**1AC - Trad**

**I affirm the resolution, Resolved: The Member Nations of the World Trade Organization ought to reduce intellectual property protections for medicines.**

**Framing**

**Definitions:**

#### Intellectual Property Rights:

WTO 21’

"intellectual property (TRIPS) - what are intellectual property rights?." None, None. <https://www.wto.org/english/tratop_e/trips_e/intel1_e.htm> Accessed on August 08, 2021. [No initials set.]  
"Intellectual property rights are the rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time. Intellectual property rights are customarily divided into two main areas: (i) Copyright and rights related to copyright.back to top The rights of authors of literary and artistic works (such as books and other writings, musical compositions, paintings, sculpture, computer programs and films) are protected by copyright, for a minimum period of 50 years after the death of the author. Also protected through copyright and related (sometimes referred to as “neighbouring”) rights are the rights of performers (e.g. actors, singers and musicians), producers of phonograms (sound recordings) and broadcasting organizations. The main social purpose of protection of copyright and related rights is to encourage and reward creative work. (ii) Industrial property.back to top Industrial property can usefully be divided into two main areas: One area can be characterized as the protection of distinctive signs, in particular trademarks (which distinguish the goods or services of one undertaking from those of other undertakings) and geographical indications (which identify a good as originating in a place where a given characteristic of the good is essentially attributable to its geographical origin). The protection of such distinctive signs aims to stimulate and ensure fair competition and to protect consumers, by enabling them to make informed choices between various goods and services. The protection may last indefinitely, provided the sign in question continues to be distinctive. Other types of industrial property are protected primarily to stimulate innovation, design and the creation of technology. In this category fall inventions (protected by patents), industrial designs and trade secrets. The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities. A functioning intellectual property regime should also facilitate the transfer of technology in the form of foreign direct investment, joint ventures and licensing. The protection is usually given for a finite term (typically 20 years in the case of patents). While the basic social objectives of intellectual property protection are as outlined above, it should also be noted that the exclusive rights given are generally subject to a number of limitations and exceptions, aimed at fine-tuning the balance that has to be found between the legitimate interests of right holders and of users."

**Observations:**

According to Cambridge dictionary, reduce is defined as

Cambridge 21’ <https://dictionary.cambridge.org/us/dictionary/english/reduce>.

to become or **to make** something become **smaller in** size, **amount**, degree, importance, etc.: Do nuclear weapons really reduce the risk of war? The plane reduced speed as it approached the airport. My weight reduces when I stop eating sugar. We bought a TV that was reduced from $600 to $400 in their spring sale. I reduced the problem to a few simple questions.

* **This means that Intellectual Property Protections are only being reduced, not removed entirely, reject negative arguments based on the entire removal of IPR. This also means that they cannot specify specific IP protections that would be harmful if removed, because the resolution is a general principle.**

**Framework**

1. **The value is justice, defined as giving each their due.**

#### Finding a fair social structure is most important since the organization of society has a profound impact on an individual’s life path; the primary concern of justice must be to structure institutions such that arbitrary matters do not shape the entirety of someone’s life:

Rawls 85

Rawls 85: John Rawls Harvard Philosophy Professor Justice as Fairness: Political not Metaphysical, Philosophy and Public Affairs, Vol. 14, No. 3. 1985. 176-77.

Many different kinds of things are said to be just [:]and unjust: not only laws, institutions, and social systems, but also particular actions of many kinds, including decisions, judgments, and imputations. We also call the attitudes and dispositions of persons, and persons themselves, just and unjust. Our topic, however, is that of social justice. For us the primary subject of justice is the basic structure of society, or more exactly, the way in which the major social institutions distribute fundamental rights and duties and determine the division of advantages from social cooperation. By major institutions I understand the political constitution and the principal economic and social arrangements. Thus the legal protection of freedom of thought and liberty of conscience, competitive markets, private property in the means of production, and the monogamous family are examples of major social institutions. Taken together as one scheme, the major institutions define men’s rights and duties and influence their life prospects, what they can expect to be and how well they can hope to do. **The basic structure is the primary subject of justice because its effects are so profound and present from the start.** The intuitive notion here is that **this structure contains various** social positions and that men **[people] born into different positions [who] have different expectations of life determined, in part, by the political system as well as by economic and social circumstances.** In this way the **institutions of society favor certain starting places** over others. **These** are especially **deep inequalities.** Not only are they pervasive, but they **affect men’s initial chances in life; yet they cannot** possibly **be justified by** an appeal to the notions of merit or **desert. It is these inequalities,** presumably inevitable in the basic structure of any society, **to which the principles of social justice must** in the **first** instance **apply. These principles,** then, **regulate the choice of** apolitical constitution and **the** main elements of the economic and **social system.** The justice of a social scheme depends essentially on how fundamental rights and duties are assigned and on the economic opportunities and social conditions in the various sectors of society.

