### Framework

#### I value morality.

#### Util is the only moral system available to policymakers.

Robert E. Goodin 95 [professor of government at the University of Essex, and professor of philosophy and social and political theory at Australian National University], “Utilitarianism as a Public Philosophy”, Cambridge Studies in Philosophy and Public Policy, May 1995, BE

Consider, first, the argument from necessity. Public officials are obliged to make their choices under uncertainty, and uncertainty of a very special sort at that. All choices - public and private alike - are made under some degree of uncertainty, of course. But in the nature of things, private individuals will usually have more complete information on the peculiarities of their own circumstances and on the ramifications that alternative possible choices might have for them. Public officials, in contrast, are relatively poorly informed as to the effects that their choices will have on individuals, one by one. What they typically do know are generalities: averages and aggregates. They know what will happen most often to most people as a result of their various possible choices. But that is all. That is enough to allow public policy-makers to use the utilitarian calculus - if they want to use it at all - to choose general rules of conduct. Knowing aggregates and averages, they can proceed to calculate the utility payoffs from adopting each alternative possible general rule. But they cannot be sure what the payoff will be to any given individual or on any particular occasion. Their knowledge of gener- alities, aggregates and averages is just not sufficiently fine-grained for that.

#### Thus, the standard is maximizing well-being.

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### **ON CASE**

#### **Status quo solves – hundreds of millions of new doses being donated.**

**Sullivan** 9-17-**21**, Peter (staff writer at The Hill,covers healthcare policy and politics). “US to Buy Hundreds of Millions More Vaccine Doses for the World: Report.” *TheHill*, 17 Sept. 2021, <https://thehill.com/policy/healthcare/572758-us-to-buy-hundreds-of-millions-more-vaccine-doses-for-the-world-report> (SPHS,LF)

**The Biden administration is planning to buy hundreds of millions more Pfizer COVID-19 vaccine doses to share with the world,** The Washington Post reported on Friday.Details of the announcement were not yet clear, and White House COVID-19 response coordinator [Jeff Zients](https://thehill.com/people/jeff-zients) declined to confirm the report or offer more details when asked during a press briefing on Friday.**The reported move comes ahead of the U.N. General Assembly next week, where boosting vaccine access in lower-income countries will be a focus.** The Post reported that the White House will also be hosting a virtual summit on global vaccinations next week, alongside the meeting.The Biden administration has been under pressure from experts and advocates to do more to help vaccinate the world.Officials point to the 140 million vaccine doses that the U.S. has already donated, as well as the purchase already announced for over 500 million doses to be donated across this year and next.But advocates note that is well short of the global need. In addition to donating vaccines, experts have also called for boosting global vaccine manufacturing capacity to help lower-income countries make more doses.News of the reported announcement also comes as the U.S. is poised to move forward on booster shots domestically. A Food and Drug Administration advisory committee is meeting Friday to discuss the issue and give a recommendation.**The World Health Organization has called on wealthy countries like the U.S. to hold off on boosters until more vulnerable people in other countries have their first shots, but the Biden administration has argued it can both provide boosters at home and more shots abroad.**

#### **Turn- IPR waiver undermines cancer cures**

#### **Spiegel’21, (Andrew, *the executive director of the Global Colon Cancer Association.*). “How the COVID IP Waiver Could Sabotage Crucial Cancer Research.” *Logan Daily News*, 23 Sept. 2021,** [**https://www.logandaily.com/comment/columns/how-the-covid-ip-waiver-could-sabotage-crucial-cancer-research/article\_4f06ff17-d3b4-539a-a130-4e3512c1d3bb.html.**](https://www.logandaily.com/comment/columns/how-the-covid-ip-waiver-could-sabotage-crucial-cancer-research/article_4f06ff17-d3b4-539a-a130-4e3512c1d3bb.html.) **(SPHS,LF)**

