# 1NC

### C1: Disease Innovation

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

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

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

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

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

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

### C2: Safety

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

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

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