**(NEG) The member nations of the World Trade Organization ought to reduce intellectual property protections for medicines**

**(Alex Li)**

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

### **Negative Framework**

**My value today is Morality. Morality is defined as the principles concerning the distinction between right and wrong.**

**My value criterion is the happiness principle. Prefer utilitarianism as it gives you a clear mechanism to weigh different paths as well as their consequences within the context of the same end state or goal.**

### **Off I: Innovation DA**

**Business is booming**

Dr. Andrew A. **Parsons 17**, initially trained as a Pharmacologist and Neuroscientist, Director of Reciprocal Minds Limited &amp; Chairman of Pharmasum Therapeutics AS, an early stage Biotech company, 10/3/17, &quot;From mega-merger to big bang?&quot;, Elsevier, Pharma R&amp;D Today, https://pharma.elsevier.com/pharma-rd/mega-merger-big-bang/

It was not so long ago that there was a perception that the **biopharma** industry was consolidating and becoming leaner and more focused in its operations, moving to a regional hotspot model from having central areas of excellence based internally (1). The mega-mergers of the past led to the loss of some famous company names (e.g. Pharmacia, Wyeth, etc.) and a concentration of revenues within the largest of the remaining companies. The nature of the business since 2005 has changed. The market share of the top 10 companies has decreased over time and global **revenues are projected to be** close to **$1** **trillion by 2020, with over 60% being held by companies out of the top 10** (1). Meanwhile **the nature of innovation is changing** as well, **with** recent history showing **increased patent approvals** from biotech companies and approvals sourced from Asia (2). Against this backdrop, it is perhaps not so surprising to see that the business model is adapting, too. The source of know-how and drug development skills has evolved, and **there has been an explosion of** contract **research** and other organizations over this period. **Organizations are managing** their infrastructure **to reduce costs and increase profits**. A consequence of this approach is that organizations are outsourcing many activities that traditionally would have been conducted inside, and their experiences range from being highly successful to those where it did not work so well. In 2012, AstraZeneca entered a long-term strategic relationship with an external provider to deliver a range of preclinical activities, and the relationship has clearly been successful and has developed over the years to provide an integrated process between pharma and contract organizations. The focus on how to operationalize the strategic relationship led to significant process innovations to allow efficient and effective workflows (3). A review of the academic literature identifies five key areas of interest for business collaborations. These include (4): External orientation – openness to share and develop ideas from outside the organization Learning capabilities – to recognize and absorb new opportunities Cluster participation – creating a “footprint” in a technically relevant biocluster where high-quality science attracts an infrastructure for commercial success Qualified business management – access to tacit knowledge of the overall drug discovery and commercialization process Organizational controls – risk management of technical and financial considerations to maximize success This whole **biopharma** sector **appears to be in a “big bang” moment.** With increasing numbers of organizations generating revenue from products, the need for technical and risk- management expertise and a geographic shift away from traditional centers of expertise, **the** total **market** (including IP generators, commercial specialists and service-based companies) **appears to be set for significant and rapid growth. One thing to focus on** during this time **is** how to ensure quality and **governance** of the system. We can take some learning from the “big bang” identified in the financial markets in 1986, as there are some patterns of boom and bust that we may want to pay attention to. It seems the world might be coming out of a global recession driven by de-regulation of the financial industry and the selling of debt. Perhaps this experience may relate to the biopharma industry? The importance of appropriate regulation and the inclusion of checks and balances into the system might be a good place to start. It is interesting to note that regulators are well aware of the challenges in the system (5). There is a need to adapt to the new types of medicines and business models that are emerging across the industry, and there is a priority for stakeholders to engage in this process sooner than later. One thing **we all need to avoid** is **a rapid implosion of the currently rapidly expanding biopharma universe.**

**TRIPS IP rights are key for innovation**

James **Bacchus 20**, adjunct scholar at CATO, “An Unnecessary Proposal: A WTO Waiver of Intellectual

Property Rights for COVID-19 Vaccines,” December 16 th , 2020, https://www.cato.org/free-trade-

bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#does-novel-

virus-present-novel-issues

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this **lengthy WTO dispute** has largely been **between developed countries trying to uphold IP rights** **and developing countries trying to limit them.** The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting **IP rights** is that they **are incentives for innovation**, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by **“enabling innovators to capture** enough of the **benefits of their own innovative** **activity** to justify taking considerable risks.”18 The **knowledge from** innovations inspired by **IP rights** **spills over** to inspire other innovations. The protection of **IP rights promotes** the **diffusion**, domestically and internationally, **of innovative technologies** and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. **Without IP** **rights** as incentives, **there would be less new knowledge and thus less innovation.** In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, **undermining private IP** **rights** would **eliminate** the **incentives that inspire innovation**, thus **preventing the discovery and** **development of knowledge for new goods and services that the world needs.** This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19

