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

### Contention 1

My thesis is that intellectual property protections are fundamental to motivating companies to take the risk to make new drugs

**[a] The research and development of new drugs takes billions of dollars and a huge time investment only for the smallest fraction of these drugs to make it to market. Intellectual property protection is necessary to motivate companies to endure this process. Thus not having adequate means IPP there would be NO innovation.**

**Grabowski explains in 2015**

[(Henry, Professor of Economics, member of the faculty for the Health Sector Management Program, and Director of the Program in Pharmaceuticals and Health Economics at Duke University) “The Roles of Patents and Research And Development Incentives In Biopharmaceutical Innovation,” Health Affairs, 2/2015] JL

The essential rationale for patent protection for biopharmaceuticals is that **long-term benefits** in the form **of continued future innovation by pioneer or brand-name drug manufacturers outweigh the relatively short-term restrictions on imitative cost competition associated with market exclusivity.** Regardless, the entry of other branded agents remains an important source of therapeutic competition during the patent term.

Several economic characteristics make patents and **intellectual property protection [is] particularly important to innovation incentives for the biopharmaceutical industry**. 5 **The R&D process often takes more than a decade to complete**, and according to a recent analysis by Joseph DiMasi and colleagues, per new drug approval (including failed attempts), **it involves more than a billion dollars in out-of-pocket costs.** 6 **Only** approximately **one in eight drug candidates survive clinical testing**.

**As a result of the high risks of failure and the high costs, research and development must be funded by the few successful, on-market products** (the top quintile of marketed products provide the dominant share of R&D returns). 7,8 **Once a new drug’s patent** term and any regulatory exclusivity provisions have **expire[s]**d, **competing manufacturers are allowed to sell generic equivalents that require the investment of only several million dollars and that have a high likelihood of commercial success.** **Absent intellectual property protections that allow marketing exclusivity, innovative firms would be unlikely to make the costly and risky investments needed to bring a new drug to market.**

Patents confer the right to exclude competitors for a limited time within a given scope, as defined by patent claims. However, they do not guarantee demand, nor do they prevent competition from nonidentical drugs that treat the same diseases and fall outside the protection of the patents.

New products may enter the same therapeutic class with common mechanisms of action but different molecular structures (for example, different statins) or with differing mechanisms of action (such as calcium channel blockers and angiotensin receptor blockers). 9 Joseph DiMasi and Laura Faden have found that the time between a first-in-class new drug and subsequent new drugs in the same therapeutic class has been dramatically reduced, from a median of 10.2 years in the 1970s to 2.5 years in the early 2000s. 10 Drugs in the same class compete through quality and price for preferred placement on drug formularies and physicians’ choices for patient treatment.

Patents play an essential role in the economic “ecosystem” of discovery and investment that has developed since the 1980s. Hundreds of start-up firms, often backed by venture capital, have been launched, and a robust innovation market has emerged. 11 The value of these development-stage firms is largely determined by their proprietary technologies and the candidate drugs they have in development. As a result, **the strength of intellectual property protection plays a key role in funding and partnership opportunities** for such firms.

**[b] Secondly, a statistical analysis of MULTIPLE studies confirms that intellectual property protections are key to productive research and development. We warrant exactly how patent rights have a direct relationship to research and development.**

**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**

**I**ntellectual **p**roperty **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 In contrast, **IPR reform has been associated with increased innovative activity**, 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 activity** in an economy. Studies by Varsakelis and by Kanwar and Evenson found that ***R&D to GDP ratios are positively related to the strength of patent rights***, 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

**Innovation is crucial 1. Increasing accessibility of medicines around the world and increasing their effectiveness 2. to respond to future health crises 3. increasing life expectancy for diseases without treatments yet**

**Jenner ‘16**

Jenner, Andrew. “Value of Innovation.” IFPMA, IFPMA, 23 Feb. 2016, www.ifpma.org/subtopics/value-of-innovation/.

Many lower and middle-income countries are making important investment in developing their healthcare infrastructure as part of their commitment to achieving Universal Health Coverage. Increasing access to new medicines and vaccines can help sustain such investment by reducing the need for costly surgical interventions and hospitalization. In many cases, the **use of innovative medicines** by health system**s can pay for themselves several times over**. One study found that a reduction in the age of drugs used reduces non-drug spending 7.2 times as much as it increases drug expediture, with most of the savings coming from reduced hospitalization and physician office-visit expenditures. Vaccines, for instance, have proven to be one of the most effective preventative technologies in the fight against infectious diseases with an almost unparalleled impact on public health, saving the lives of over 2.5 million children each year. Estimates show that increasing access to six vaccines (including new vaccines for rotavirus and malaria) **could save USD 6.2 billion in treatment costs globally. Increased productivity** due to averted illness **could gain** the world **an additional $145bn**. The upfront cost of procuring vaccines is dwarfed by these benefits. **In addition to** these **economic benefits,** the **innovation** we bring along **has transformed the lives of millions of patients all over the world.** For instance, **improvements in existing cancer treatments have cut** annual **death rates by half** in the United States. High cholesterol and **other** heart **diseases, which required extensive treatment** in the 1970s, **can now be easily managed** with oral therapy. Our industry has played a crucial role in researching and developing the medicines that have contributed to this.

