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## Contention 1 - Innovation DA

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#### Costs for R&D are increasing, requiring increasing drug prices as well.

**WTO 20** [World Trade Organization, 2020, “Promoting Access to Medical Technologies and Innovation”, World Trade Organization, https://www.wto.org/english/res\_e/booksp\_e/who-wipo-wto\_2020\_e.pdf]/Triumph Debate

Costs of pharmaceutical R&D can be viewed in various ways. “Out-of-pocket” costs describe actual cash expenditures by the developer. These costs can be further risk adjusted to account for the cost of a failed drug candidate. The costs can also be “capitalized”; capitalized costs include the theoretical losses incurred from investing in pharmaceutical R&D instead of an alternative investment that would have earned returns at a certain percentage over the years before the R&D yields a successful product. **One series of studies has estimated the cost of bringing an [new drug] to market was US$ 114 million (US$ 231 million capitalized) in 1987, US$ 403 million (US$ 802 million capitalized) in 2000, and US$ 1.4 billion (US$ 2.6 billion capitalized) in 2013** (DiMasi et al., 1991; DiMasi et al., 2003; DiMasi et al., 2016). Both lower and higher estimates are available, ranging from US$ 100 million to US$ 5 billion (DNDi, 2014; Morgan et al., 2011; Herper, 2012; Prasad and Mailankody, 2017). **In some disease areas, returns on R&D investments can be very large;** for example, in oncology, for drugs approved during the period 1989– 2017, **sales of final products brought in US$ 14.50 for every US$ 1.00 invested in R&D** (Tay-Teo et al., 2019).

#### Patents protect 80% of revenue for pharma - removing them combined with increasing R+D costs guts their financial solvency and ability to make drugs.

**CRS 12** [CRS, 10/28/2021, “Drug Patent Expirations: Potential Effects on Pharmaceutical Innovation”, Congressional Research Service, https://www.everycrsreport.com/files/20121128\_R42399\_8beca70723872957efe4a267a5ae0df4805469ad.pdf] /Triumph Debate

A critical component of many of these federal efforts concerns patents.3 **Patent ownership can provide an economic incentive for companies to take the results of research and make the often substantial investment necessary to bring new goods and services** to the marketplace**.** The grant of a patent provides the inventor with a mechanism to capture the returns to his invention through exclusive rights on its practice for a limited time. In the pharmaceutical industry, patents are perceived as particularly important to innovation due, in part, to the ease of duplicating the invention. **Recently, patents on a significant number of “blockbuster”4 drugs have expired.** At the end of 2011, Lipitor, with 2010 retail sales in the United States of $5.8 billion5 and the world’s best selling medication, lost patent protection. Between 2012 and 2016, branded pharmaceuticals with an estimated $117.2 billion in U.S. sales are expected to go off patent.6 **Once patent protection is lost, these drugs are expected to lose up to 80% of the revenue generated for the innovator companies. “In the case of the top selling drugs, generics are capturing most of the market within weeks of their launch.”**7 Innovator companies depend on the funds generated from sales of blockbuster drugs to invest in additional R&D leading to new products that can improve the health and welfare of the public. **At the same time, generic versions of these pharmaceuticals benefit the public due to their lower cost and greater availability;** according to one estimate, **over the 10 years between 2001 and 2010, generic drugs “saved the U.S. health care system more than $931 billion.**”8 However, “while consumers and companies [that] provide health benefits could gain from the substantial slashes in costs, big pharma has to look at new ways and strategies to fill the [revenue] gap” created by the unprecedented number of patent expirations on blockbuster drugs.

#### Thus, higher drug prices are justified - removing them would collapse the pharma industry and complete destroy innovation

**Mullainathan 17** [Sendhil Mullainathan, University Professor of Computation and Behavioral Science at Chicago Booth, 6-30-2017, "High Drug Prices Are Bad. Cutting Them Could Be Worse. (Published 2017)," No Publication, <https://www.nytimes.com/2017/06/30/upshot/high-drug-prices-are-bad-cutting-them-could-be-worse.html>]/Kankee