**The Value Criterion is Minimizing Structural Violence**

**Prefer**

1. **Structural violence is hidden and embedded, causing it to produce as much damage as direct violence, particularly to marginalized groups.**

**Winter & Leighton 99**

[Deborah DuNann Winter and Dana C. Leighton, Winter is a Professor at Whitman College and Leighton is a Professor at Texas A&M University, “Peace, Conflict, and Violence: Peace Psychology for the 21st Century” 1999, <http://sites.saumag.edu/danaleighton/wp-content/uploads/sites/11/2015/09/SVintro-2.pdf> **- *Last Accessed 8/11/21 @3:45 p.m. - Ownby***

Direct violence is horrific, but its brutality usually gets our attention: we notice it, and often respond to it. **Structural violence**, however, **is** almost always **invisible, embedded in** ubiquitous **social structures, normalized by** stable **institutions** and regular experience. Structural violence **occurs whenever people are disadvantaged** by political, legal, [and] economic or cultural traditions. Because they are longstanding, **structural inequities usually seem ordinary, the way things are and always have been.** The chapters in this section teach us about some important but invisible forms of structural violence, and alert us to the powerful cultural mechanisms that create and maintain them over generations. **Structured inequities produce suffering and death as often as direct violence does,** though the **damage is slower, more subtle, more common, and more difficult to repair. Globally, poverty is correlated with infant mortality, infectious disease, and shortened lifespans.** Whenever people are denied access to society’s resources, physical and psychological violence exists.

1. Prioritizing structural violence is necessary because it compounds exponentially and acts as a threat multiplier, meaning that problems that exist right now, will only continue to get significantly worse if left unchecked.

**Nixon 11**

[Rob Nixon, Professor of English and the Princeton Environmental Institute, “Slow Violence and the Environmentalism of the Poor”, 2011, https://books.google.com/books/about/Slow\_Violence\_and\_the\_Environmentalism\_o.html?id=bTVbUTOsoC8C] **- *Last Accessed 8/11/21 @3:45 p.m. - Ownby***

Three primary concerns animate this book, chief among them my conviction that **we urgently need to rethink-**politically, imaginatively, and theoretically-what I call **"slow violence." By slow violence I mean a violence that occurs gradually and out of sight, a violence of delayed destruction that is dispersed across time and space,** an attritional violence that is typically not viewed as violence at all. Violence is customarily conceived as an event or action that is immediate in time, explosive and spectacular in space, and as erupting into instant sensational visibility. **We need**, I believe, **to engage a different kind of violence, a violence that is neither spectacular nor instantaneous, but rather incremental and accretive, its calamitous repercussions playing out across a range of temporal scales**. In so doing, we also need to engage the representational, narrative, and strategic challenges posed by the relative invisibility of slow violence. Climate change, the thawing cryosphere,toxic drift, biomagnification, deforestation, the radioactive aftermaths of wars, acidifying oceans, and a host of other slowly unfolding environmental catastrophes present formidable representational obstacles that can hinder our efforts to mobilize and act decisively. The long dyings-the staggered and staggeringly discounted casualties, both human and ecological that result from war's toxic aftermaths or climate change-are underrepresented in strategic planning as well as in human memory. Had Summers advocated invading Africa with weapons of mass destruction, his proposal would have fallen under conventional definitions of violence and been perceived as a military or even an imperial invasion. Advocating invading countries with mass forms of slow-motion toxicity, however, requires rethinking our accepted assumptions of violence to include slow violence. **Such a rethinking requires that we complicate conventional assumptions about violence as a highly visible act that is newsworthy because it is event focused, time bound, and body bound. We need to account for how the temporal dispersion of slow violence affects the way we perceive and respond to a variety of social afflictions**-from domestic abuse to posttraumatic stress and, in particular, environmental calamities. A major challenge is representational: how to devise arresting stories, images, and symbols adequate to the pervasive but elusive violence of delayed effects. Crucially, **slow violence is often not just attritional but also exponential, operating as a major threat multiplier; it can fuel long-term, proliferating conflicts in situations where the conditions for sustaining life become increasingly but gradually degraded.** Politically and emotionally, different kinds of disaster possess unequal heft. Falling bodies, burning towers, exploding heads, avalanches, volcanoes, and tsunamis have a visceral, eye-catching and page-turning power that tales of slow violence, unfolding over years, decades, even centuries, cannot match. Stories of toxic buildup, massing greenhouse gases, and accelerated species loss due to ravaged habitats are all cataclysmic, but they are scientifically convoluted cataclysms in which casualties are postponed, often for generations. In an age when the media venerate the spectacular, when public policy is shaped primarily around perceived immediate need, a central question is strategic and representational: how can we convert into image and narrative the disasters that are slow moving and long in the making, disasters that are anonymous and that star nobody, disasters that are attritional and of indifferent interest to the sensation-driven technologies of our image-world? How can we turn the long emergencies of slow violence into stories dramatic enough to rouse public sentiment and warrant political intervention, these emergencies whose repercussions have given rise to some of the most critical challenges of our time?