President Biden craves a cure for cancer. In a speech to Congress this spring, he vowed to “end cancer as we know it.” And as vice president, he helped start the Cancer Moonshot initiative.**Yet by giving his backing to a global waiver of intellectual property rights for COVID-19 vaccines, President Biden may have endangered millions of Americans living with cancer.**The Biden administration has said that it would join a World Trade Organization move to suspend IP safeguards for the vaccines. Its intentions are no doubt sincere, founded in the belief that a waiver will help rid the world of Covid. Yet the setting aside of IP protections has consequences that the administration seems to have overlooked.**If adopted, the waiver won’t galvanize the supply of vaccines bound for the developing world – certainly not in the immediate term. What it will do is threaten scientific innovation that could lead to cures for cancer and other diseases**.I’ll explain why. Technically, the waiver supported by the United States would only apply to IP on COVID vaccines. So what has this got to do with cancer?There are two consequences. **First, intellectual property underpins scientists’ incentives to make discoveries. Without proprietary “armor” to protect research, rivals could blithely – and lawfully – use scientists’ know-how, data, or manufacturing processes.Second, waiving IP on underlying vaccine technology has ramifications for drug innovation. Since the same technologies are used for potential treatments for other diseases, vaccine-makers would have to give up IP on those projects too.**Consider the Pfizer-BioNTech and Moderna vaccines. They use “mRNA” to promote an immune response to COVID-19, a technology that took decades to develop. With the successful rollout of mRNA COVID-19 vaccines, researchers in the United States and Germany now hope they can use mRNA to fight other viruses. Moderna has active trials for mRNA vaccines for Zika, HIV, and the flu.Cancer doctors and patients pray that mRNA is the key to a cure. Moderna, in fact, has two mRNA vaccine candidates for cancer. **Researchers hope that mRNA could instruct the body to combat cancerous tumors like it fights a virus.With the IP waiver, Moderna’s mRNA technology could end up with rivals, leaving the company with greatly diminished incentives – and greatly diminished investment dollars – to continue with mRNA clinical trials, including ones for cancer.** Advanced drug innovation could come to a halt. What investor would fund biotech startups if copycats can swoop in?This scenario is made especially distressing by the fact that the upsides of the IP waiver are negligible. Manufacturers need specialized facilities and hundreds of ingredients to make vaccines. Vaccine-makers have struck licensing deals to scale up production. Every facility on earth that can safely produce effective vaccines is already doing so. **Getting rid of IP won’t make the scale-up go any faster. It could, however, unleash millions of shoddy copycats and event counterfeit vaccine doses**.President Biden has shown how he can help vaccinate the world without holding mRNA research hostage. For instance, he has already agreed to donate 580 million of the United States’ surplus vaccine doses to COVAX – a WHO, CEPI, and Gavi co-led initiative to distribute COVID-19 vaccines to developing countries.With President Biden, the cancer community has an ally in the White House. And yet**, with the IP waiver, he’s undermining the only industry that may find a cure for cancer.**

**Many countries couldn’t reproduce the vaccines even if they had the formula or even if they had the rights to produce them.**

**Paton’21 (**James,specializes in corporate restructurings, cross-border insolvencies, and mass tort insolvencies.)|. “Analysis | )Rich Countries Hog Vaccines. Is There a Solution?” *The Washington Post*, WP Company, 6 Sept. 2021,/ [https://www.washingtonpost.com/business/rich-countries-hog-vaccines-is-there-a-solution/2021/09/03/a0b95b8a-0ce3-11ec-a7c8-61bb7b3bf628\_story.html.)](https://www.washingtonpost.com/business/rich-countries-hog-vaccines-is-there-a-solution/2021/09/03/a0b95b8a-0ce3-11ec-a7c8-61bb7b3bf628_story.html.) (SPHS,LF)