High drug prices are harmful. Medical costs and out-of-pocket expenses result in high rates of bankruptcies, and 10-25 percent of patients either delay, abandon or compromise treatments because of financial constraints. Survival is also compromised. For example, in chronic myeloid leukemia, the 8-10 year survival rate is 80 percent in Europe (where treatment is universally affordable); in the U.S., where finances may limit access to drugs, the 5-year survival is 60 percent. In surveys, 78 percent of Americans worry most about costs of drugs. Sadly, three years after the issue was raised, there has been little progress. The problem is compounded by 2 additional factors. First is the increasing shift in the cost of care and drugs to patients. Insurers justify this "skin-in-the-game" strategy as effective in reducing costs, but the high out-of-pocket expenses have turned this into "deterrence-in-the-game," discouraging patients from seeking care or purchasing drugs. In a recent survey, one-third of insured Texans delayed or did not pursue care because of high out-of-pocket expenses. Second is the spill-over of high drug prices to generics. Complex regulatory issues and shortages allow companies to increase prices of generics to levels as high as patented drugs. The latest scandals – Turing, Valiant and Mylan – are only the most extreme examples of a common strategy in pricing drugs. Generic Imatinib to treat chronic myeloid leukemia is priced at $5,000-8,000/year in Canada, $400/year in India, but $140,000/year in the U.S. For generic drugs to be priced low, four to five generics have to be available. The average cost of filing for FDA approval of a drug is $5 million in 2016, and the average time to approval is 4 years. There are currently more than 3,800 generic drug applications awaiting FDA action. The FDA should overhaul its procedures to reduce the cost of filing to less than $1 million per drug, reduce the timeline to approval to 6-12 months and monitor for the availability of multiple generics at all times. Because industry pays for a large share of research, high drug prices do not just generate profits; they also become a funding source for important scientific work. In some cases, the experimental drugs that provide meager benefits to the patients taking them are indirectly providing a much broader public good. Take Inclisiran, a drug that recently completed Phase 2 trials in which it showed remarkable reductions in LDL cholesterol levels. Since cholesterol levels are only a marker for disease, more trials are needed to determine how the drug actually affects more consequential outcomes such as heart attacks and strokes. It’s possible that these future trials will yield disappointing news: Cholesterol reductions may simply not translate into particularly impressive health benefits. Yet whatever its ultimate health benefits turn out to be, Inclisiran is anything but incremental. To the contrary, it is cutting edge in one important way. It relies on a novel mechanism for producing its effects, directly targeting genes that are known to increase cholesterol levels via a mechanism known as RNA interference. Biologists have known about RNA interference for some time: Andrew Z. Fire and Craig C. Mello shared the 2006 Nobel Prize for their 1998 work on it. But translating these insights into medical advances is an arduous process. The Inclisiran effort is not only one of the largest drug trials that exploits this mechanism, but it also manages to target an ailment that afflicts a broad swath of the population. In short, the drug’s ultimate value cannot be measured in its immediate benefits to patients alone. The research that went into this drug — from basic science all the way through to the clinical trial — can have **ripple effects**. Work like this expands our understanding of how to harness a biological mechanism into a practical therapeutic. Who knows how many **unexpected therapeutics** based on RNA interference will build on the lessons learned in the process of producing this and other drugs like it? Research is not just about what is discovered but facilitating others’ discovery. Groundbreaking work is needed to lay the foundation for someone else’s skyscraper: The wonder drugs of today are built on previous failures and marginal successes. Perversely, curbing prices risks squeezing out this kind of innovation. The consequences will not be felt today, but it could be a **disaster** in years to come. Constrict that **research pipeline**, and we reduce our chance of future **breakthroughs**. Of course, research that benefits many others, not just the researcher, is exactly what government should be funding. Such research is a **public good**, yet we are relying largely on the private sector to provide it. Huge pharmaceutical profits from overpriced drugs are an extremely indirect way to fund the foundational research. Now let me be clear. I am not supporting the current setup. It’s an extremely indirect and wasteful way to build the foundation of knowledge. Most of the additional profits from overly lucrative drugs go elsewhere, not to research. Even the dollars that are funneled toward research and development do not go toward the cutting-edge foundational research that others can build upon. Worst of all, even when the money does go toward such research, no one else may ever benefit from it. The Inclisiran trial was published in The New England Journal of Medicine, but pharmaceutical research is not always so public: Results may never be published. Hidden discoveries or failures do not contribute to the public good. Despite these glaring problems, current policy choices must confront the real world we are living in. In the current situation, drug pricing and research funding are **intertwined**. This link is only becoming more important. But, unfortunately, the Trump administration has been considering an executive order that eases regulations on drug companies, even as it has proposed cuts in federal funding for drug research. The net effect would increase our reliance on private companies to provide public research. Instead, we should look to cut drug prices, but couple those cuts with increased funding, in some form, for work on novel drugs that lay the foundation for future discoveries. While the current setup may be a foolish way of funding research, it would be much worse to have no funding at all.

#### Protecting patents are necessary for a few reasons:

#### 1] Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies

**Ezell and Cory 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

IPRs Strengthen Innovation

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46

IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that *without protection from potential abuse of their newly developed technologies*, foreign *enterprises may be less willing to reveal technical information associated with their innovations*.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development. The relationship between IPR rights and innovation can also be seen in studies of how the introduction of stronger IPR laws, with regard to patents, copyrights, and trademarks, affect R&D in an economy. Studies by Varsakelis and by Kanwar and Evenson found that and are conditional on other factors.53 Cavazos Cepeda et al. found a positive influence of IPRs on the level of R&D in an economy, with each 1 percent increase in the level of protection of IPRs in an economy (as measured by improvements to a country’s score in the Patent Rights Index) equating to, on average, a 0.7 percent increase in the domestic level of R&D.54 Likewise, a 1 percent increase in copyright protection was associated with a 3.3 percent increase in domestic R&D. Similarly, when trademark protection increased by 1 percent, there was an associated R&D increase of 1.4 percent. As the authors concluded, “Increases in the protection of the IPRs carried economic benefits in the form of higher inflows of FDI, and increases in the levels of both domestically conducted R&D and service imports as measured by licensing fees.”55 As Jackson summarized, regarding the relationship between IPR reform and both innovation and R&D, and FDI, “In addition to spurring domestic innovation, strong intellectual property rights can increase incentives for foreign direct investment which in turn also leads to economic growth.”56

#### 2] Continuing Biopharmaceutical innovation is key to prevent future pandemics and bioterror

**Marjanovic and Feijao 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences 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 context.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 competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, mak[ing] 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 pharmaceutical 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 sector. 2 It is therefore unsurprising that we are seeing industry-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 compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials 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 accelerate 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 relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure 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 combination product that is being tested for therapeutic potential 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, bioterrorism 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 immediate term. The pharmaceutical industry has responded to previous public health emergencies associated with infectious 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 contributions 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 innovation conditions.