Case

**Contention 1: Research and Development**

#### Extensive IP restrictions encourage the production of trivial patents that stifle R&D by creating legal minefields.

Lindsey '21

(Brink Lindsey; Lindsey is a vice president at the Niskanen Center, where his research focuses on policy responses to slow growth and high inequality. Prior to joining Niskanen, Lindsey was vice president for research at the Cato Institute. From 2010 to 2012, he was a senior scholar in research and policy at the Ewing Marion Kauffman Foundation.; 6-3-2021; "Why intellectual property and pandemics don’t mix"; https://www.brookings.edu/blog/up-front/2021/06/03/why-intellectual-property-and-pandemics-dont-mix/, Brookings, accessed 7-31-2021; JPark)

When we take the longer view, **we can see a fundamental mismatch between** the policy design of **intellectual property protection and** the policy requirements of **effective pandemic response**. Although patent law, properly restrained, constitutes one important element of a well-designed national innovation system, the way it goes about encouraging technological progress is singularly ill-suited to the emergency conditions of a pandemic or other public health crisis. Securing a TRIPS waiver for COVID-19 vaccines and treatments would thus establish a salutary precedent that, in emergencies of this kind, governments should employ other, more direct means to incentivize the development of new drugs. Here is the basic bargain offered by patent law: encourage the creation of useful new ideas for the long run by slowing the diffusion of useful new ideas in the short run. The second half of the bargain, the half that imposes costs on society, comes from the temporary exclusive rights, or monopoly privileges, that a patent holder enjoys. Under U.S. patent law, for a period of 20 years nobody else can manufacture or sell the patented product without the permission of the patent holder. This allows the patent holder to block competitors from the market, or extract licensing fees before allowing them to enter, and consequently charge above-market prices to its customers. Patent rights thus slow the diffusion of a new invention by restricting output and raising prices. The imposition of these short-run costs, however, can bring net long-term benefits by sharpening the incentives to invent new products. In the absence of patent protection, the prospect of easy imitation by later market entrants can deter would-be innovators from incurring the up-front fixed costs of research and development. But with a guaranteed period of market exclusivity, inventors can proceed with greater confidence that they will be able to recoup their investment. For the tradeoff between costs and benefits to come out positive on net, patent law must strike the right balance. Exclusive rights should be valuable enough to encourage greater innovation, but not so easily granted or extensive in scope or term that this encouragement is outweighed by output restrictions on the patented product and discouragement of downstream innovations dependent on access to the patented technology. Unfortunately, **the** U.S. patent **system** at present **is out of balance.** Over the past few decades, the expansion of patentability to include software and business methods as well as a general relaxation of patenting requirements have led to wildly excessive growth in these temporary monopolies: **the number of patents** granted annually **has skyrocketed** roughly fivefold since the early 1980s. One unfortunate result has been the rise of “non-practicing entities,” better known as **patent trolls**: firms that make nothing themselves but buy up patent portfolios and monetize them through aggressive litigation. As a result, **a law** that is **supposed to encourage innovation has turned into a legal minefield** for many would-be innovators. In the pharmaceutical industry, firms have abused the law by **piling up patents for** trivial, therapeutically **irrelevant “innovations” that allow them to extend** their **monopolies and keep raising prices** long beyond the statutorily contemplated 20 years. Patent law is creating these unintended consequences because policymakers have been caught in an ideological fog that conflates “intellectual property” with actual property rights over physical objects. Enveloped in that fog, they regard any attempts to put limits on patent monopolies as attacks on private property and view ongoing expansions of patent privileges as necessary to keep innovation from grinding to a halt. In fact, patent law is a tool of regulatory policy with the usual tradeoffs between costs and benefits; like all tools, it can be misused, and as with all tools there are some jobs for which other tools are better suited. A well-designed patent system, in which benefits are maximized and costs kept to a minimum, is just one of various policy options that governments can employ to stimulate technological advance—including tax credits for R&D, prizes for targeted inventions, and direct government support.

#### Pharmaceutical innovation is key to protecting against future pandemics, bioterrorism, and antibiotic resistance.

Marjanovic and Fejiao ‘20

Marjanovic, Sonja, and Carolina Feijao. Sonja Marjanovic, Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitive biology, Imperial College London; B.Sc. in biology, University of Lisbon. "Pharmaceutical Innovation for Infectious Disease Management: From Troubleshooting to Sustainable Models of Engagement." (2020). [Quality Control]

As key actors in the healthcare innovation landscape, pharmaceutical and life sci-ences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a **bioterrorism con-text**.1 The general threat to public health that is posed by **antimicrobial resistance** is also **well-recognised** as an area **in need of pharmaceutical innovation**. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and compe-tition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an **indispensable** partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceu-tical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is **essential** for socially responsible companies in the sec-tor.2 It is therefore unsurprising that we are seeing indus-try-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing com-pounds to assess their utility in the fight against COVID-19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating tri-als for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accel-erate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to **benefit patients** and wider **population health**. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be rela-tively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pres-sure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing com-bination product that is being tested for therapeutic poten-tial against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other **infectious diseases**, **bioterror-ism** agents **and antimicrobial resistance**) are **urgently in need of pharmaceutical innovation**, **even if their impacts are not as visible** to society **as COVID**-19 is in the imme-diate term. The pharmaceutical industry has responded to previous public health emergencies associated with infec-tious disease in recent times – for example those associated with Ebola and Zika outbreaks.11 However, it has done so to a lesser scale than for COVID-19 and with contribu-tions from fewer companies. Similarly, levels of activity in response to the threat of antimicrobial resistance are still **low**.12 There are important policy questions as to whether – and how – industry could engage with such public health threats to an even greater extent under improved innova-tion conditions.

