order to bring a new medicine to market, while also providing a means to support greater access to those new medicines and over time, to generic medicines as well.

Since USAID’s NTD Program began distributing donated drugs in 2007, the drug donation programs have expanded significantly. The NTD drugs donated to the USAID-supported countries have been valued at over $27.6 billion, representing the largest public-private partnership in the Agency, with a leverage of $26 in donated drugs for every tax dollar spent by USAID.

#### Weakening patents is worse – eliminates funds for R&D and halts pharma innovations that prevents an effective development of a right to health.

Sarah Joseph 11, Professor of Human Rights Law, and the Director of the Castan Centre for Human Rights Law at Monash University, Sarah, “Blame it on the WTO?” http://www.oxfordscholarship.com/view/10.1093/acprof:oso/9780199565894.001.0001/acprof-9780199565894-chapter-8#acprof-9780199565894-note-1350

IP protection restricts trade and competition, so IP clauses are somewhat anomalous in trade agreements, which are normally designed to decrease trade barriers. What is the justification for IP protection?44 Due to their relevance to this chapter, I will concentrate on arguments in favour of patents.45 Patents reward people for their inventions, thus encouraging creativity and innovation. Patents operate on the assumption that people are not inherently altruistic, and expect rewards for their endeavours, especially when those endeavours are risky as they may, and often do, result in costly failure.46 Furthermore, the money raised from patent protection is said to be necessary to fund the considerable costs of research and development (R&D).47 Therefore, without patents, innovation in the pharmaceutical field (or any industrial field) might grind to a standstill. While it is true that the high prices generated by patent protection may render access to drugs selective, (p.221) it is nevertheless better that a drug is available to some rather than non-existent and available to no one. The global extension of patent law mandated by TRIPS helps to ensure that patents are not undermined by the sale of competing pirated copies. Furthermore, global IP regimes should theoretically encourage greater technology transfer between countries, greater foreign direct investment, and greater local innovation within compliant states.48 All of these outcomes should accelerate the economic development of poor countries, with positive knock-on effects for human rights. Thus, perhaps it is arguable that pharmaceutical patents are justifiable under international human rights law, as they promote R&D which is essential for the future enhancement of rights to life and health. Furthermore, to the extent that they are held by natural persons, they are one way of protecting that person’s rights under Article 15(1)(c) of the ICESCR.