### **Framework**

**The affirmative may only defend that the member nations of the World Trade Organization ought to reduce intellectual property protections for medicines, and may only garner offense off the desirability of the hypothetical enactment of that resolution.**

***Only* pleasure and pain are intrinsically valuable – all others exist in relation**

**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] SJDI

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.**

#### **Thus, the standard is maximizing expected well-being. Prefer additionally –**

#### **Death is bad and outweighs – agents can’t act if they fear for their bodily security which constrains every ethical theory**

#### **Intuitions outweigh - since they’re the foundational basis for any argument and theories that contradict our intuitions are most likely false even if we can’t deductively determine why**

#### **Actor spec—governments must use util because they don’t have intentions and are constantly dealing with tradeoffs**

#### **Extinction o/w -**

**Pummer 15** [Theron, Junior Research Fellow in Philosophy at St. Anne's College, University of Oxford. “Moral Agreement on Saving the World” Practical Ethics, University of Oxford. May 18, 2015] AT

**There appears to be lot of disagreement in moral philosophy. Whether these many apparent disagreements are deep and irresolvable, I believe there is at least one thing it is reasonable to agree on right now**, whatever general moral view we adopt**: that it is very important to reduce the risk that all intelligent beings on this planet are eliminated by an enormous catastrophe, such as a nuclear war.** How we might in fact try to reduce such existential risks is discussed elsewhere. My claim here is only that **we – whether we’re consequentialists, deontologists, or virtue ethicists – should all agree that we should try to save the world.** According to consequentialism, we should maximize the good, where this is taken to be the goodness, from an impartial perspective, of outcomes. **Clearly one thing that makes an outcome good is that the people in it are doing well. There is little disagreement here.** If the happiness or well-being of possible future people is just as important as that of people who already exist, and if they would have good lives, it is not hard to see how **reducing existential risk is easily the most important thing in the whole world. This is for the familiar reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. There are so many possible future people that reducing existential risk is arguably the most important thing in the world, even if the well-being of these possible people were given only 0.001% as much weight as that of existing people.** Even on a wholly person-affecting view – according to which there’s nothing (apart from effects on existing people) to be said in favor of creating happy people – the case for reducing existential risk is very strong. As noted in this seminal paper, **this case is strengthened by the fact that there’s a good chance that many existing people will, with the aid of life-extension technology, live very long and very high quality lives. You might think what I have just argued applies to consequentialists only. There is a tendency to assume that, if an argument appeals to consequentialist considerations (the goodness of outcomes), it is irrelevant to non-consequentialists. But that is a huge mistake.** **Non-consequentialism is the view that there’s more that determines rightness than the goodness of consequences or outcomes; it is not the view that the latter don’t matter.** Even John Rawls wrote, “**All ethical doctrines worth our attention take consequences into account in judging rightness. One which did not would simply be irrational, crazy.**” **Minimally plausible versions of deontology and virtue ethics must be concerned in part with promoting the good, from an impartial point of view.** **They’d thus imply very strong reasons to reduce existential risk**, at least when this doesn’t significantly involve doing harm to others or damaging one’s character. What’s even more surprising, perhaps, is that even if our own good (or that of those near and dear to us) has much greater weight than goodness from the impartial “point of view of the universe,” indeed even if the latter is entirely morally irrelevant, we may nonetheless have very strong reasons to reduce existential risk. **Even egoism, the view that each agent should maximize her own good, might imply strong reasons to reduce existential risk.** It will depend, among other things, on what one’s own good consists in. If well-being consisted in pleasure only, it is somewhat harder to argue that egoism would imply strong reasons to reduce existential risk – perhaps we could argue that one would maximize her expected hedonic well-being by funding life extension technology or by having herself cryogenically frozen at the time of her bodily death as well as giving money to reduce existential risk (so that there is a world for her to live in!). I am not sure, however, how strong the reasons to do this would be. But views which imply that, if I don’t care about other people, I have no or very little reason to help them are not even minimally plausible views (in addition to hedonistic egoism, I here have in mind views that imply that one has no reason to perform an act unless one actually desires to do that act). **To be minimally plausible, egoism will need to be paired with a more sophisticated account of well-being.** To see this, it is enough to consider, as Plato did, the possibility of a ring of invisibility – **suppose that, while wearing it, Ayn could derive some pleasure by helping the poor, but instead could derive just a bit more by severely harming them. Hedonistic egoism would absurdly imply she should do the latter. To avoid this implication, egoists would need to build something like the meaningfulness of a life into well-being**, in some robust way, where this would to a significant extent be a function of other-regarding concerns (see chapter 12 of this classic intro to ethics). But **once these elements are included, we can (roughly, as above) argue that this sort of egoism will imply strong reasons to reduce existential risk.** Add to all of this Samuel Scheffler’s recent intriguing arguments (quick podcast version available here) that most of what makes our lives go well would be undermined if there were no future generations of intelligent persons. On his view, my life would contain vastly less well-being if (say) a year after my death the world came to an end. So obviously if Scheffler were right I’d have very strong reason to reduce existential risk. **We should also take into account moral uncertainty.** **What is it reasonable for one to do, when one is uncertain not (only) about the empirical facts, but also about the moral facts?** I’ve just argued that **there’s agreement among minimally plausible ethical views that we have strong reason to reduce existential risk – not only consequentialists, but also deontologists, virtue ethicists, and sophisticated egoists should agree.** But **even those (hedonistic egoists) who disagree should have a significant level of confidence that they are mistaken, and that one of the above views is correct. Even if they were 90% sure that their view is the correct one** (and 10% sure that one of these other ones is correct), **they would have pretty strong reason, from the standpoint of moral uncertainty, to reduce existential risk.** Perhaps most disturbingly still, **even if we are only 1% sure that the well-being of possible future people matters, it is at least arguable that, from the standpoint of moral uncertainty, reducing existential risk is the most important thing in the world.** Again, this is largely for the reason that there are so many people who could exist in the future – there are trillions upon trillions… upon trillions. (For more on this and other related issues, see this excellent dissertation). Of course, it is uncertain whether these untold trillions would, in general, have good lives. It’s possible they’ll be miserable. **It is enough for my claim that there is moral agreement in the relevant sense if**, at least given certain empirical claims about what future lives would most likely be like, **all minimally plausible moral views would converge on the conclusion that we should try to save the world.** While there are some non-crazy **views that place significantly greater moral weight on avoiding suffering than on promoting happiness**, for reasons others have offered (and for independent reasons I won’t get into here unless requested to), they nonetheless **seem to be fairly implausible views.** And **even if things did not go well for our ancestors, I am optimistic that they will overall go fantastically well for our descendants, if we allow them to. I suspect that most of us alive today – at least those of us not suffering from extreme illness or poverty – have lives that are well worth living, and that things will continue to improve.** Derek Parfit, whose work has emphasized future generations as well as agreement in ethics, described our situation clearly and accurately: “We live during the hinge of history. **Given the scientific and technological discoveries of the last two centuries, the world has never changed as fast.** We shall soon have even greater powers to transform, not only our surroundings, but ourselves and our successors. **If we act wisely in the next few centuries, humanity will survive its most dangerous and decisive period.** Our descendants could, if necessary, go elsewhere, spreading through this galaxy…. **Our descendants might, I believe, make the further future very good. But that good future may also depend in part on us. If our selfish recklessness ends human history, we would be acting very wrongly.**” (From chapter 36 of On What Matters)