#### Marginalized communities are hit hardest by a bioterror attack – current perceptions of public health institutions as unfair hinders effective response due to a lack of trust among disadvantaged populations.

According to professor of medicine David Eisenman and others in 2004, Eisenman, David P; Wold, Cheryl; Setodji, Claude; Hickey, Scot; Lee, Ben; Stein, Bradley D.; Long, Anna (2004). Accessed 9/10/21. “Will Public Health's Response to Terrorism Be Fair? Racial/Ethnic Variations in Perceived Fairness During a Bioterrorist Event. Biosecurity and Bioterrorism: Biodefense Strategy, Practice, and Science”, Vol. 2, No. 3, pgs.146–156. doi:10.1089/bsp.2004.2.146.

The effectiveness of public health institutions during a bioterrorist event may be partially influenced by how they are viewed by **vulnerable populations** in the community. Historical **perceptions of unfairness** in the public health structure on the part of racial and ethnic minorities, undocumented immigrants, or other vulnerable and disenfranchised groups may be an obstacle to **effective responses**. Public health officials charged with preparing and responding to a bioterrorist event can address perceptions of unfairness by continuing to improve relationships with minority communities, including minority community representatives in bioterrorism planning, and employing proven methods for gaining community participation early in their preparedness activities and throughout the response. Addressing provisions of the current welfare and immigration laws may also be important for designing and implementing strategies to ensure an effective response to a bioterrorist attack. Improving perceptions that public health agencies will respond fairly to bioterrorism events will additionally enhance their capacity to deal with emerging natural disease outbreaks.

**Contention 2: Vaccination**

#### Intellectual Property Protections cover vaccines, this makes competition fragile.

**Garrison 04’**

Christopher **Garrison**. “Intellectual Property Rights and Vaccines in Developing Countries.” April 19th 20**04**. <https://www.who.int/intellectualproperty/events/en/Background_paper.pdf?ua=1> // Last Accessed 9/10/21 @10:32 p.m. - Ownby

“In order to recoup these [vaccine development] costs and make a profit, vaccine manufacturers subsequently set a high price for each new vaccine. Exclusive rights to an initial 20-year period following the introduction of the vaccine is protected by patents under the Agreement on Trade Related Aspects of Intellectual Property Rights (also known as the TRIPS Agreement). Patents give the manufacturer exclusive rights to either produce the vaccine themselves or licence production to another manufacturer in return for payment of royalties. Once the patents have expired, other vaccine manufacturers are free to produce the vaccine without payment of royalties. Over time, this leads to competition**, which** in turn maylead to overcapacity and a willingness to sell at a low profit margin.In the meantime, millions of childrens lives are being lost in developing countries, where governments are unable to afford the new vaccines until the price is reduced, 10-20 years later”. This is a pretty damning indictment21. The WHO/WTO document addresses access to patented vaccines in the rather different terms (box 15, p97): Does patent protection restrict access to essential vaccines? Until recently there has been about a 15 year time lag between the introduction of a new vaccine in the developed world, and its uptake in developing countries. Clearly, LEADING GARRISON TO CONCLUDE the higher prices of relatively new vaccines are one of the barriers to their adoption, and royalties do contribute to the cost of vaccine production. However WHO experts note that utilization is no greater for off-patent vaccines than for patented vaccines against the same antigen, even where they are equally effective. This has been shown for hepatitis B and acellular pertussis. Furthermore, the contribution of royalties to selling price is generally in the range of zero to six percent. In general, patent protection does not appear to be a major barrier to current vaccine uptake and utilization in developing countries.”

#### This is key, as recently there is no balance between innovation and availability.

**Oxfam 21’**

[**Oxfam**]. “Intellectual Property and Access to Medicine.” 20**21**. <https://www.oxfamamerica.org/explore/issues/economic-well-being/intellectual-property-and-access-to-medicine/> // Last Accessed 9/10/21 @10:32 p.m. - Ownby