#### A] That causes extinction

**Millett & Snyder-Beattie ‘17**. Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to **remote populations**, overcome **rare genetic resistances**, and **evade detection**, cures, and **countermeasures**. Even evolution itself may work in humanity's favor: **Virulence and transmission is often a trade-off**, and so **evolutionary pressures** could push against maximally lethal wild-type pathogens.5,6 While skeptic arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include **native American tribes** exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But **many diseases are proof** of principle that **each worst-case attribute can be realized independently**. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, **natural evolution** would be an **unlikely** source for pathogens with the **highest possible levels of transmissibility, virulence, and global reach**. But **advances in biotech**nology might allow the creation of diseases that **combine such traits**. Recent controversy has **already emerged** over a number of **scientific experiments** that resulted in viruses with enhanced **transmissibility**, **lethality**, and/or the ability to overcome **therapeutics**.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and **m**utually **a**ssured **d**estruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

## Contention 2 – Debt Ceiling DA

1:30

#### Debt ceiling passes now despite fights, but any more GOP backlash derails the bill

Bartholomeusz August 5th [Stephen Bartholomeusz, associate editor and senior columnist at The Australian covering business and politics, 8-5-2021, "America has hit its debt ceiling, and the ‘X-date’ looms large," Sydney Morning Herald, https://www.smh.com.au/business/banking-and-finance/america-has-hit-its-debt-ceiling-and-the-x-date-looms-large-20210805-p58g42.html]/Kankee

The US Treasury has started emergency cash conservation measures after the government reached its debt ceiling on Monday. The Biden administration is now facing an intense partisan brawl as it seeks to head off a US default on its debts. To say it upfront, it’s pretty unlikely that the US will actually default, however technically, on its $US28.5 trillion ($38.6 trillion) of borrowings. There has been regular congressional wrangling over the debt ceiling in the past, most notably in 2011 during the Obama administration when the Republicans refused to raise it without significant spending cuts. But there’s never been a default. However, looking at the debt brawls of the past, expect to see some brinkmanship manoeuvres again this time. The 2011 impasse was ultimately resolved, with Democrat concessions, it did lead to Standard & Poor’s downgrading US government debt for the first time in history. There were also government shutdowns in 2013 and 2018 – the government closed down non-essential services, closed national parks and federal institutions and sent federal employees on forced leave – and a 35-day shutdown in 2018 over Donald Trump’s demand for $US5.7 billion of funds for his controversial wall on America’s southern border. There is some hypocrisy in the Republicans’ attempt to use the leverage of the debt ceiling this time to try and force the Democrats to reduce spending on programs like Medicare and social security. They are demanding “structural” and “institutional” reforms to spending in exchange for agreeing to raise the debt ceiling. In 2019 the Democrats agreed to suspend the then-$US22 trillion debt ceiling for two years and allow government debt between then and July 31 this year to be incorporated into a new ceiling, which turned out to be the $US28.5 trillion it hit at the start of this week. Most of that debt relates to spending by the Trump administration. When Trump took office in 2016, US government debt was just below $US20 trillion. By the time he departed in January it was, thanks to his massive tax cuts and increased spending, some of it pandemic-related, more than $US27 trillion. While the Biden administration has an ambitious spending agenda – it launched a $US1.9 trillion pandemic relief program of its own, has a $US1 trillion infrastructure program before Congress and plans a $US3.5 trillion budget (albeit largely funded by tax increases) -- much of its spending has yet to occur. Treasury’s initial response to hitting the debt ceiling has been to run down its cash reserves to avoid issuing new debt, selling some investments and ceasing to make contributions to some government employee retirement funds. The decision to reduce its cash reserves from $US1.6 trillion earlier this year to about $US450 billion now has - along with the cessation of new issues of Treasury securities and a lengthening of the maturity profile of its borrowings - been cited as a factor in the massive infusions of liquidity into the US financial system that has created a shortage of Treasury bills and driven short-term US Treasury yields down to near-zero this year, despite historically high inflation numbers. That cash and liquidity has been flowing, via the government, into the US economy and banking system and, because of the surplus of liquidity in the system, has been parked overnight at the US Federal Reserve at record levels. It might also have had an influence on the US stockmarket, given that the continuing slide in yields has further reduced the alternatives for even barely-positive returns. Treasury Secretary Janet Yellen has suspended new debt issuance from Monday until at least the end of September. The Congressional Budget Office has estimated that, even with the extraordinary measures to conserve cash, the government is likely to run out of cash in October or, at the latest, November. If that were to happen, the US would be unable to pay the interest on its debts – now running at about $US300 billion a year -- and would be in technical default. [is] improbable, even though there are some Republicans who profess to be unfussed by that prospect and Trump himself, citing his own personal experience with debt, once suggested that as president he would keep borrowing, knowing that if the economy crashed “you could make a deal” with creditors to buy back US bonds at a discount. A resolution that raises the debt ceiling is likely, via either political manoeuvrings by the Democrats, who might be able to use the budget “reconciliation” process to pass it with a simple majority, or through Democrat concessions on social spending. But it is likely that the aggressively partisan and uncooperative stance the Republicans have adopted in response to the Democrats’ election victory will drag the process out to the eleventh hour. That wouldn’t be good for financial markets. Past shutdowns have hurt the economy and financial markets, and the closer Congress gets to the “X-date” -- the moment there would be a default – the more volatile markets are likely to be. Given that the US bond market, and the short end of it in particular, provides the key benchmarks for global debt, the impact of the shutdown and how and when it might be resolved -- or not -- has global implications. In previous shutdowns there has been, paradoxically, floods of money into short-term government debt in a rather peculiar version of a “flight to safety.“ Another phenomenon of past shutdowns has been an avoidance by investors of Treasury securities expiring during the shutdown period, which caused some aberrative trading within the bond market. If investors took the risk of default seriously, of course, yields could be expected to spike – and the US sharemarket to fall – as people cashed out of the market to avoid losses. The ripples from that would be significant and would flow through international markets and financial systems. The “domestic” US politicians are now engaged in is occurring at a vulnerable moment for the US and global economies, given the new threats to the world’s largest economy posed by the spread of the Delta version of the coronavirus. Signs are the developed world is already past the peak in the recovery from the economic effects of the pandemic. Yellen has said that a failure to increase the debt limit would have “absolutely catastrophic economic consequences” and could ignite a financial crisis. Hopefully sanity will prevail - but in the Trump era of US politics and with a Republican party whose make-up is very different to its predecessors, nothing can be taken for granted.