### **Definitions**

**Words and Phrases 64**

**Definition of the word “resolve,” given by Webster is “to express an opinion or determination by resolution or vote; as it was resolved by the legislature;” It is of similar force to the word “enact,” which is defined by Bouvier as meaning “to establish by law”.**

**What is the WTO?**

**The World Trade Organization (WTO) is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world’s trading nations and ratified in their parliaments. The goal is to help producers of goods and services, exporters, and importers conduct their business.**

**Reduce means to diminish**

**Idaho State Court of Appeals 03**

(State v. Knutsen, 71 P. 3d 1065 - Idaho: Court of Appeals 2003)

**By its plain language, Rule 35 grants a district court the authority within a limited period of time to reduce or modify a defendant's sentence after relinquishing jurisdiction. To "reduce" means to diminish in size, amount, extent or number, or to make smaller, lessen or shrink. WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 1905 (1993). To "modify" means to make more temperate and less extreme, or to lessen the severity of something. Id. at 1452. Thus, under the plain meaning of its language, Rule 35 authorizes a district court to diminish, lessen the severity of, or make more temperate a defendant's sentence. An order placing a defendant on probation lessens the severity of a defendant's sentence and thus falls within the district court's authority granted by Rule 35. Other state jurisdictions have held likewise in interpreting similar rules for reduction of sentence. See State v. Knapp, 739 P.2d 1229, 1231-32 (Wy.1987) (similar rule of criminal procedure authorizes reduction of a sentence of incarceration to probation); People v. Santana, 961 P.2d 498, 499 (Co.Ct.App.1997) (grant of probation is a "reduction" under Colorado Cr. R. 35(b))**