The mission of the life sciences industry – in New Jersey, across the United States and around the world – is as ambitious as it is straightforward: to research and develop new medicines, therapies, medical devices, technologies and diagnostics to detect, treat and cure disease and improve the quality of life for patients. Driven to improve global human health, for more than 100 years, the life sciences industry – which includes biopharmaceutical, biotechnology and medical technology, device and diagnostics companies – has helped people live longer, more productive and fulfilling lives. **Medical innovation has consistently responded to the challenge in times of crisis and is currently at the forefront of the battle against the COVID-19 pandemic** as it has been through so many other health emergencies. **Discovering and developing new medicines,** therapies, medical devices and technologies **is a complex, time-consuming, expensive and risk-laden process** that life sciences companies willingly undertake, spending more than $100 billion annually in search of alleviating human suffering. **The societal value of new medical innovation lies not only in improving human health, but in doing so in a cost-effective manner that brings efficiency to the delivery of health care.  When medical breakthroughs can cure a disease** rather than requiring an organ transplant, or when chemotherapy can be administered orally rather than by infusion, **the patient, the health care system and the economy all benefit**. MEDICAL INNOVATION: EXTENDING LIFE – SAVING LIVES **Collectively, new therapies have been among the greatest contributors to increased life expectancy over the past century. U.S. life expectancy at birth has risen from 47 years** at the turn of the 20th century **to 78 years today. New therapies accounted for 73 percent of the increased life expectancy in 30 developing and high-income countries** between 2000-09. U.S. **cancer survivorship alone has more than tripled** since 1970, **with nearly 16.9 million** cancer **survivors alive** in the country as of January 1, 2019. **This number is expected to increase to 22.2 million by 2030. As of 2018, the cancer death rate** for men and women combined **had fallen 31 percent from its peak in 1991.** This decline translates to **3.2 million deaths avoided.  Biopharmaceutical innovation**, through improvements in treatment**, has contributed to 76 percent of the improvements in mortality rates for HIV/AIDS patients and 60 percent of improvements in life expectancy** for breast cancer patients. **Heart disease mortality has been improved by 52 percent due to advancements** in medicines. MEDICAL INNOVATION’S ADDED VALUE – COST SAVINGS AND ECONOMIC PRODUCTIVITY In addition to improving patient outcomes, medical innovation offers other, often underappreciated benefits – reducing costs in the health care system and increasing economic productivity**.  With new technologies and therapies that can detect and treat a disease earlier in its onset, and medicines to manage chronic disease, the cost of health care can be significantly reduced**. Less than 10 cents of the U.S. health care dollar was spent on prescription medicines in 2019. This percentage has remained unchanged since the 1960’s. In 2013, the Congressional Budget Office (CBO) started to incorporate the savings from prescription medicines into the cost of Medicare policies. For every 1 percent increase in the number of prescriptions, the CBO incorporates a 0.2 percent decrease in spending on medical services.  According to the Centers for Disease Control and Prevention, improved medication adherence can save $100-$300 billion annually in direct health care costs. Between 1980 and 2010, advanced medical technology helped cut the number of days patients spent in hospitals by 58 percent. Treating people with chronic disease (e.g., heart disease, stroke, cancer, diabetes, obesity, arthritis) (about half of all U.S. adults) accounts for 86 percent of our nation’s health care costs. **By investing in** prevention and **treatment** of the most common chronic diseases, the **cost of treatment in the U.S. could decrease by $218 billion per year, and the impact of disease on the economy would be reduced by $1.1 trillion annually.** MEDICATION ADHERENCE – KEY TO IMPROVED OUTCOMES AND REDUCING HEALTH CARE COSTS Medication **adherence is a critical factor in improving patient outcomes** and bringing efficiency and cost savings to the health care system. Of the approximately 187 million Americans who take one or more prescription medications, it is estimated that up to one-half do not take their medications as prescribed, with more than 1 in 5 new prescriptions not being filled. Non-adherence in the U.S. is estimated to result in approximately 125,000 deaths and at least 10 percent of hospitalizations. Medication **non-adherence costs the U.S. roughly $330 billion annually in unnecessary medical expenses**, as estimated by Express Scripts in 2015. An extra $1 spent on medicines for adherent patients with congestive heart failure, high blood pressure, diabetes and high cholesterol can generate $3-$10 in savings on emergency room visits and inpatient hospitalizations. Adherence to medications for congestive heart failure could result in $22.4 billion saved in the U.S. over a 10-year period. Nearly 1 million hospitalizations could be avoided with better adherence to, and treatment with, hypertensive medicines. LIFE SCIENCES RESEARCH AND DEVELOPMENT – RESOURCES AND RISK IN SEARCH OF THE NEXT TREATMENT  Thousands of scientists go to their labs every day in search of the next treatment, therapy or technology to improve human health and alleviate the suffering of patients.  With the odds heavily against success, life sciences companies invest billions of dollars annually to support the work of these dedicated scientists in their quest to discover the next medical breakthrough.  America’s biopharmaceutical industry in total invested $102 billion in U.S. research and development in 2018. **The biopharmaceutical industry is responsible for 17 percent of R&D spending** by U.S. businesses, the single largest share of any industry. **91 percent of drugs are developed by the private sector** with no direct government role. **On average, it costs $2.6 billion and takes 10-15 years to discover, develop and bring a new medicine to market. Only 5 of 5,000 compounds** that enter preclinical testing **will enter a clinical trial, and only one** will be **commercialized**. **Only 12 percent of new molecular entities** that enter clinical trials eventually **receive FDA approval**. **Only 2 of 10 new medicines** that come to market **will be deemed a commercial success – meaning** they will **produce revenues that exceed** the average R&D **cost**. **More than 7,000 medicines currently are in development** around the world for cancer, cardiovascular disease, diabetes, HIV/AIDS, immunological disorders, infectious disease and other disease states. **Of these 7,000 treatments, 70 percent are potential first-in-class therapies,** meaning they use a completely new approach to fighting disease.