#### Even small changes make pharma companies fear patent reform

Asgari et al. 21 [Nikou Asgari, markets reporter for the Financial Times, Donato Paolo Mancini, FT's pharma reporter, and Hannah Kuchler, FT’s global pharmaceutical correspondent, 05-06-2021, "Pharma industry fears Biden’s patent move sets precedent," FT, https://amp.ft.com/content/f54bf71b-87be-4290-9c95-4d110eec7a90]/Kankee

Profits in the pharmaceutical industry are protected by a fortress of patents that guarantee drugmakers a stream of income until they expire. On Wednesday, Joe Biden[‘s] broke with decades of US orthodoxy and made a crack in the wall. His administration’s decision to support a temporary waiver of Covid-19 vaccine patents prompted instant outrage in the pharmaceutical sector, which argues that the move rides roughshod over their intellectual property rights and will discourage US innovation while sending jobs abroad. “Intellectual property is the lifeblood of biotech, it’s like oxygen to our industry,” said Brad Loncar, a biotech investor. “If you take it away, you don’t have a biotech sector.” Biden’s top trade adviser Katherine Tai said that while the US government still “believes strongly” in intellectual property protections, it supported waiving patents for Covid-19 vaccines to help boost global production of jabs. The move comes as some countries, including India, struggle to tackle further waves of the virus even as others have rolled out successful vaccination campaigns that are driving down infections, hospitalisations and deaths. The waiver proposal was put forward at the World Trade Organization in October and has since been supported by more than 60 countries who say worldwide vaccine production must increase dramatically. Washington’s support marks a pivotal step in making the proposal a reality and Tai said the US would engage in negotiations to hammer out the details at the WTO. Tedros Adhanom Ghebreyesus, the WHO’s director-general, told the Financial Times the decision was a “monumental moment” in the fight against Covid-19. “I am not surprised by this announcement. This is what I expected from the administration of President Biden.” However, the pharma industry did not expect it; the US has tended to fiercely protect domestic companies’ intellectual property rights in trade disputes. Industry leaders described the decision as a heavy blow for innovation that would do little to boost global production because there is a shortage of manufacturing facilities and skilled employees. In an earnings call Thursday, Stéphane Bancel, chief executive of Moderna, said a patent waiver “will not help supply more mRNA vaccines to the world any faster in 2021 and 2022, which is the most critical time of the pandemic”. “There is no idle mRNA manufacturing capacity in the world,” he said. “The administration’s steps here are very unnecessary and damaging,” said Jeremy Levin, chair of biotech trade association Bio. “Securing vaccines rapidly will not be the result, and worse yet, it sets a principle that companies who invested in new tech will stand the risk of having that taken away.” Shares in the big makers of Covid-19 vaccines were hit by the announcement. Frankfurt-listed shares in BioNTech closed down 12 per cent on Thursday while Moderna and Novavax pared losses after tanking on Wednesday in New York, trading 2.4 per cent lower and 1 per cent lower, respectively. CanSino Biologics, a Chinese private company that developed a single-shot adenovirus-vectored vaccine with Chinese military researchers, fell 14 per cent on Thursday. Fosun Pharma, which has a deal to supply BioNTech vaccines in China, lost 9 per cent. Sven Borho, a managing partner at OrbiMed Advisors, a healthcare investment company, said pharma executives feared the administration’s move set a precedent that would make it easier to suspend patents in the future. “They are worried in the long term that this is a foot in the door — ‘OK, we did it with Covid-19, let’s do it with the next crisis, and the next one’,” he said. “And then suddenly it’s a cancer drug patent that needs to be invalidated. They fear it is a mechanism that sets the stage for actions in the future.” Peter Bach, director of Memorial Sloan Kettering’s Center for Health Policy and Outcomes, said there was a potential trade-off that pitted the imminent need to contain the pandemic against the risk that drugmakers would be more cautious when investing in pioneering therapies in the future.