**Empirical evidence proves**

**Ohlhausen 16**, Harvard Journal of Law & Technology Volume 30, Number 1 Fall 2016

<https://www.ftc.gov/system/files/documents/public_statements/1050923/ohlhausen_-_harvard_article_1-18-17.pdf>

Those who find the **economic justification for a patent system** convincing **encounter** much support in the relevant **empirical research**. As the following review shows, the **evidence is consistent with the proposition that patents lead to greater investment in R&D**. IP rights strength positively correlates with R&D investment, at least in developed countries.131 **Two leading studies particularly warrant** attention. **Using** cross-country **data from thirty-two nations** on R&D investment and patent protection from 1981 to 1995, **Kanwar and Evenson** in 2003 **concluded**, “**[t]he evidence** unambiguously **indicates the** significance of **intellectual property rights as incentives for** spurring **innovation**.”132 They found that “[t]he strength of intellectual property protection is positively and significantly associated with R&D . . . . Thus, countries which provided stronger protection tended to have larger proportions of their GDP devoted to R&D activities.”133 A study by **Park and Ginarte six years earlier created an index of patent strength using data from sixty countries from 1960–1990 “to determine the role of IP rights in economic growth.**”134 The authors **concluded that** “**IP [rights] affect economic growth** **by stimulating** the accumulation of factor inputs like **research and development capital** and physical capital” and that IP rights’ “**benefits to growth are** from **encouraging the research sector to** invest and **take risk**,” except in developing countries.135 A host of other empirical work similarly finds a statistically significant relationship between patent strength and R&D investment. A 2013 Brookings report observed, “[r]esearch has established that patents are correlated with economic growth across and within the same country over time” and “R&D spending since 1953 is highly correlated with patenting and the patent rate.”136 Studying U.S. data between 1980 and 2010, the report concluded that “patenting is associated with higher metropolitan area productivity” and that “the most likely explanation is that patents cause growth.”137 In a 2012 study, Duguet and LeLarge examined the relationship between patents and innovation performance between 1997 and 1999 for the French manufacturing sector.138 They concluded that “patents significantly promote product innovations but not process innovations.”139 In short, “patents do increase the private incentives to innovate, but through a specific, unbalanced, channel.”140 Studying fifty-eight countries’ data from 1980–2003, Hasan and Tucci found in 2010 that “countries hosting firms with higher quality patents also have higher economic growth.”141 They also identified “some evidence that those countries that increase the level of patenting also witness a concomitant increase in economic growth.”142 In a 2011 study, Shih-tse Lo examined the effects of Taiwanese patent reform in 1986 in response to U.S. pressure, concluding that the “patent reforms stimulated R&D spending. Industries that were highly R&D-intensive experienced an increase in their patenting in the United States. The favorable impact was most pronounced in the electronic and electrical industry.”143 In two studies in the 1990s, Thompson and Rushing explored the relationship between patent protection and economic growth.144 Using data from 1970 to 1985, their 1996 study found evidence that “**strong intellectual property rights laws and effective enforcement policies result in more rapid economic growth in countries with an initial level of [per capita] GDP greater than or equal to $3,400 [in 1980 dollars].**”145 **The authors explained this effect as presumably being due to the fact that “protection from patents is the foundation for payoffs to entrepreneurs starting off the chain of events that leads to economic expansion.**”146 Expanding on those conclusions in a 1999 study, Thompson and Rushing sought further insight into the contribution that patents make to factor productivity growth. 147 They found that, “in wealthier countries, patent protection shares a positive relationship with changes in total factor productivity and, in turn, total factor productivity positive[ly] influences the rate of economic growth.”148 In short, “strong patent protection and enforcement do have a positive and significant impact on the growth of factor productivity.”149 Finally, **there is some evidence that patent rights correlate with greater innovation in developing countries, too. In a 2006 study, regressed data** on **seventy-nine countries** **showed** that, Whilst the effect of **IPR protection** on growth depends upon the level of development, it is **positively and significantly related to growth for low**-and high**income countries**, but not for middle-income countries. This suggests that, although IPR protection encourages innovation in high-income countries, and **technology flows to low-income countries**, middleincome countries may have offsetting losses from reduced scope for imitation.162 In 2005, Chen and Puttitanun analyzed data for sixty-four developing countries, finding “some evidence that **innovations in developing countries are indeed positively and significantly impacted by IPRs**, and the levels of IPRs exhibit a U-shaped relationship with per capita GDP.”