**Intellectual property refers to creations of the mind such as commercial art, designs, and innovations**

**WTO no date** (<https://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm>

)

**The TRIPS Agreement plays a critical role in facilitating trade in knowledge and creativity, in resolving trade disputes over intellectual property, and in assuring WTO members the latitude to achieve their domestic objectives. The Agreement is legal recognition of the significance of links between intellectual property and trade. "Intellectual property" refers to creations of the mind. These creations can take many different forms, such as artistic expressions, signs, symbols and names used in commerce, designs and inventions. Governments grant creators the right to prevent others from using their inventions, designs or other creations — and to use that right to negotiate payment in return for others using them. These are “intellectual property rights”. They take a number of forms. For example, books, paintings and films come under copyright; eligible inventions can be patented; brand names and product logos can be registered as trademarks; and so on. Governments grant creators these rights as an incentive to produce and spread ideas that will benefit society as a whole.**

**The extent of protection and enforcement of these rights varied widely around the world; and as intellectual property became more important in trade, these differences became a source of tension in international economic relations. New internationally-agreed trade rules for intellectual property rights were seen as a way to introduce more order and predictability, and to settle disputes more systematically.**

### **1NC - Developing Countries**

### **Developing Countries Make Up an Ever-Increasing Share of the IP Market**

**Ezell and Cory 19**

**Although developed economies as a group dominate knowledge‐intensive flows, de‐**

**veloping countries’ share is growing rapidly.** China’s knowledge‐intensive flows are

the world’s second largest. Indicative of a broadening distribution, **a recent** Euro‐

pean Commission (EC) and Organization for Economic Cooperation and Development

(**OECD**) **report into intellectual property and the world’s top 2,000 companies by R&D**

**spending showed these companies’ headquarters were distributed across 44 countries, while their subsidiaries were spread across more than 100 countries.** While multinationals may only represent one source of R&D investment, the broader trend is evident as **emerging economies’ world share of R&D expenditure increased from 12 percent in 1992 to 26 percent in 2010.** Furthermore, as a common measure of innovative activity, **patent applications filed by the residents of emerging economies at their national offices grew by 10.4 percent annually from 1992 to 2011, compared with 2.3 percent growth for OECD countries.** In 2015, the World Intellectual Property Organization (WIPO) reported that IP offices in Asia received the bulk of world IP filings (for industrial designs, patents, trademarks, and utility models). **In China alone, the number of patents increased from 600,000 in 2010 to almost 1.5 million in 2014, while the country also has the most active trademarks in the world and one‐third of the world’s industrial design registrations.** In 2015, for the second consecutive year, Huawei Technologies of China was the top Patent Cooperation Treaty applicant, with 3,898 applications published.

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**Strong IP laws benefit developing countries by inducing foreign investment**

**Ezell and Cory 19**

Stephen Ezell (vice president of global innovation policy at the Information Technol‐

ogy and Innovation Foundation; founder of Peer Insight, an innovation research and

consulting firm) and Nigel Cory (associate director covering trade policy at the Infor‐

mation Technology and Innovation Foundation; formerly a researcher in the South‐

east Asia Program at the Center for Strategic and International Studies and worked for

eight years in Australia’s Department of Foreign Affairs and Trade). “The Way For‐

ward for Intellectual Property Internationally.” Information Technology & Innovation

Foundation. 25 April 2019. JDN. https://itif.org/publications/2019/04/25/way‐forward‐

Intellectual‐property‐internationally

**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**. 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**. 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 Foreign Direct Investment in the country producing the original innovation**. 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).