#### Pharma wins no matter what – they will just water down reforms

**Florko and Facher 19** [Nicholas Florko, Stat News Washington correspondent, and Lev Facher, Stat News health and life sciences writer, 07-16-2019, “How pharma, under attack from all sides, keeps winning in Washington,” Stat News, https://www.statnews.com/2019/07/16/pharma-still-winning/]/Kankee

pharmaceutical industry has maintained its reputation among the nation’s most powerful lobbies, said Sheila Krumholz, the executive director of the Center for Responsive Politics, an organization that tracks political influence. “Their access and influence goes beyond this Congress or even the administration,” Krumholz said in an interview, adding that she “was struggling to think of evidence” it had waned. Pharma has a reputation here for winning on policy — often thanks to the lawmakers who are among the biggest recipients of the millions that drug corporations, employees, and the industry political arms donate each year. Even as the rhetoric has escalated, the industry has quietly worked to insulate itself from any major legislative changes. Take, for example, a recent about-face from Cornyn, the Texas Republican who took in some campaign cash alongside Tillis. As recently as February, Cornyn seemed to be positioning himself as a rare Republican figurehead for anti-pharma congressional wrath. At a widely publicized hearing before the Senate Finance Committee, he went head-to-head with AbbVie CEO Richard Gonzalez, pressing him to explain why the company had filed more than 100 patents on its blockbuster arthritis drug Humira. Cornyn introduced legislation soon after the skirmish to crack down on patent “thicketing,” a term for a drug company tactic to accumulate tens, if not hundreds, of patents to shield a drug from potential generic competition. Pharma sprung into action. They recruited congressional allies, including Tillis, to pressure Cornyn to significantly rework the bill, and they succeeded. The version of the bill that eventually cleared the Senate Judiciary Committee was stripped of language that would have empowered the Federal Trade Commission to go after patent thicketing. Instead, the bill limited how many patents a drug maker could assert in a patent lawsuit. The new version of the bill lost “a lot of teeth” and “solves a narrower problem in a narrow way,” advocates told STAT when the change was first introduced. It is far from the only example of the industry’s aggressive interventions to water down legislation. “In lots of ways they’re like the [National Rifle Association], because they have an incredible power to squash out any negative opinion, nor to feel any of the ill effects of

#### US default causes an irreparable, global economic crisis

Egan September 8th [Matt Egan, financial reporter for Cnn Business with a degree from the College of New Jersey, 9-8-2021, "'Financial Armageddon.' What's at stake if the debt limit isn't raised," CNN, https://www.cnn.com/2021/09/08/business/debt-ceiling-default-explained/index.html]/Kankee

The easiest way to spark a financial crisis and wreck the US economy would be to allow the federal government to default on its debt. It would be an epic, unforced error — and millions of Americans would pay the price. And yet that unlikely situation is once again being contemplated. If Congress doesn't raise the limit on federal borrowing the federal government will most likely run out of cash and extraordinary measures next month, Treasury Secretary Janet Yellen warned lawmakers on Wednesday. In short, a default would be an economic cataclysm. Interest rates would spike, the stock market would crater, retirement accounts would take a beating, the value of the US dollar would erode and the financial reputation of the world's only superpower would be tarnished. "It would be financial Armageddon," Mark Zandi, chief economist at Moody's Analytics, told CNN. "It's complete craziness to even contemplate the idea of not paying our debt on time." But it's a crazy world. Lawmakers in Washington are again playing chicken with America's creditworthiness. And the path to raising the debt ceiling is not clear. Even though Congress has in the past raised the debt ceiling with a bipartisan vote, Senate Minority Leader Mitch McConnell vowed in July that Republicans will not vote to raise the debt ceiling. JPMorgan Chase (JPM) CEO Jamie Dimon urged lawmakers not to even think about going down this path again. During a hearing in May, Dimon said an actual default "could cause an immediate, literally cascading catastrophe of unbelievable proportions and damage America for 100 years." 'Irreparable damage' In her letter to Congress, Yellen said history shows that waiting "until the last minute" to suspend or increase the debt limit "can cause serious harm" to business and consumer confidence, raise borrowing costs for taxpayers and hurt America's credit rating. "A delay that calls into question the federal government's ability to meet all its obligations would likely cause irreparable damage to the U.S. economy and global financial markets," Yellen wrote. A US default would undermine the bedrock of the modern global financial system. "We pay our debt. That's what distinguishes the United States from almost every other country on the planet," Zandi of Moody's said. Because of America's long track record of paying its debt, it's very cheap for Washington to borrow. But a default would force ratings companies to downgrade US debt and shatter that borrowing advantage. Markets plunged in 2011 when that debt ceiling standoff caused Standard & Poor's to downgrade America's credit rating. Higher borrowing costs would make it much harder for Washington to borrow to pay for infrastructure, the climate crisis or to fight future recessions. And refinancing America's nearly $29 trillion mountain of existing debt would become that much more expensive. Interest expenses, which totaled $345 billion in fiscal 2020, would quickly rival what Washington spends on defense. Market chaos Soaring Treasury rates would set off a chain reaction in financial markets. That's because Treasuries, viewed as risk-free investments backed by the full faith and credit of the federal government, serve as the benchmark by which virtually all other securities are measured. Everything from stocks and bonds to exotic securities take their cues from Treasuries. A spike in Treasury rates sparked by a default would cause booming stock markets to become unglued. "Stock prices would crater," Zandi said. "We'd all be less wealthy, instantaneously." Not only would millions of Americans lose money in the stock market, but it would suddenly become more expensive for families and companies to borrow. That's because Treasuries serve as the benchmark for mortgages, car loans, credit cards and corporate debt. A spike in borrowing costs is a huge problem for an economy that relies on access to credit. If the debt ceiling is not lifted, then the federal government will technically default on some of its obligations. It would be forced to prioritize payments, deciding who will get paid and who won't. Ultimately, someone will lose out, whether it's federal employees, veterans, Social Security recipients or defense contractors. For all these reasons, investors are not freaking out about the debt ceiling. Wall Street expects Washington will eventually raise borrowing limit, like it always does. Failure to do so would simply be too dangerous. 'Uniquely childish' The precise timing of when the debt ceiling must be lifted is a bit unclear. In late July, the nonpartisan Congressional Budget Office projected that if the debt limit is not raised, Treasury would probably "run out of cash" and be unable to make payments sometime during the final three months of the year, most likely in October or November. But that so-called "X date" could shift based on how much tax revenue the federal government takes in. For now, Treasury is taking extraordinary measures to avoid a default. Those moves are not a permanent fix, however, and eventually the debt limit will need to get lifted to avoid a financial disaster. "Once all available measures and cash on hand are fully exhausted, the United States of America would be unable to meet its obligations for the first time in our history," Yellen wrote. Yellen put a finer point on it later in Wednesday's letter, saying "based on our best and most recent information, the most likely outcome is that cash and extraordinary measures will be exhausted during the month of October." Of course, this debate isn't taking place in a vacuum.