### **Off II: Health Diplomacy DA**

**TRIPS is essential to modern health diplomacy**

Obijiofor **Aginam 10**, Academic Programme Officer &amp; Director of Studies, Institute for Sustainability and Peace, United Nations University headquarters, Tokyo, Japan; Adjunct Research Professor of Law, Carleton University, Ottawa, Canada, “HEALTH OR TRADE? A CRITIQUE OF CONTEMPORARY APPROACHES TO GLOBAL HEALTH DIPLOMACY,” https://poseidon01.ssrn.com/delivery.php?ID=1490970830811231051130850991231230911040140590 82060018071001088023116023118119002064117119051059021051011085110010121013091016020 07001105101501801100806501910412708404207609808100710209912008703108509311907112712 2005124010118009001092104124120121094&amp;EXT=pdf&amp;INDEX=TRUE

The third limb of **global health diplomacy** critique **reflects** the **complex linkages between “health and trade**”18 where the modest **achievements in** global health **diplomacy** in the past decade **are substantially driven** not by events in the health sector but **by** the normative **developments in the trade** and economic **relations of states enforced by the WTO.** Although this sounds like “economic globalization triumphalism”, it is nonetheless hard to dispute the fact that it was the patent requirements for pharmaceuticals and other inventions in the WTO **TRIPS** Agreement that substantially **catalyzed (accelerated) the health diplomacy** on access to anti-retroviral drugs for HIV/AIDS for millions of poor HIV- positive who live mostly in developing countries. Food safety and security concerns and the hard diplomacy animated by biotechnology advances in food production, although **global health issues** in their own right**, are catalyzed by the developments in the WTO** on the SSPS Agreement, and not the subtle “diplomacy” around the WHO/FAO jointly administered Codex Alimentarius Commission standards. The migration of qualified health professionals from most of Africa to the West is now being driven in complex ways by one of the modes of service supply in the GATS Agreement.

**Health diplomacy’s key to global cooperation that solves multiple existential threats James 17**, Wilmot James, Honorary Professor in the Division of Human Genetics at the University of Cape Town&#39;s Medical School and Non-residential Senior Fellow at Bard College’s Hannah Arendt Centre, Ph.D. from University of Wisconsin at Madison, “In an Age of Zika and a Threat of Biochemical Terror, Health Security Must Be Everybody’s Concern”, Daily Maverick, 4-2, https://www.dailymaverick.co.za/article/2017-04-02-op-ed-in-an-age-of-zika-and-a-threat-of- biochemical-terror-health-security-must-be-everybodys-concern/#.WOY8xTvDHHw [language modified]

**With Zika there too was political failure to act quickly,** give honest advice and confront the abortion conundrum head-on, the result being that 3,000 and likely more children with microcephaly will test the emotional resilience and financial resources of their families to breaking point. We should never cease to invest in the public health and medical science of disease, but it seems to me that **our fundamental problem is not the quality of the health sciences but the grim mediocrity of our politics**. Party-political bickering for short-term gain paralyses and drains the national effort in South 147 File Title Africa as much as it does in the United States, undermining our ability to see with compelling clarity the solutions the issues of the day deserve. **Health** security **is humanity’s shared concern.** Promoting health and preventing death define us at our most altruistic and advanced. The Hippocratic Ideal, the concept of the physician as the guardian of human health, encapsulates a fundamental human quality common to all the world’s great religions. **Medicine** is one of the earliest and greatest human achievements because it **is a co-operative enterprise** involving highly skilled individuals; **and** it is **as a result** of cooperation – and our unusual ability for complex language – that cumulative **civilisation is possible.** In the age of globalisation, it is **health security**, a recent Lancet editorial stated, that “**is** now **the most important foreign policy issue of our time**”. The **rapid emergence** and re-emergence **of** pathogenic infectious **disease**, of which Zika is the most recent, the slow but steady cumulative acts of nature associated with **climate change**, high-risk **forced migration** caused by desperation and war, the creeping reality of **biochemical [use]** terror **and** the threat of **nuclear war, propel human survival** and well-being **to the frontline** of what today must be everybody’s concern. The field of **health diplomacy provides** an **unprecedented opportunity to build** human **solidarity. It** is an area of human endeavour that **cuts through** inherited **antagonisms. Governments** that **offer health improvements** as part of aid to nations with whom they wish **to develop** stronger **diplomatic links** succeed in cultivating deeper cultural relationships precisely because of their direct benefit to citizens. To advance health diplomacy requires health leaders with an inclusive global vision...