**IP is key to the vitality of medical systems globally—especially in emerging**

**economies**

**Ezell and Cory 19**

Stephen Ezell (vice president of global innovation policy at the Information Technol‐

ogy and Innovation Foundation; founder of Peer Insight, an innovation research and

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Intellectual‐property‐internationally

Many opponents of robust IPR rights view them as antithetical to the interests of developing countries in terms of access to medicines or the provision of national health care services. Yet the reality is that stronger IPR rights in developing nations actually unleash the power of developing‐country innovators to contribute to solving health challenges both in their own nations and across the global economy. **First, opponents of IP fail to recognize that intellectual property rights matter for healthcare innovation in emerging economies**. **An** Information Technology and Innovation Foundation (**ITIF**) and George Mason University Center for Intellectual Property Protection **report**, “How Innovators Are Solving Global Health Challenges,” **provides 25 case studies that show innovators in developing countries relying on IP to invent and bring solutions to market. The 25 case studies revealed a number of key themes, including that there is opportunity in adapting health care interventions for developing‐country environments where resources and infrastructure are scarce, and that local innovation and IP can contribute substantially toward providing both affordable and robust tests for diagnosing diseases and affordable interventions to meet basic needs in challenging environments.** **Second, opponents of IP tend to ignore broader systemic issues that contribute to poor health care outcomes in developing countries.** While cost is a central factor for policymakers in all countries, given resource scarcity, these trade‐offs are not unique to health. The greater the resource scarcity, the greater the need for innovation. **One of the biggest challenges** policymakers and innovators in developing countries confront again and again **is scarcity in access to trained professionals**, in transportation, and in other infrastructure. For example, **reports estimate that as many as 1 billion people lack access to essential health care because of a shortage of trained health professionals. A 2014 World Health Organization study estimated a shortage of 7 million public healthcare workers, with that number expected to rise to 13 million by 2035**. **More than 80 countries currently fail to meet the basic threshold of 23 skilled health professionals per 10,000 citizens. The challenge is even more daunting when it comes to specialists. For instance, Cameroon has fewer than 50 cardiologists supporting a population of over 23 million citizens. And Ethiopia, a country of some 90 million residents, is served by a single radiation‐treatment center located in the capital of Addis Ababa.**

**In other instances, individuals lack access to essential medicines, with cost being a relatively small part of the problem**. For instance, in 2014, researchers at the University of Utrecht in the Netherlands found that, **on average, essential medicines are available in public‐sector facilities in developing countries only 40 percent of the time**. Again, the cost of medicines is far from the most serious problem in the provision of health care services in developing nations. **Indeed, the vast majority of drugs—at least 95 percent—on the World Health Organization’s Essential Medicines list are off‐patent, and thus potentially available in generic versions. The problem, in much larger part, stems from countries’ underdeveloped health systems and the fact that many people live in rural areas far from care. Stronger IP rights create an environment wherein entrepreneur can innovate to meet health challenges in their own nations, the benefits thereof spilling over to benefit the entire international community.**

**IPs boost economic growth in developing countries**

**Ezell and Cory 21**

Throughout this difficult time, the world has seen unexpected collaborations, especially between biopharmaceutical companies worldwide such as Gilead and Eva Pharma or Bharat Biotech and Ocugen, Inc. Throughout history, and most significantly in the nineteenth century through the widespread development of patent systems and the ensuing Industrial Revolution, IP has contributed toward greater economic growth. This is promising news as the world struggles for economic recovery. A 2021 joint study by the EU Intellectual Property Office (EUIPO) and European Patent Office (EPO) shows a strong, positive correlation between IP rights and economic performance. It states that “IP‑owning firms represent a significantly larger proportion of economic activity and employ‑ ment across Europe,” with IP‑intensive industries contributing to 45 percent of gross domestic product (GDP) (€6.6 trillion; US$7.9 trillion). The study also shows 38.9 percent of employment is directly or indirectly attributed to IP‑intensive industries, and IP generates higher wages and greater revenue per employee, especially for small‑to‑medium‑sized enterprises.26 That concords with the United States, where the Department of Commerce estimated that IP‑intensive industries support at least 45 million jobs and contribute more than $6 trillion dollars to, or 38.2 percent of, GDP.27 In 2020, global patent filings through the World Intellectual Property Organization’s (WIPO) Patent Cooperation Treaty (PCT) system reached a record 275,900 filings amidst 136 7 Negative Evidence the pandemic, growing 4 percent from 2019.28 The top‑four nations, which accounted for 180,530 of the patent applications, were China, the United States, Japan, and Korea, respectively.29 While several countries saw an increase in patent filings, Saudi Arabia and Malaysia both saw significant increases in the number of annual applications, with the top two filing growths of 73 percent and 26 percent, respectively.30 The COVID‑19 pandemic slowed a lot of things, but it certainly couldn’t stop innovation.