#### Decline causes nuclear war

Stein Tønnesson 15, Research Professor, Peace Research Institute Oslo; Leader of East Asia Peace program, Uppsala University, 2015, “Deterrence, interdependence and Sino–US peace,” International Area Studies Review, Vol. 18, No. 3, p. 297-311

Several recent works on China and Sino–US relations have made substantial contributions to the current understanding of how and under what circumstances a combination of nuclear deterrence and economic interdependence may reduce the risk of war between major powers. At least four conclusions can be drawn from the review above: first, those who say that interdependence may both inhibit and drive conflict are right. Interdependence raises the cost of conflict for all sides but asymmetrical or unbalanced dependencies and negative trade expectations may generate tensions leading to trade wars among inter-dependent states that in turn increase the risk of military conflict (Copeland, 2015: 1, 14, 437; Roach, 2014). The risk may increase if one of the interdependent countries is governed by an inward-looking socio-economic coalition (Solingen, 2015); second, the risk of war between China and the US should not just be analysed bilaterally but include their allies and partners. Third party countries could drag China or the US into confrontation; third, in this context it is of some comfort that the three main economic powers in Northeast Asia (China, Japan and South Korea) are all deeply integrated economically through production networks within a global system of trade and finance (Ravenhill, 2014; Yoshimatsu, 2014: 576); and fourth, decisions for war and peace are taken by very few people, who act on the basis of their future expectations. International relations theory must be supplemented by foreign policy analysis in order to assess the value attributed by national decision-makers to economic development and their assessments of risks and opportunities. If leaders on either side of the Atlantic begin to seriously fear or anticipate their own nation’s decline then they may blame this on external dependence, appeal to anti-foreign sentiments, contemplate the use of force to gain respect or credibility, adopt protectionist policies, and ultimately refuse to be deterred by either nuclear arms or prospects of socioeconomic calamities. Such a dangerous shift could happen abruptly, i.e. under the instigation of actions by a third party – or against a third party. Yet as long as there is both nuclear deterrence and interdependence, the tensions in East Asia are unlikely to escalate to war. As Chan (2013) says, all states in the region are aware that they cannot count on support from either China or the US if they make provocative moves. The greatest risk is not that a territorial dispute leads to war under present circumstances but that changes in the world economy alter those circumstances in ways that render inter-state [make] peace more precarious. If China and the US fail to rebalance their financial and trading relations (Roach, 2014) then a trade war could result, interrupting transnational production networks, provoking social distress, and exacerbating nationalist emotions. This could have unforeseen consequences in the field of security, with nuclear deterrence remaining the only factor to protect the world from Armageddon, and unreliably so. Deterrence could lose its credibility: one of the two great powers might gamble that the other yield in a cyber-war or conventional limited war, or third party countries might engage in conflict with each other, with a view to obliging Washington or Beijing to intervene.

## Framing

0:35

#### The standard is maximizing expected wellbeing. [util]. Prefer –

#### 1] Only pain and pleasure are intrinsically valuable – all other frameworks collapse.

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

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

#### 2] Util (the doctrine of minimizing pain and maximizing happiness) is key to debates about IP.

Kar 19 [Mohit; Writer at the Original Position; “Utilitarianism in the Context of Intellectual Property,” The Original Position; 9/18/19;<https://originalpositionnluj.wordpress.com/2019/09/18/utilitarianism-in-the-context-of-intellectual-property/>]

Jeremy Bentham is known as the founder of modern utilitarianism. He believed in production of the *greatest possible quantity of happiness*, on the part of those whose interest is in view. With regards to intellectual property, he had opined that inventors and authors should be given absolute privilege over their work, which would ensure they get remunerated duly for their work, thus leading to further creative actions being taken by them. In this article, the author will make an analysis of the utilitarian theory as proposed by Jeremy Bentham and its *interplay[s] with IP*

According to utilitarians, the main purpose of property rights is the *maximization of common well-being*.[i] According to Jeremy Bentham, the common well-being here mentioned is the good for the greatest number of people in a population. He defined the principle of utility as carrying an *object of production* of maximum happiness in a given time in a particular society.[ii]

The wealth of a society consists of the cumulative wealth of each of its individual members. The most effective way to increase individual wealth is to leave the management of wealth to the individual himself, since – between the individual and the government – it is the individual who can best manage his own wealth. The society gains benefits because the increase in individual wealth is also the increase of collective wealth. Sharing this wealth is managed by the government, through taxes. Bentham argued that the value of outcome of a society is positive if the total quantity of pleasure gained by each individual under its influence is greater than the total quantity of pain.[iii] Thus, Bentham put stress on the happiness and wealth of individuals in a society.