**Wealthy countries have hogged Covid-19 vaccines, providing a glaring illustration of how unfair the world can be.** While 57% of people in high-income countries had received at least one dose of vaccine by Aug. 30, the figure in low-income countries was just 2%, according to the United Nations. **Health advocates worry that the imbalance will be aggravated by plans in wealthy countries to provide booster shots to fully inoculated people to combat the super-contagious delta variant of the coronavirus. The uneven distribution -- which many scientists say will likely prolong the global health crisis -- has prompted proposals to expand production of Covid shots, reallocate rich countries’ excess doses, and ensure vaccines are deployed more equitably in future pandemics.1**. Why were some countries first in line?As inoculations were being developed, a number of affluent countries signed advance contracts with a variety of companies, securing the lion’s share of initial doses. The U.S., as part of its multibillion-dollar program hastening the development of Covid vaccines, also used wartime powers to require manufacturers to fill massive U.S. government orders first. The U.S., U.K. and European countries had the added advantage that companies with local manufacturing plants were the first to deliver vaccines with proven efficacy; China and Russia also rolled out vaccines early, before final trial results were in. 2. Where did this leave other nations? A number of middle-income countries, such as Turkey, Malaysia, Serbia and El Salvador, have now managed to procure enough supply to inoculate significant portions of their populations. But **the poorest nations are still waiting for anything beyond a trickle of the life-saving doses. Because many lack the financial clout to secure contracts for Covid vaccines on their own, they depend for supplies largely on Covax, an initiative backed by groups including the World Health Organization that was designed to provide fair access to the shots for every country. And Covax has fallen short of its goals.** 3. What happened with Covax? Covax uses funding provided by governments and donors such as the Bill & Melinda Gates Foundation to make its own contracts with vaccine manufacturers. But it has struggled to get hold of doses, especially after India -- home to the Serum Institute, the world’s biggest vaccine manufacturer -- pared back exports to supply the domestic market following a new wave of infections there in March. The original aim of Covax was to distribute at least 2 billion doses, two-thirds of them to lower-income nations, by the end of 2021. By Aug. 30, it had shipped just 11% of that.4. Will countries with ample supplies share them? China and Russia were early to export vaccines as a tool of diplomacy, and in August China pledged to dramatically expand exports to 2 billion doses this year. In June, leaders of the Group of Seven nations upped their commitments so that in all they’ve promised to provide 2.3 billion shots to developing nations by next year. So far the actual contributions have been paltry. Health advocates say that billions more doses are needed and stressed that the speed of donations is as important as the quantity. They also worried that the flow of supply to the neediest countries would be interrupted by decisions in high-income nations to offer booster shots to people who’ve already been fully inoculated and to younger children. 5. What’s at stake?The coronavirus has flourished in some places where vaccines have been scarce. In addition to causing misery locally, that increases the risk of the emergence of additional, worrisome variants, which will inevitably make their way elsewhere and may not be neutralized by existing shots. Many countries short of vaccines are relying on continued lockdowns to suppress the virus, stifling economic activity, while wealthier countries have been opening up. It’s possible that sub-Saharan Africa, where doses are in shortest supply, will be spared the worst effects. Researchers noted in a paper published in July that Covid’s impact has been significantly lower in the region than elsewhere and argued that the main factors are the relative youth of the population and the low numbers of elderly living in long-term care facilities. Still, many African countries are struggling to combat Covid on top of a string of other health threats. And there’s no guarantee the next pandemic won’t target the young, making future vaccine rollouts a concern for African health specialists.6. What are the proposals for expanding vaccine access? A group of countries led by South Africa and India has called for the World Trade Organization to lift intellectual property protections for makers of Covid vaccines to enable additional plants to produce more shots. Vaccine companies argue that they are already expanding production and that the move would have little if any practical effect. **Few countries have the trained personnel to produce Covid vaccines even if they had the formulas**. Some advocates of the waiver say it can serve as leverage to push pharmaceutical companies to voluntarily share their expertise more broadly. The WHO proposes serving as a coordinator of technology transfers, facilitating training and helping countries organize the necessary investments in factories. Global health advocates argue that it’s vital not just for this pandemic but for the next one to expand vaccine production beyond the current concentration in the U.S., Europe, India and China. The African Union’s Centers for Disease Control and Prevention announced an ambitious plan in April to establish new vaccine factories with the aim of reducing the continent’s reliance on imports from 99% to 40% of supply by 2040.

-No Solv- Manufacturing

*Limiting IP protections won’t help developing countries increase access to vaccines due to manufacturing obstacles*

**Silverman 3/15**/21 (Rachel Silverman is a policy fellow at the Center for Global Development, where she leads policy-oriented research on global health financing and incentive structures. Silverman’s current research focuses on the practical application of results-based financing; global health transitions; efficient global health procurement; innovation models for global health; priority-setting for UHC; alignment and impact in international funding for family planning; and strategies to strengthen evidence and accountability. Before joining CGD in 2011 she worked with the National Democratic Institute to support democracy and governance strengthening programs in Kosovo. She holds a master’s of philosophy with distinction in public health from the University of Cambridge, which she attended as a Gates Cambridge Scholar. She also holds a BA with distinction in international relations and economics from Stanford University.), “Waiving vaccine patents won’t help inoculate poorer nations”, The Washington Post, <https://www.washingtonpost.com/outlook/2021/03/15/vaccine-coronavirus-patents-waive-global-equity/> NT