### **1NC - Counterfeiting**

**Counterfeiting of Drugs an Emerging Problem in Developing Countries**

**Ezell and Cory 19**

In 2018, Forbes identified counterfeiting as the largest criminal enterprise in the world. The global struggle against counterfeit and non‑regulated products, which has hit Latin America particularly hard during the pandemic, proves the need for safety and quality assurance in supply chains. Some communities already ravaged by COVID‑19 are seeing higher mortality rates related to counterfeit vaccines, therapeutics, PPE, and cleaning and sanitizing products. Polish authorities discovered vials of anti wrinkle treatment labeled as COVID‑19 vaccines. In Mexico, fake vaccines sold for approximately $1,000 per dose.19 Chinese and South African police seized thousands of counterfeit vaccine doses from warehouses and manufacturing plants. Meanwhile, dozens of websites worldwide claiming to sell vaccines or be affiliated with vaccine manufacturers have been taken down. But the problem is not limited to biopharmaceuticals. The National Intellectual Property Rights Coordination Center has recovered $48 million worth of counterfeit PPE and other products. Collaborative efforts between law enforcement and manufacturers have kept numerous counterfeits from reaching the population. **In countries with strong IP protection, the chances of counterfeit products reaching the market are significantly lower.** This is largely because counterfeiting tends to be an IP‑related issue, and these countries generally provide superior means of tracking the supply chain through trademarks, trade secrets, and licensing agreements. This enables greater quality control and helps manufacturers maintain a level of public confidence in their products. By controlling the flow of knowledge associated with IP, voluntary licensing agreements provide innovators with opportunities to collaborate, while ensuring their partners are properly equipped and capable of producing quality products.

**IP Solves for Counterfeit Drugs**

**FIFARMA 21**

**There is a threat to health security that is present in every country in the world: counterfeit medicines.** These may appear as a promise to cure any disease, but they contain excessive, insufficient or no doses of the active ingredient that treats the disease. Counterfeit medicines also include stolen drugs, drugs that have been stored in poor conditions or are expired, so they may be ineffective or may be contaminated.

**In the end, the only goal of counterfeit medicines is to make money, regardless of the consequences they may have on people’s health. In fact, according to the World Health Organization (WHO), this business represents more than $30 billion dollars in low- and middle-income countries.**

Recently, EFPIA did a podcast where it deepens the relationship between the decrease in the distribution of counterfeit medicine and Intellectual Property. You can find it in the following link: [Fighting the fakes – what’s industry’s role?](https://shows.acast.com/19-conversations/episodes/fighting-the-fakes-whats-industrys-role)

Why does this relationship occur? **Counterfeit medicines are more present where there is less strict regulatory control, where there is a lack of basic medicines, where there are unregulated supply chains, where medicines are priced very differently in the market, where intellectual property is not protected, and where no attention is paid to quality assurance.**

Therefore, this is a transversal issue to different sectors outside the health industry. It is necessary for different actors to be part of the solution. Decision-makers can create campaigns to inform people about the existence of these medicines. They must go hand in hand with regulatory agencies, as they are the ones that control the entry of medicines into countries.

Likewise, the pharmaceutical industry must take action, since they are the ones who research and manufacture products. Thus, the international Fight The Fakes campaign, supported by FIFARMA, aims at raising awareness regarding the dangers of counterfeit medicines.

Each actor must play a role, however, without partnerships and collaboration between different parties, it is difficult to fight the problem. Moreover, **there are other tools that contribute to the elimination of these threats to public health, such as Intellectual Property (IP).**

In addition to functioning as a tool to maintain constant innovation in the industry, **IP helps reducing counterfeit medicines because medicines have better technologies and ingredients are more difficult to copy. This means that, through market incentives, the industry manages to have high quality infrastructure, new technology and trained personnel, to create specialized and specific medicines and therapies, which is why they are difficult to replicate.**

On the other hand, political will functions as another important axis, as it must prosecute those who are making counterfeit medicines. This is achieved through a constant conversation between industry and governments. Therefore, it will be absolutely clear how to identify the authenticity of medicines.