Jeremy Bentham’s utilitarianism advocates the maximization of common well-being and the proper use of resources available. To show us a practical point of view, he criticized the kind of trade strategies where a country prevents the purchase of cheaper products from another country only to protect its market. In his opinion, to pay more for a product that can be manufactured elsewhere with the same quality standards only to favor the national industry is a waste of resources.[iv] Bentham believed that trade barriers to foreign imports cannot increase trade and commerce in a particular country.[v] He termed it as a necessary evil which would give rise to monopolies and lower the quality of production.[vi]

Transposing this theory to intellectual property rights, for the maximization of common welfare to be made, the legislators should *strike a balance between, the monopoly of rights to stimulate creation and giving access to the population to inventions*. Bentham defended the idea of ​​a limited period of protection for patents and he believed in the absolute privilege of the inventor, so that the latter can recover the amounts invested during the inventive process, while being paid for his creative activity.[vii] The right must also help the inventor since without any laws to protect him; any third party could copy his invention and thus enjoy his work without any compensation being granted. The logic to defend the monopoly stems from the fact that, without the latter, the inventor would not be encouraged to put his product or invention on the market. In this case, it would be the society that would have lost wealth which could have been added to the common well-being. In the name of enriching common well-being, Bentham stresses the importance of patents in a society and even argues that their concession should be a free service offered to inventors.[viii]

The contemporary version of this theory has been presented to us by William Landes and Richard Posner in two separate works, one on copyright and the other on trademark law.[ix] *Economic* analysis of intellectual property rights presented by these two authors demonstrates that the protection of intellectual property may be too expensive for society and it limits the use of products. If we extrapolate a little, this contemporary utilitarian vision can assert that the products by intellectuals should be easily copied since the copies of a product do not prevent the use of the *same product by several people.*

William Landes and Richard Posner consider the creative process as divided into two parts.[x] If we use a book as an example, its production is split between the part comprising author’s time and effort plus publishing costs, and the second part includes publication and distribution costs of the book. Generally, it is the first of these two elements that demands the most investment. The second will be more or less expensive, depending on the quantity of copies that will be produced. When the work is complete, its reproduction does not require any investment at the creative level. Hence, they stated that striking a correct balance between access and incentives is one of the central problems of copyright law.[xi] In this way, as already mentioned, the lack of remuneration of creators for the exploitation of their works may have as a consequence the diminution of the cultural wealth of a society, given that the creators will not have the desire to continue to create unless paid. It is important to note that the lack of protection conferred by copyright would not change this problem. In a society where copyright protection does not exist, a book could be easily copied without the act of copying being considered an offense. When the contemporary utilitarian vision is applied, it indicates that the benefits that they bring to a society are: It makes it easier for consumers to choose the product which has the qualities corresponding most to its needs. Since consumers already know the brand, they should not search among a whole range of products available on the market; It encourages producers to maintain good quality of their products, because consumers associate the product quality with the brand attached to it; It improves the language. Landes and Posner believe that the brands create new words that end up being incorporated in the lexicon of the language.[xii]

Suppose the utilitarian theory – that of Bentham, or Posner’ and Landes’ – would be applied to intellectual property as it stands today: the *benefits* that would be brought to society by this analysis would be the *incentive for creativity*, the *optimization of production* and the disappearance *or diminution of similar inventions* made by different individuals.

Among these three advantages, we can consider the incentive to creation as the most important. In this case, the monopoly guaranteed by intellectual property stimulates creation in a society and, especially with regard to patents; inventions will bring more happiness and pleasure to society in general. This justifying argument is in harmony with Bentham’s utilitarianism. The problem here is that no one really knows what kind of invention would bring more or less happiness or pleasure to the society. Moreover, the term “monopoly concession” for patents, trademarks and copyright is not based on any empirical or objective study and is rather random.

Optimization of production sees ownership monopolies intellectual property as a “service” to society since data from sale indicates the products for which the company has the most need. This approach could even justify increasing the period of protection of intellectual property products. The logic here is that the decrease in the protection period or even the removal of the protection would deprive the producers of information that enables them to optimize their production. Thereby, the withdrawal or diminution of protection could even be considered harmful to society. However, if we do not impose limitations to this theory, the result could be a disparity of investments in intellectual property over investments in other areas, such as education and health, as well as in general research activities.

CONCLUSION

Utilitarianism, as it stands today, is *intimately linked to the information obtained from the use of intellectual property* monopolies. The goal is to avoid duplication of production. The problem in this case is that in a society which values ​​and encourages the production of new patents and new technologies, the plethora of patents complicates the process. This finding is based on the fact that new inventions normally rely on existing patents and the production of a new patented product will require a large number of licenses before it can begin. As Richard Posner said in his blog: ‘Patents are a source of great social costs, and only occasionally of commensurate benefits. Most firms do not actually want patents; for those firms, the costs involved in obtaining licenses from patentees are not offset by the prospect of obtaining license fees on their own patents.’