Today, more than two billion people across the developing world lack access to affordable medicines, including many patients in countries negotiating in the Trans-Pacific Partnership (TPP) free trade agreement.Two critical factors limit access to treatment**:** thehigh prices of new medicines, particularly those that are patent-protected, and the lack of medicines and vaccines to treat neglected diseases, a consequence of lack of R&D. Intellectual property (IP) has different forms; in the case of access to medicines, we are talking about patents. Patents are a public policy instrument aimed at stimulating innovation. By providing a monopoly through a patent—which gives inventors an economic advantage—governments seek to provide an incentive for R&D. At the same time, the public benefits from technological advancement. This trade-off underpins patent systems everywhere. **Governments need to maintain an appropriate balance between incentivizing** innovation**,** on the one hand, and, on the other, **ensuring** that new products are widely available**.** High levels of IP protection in developing countries exacerbate, rather than help solve, the problem of access to affordable medicines. Extensivepatent protectionfor new medicines delays the onset of generic competition.And because generic competition is the onlyprovenmethod of reducingmedicinepricesin a sustainable way, suchhigh levels of IP protection are extremely damaging to public healthoutcomes**.**

#### R&D productivity is failing because IPR restricts knowledge access and drives companies away from truly innovative research

**Cimoli et al. 14’**

*(Mario Cimoli, Professor of Economics at the University of Venice (Ca’Foscari), Giovanni Dosi, Professor of Economics and Director of the Institute of Economics at the Scuola Superiore Sant'Anna in Pisa, Keith Maskus, professor of economics and associate dean for social sciences at the University of Colorado, Ruth L. Okediji, Jerome H. Reichman, “Intellectual Property Rights: Legal and Economic Challenges for Development”, 223-225, Google Books)* // Last Accessed 9/10/21 @10:32 p.m. - Ownby

A slightly different question concerns the strengthening of patent regimes. First, it has been noted that reforms of patent laws do not appear to have had a significant impact on the innovative capabilities of industries like the Italian or Japanese pharmaceuticals industries. If anything, patent protection to drugs might have had a negative effect, further weakening national industriesmainly composed of generic producers (Scherer and Weisburst 1995). Conversely, the cases of India, Israel, and partially Brazil are examples where vibrant domestic production of generics has been developed in the absence of patent protection (see, among others: Lanjouw, 1998a; Ramani and Maria, 2005; and Chaudhuri, 2005). Here, the little evidence available so far suggests that the introduction of TRIPS might have deleterious effects, without promoting indigenous innovative activities. A few Indian companies are actually trying to enter the club of innovative firms, with mixed results thus far. On the other hand, while evidence does not yet show and dramatic shake-out of local producers of generics, most analysts seem to agree that a substantial restructuring is bound to occur. Similarly, data concerning the Brazilian case show a marked increase in domestic patenting activities, which is, however, due almost exclusively to foreign multinationals (Laforgia et al., 2008). These insights are confirmed by other studies, which suggest that the relationship between innovation and the strength of IPR regime has an inverted U-shape. With specific reference to pharmaceuticals, Qian (2007) examines the effects of patent protection on pharmaceutical innovations for twenty-six countries that established pharmaceutical patent laws during the period 1978 to 2002. Controlling for country characteristics through matched sampling techniques she finds that national patent protection alone does not stimulate domestic innovation. Domestic innovation accelerates in countries with higher levels of economic development, educational attainment, and economic freedom. But, if anything, above a threshold further enhancement of IPRs actually reduces innovative activities. In sum there are strong reasons to doubt that strengthening IPRs—especially in developing countries—would have a positive impact on domestic innovative activities. Such an effect presumes sufficient scientific and technological capabilities access to knowledge and active participation in research networks, and large domestic markets and/or the ability to export. Conversely, stronger IPRs might possibly make life more difficult to local brands and generics producers, especially if data-exclusivity agreements and patentability for second use provisions are enforced. Similarly, there is so far no evidence that stronger IPRs in developing countries have introduced incentives for developing drugs for local diseases—for example, malaria. Decisions concerning the direction of innovative activities are still influenced by considerations of profitability, both by local and foreign innovators (Ramani and Maria, 2005). Finally it is important to notice that over the last two decades the productivity of R&D and the innovative performance of the industry have been failing. Despite the enormous opportunities opened by the “molecular biology revolution” since the mid 1970s and in a period when the patent regime was becoming increasingly stronger, R&D expenditures have increased tenfold while patenting output increased only sevenfold since 1978 (Nightingale and Martin, 2004). The number of New Chemical Entities (NCE) approved by the FDA in the USA has been declining since the early 1990. Similarly, Pisano (2006) shows that the number of compounds developed by commercial organizations that have progressed at least to human clinical testing has not increased significantly since the advent of the biotechnology revolution. Moreover, only a half of NME approvals result from “priority” NMEs—those judged by the FDA to provide “a significant therapeutic or public health advance” over existing drugs—and only about one-third of new-drug applications submitted to the FDA are for new molecular entities. Most of the rest are either for reformulations or incremental modifications of existing drugs or for new “only-label” uses. The issue remains, however, hotly contested, given that these kinds of drugs do sometimes entail significant benefits. Various explanations have been suggested to explain the “falling productivity” paradox. Some interpretations are relatively optimistic, emphasizing that the production of new drugs is characterized by strong cyclical components. The current downswing might therefore be considered as a temporary phenomenon. Other explanations point to either more stringent regulation, or to an intrinsic difficulty in discovering new drugs for increasingly complex pathologies (signaling an incumbent “maturity” of the industry, see Nightingale and Martin, 2004). In a more radical stance, it is suggested that large pharmaceutical companies have moved away from truly innovative research, either developing compounds originating from basic research conducted at universities, hospitals and biotechnology companies (one third of new drugs) or concentrating on the development of me-too drugs and minor improvements upon existing products. According to this interpretation, now big pharma does little more than serve as a manufacturing and especially marketing organization, exploiting knowledge generated by public research and biotechnology firms.