I**n short, IP allows quality standards to be clearer and stricter, and regulators to have greater knowledge and traceability of each product that enters the market. Through IP, you can establish a record of all products globally, which makes it easier to find possible counterfeit medicines.**

**Consequently, the best way to fight counterfeit medicines is through accessing the best quality medicines and for this to happen, an ecosystem between countries, regulators and industry is needed. This ecosystem shall take into account the structural deficiencies of each country and addresses them in a holistic manner, to provide the best quality medicines.**

**In the end, with the Intellectual Property associated with the creation of the product, there are also associated standards of transparency and detailed information that every regulatory agency can access.** Moreover, the value chains will receive all this information in order to be aware of the appearance of products that are not registered with the standards of a product protected by IP.

**Also,IP helps to combat counterfeit medicines internationally, since there are laws that cover all member countries of the United Nations and punish more severely those who commit this crime.** Likewise, these laws provide countries with the necessary mechanisms to take concrete action once a counterfeit medicine is discovered. This, of course, must go hand in hand with the political will of each country, because only with collaboration between different actors will it be possible to prosecute the entire chain of counterfeit medicines.

**Plus, IP owners can receive electronic notifications worldwide more quickly and can take direct communication actions. In a nutshell, IP allows the industry to show the public almost immediately that there is a counterfeit medicine in a country or that a website is selling counterfeit medicines. This is because legally infringing a product protected by IP allows action to be taken to prosecute the counterfeit products.**

This is especially important for those consumers or small organizations that do not have access to information like a hospital or public health center has. However, it is necessary to involve other actors of the health system so that information about counterfeit medicines reaches remote regions or places, which do not have an internet connection.

**On the other hand, thanks to IP, the industry is creating specialized safety technology in order for each country to easily identify a drug that comes with a brand but does not belong to that brand.** The industry has also used mobile laboratories to test samples of suspected medicines and report them quickly to the value chain. Thus, technology is becoming an important element in fighting this problem.

Counterfeit medicines have a wide range of negative effects for different actors and especially for the people who fall victim of them. However, more and more governments and industries are creating concrete actions to pursue the entire chain of counterfeiters, as this is the only way to eradicate the problem all together. The tools to combat counterfeiting exist, the important thing is that actors know how to use them for the benefit of the greatest number of people in the world.

**Counterfeiting can Potentially Take Lives in Developing Countries (Impact)**

**OECD 20**

**As indicated above, people taking counterfeit medicine may be putting their lives at risk. Estimates show that between 72 000 and 169 000 children may die from pneumonia every year after receiving counterfeit drugs, and that fake anti-malarial medication might be responsible for an additional 116 000 deaths (WHO, 2017c). Renschler et al. (2015) estimate that each year over 120 000 under-five malaria-positive children may die across 39 sub-Saharan countries due to taking poor-quality anti-malarials, including counterfeit and substandard pharmaceuticals. In their rather conservative review of the published literature on the health consequences of falsified medicines, Rahman et al. (2018) analysed 48 reported incidents in which falsified medicines caused serious adverse effects to patients. These incidents involved approximately 7 200 casualties, including 3 604 deaths. The results of the study indicate that a similar number of incidents affect developing and developed countries alike, and the counterfeiters target all types of medications (Rahman et al. 2018).**

**Forensic tests of suspect samples performed by the pharmaceutical industry also demonstrate that counterfeit medicines, in 90% of those cases tested, could cause harm to the patient (Novartis in Society Report, 2019).**

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# **NT: Innovation/Compulsory Licensing/IP Holiday**

**Innovation Stems from Strong IP Laws**

**Ezell and Cory 21**

**There are at least five principal benefits strong IP rights can generate, for both developing and developed countries alike. First, stronger IP protection spurs the virtuous cycle of innovation by increasing the appropriability of returns, enabling economic gain and catalyzing economic growth. Second, through patents—which require innovators to disclose certain knowledge as a condition of protection—knowledge spillovers build a platform of knowledge that enables other innovators**. For instance, studies have found that the rate of return to society from corporate R&D and innovation activities is at least twice the estimated returns that each company itself receives. **Third, countries with robust IP can operate more efficiently and productively by using IP to determine product quality and reduce transaction costs. Fourth, trade and foreign direct investment enabled and encouraged by strong IP protection offered to enterprises from foreign countries facilitates an accumulation of knowledge capital within the destination economy. That matters when foreign sources of technology account for over 90 percent of productivity growth in most countries.** There’s also evidence suggesting that developing nations with stronger IP protections enjoy the earlier introduction of innovative new medicines. **And fifth, strong IP boosts exports, including in developing countries. Research shows a positive correlation between stronger IP protection and exports from developing countries as well as faster growth rates of certain industries.**