Reality is more complicated, however. **Because of the technical complexity of manufacturing coronavirus vaccines, waiving intellectual-property rights, by itself, would have little effect.** **It could even backfire, with companies using the move as an excuse to disengage from global access efforts. There are more effective ways to entice — and to pressure — companies to license and share their intellectual property and the associated know-how, without broadly nullifying patents**. The Moderna vaccine illustrates the limits of freeing up intellectual property. Moderna announced in October that it would not enforce IP rights on its coronavirus vaccine — and yet it has taken no steps to share information about the vaccine’s design or manufacture, citing commercial interests in the underlying technology. Five months later, production of the Moderna vaccine remains entirely under the company’s direct control within its owned and contracted facilities. Notably, Moderna is also the only manufacturer of a U.S.- or British-approved vaccine not yet participating in Covax, a global-aid-funded effort (including a pledged $4 billion from the United States) to purchase vaccines for use in low- and middle-income countries. It is true, however, that activist pressure — including threats to infringe upon IP rights — can encourage originators to enter into voluntary licensing arrangements. So the global movement to liberate the vaccine patents may be useful, even if some advocates make exaggerated claims about the effects of waivers on their own. We focused on covid. Now our other patients are suffering. One reason patent waivers are unlikely to help much in this case is that vaccines are harder to make than ordinary drugs. Because most drugs are simple chemical compounds, and because the composition of the compounds is easily analyzable, competent chemists can usually reverse-engineer a production process with relative ease. When a drug patent expires, therefore — or is waived — generic companies can readily enter the market and produce competitive products, lowering prices dramatically. Vaccines, in contrast, are complex biological products. Observing their contents is insufficient to allow for imitation. Instead, to produce the vaccine, manufacturers need access to the developer’s “soft” IP — the proprietary recipe, cell lines, manufacturing processes and so forth. While some of this information is confidentially submitted to regulators and might theoretically be released in an extraordinary situation (though not without legal challenge), **manufacturers are at an enormous disadvantage without the originator’s cooperation to help them set up their process and kick-start production. Even with the nonconsensual release of the soft IP held by the regulator, the process of trial and error would cause long delays in a best-case scenario.** Most likely, the effort would end in expensive failure. Manufacturers also need certain raw ingredients and other materials, like glass vials and filtration equipment; overwhelming demand, paired with disruptive export restrictions, has constricted the global availability of some of these items.

No Solv- Multi Factors

Aff fails-laundry list of barriers :bilateral agreement, R&D innovation, extensive timeframe etc.

**Bonadio and Chandler ‘2/24**

(Enrico Bonadio and Dhanay M. Cadillo Chandler, Feburary 24, 2021, Bonadio is a reader in intellectual property law at Univerity of London, Chandler is a postdoctoral research fellow at the University of Turku, “Intellectual property and COVID-19 medicines: why a WTO waiver may not be enough,” <https://theconversation.com/intellectual-property-and-covid-19-medicines-why-a-wto-waiver-may-not-be-enough-155920>, HM)