#### IPR creates barriers for access to COVID-19 Vaccine for developing countries

**Sariola 21** [Salla, BMJ Global Health, "Intellectual Property Rights Need to be Subverted to Ensure  Global Vaccine Access" April. 1 https://www.ncbi.nlm.nih.gov/pmc/articles/PMC8021739/

IPRs block global vaccine access in two ways**.** First, IPRs legitimate the pharmaceutical industry to make exclusive decisions to whom vaccines are sold and at what price. Under the Trade Related Intellectual Property Rights Agreement (TRIPS) by WTO, companies that own the intellectual property hold exclusive rights to produce vaccines without competing generic products on the market. This way, they are able to keep a foothold of the markets and the prices high, as there is little competition over similar products. Vaccines currently on the market have been priced such that developing countries cannot afford them. Prices may also vary depending on the contract: for example, contradictory to **a social** justice logic, the AstraZeneca vaccine was sold to South Africa at $5.25 per dose but to EU at a lower rate of $2.16.3 The second reason follows from the first. Availability of vaccines at national level is made possible via bilateral prepurchase agreements between vaccine producers and countries or regions, such as the European Union or the African Union. The African Union, with the help of the African Export-Import Bank, has negotiated an agreement to prefinance 670 million doses of vaccines while African countries pool their funds,4 but still, very few low-income countries have contracts that would provide sufficient volumes to cover their entire populations. **In short,** different countries are not on an equal footing on funding and networks in the negotiations, and the African Union has been a low priority.

#### [1] Happiness is subjective – what makes you happy might not make me happy and vice versa, which proves that a) it’s impossible to come to objective moral conclusions under util, and b) util can justify any action insofar as it’s subjective.

#### [2] Util is racist because it argues we ought to do what benefits the largest number of people. However, considering the majority of the U.S. is white, the interest of white people would be valued over that of minorities.

#### [3] There’s no brightline for impact weighing – I might think that bodily pain is worse than financial insecurity, but lots of people disagree, which proves that we can weigh impacts slightly differently and come out to completely contradictory conclusions – that means you should automatically reject their framework because it’s impossible to ever use *insofar as aggregating pleasure and pain is impossible*.

#### [4] *Rights are inviolable – I can't just go and murder some innocent person on the street to harvest their organs to save 3 lives via transplants, even though I would be saving more lives than ending so it’s a good under util*.

#### [5] It’s not plausible to sit and calculate all the potential consequences of your action, consider all the possible alternative courses of action, and then do the same for all those other actions, which proves util cannot create binding obligations because we can’t be expected to do a utilitarian calculus every time we act.

#### Reforming the Patent Process would lower Drug Prices and incentivize Pharma Innovation by revitalizing the Market.

Stanbrook 13, Matthew B. "Limiting “evergreening” for a better balance of drug innovation incentives." (2013): 939-939. (MD (University of Toronto) PhD (University of Toronto))//Elmer

At issue in the Indian case was “evergreening,” a now widespread practice by the pharmaceutical industry designed to extend the monopoly on an existing drug by modifying it and seeking new patents.2 Currently, half of all drugs patented in Canada have multiple subsequent patents, extending the lifetime of the original patent by about 8 years.3 Manufacturers, in defence of these practices, predictably tout the advantages of new versions of their products, which often represent more potent isomers or salts of the original drugs, longer-lasting formulations or improved delivery systems that make adherence easier or more convenient. But the new versions are by definition “**me too” drugs**, and demonstration that the resulting **incremental benefits** in efficacy and safety are clinically meaningful **is often lacking**. Moreover, the original drugs have often been “blockbusters” used for years to improve the health of millions of patients. It seems hard to argue convincingly why such beneficial drugs require an upgrade, often just before their patents expire. Rather than the marginal benefits accrued from tinkering with already effective agents, patients worldwide are in desperate need of new classes of pharmaceuticals for the great many health conditions for which treatments are presently inadequate or entirely lacking. But developing truly innovative drugs is undeniably a high-risk venture. It is important and necessary that pharmaceutical companies continue to take these risks, because they are usually the only entities with sufficient resources to do so. Therefore, companies must continue to perceive **sufficient incentives** to continue investing in innovation. Indeed, there is evidence that the prospect of future evergreening has become part of the incentive calculation for innovative drug development.4 But surely it is perverse to extend unpredictably a period of patent protection that the government intended to be clearly defined and predictable, and to maintain incentives that drive companies to divert their **drug-development resources away from innovation**. **Current patent legislation may not be optimal** for striking the right balance between encouraging innovation and facilitating profiteering. Given the broad societal importance of patent legislation, ongoing research to enable active governance of this issue should be a national priority. In the last decade, Canada’s laws have been among the friendliest toward evergreening in the world.5 We should now reflect on whether this is really in our national interest. Governments, including Canada’s, would do well to take inspiration from India’s example and tighten regulations that currently facilitate evergreening. This might involve **denying future patents for modifications** that currently would receive one. An overall reduction in the duration of all secondary patents on a therapy might also be considered. Globally, a more flexible and individualized approach to the length of drug patents might be a more effective strategy to align corporate incentives with population health needs. Limits on evergreening would likely reduce the **extensive patent litigation** that contributes to the **high prices of generic drugs** in Canada.3 Reducing economic pressure on generic drug companies may facilitate current provincial initiatives to lower generic drug prices. As opportunities to generate revenue from evergreening are eliminated, research-based pharmaceutical companies would be left with no choice but to invest more in innovative drug development to maintain their profits.