# Case

#### 1] Patents are key to global South pharmaceutical industries that stop neglected diseases - k2 helping impoverished communities

**Soyeju and Wabwire 18** [Olufemi Soyeju, Lecturer at Lagos State University, and Joshua Wabwire, educator at the Catholic University of Eastern Africa, 01-2018, “The WTO-TRIPS Flexibilities on Public Health: A Critical Appraisal of the East African Community Regional Framework,” World Trade Review; Cambridge [https://www-proquest-com.ezproxy.library.unlv.edu/docview/1994279823?accountid=3611&pq-origsite=primo]/Kankee](https://www-proquest-com.ezproxy.library.unlv.edu/docview/1994279823?accountid=3611&pq-origsite=primo%5d/Kankee)

Conclusions The problem that this research has highlighted is the already too familiar tension between patent protection and access to medicines. The legal framework for patents and access to medicines in the EAC region consists of the Policy and the accompanying Protocol. What has emerged from the analysis is that the policy tools are aimed at enhancing access to medicines mainly through price reduction. This is done at the direct expense of promoting research and development of medicines, which, in line with the utilitarian justification, is achievable through patent protection. This policy position that weakens patent protection is not appropriate for developing African countries. This is because African countries arefaced with, **region-specific** diseases. Currently, these diseases are largely. Most of these pharmaceutical companies are foreign, largely based in the Global North. Since these companies do not have economic incentives to invest in the research and development of medicines for developing countries' diseases, even patent protection has not necessarily been an attractive incentive.194The focus of these companies is now on developed countries' diseases. In these circumstances, the **only** standing incentive, especially spurring **domestic innovation**, from within developing countries is patent protection. Consequently, any strategy that eliminates this **last straw** will only **worsen** thealready bad situation. The situation described above **underscores** the **urgent need** to develop local pharmaceutical industries and to create alternative incentives for investment in research anddevelopment of medicines for neglecteddiseases, for example through Public-Private Partnerships (PPPs). Both of these can be attained throughan appropriate patent protectionregime that does not weaken patent protection. Such a regime must, for instance, be omniscient of domestic innovators' limited capacity and, consequently, avoid strict patentability criteria, which cannot be met by the small-scale, underfunded domestic innovators. Strict patentability criteria may also discourage disclosure of certain important discoveries, for fear of not attaining the criteria and losing out by disclosure. In developing local pharmaceutical industries, it is also necessary to find ways of affording patent protection to indigenous medicines and practices, which, for centuries, have been as useful to the populations as western medicine now is. It is the failure to protect these medicines and practices in the first place that has resulted in foreign pharmaceuticals **appropriating** the knowledge and patenting it, only to return with expensive medicines.195 It is the argument here that a patent protection policy would only achieve the greatest good for the greatest number of people, in line with utilitarianism, if it balances the goal of price reduction with the need to encourage further research and development of medicines by ensuring that inventors are able to recoup their investments in research and development. It is only through research and development that the medicines will be made available.

#### 2] Turn - IP protections are key to pharmaceutical investment in developing countries – that’s necessary for vaccine production

**Ezell and Cory 19** [(Stephen, vice president, global innovation policy, at the Information Technology and Innovation Foundation, B.S. from the School of Foreign Service at Georgetown University, and Nigel, associate director covering trade policy at the Information Technology and Innovation Foundation, former researcher in the Southeast Asia Program at the Center for Strategic and International Studies, MA in public policy from Georgetown University) “The Way Forward for Intellectual Property Internationally,” Information Technology and Innovation Foundation, 4/25/2019] TDI

Academic research also signals a strong correlation between IPR and technology transfer. Lippoldt showed that

**IPR strengthening in countries—particularly with respect to patents—is associated with increased technology transfer via trade and investment**.34 Research has revealed that a country’s level of intellectual property protection considerably affects whether foreign firms will transfer technology into it.35 That matters because the welfare gains from the importation of technology via innovative products, while differing across countries, can be substantial.36 For instance, **foreign sources of technology account for over 90 percent of domestic productivity growth in all but a handful of**

**countries**.37 The research on this matter is clear and consistent. For example, a 1986 United Nations Conference on Trade and Development (UNCTAD) study found that direct investment in new technology areas such as computer software, semiconductors, and biotechnology is supported by stronger intellectual property rights policy regimes.38 (However, as this report later clarifies, subsequent UNCTAD reports have lamentably taken a more skeptical view toward IP.) A 1989 study by the United Nations Commission on Transnational Corporations (UNCTC) found that weak IP rights reduce computer software direct investment; and a 1990 study by UNCTC found that **weak IP rights reduce pharmaceutical investment**.39 Mansfield conducted firm-level surveys and found that perceptions of strong IP rights abroad have a positive effect on incentives to transfer technologies abroad. Likewise, survey research by the World Bank’s International Finance Corporation found that, with variations by sector, country, and technology, **at least 25 percent of American and Japanese high-tech firms refuse to directly invest, or enter into a joint venture, in developing countries with weak intellectual property rights**; and a later study confirmed those survey findings with actual foreign direct investment data.40 And an Institute for International Economics study of World Bank data concluded that weak intellectual property rights reduce flows of all these commercial activities, regardless of nations’ levels of economic development.41

Studies have also shown how the benefits of intellectual property extend to developing countries. Diwan and Rodrik demonstrated that stronger patent rights in developing countries give enterprises from developed countries a greater incentive to research and introduce technologies appropriate to developing countries.42 Similarly, Taylor showed that **weak patent rights in developing countries lead enterprises from developed countries to introduce less-than-best-practice technologies to developing countries**.43 Interestingly, the relationship goes in both directions. Branstetter and Saggi showed that strengthened IPR protection not only improves the investment climate in the implementing countries, but also leads to increased FDI in the country producing the original innovation.44 They concluded that IPR reform in the “global South” (e.g., developing countries) may be associated with FDI increases in the “global North” (e.g., developed countries). As northern firms shift their production to southern affiliates, this FDI accelerates southern industrial development, creating a cyclical feedback mechanism that also benefits the North. Another study by Liao and Wong, which focused on firm-level analysis, highlights the inter-relationship of IPR reform in developed and developing countries. Their study concluded that

**developing countries can entice technology transfer from the North by providing IPR protection for incoming products** (although they note there is a need for redoubled R&D efforts in developed countries to spur needed innovations).45