### **Off III: Counterfeit Medicine**

**Fifarma** [Latin American Federation of the Pharmaceutical Industry] “This is how we fight counterfeit medicines with Intellectual Property.” 20**21**. https://fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/ AL

There is a threat to health security that is present in every country in the world: **counterfeit medicines.** These may **appear as a promise to cure any disease, but** they **contain excessive, insufficient or no doses of** the active **ingredient that treats the disease. Counterfeit medicines also include stolen drugs, drugs that have been stored in poor conditions or are expired, so they may be ineffective or may be contaminated.**In the end, **the only goal of counterfeit medicines is to make money**, **regardless of** the **consequences** they may have **on people’s health**. In fact, according to the World Health Organization (WHO), **this business represents more than $30 billion dollars in low-** and middle-**income countries.**. It is necessary for different actors to be part of the solution. Decision-makers can create campaigns to inform people about the existence of these medicines. They must go hand in hand with regulatory agencies, as they are the ones that control the entry of medicines into countries. Likewise, the pharmaceutical industry must take action, since they are the ones who research and manufacture products. Thus, the international Fight The Fakes campaign, supported by FIFARMA, aims at raising awareness regarding the dangers of counterfeit medicines. Each actor must play a role, however, without partnerships and collaboration between different parties, it is difficult to fight the problem. Moreover, there are other tools that contribute to the elimination of these threats to public health, such as Intellectual Property (IP). In addition to functioning as a tool to maintain constant innovation in the industry, **Intellectual Property Rights help**s **reduc**ing **counterfeit medicines because medicines have better technologies and ingredients that are more difficult to copy.** This means that, **through market incentives, the industry manages to have high quality infrastructure,** new **technology** and **trained personnel,** to create specialized **and specific medicines and therapies,** which is why they **are difficult to replicate.** On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines. In short, **IP allows quality standards to be clear**er **and strict**er, and **regulators** to **have greater knowledge and traceability of each product that enters the market.** Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines. Consequently, **the best way to fight counterfeit medicines is** through **accessing** the best **quality medicines** and for this to happen, an ecosystem between countries, regulators and industry is needed...Thus, technology is becoming an important element in fighting this problem. **Counterfeit medicines have** a wide range of **negative effects** for different actors and especially **for the people who fall victim** of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The **tools to combat counterfeiting exist**, the important thing is that actors know how to use them **for the benefit of the greatest number of people** in the world.

Dr. Kristina **Lybecker**, 20**16** [Associate Professor of Economics at Colorado College] https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/ AL

While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting. The World Health Organization has determined that **counterfeiting is facilitated where “there is weak** drug **regulatory control and** enforcement; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is **lack of effective intellectual property protection**; due regard is not paid to quality assurance”.[3] [Kristina] According to **INTERPOL estimates**, approximately **30 percent of drugs sold worldwide are counterfeit.**[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from **the World Health Organization**, which **estimates that 10 percent of the global market** for pharmaceuticals **is comprised of counterfeits** and reports place the share in some developing countries as high as 50-70%.[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that **192,000 people are killed in China each year by counterfeit medicines.**[7] According to work done by the International Policy Network, an estimated **700,000 deaths from malaria and tuberculosis are attributable to fake drugs.** [8] The World Health Organization presents a much more modest number noting that malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems poised to prevent a series of recommendations that will undermine public health under the guise of enhancing access. **Without** the **assurance of quality medicines, access is meaningless.** Moreover, while falsely **presenting intellectual property rights as the primary obstacle to global health care**, the High Level Panel **downplays** a host of **other factors that prevent developing country patients** **from getting** the **drugs** they need:  **inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives.** If the United Nations is serious about addressing the critical need for access to medicines, the Secretary General must come to terms with the reality surrounding the challenges of access to medicine. Although the international patent system may be in need of improvement, it is overly simplistic to blame drug patents, international trade agreements and the global pharmaceutical industry for the access problem. The problem is far more nuanced and complicated than portrayed by the High Level Panel. **As the WHO**, OECD and Senator Hatch **recognize, intellectual property rights are part of the solution.** **To truly address the access problem, we must move beyond blaming IPRs and begin the difficult work of grappling with structural deficiencies and poverty.**

**In the context of today’s debate, it must be proven that the resolution would allocate more good for the greatest number of people when compared to the status quo. Thus under the resolution’s circumstances that undermine the world’s safety and security, positive impacts are better met through negating.** **(Move to Opponents Args)** Thus I urge the judge to vote for a negative ballot.