Contention 2:

Weakening IPRs reduces trust in vaccines and other medicines which results in people not taking them at all. Baschuk 2021

Specifically, opponents to the waiver say it would create a chaotic patchwork of laws, unravel existing industry partnerships, lead to a supply crunch for scarce vaccine inputs and inject even more uncertainty into already complex arrangements. There’s also the possibility that **an IP waiver** **could result in the production of counterfeit and substandard medicines, which** **could increase vaccine hesitancy that’s already pervasive in even the world’s wealthiest nations.**

**Strong IP is also necessary to ensure that**

Vaccine trust is crucial in pandemic responses. OECD 21 states that

While the development of COVID‑19 vaccines has been an extraordinary success, **vaccinating most of the global population [requires]** is an enormous challenge, one for which gaining – and maintaining – **public trust in** COVID‑19 **vaccines and vaccination** will be as essential as the effectiveness of the vaccines themselves. Moreover, the experience with COVID‑19 will likely shape confidence in other vaccines making it even more important to build confidence at this time. **[However] Trust in vaccination**, and in the ability of governments to communicate, and to successfully deliver a vaccination programme, **is critically dependent on**: the extent to which the government can instil and maintain public confidence in the effectiveness and safety of the vaccines; **the competence and reliability of the institutions that deliver them**; the principles and processes that guide government decisions and actions in vaccine procurement, distribution, prioritisation, and administration; the capacity and effectiveness of regulatory agencies in handling issues and communicating consistently as events arise, while retaining public confidence in their review processes; and the effectiveness of the public engagement and communications that accompany these.

Which requires IPR regulation.

#### The impact of this contention is that people need to have trust in vaccines to take them, the only way you solve any of your impacts is if you are able to make people take vaccines. IP protections make everything official, since it has to go through a testing period and patent offices to verify that the drug is safe and effective.

# Aff

#### If you buy that overpatenting is true, there are two possible cases.

#### Either a. these patents are obtained justifiably.

#### Findlaw 18 [Findlaw. . “Patent Eligibility Requirements FAQ”. 2-15-2018. Findlaw. https://www.findlaw.com/smallbusiness/intellectual-property/patent-eligibility-requirements-faq.html. Accessed 9-16-2021]

#### The invention must have a "utility," or in other words, be useful. Note that this requirement is only for utility patents (see next question, below).

#### The invention must be "novel," or new.

#### The invention must be "non-obvious," meaning its use or function can't be something that is simply the next logical step of an already patented invention. Much of the argument between the USPTO and patent applicants revolves around the issue of non-obviousness.