The COVID-19 pandemic, and the race to make vaccines and other useful technologies more accessible to people around the world, has once again [highlighted](https://theconversation.com/drug-companies-should-drop-their-patents-and-collaborate-to-fight-coronavirus-135241) the tension between intellectual property rights and the promotion of public health. There is no doubt that the monopolies offered by exclusive rights such as patents are necessary to incentivise pharmaceutical companies to invest huge resources and develop useful drugs. These rights help manufacturers recoup those investments. It is not only drugs and medical equipment like [ventilators](https://www.bbc.co.uk/news/health-52036948) which are needed, but **also essential technologies** such as copyright-protected [virus-tracing software](https://www.standard.co.uk/tech/coronavirus-apps-data-software-a4402561.html). Yet, as companies which own intellectual property have a monopoly over their products, they are able to raise prices. This may – in the case of anti-COVID technologies – mean less access to life-saving treatments. Imposing high prices would also be unfair considering that over US$12 billion of [public funding](https://msf.org.uk/article/governments-must-demand-pharma-make-all-covid-19-vaccine-licensing-deals-public) has been poured into the research and development of the six COVID-19 vaccines. **As a potential remedy,** [**calls**](https://www.nature.com/articles/s41587-020-0682-1) **have been made for companies to voluntarily pledge to make their intellectual property available to fight the COVID-19 emergency**. The World Health Organisation has also launched a [voluntary pool](https://www.statnews.com/pharmalot/2020/05/29/who-covid19-coronavirus-patents/) to collect patent and other rights which could be shared for manufacturing vaccines, therapeutics and diagnostics to combat coronavirus. Deep knowledge, daily, in The Conversation's newsletter Sign up South Africa and India, supported by many other developing countries which face extra difficulties accessing affordable COVID-19 treatments, are pushing for a stronger measure. They have proposed a [waiver](https://www.thelancet.com/journals/lancet/article/PIIS0140-6736(20)32581-2/fulltext) of certain parts of the TRIPS Agreement, the WTO international treaty which protects intellectual property at global level. The proposal is still [under discussion](https://www.wto.org/english/news_e/news20_e/trip_10dec20_e.htm). If agreed, it would allow countries to produce and use all anti COVID-19 technologies without fear of infringing intellectual property rights. The measure would be time-limited. As one may expect, this proposal is facing [opposition](https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines), especially by developed countries like the US, Canada, the EU and the UK, which want to protect their pharmaceutical industries. **But would a waiver be enough? We argue not.** This is because **it might not allow all developing countries to secure medicines and other anti-COVID technologies in a timely way**. Many would need to introduce **swift changes** to their own **national laws**. This might be difficult, if not impossible, to do. In view of these difficulties, we argue that it may be more helpful to intensify plans to share vaccines, making jabs and other useful technologies available quickly for as many developing countries as possible. The difficulties One argument against the waiver is that the TRIPS Agreement already contains flexibilities. These include the freedom to use [parallel imports](https://brill.com/view/journals/ajls/6/2-3/article-p287_7.xml?language=en) and [compulsory licences](https://www.southcentre.int/wp-content/uploads/2019/04/RP85_Access-to-Medicines-Experiences-with-Compulsory-Licenses-and-Government-Use-The-Case-of-Hepatitis-C_EN.pdf) that help countries get access to medicines. Yet such flexibilities are not always easy to use. Take compulsory licences. Since 2003 a mechanism has been made available which in principle allows countries with no manufacturing capacity in the pharmaceutical field to use and benefit from compulsory licences. But the system is riddled with levels of [complexity](https://msfaccess.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_NeitherExpeditiousNorSolution_WTO_ENG_2006.pdf) that render it useless and not fit for purpose. It’s only been used once in 17 years – in 2007, when Canada issued a [compulsory licence](https://www.wto.org/english/news_e/news07_e/trips_health_notif_oct07_e.htm) to meet Rwanda’s need for AIDS drugs. [Other arguments against the waiver](https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3789820) are that it would not alleviate the burden of access to effective and affordable medicines and vaccines because of poor healthcare provision and infrastructure in some countries. And that it could potentially hamper R&D and innovation in the pharmaceutical sector. **There are other barriers that the waiver wouldn’t address. One is that some developing countries have entered into bilateral agreements, especially with the US, the EU and other industrialised nations. These have limited the ability of generics producers to manufacture and distribute cheap medicines.** One example is that this has limited the freedom to rely on parallel imports. These usually guarantee the importation of cheaper medicines purchased in countries where the drugs are sold at a lower price. Also, certain free trade agreements have introduced provisions which prevent national drug regulatory authorities from registering and allowing the sale of generics if the medicine is still patented. This is the so-called “[patent linkage](https://www.drugpatentwatch.com/blog/patent-linkage-resolving-infringement/)”. Among the countries that have signed these agreements are those who are part of the Comprehensive and [Progressive Agreement for Trans-Pacific Partnership](https://link.springer.com/article/10.1007/s40319-018-0758-3). They include Brunei, Chile, Malaysia, Mexico, Peru and Vietnam. Other trade and partnership agreements have also obliged certain developing countries to provide an absolute protection of clinical [test data](http://www.hjil.org/wp-content/uploads/Nsour-FINAL.pdf) submitted to regulatory agencies to demonstrate the quality, safety and efficacy of new medicines. This strong exclusivity stops the manufacturers of generics from using such data while applying for their own marketing authorisation. This inevitably slows down the availability of cheaper drugs. Countries like Morocco, Jordan, El Salvador, Guatemala, Honduras and Nicaragua do protect such data as a consequence of trade agreements concluded with the US. French President [Emmanuel Macron](https://www.theguardian.com/world/2021/feb/18/macron-proposes-vaccine-plan-as-uk-prepares-to-host-g7) and British Prime Minister [Boris Johnson](https://www.theguardian.com/world/2021/feb/18/macron-proposes-vaccine-plan-as-uk-prepares-to-host-g7) have recently pushed for plans to share vaccines instead. And the COVAX scheme, led by the [World Health Organisation](https://www.who.int/initiatives/act-accelerator/covax), the Global Vaccine Alliance and the Coalition for Epidemic Preparedness Innovations, has raised [hopes](https://www.bbc.co.uk/news/world-55795297) for more than two billion doses to reach people in 190 countries by the end of 2021. History repeating This is not the first time a stark conflict between intellectual property protection and access to life-saving drugs has emerged. In 1998, a group of pharmaceutical companies [brought a legal case](https://www.theguardian.com/uk/2001/apr/19/highereducation.world) against the South African government to stop it introducing laws aimed at making various medicines more affordable, especially HIV and AIDS drugs. The main objection was that such laws would weaken patent protection. The dispute sparked controversy worldwide and enhanced public awareness of the (sometimes) negative impact of intellectual property rights on human health. The companies eventually abandoned the case. The COVID-19 emergency is clearly more serious. It is a global crisis, with the death toll still increasing and uncertainties growing over whether new variants of the virus are [more infectious](https://www.thelancet.com/journals/lanres/article/PIIS2213-2600(21)00005-9/fulltext). A waiver of TRIPS intellectual property obligations may not provide an **expeditious solution**. But there is no doubt that this unprecedented public health tragedy should trigger a rethink of the current intellectual property policies adopted by developed countries and often exported to poor nations