#### IPR doesn’t solve innovation

Main 9 (Sherry Main is Chief Communications & Marketing Officer at University of California, Santa Cruz, with degrees from Harvard and John F. Kennedy School of Government. “Study Finds Patents Systems May Discourage Innovation” 7/27/2009. https://phys.org/news/2009-07-patent-discourage.html)

(PhysOrg.com) -- A new study challenges the traditional view that patents foster innovation, suggesting instead that they may hinder technological progress, economic activity and societal wealth. These results could have important policy implications, because many countries count on patent systems to spur new technology and promote economic growth**.**∂ To examine the effect of patents on technological innovation, Bill Tomlinson of UC Irvine’s Donald Bren School of Information and Computer Sciences and Andrew Torrance of the University of Kansas School of Law developed an online game simulating the U.S. patent system.∂ PatentSim features an abstract model of the innovation process, a database of potential innovations and a network through which users can interact with one another to license, assign, buy, infringe and enforce patents. The software allows players to simulate the innovation process under a traditional patent system; a “commons” system, in which no patent protection is available; or a system with both patents and open-source protection.∂ “In PatentSim, we found that the patent system did not work to spur innovation,” said Tomlinson, associate professor of informatics. “In fact, participants were more likely to innovate when there was no intellectual property protection at all, or when they could open-source their innovations and share them with other people.”∂ The researchers measured the efficacy of the three systems based on innovation, the number of inventions; productivity, a measure of economic activity; and societal wealth, the ability to generate money.∂ Players were first-year law students who had never had intellectual property coursework. Tomlinson and Torrance plan further studies with subjects of different backgrounds, including M.B.A. students at Harvard University.∂ **“**Current patent laws are based on century-old assumptions that patents spur technological progress, and few have questioned this,” said Torrance, associate professor of law. “If it turns out that our laws are based upon misinformation and bad assumptions, society may be failing to promote beneficial new technologies that could improve quality of life.**”**

## AT: No LDC Production

#### Reducing IP allows generic manufacturers to create affordable alternatives. According to pharmaceutical researcher Victoria Rees in 2019, the top 5 generic manufacturers are based India, Germany, Netherlands, and Israel. LDCs are not producing the medications – their evidence is non-responsive.

Rees ’19 Victoria Rees, “Top five generic drug makers,” European Pharmaceutical Review. Published 12 July 2019. Accessed 9/11/2021. https://www.europeanpharmaceuticalreview.com/article/93095/top-five-generic-drug-makers/.