**Strong IP rights are critical to the pharma system; restrictions like compulsory**

**licensing decimate innovation**

**DeRoo 11**

**Government healthcare programs, however, when combined with compulsory licensing and important pharmaceutical markets, represent a corresponding threat to the current R&D infrastructure of drug development**, which is funded both by purchasers of pharmaceutical products and by taxpayers via public research entities. **With only one of every 5,000‐10,000 tested compounds reaching the market and taking an average of 11.8 years to get there, drug R&D investment requires a high risk premium.** Although the exact amount is disputed, **current estimates to develop an innovative, new molecular entity drug range from $802‐$868 million, and costs continue to rise**. Pharmaceutical development is also far from a purely private enterprise, with the NIH annually spending over $31 billion in taxpayer dollars in basic medical research, which supports downstream drug development by the pharmaceutical industry. R&D therefore usually targets drugs that have an expected return high enough to generate substantial profit and fund subsequent R&D. **Because R&D investment decisions are guided by the expected economic return for a particular line of research, palatability of risk is proportional to the magnitude of the expected returns.’” Assuming that research into risky, unexplored areas of health is desirable, low expected returns, whether due to a small market for a particular drug or weakened patent exclusivity rights as a result of compulsory licensing, may chill such R&D**. After a pharmaceutical drug runs the gamut of patenting, clinical trials, and regulatory approval procedures, the patent specification and a wealth of safety and efficacy data are available to the public, resulting in serious appropriability concerns.’ In the absence of strong patent protection and regulatory data exclusivity, generic producers are able to rapidly reverse‐engineer drugs, obtain regulatory approval by relying on the patent holder’s safety and efficacy data, and sell the generic version on a competitive market against the innovative firm that incurred the stratospheric R&D and original regulatory approval costs. Without such protection, the innovative pharmaceutical developer could expect little return on investment, and private R&D would dissipate. Indeed, pharmaceutical appropriability in India resulted in a commodified Indian pharmaceutical market devoid of R&D. In the Indian Patents Act of 1970, India abolished pharmaceutical compound patentability in favor of short seven‐year pharmaceutical production‐process patents, creating incentives to devise increasingly efficient production processes while permitting any manufacturer to produce the pharmaceutical compound itself.’” **Drug firms flooded the market as the number of licensed manufacturers grew from 2,237 enterprises in 1969‐70 to an estimated 16,000 by 1992‐93**, illustrating that barriers to entry into the pharmaceutical market were not onerous. **Profitability predictably plunged over that period, reducing R&D expenditures from 15.5% of sales prior to the 1970 Patents Act to a mere 1.4% in 1992‐93 because of comparative declines in expected returns on R&D investment due to the absence of exclusivity for drug compounds.’**” 1.4% does not fund much R&D: India has become the world’s leading generic pharmaceutical producer, but contributes little to the development of new pharmaceutical medicines.” The most powerful developing countries followed India in prohibiting patent protection for pharmaceuticals. Between 1971 and 1996, Brazil prohibited patents for both pharmaceutical products and processes.”’ Mexico and Argentina had similarly lowered pharmaceutical patent protection prior to TRIPS.” As a result, today only a handful of developed countries have a sufficiently sophisticated pharmaceutical industry and research base to conduct complex R&D. Compulsory licensing, if widely used as an escape‐hatch from patent protection, presents a potential threat to continued research by relegating innovative producers to a level playing field with generic producers.’ **Once a compulsory license is granted, licensees simply have to send a royalty check to the patent holder. These royalty payments are uniformly puny. For example, Indonesia offered a mere 0.5% royalty on the generic sale price for its HIV/AIDS compulsory licenses,”’ Zambia offered 2.5%,”’ and Mozambique offered 2%. Meanwhile, Thailand has offered 0.5% to 2.0%.** The pharmaceutical market has already encountered the likely bleak effects of widespread compulsory licensing and its low royalty rates. The post‐1970 Indian pharmaceutical industry demonstrated that extremely low margins do not incentivize R&D. In a similar vein, the Egyptian pharmaceutical industry is currently discovering that its cost‐plus price setting system, using the costs of ingredients as the benchmark, establishes a profit ceiling that acts as a de facto limit on R&D expenditures. **Limiting economic returns on pharmaceutical R&D through abusive compulsory licensing, especially if in one or more of the few countries with innovative pharmaceutical industries, therefore poses a threat to continued R&D into unexplored areas of medicine.**