### OFF CASE

# *Negative effect -Counterfeit medicines*

#### **IPP reductions promote counterfeit medicines and access is meaningless without quality medicine**

**Lybecker**, Kristina. [Associate Professor of Economics at Colorado College] “Counterfeit Medicines and the Role of IP in Patient Safety.” IPWatchDog, 20**16**.<https://www.ipwatchdog.com/2016/06/27/counterfeit-medicines-ip-patient-safety/id=70397/> //CS

The threat of counterfeit goods took center stage on June 15th in a hearing convened by Senate Finance Committee Chairman Orrin Hatch (R-Utah). Focusing on trade opportunities and challenges for American businesses in the digital age, Senator Hatch stated: “The Organization for Economic Co-Operation and Development (OECD) recently released a study that shows that **counterfeit products accounted for** up to 2.5 percent of world trade, or **$461 billion, in 2013**. This is a dramatic increase from a 2008 estimate that showed that fake products accounted for less than half that amount. Counterfeits are a worldwide problem, but the OECD estimates that the United States is the hardest hit, followed by Italy and France. Of the estimated $461 billion in counterfeit trade in 2013, goods with registered intellectual property rights in the U.S. represented 20 percent, or $92 billion, of the OECD estimate.”[1] As the author of the chapter on illicit trade in counterfeit medicines within the OECD report, I worry that global policymakers may be working against each other when it comes to battling counterfeit drugs, especially in the context of intellectual property rights. While **the Senate Hearing and the OECD report highlight the importance of strong IP protection in combating the growing threat of counterfeit goods**, their efforts coincide with an initiative by the UN Secretary-General that has the potential to greatly worsen the problems of counterfeit pharmaceuticals. UN Secretary General Ban Ki Moon’s High Level Panel on Access to Medicines proposes “to review and assess proposals and recommend solutions for remedying the policy incoherence between the justifiable rights of inventors, international human rights law, trade rules and public health in the context of health technologies.”[2] The High Level Panel is a thinly veiled attempt to undermine the intellectual property rights architecture that incentivizes pharmaceutical innovation and protects patients from counterfeit medicines. **While patents and other forms of intellectual property rights are widely recognized as fostering pharmaceutical innovation, they also serve to inhibit counterfeiting.** **The World Health Organization has determined that counterfeiting is facilitated where “there is weak drug regulatory control and enforcement**; there is a scarcity and/or erratic supply of basic medicines; there are extended, relatively unregulated markets and distribution chains, both in developing and developed country systems; price differentials create an incentive for drug diversion within and between established channels; there is lack of effective intellectual property protection; due regard is not paid to quality assurance”.[3] According to INTERPOL estimates, approximately 30 percent of drugs sold worldwide are counterfeit.[4] However, as is the case with many other counterfeit trade statistics, the origins of this figure are somewhat uncertain, as is the methodology used to make the calculation. Perhaps the most widely-cited statistic originates from the World Health Organization, which estimates that 10 percent of the global market for pharmaceuticals is comprised of counterfeits and reports place the share in some developing countries as high as 50-70%.[5] While difficult to measure, estimates do exist on the extent of the market for counterfeit drugs and the harm done to human health. As noted in my chapter in the OECD report, “INTERPOL estimates that more than one million people die each year from counterfeit drugs.[6] While counterfeit drugs seem to primarily originate in Asia, Asian patients are also significantly victimized by the problem. A 2005 study published in PLoS Medicine estimate that 192,000 people are killed in China each year by counterfeit medicines.[7] According to work done by the International Policy Network, an estimated 700,000 deaths from malaria and tuberculosis are attributable to fake drugs. [8] The World Health **Organization presents** a much more modest number noting that **malaria claims one million lives annually and as many as 200,000 may be attributed to counterfeit medicines** which would be avoidable if the medicines available were effective, of good quality and used correctly.[9] Even this number is double that presented by academic researchers Amir Attaran and Roger Bate who claim that each year more than of 100,000 people around the world may die from substandard and counterfeit medications.[10]” [11] **Given the devastating impact of counterfeit medicines on patients and the importance of intellectual property protection in combating pharmaceutical counterfeiting, it is troubling that the UN High Level Panel seems**poised **to prevent** a series of **recommendations that will undermine public health under the guise of enhancing access. Without the assurance of quality medicines, access is meaningless.** Moreover, while falsely presenting intellectual property rights as the primary obstacle to global health care, the High Level Panel downplays a host of other factors that prevent developing country patients from getting the drugs they need: inadequate medical infrastructure, insufficient political will, a shortage of clinical trials in nations where neglected diseases are endemic, poverty, and insufficient market incentives. If the United Nations is serious about addressing the critical need for access to medicines, the Secretary General must come to terms with the reality surrounding the challenges of access to medicine. Although the international patent system may be in need of improvement, it is overly simplistic to blame drug patents, international trade agreements and the global pharmaceutical industry for the access problem. The problem is far more nuanced and complicated than portrayed by the High Level Panel. As the WHO, OECD and Senator Hatch recognize, intellectual property rights are part of the solution. **To truly address the access problem, we must move beyond blaming IPRs and begin the difficult work of grappling with structural deficiencies and poverty.**