The demand for generic drugs is increasing worldwide and pharmaceutical companies are realising the great potential this opportunity affords. Efficient and inexpensive drugs are always needed, making this a growing market for drug makers. The global market for generic drugs is projected to rise at a compound annual growth rate (CAGR) of 8.7 percent; meaning that, in the forecast period 2016 to 2021, the global market will increase from $352 billion to $533 billion.1 In this article, the top five generic drug makers are listed by total revenue, measured in the financial year (FY) 2018. Counting down, they are as follows: 5. Lupin Pharmaceuticals – $2.3 billion2 This pharmaceutical company is based in Mumbai, India. Lupin Pharmaceuticals is a subsidiary of Lupin Limited and one of the top five pharmaceutical companies in the country, making it a key player in the industry. The company was founded in 1968 and while its main focus is generic drugs, it also manufactures branded medications and active pharmaceutical ingredients (API).3 The company’s research programme covers the entire pharma product chain and their R&D department contains 1,400 employees. The drugs produced by Lupin reportedly reach 70 countries, yet their ambitions are greater; Lupin is looking to expand into the US market as, according to the company, they are well positioned to grow.4 On-Demand Webinar: Variable pathlength spectroscopy for dilution-free concentration measurement in GMP environments During the free one-hour session, our industry expert Dean Barton reviews VPT and how it can be used in various applications, from protein therapeutics to gene therapy. We also share real-world case studies demonstrating how companies have integrated the SoloVPE system into their manufacturing workflow for release and in-process testing. WATCH NOW Vinita Gupta, CEO of Lupin Pharmaceuticals, Inc. says: “founded on the strengths of our parent company Lupin Limited, Lupin Pharmaceuticals, Inc. intends to bring a portfolio of generics as well as branded products to the US market.” 4. Sun Pharmaceuticals – $4 billion5 Sun Pharmaceuticals, also headquartered in Mumbai, has over 2,000 marketed products and over 30,000 employees worldwide.6 According to Sun Pharmaceuticals, they have built a portfolio of about 10 speciality products, five of which are already on the market. They expect that this side of their business will be a key driver in the coming financial year.5 In addition to being a leading generic drug maker, the company also provides a range of APIs. They invest heavily in R&D, using around 7-8 percent of their annual revenues to improve this side of their business. Sun Pharma’s R&D productivity is ranked one of the highest for Indian generic companies.7 Established in 1983, Sun Pharma sold products across India before expanding internationally in 1996.8 Dilip Shanghvi, Managing Director of Sun Pharmaceuticals, said: “The US generics market has been an important driver of growth and profitability for Indian pharmaceutical companies between 2005-15. However, now with the changed dynamics, the importance of other markets has increased. It has also become imperative for companies to identify new engines of growth and invest more in innovation. It is in this context that Sun Pharma has been investing in building its global speciality business since the last few years. Through this initiative we are trying to gradually move up in the pharmaceutical value chain.” 3. Sandoz – $9.9 billion9 Sandoz is a generic and biosimilar producer division of the Novartis Group. With their products reaching an estimated 520 million patients worldwide, the company aims to reduce costs of medications as widely as possible. Headquartered in Munich, Germany,10 the company merged with Ciba-Geigy in 1996 to form Novartis. They are the leading provider of biosimilars and generic antibiotics.11 In January 2019, the company announced that it had been certified as a ‘Top Global Employer’.12 According to the company, a planned transformation for Sandoz through Novartis is expected to enable them to compete effectively in a more challenging environment by increasing their share of higher-margin differentiated products.9 Sandoz are the leading provider of biosimilars and generic antibiotics Vas Narasimhan, CEO of Novartis during FY 2018, said: “In 2018… We took major steps towards becoming a medicines company that focuses its capital on developing, launching and creating global access to breakthrough medicines. Together with delivering strong accretive growth, we also advanced our strategic priorities including building new advanced therapy platforms, ramping up productivity and digital efforts and creating a new culture. Looking ahead, we expect to sustain top- and bottom-line growth driven by the strength of our in-line brands and our exciting line-up of 10 potential blockbuster launches by 2020.” 2. Mylan NV – $4 billion13 This pharmaceutical company operates in over 165 countries, with approximately 35,000 employees worldwide. Mylan has more than 7,500 products in its portfolio and 12 R&D centres.14 Founded in 1961 in West Virginia, Mylan is now registered in the Netherlands. It also has principal offices in Hertfordshire, UK and Pennsylvania, US. The brand deals with generic drugs but also handles branded generic, brand-name and biosimilar medications. As the second largest provider of prescriptions in the US,15 the company has a large portfolio. According to Mylan, the majority of their products sold in the US are also manufactured in the US. Through several acquisitions, Mylan has expanded over the years to become an established provider of generic drugs. “Our business model is predicated on prioritising long-term sustainable growth. Therefore, we will be making incremental investments in our sales and marketing and research and development efforts.”Mylan CEO Heather Bresch commented: “Looking forward, I can confidently say, through leveraging the diversification across our commercial, operational and scientific platforms, we feel incredibly positive about our ability to deliver a strong top-line financial performance in 2019. Specifically, we expect to generate total revenues of between $11.5 billion and $12.5 billion, reflecting top-line growth across all three of our geographic segments. 1. Teva Pharmaceutical Industries Ltd – $18.9 billion16 Based in Jerusalem, Israel, Teva is the world’s leading generic drug maker; yet it’s also active in ventures that include APIs. The business has 43,000 employees globally. In 2018, Teva produced 120 billion tablets with one in nine generic prescriptions in the US containing the company’s products.17 Despite its global position, Teva says that it has a unique understanding of local markets. Founded in 1901, Teva began as a small wholesale drug business distributing imported medications. In the 1980s, it then expanded internationally and entered the US market.18 With a speciality R&D programme, the company says it has a “robust pipeline” of high-value medications. Teva is the world’s leading generic drug maker Mr Kåre Schultz, Teva’s President and CEO, said: “2018 was the first year of our restructuring plan and we have met or exceeded all of our key financial targets for the year. The full year yielded a cost base reduction of $2.2 billion, exceeding our 2018 target and we are well on track to deliver the total $3.0 billion reduction in 2019 as compared to the 2017 spend base. “Looking ahead, we continue to expect that 2019 will be the trough for our business, a year in which we will experience similar challenges to those of 2018… Throughout the year, we will continue to execute against our restructuring plan goals, including the optimisation of our global portfolio and network.” Conclusion Generic drug makers have vast potential in the market and, due to high demand for generics, significant profits exist to return investments. Opportunities for these companies provide potential for even greater growth in the future, with the market set to increase soon.