#### **Counterfeit medicines are a global public health issue and must be prevented by legal protection**

**Brezovska, Katerina. [**[**Ss. Cyril and Methodius University in Skopje**](https://www.researchgate.net/institution/Ss_Cyril_and_Methodius_University_in_Skopje)**] “Counterfeiting of medicines as an infringement of the intellectual property rights.” Research Gate, 2016.**[**https://www.researchgate.net/publication/332638896\_Counterfeiting\_of\_medicines\_as\_an\_infringement\_of\_the\_intellectual\_property\_rights**](https://www.researchgate.net/publication/332638896_Counterfeiting_of_medicines_as_an_infringement_of_the_intellectual_property_rights)**//CS**

**Counterfeiting and piracy are one of the biggest issues of the global economy** in the last two decades, facing all industrial sectors, including pharmaceutical industry. **Counterfeiting of medicines** is a growing phenomenon affecting all type of medicines including both in- novative and generic **and represents a serious public health problem and a problem of the trade competition as an intellectual property right infringement.** In order to combat this problem, anti-counterfeit regulatory activities are undertaken on a global level through establishment of legislation, strengthening the regulatory activities, development of mechanisms for effective collaboration between the stakeholders on national and international level and communication for raising public awareness regarding the risk of using counterfeited medicines. **The role of the pharmaceutical manufacturers, wholesalers and retailers in the fight against counterfeited medicines is essential for securing the supply chain and providing quality, safety and efficacy of** the **medicine**s that reach the patients from one side and for protecting their brands and their profit from the other side. Intellectual property represents the rights given to people over the creations of their minds, usually given as an exclusive right over the use of his/her creation for a certain period of time. **Intellectual p**roperty **rights** include copyright and rights related to copyright, with a main social purpose to **encourage and reward creative work**; and industrial property, **aiming to stimulate and ensure fair competition and to protect consumers, but also to stimulate innovation**, design and the creation of technology. Industrial property includes protection of trademarks and geographical indications, but also inventions (protected by patents), industrial designs and trade secrets. The social purpose is to provide protection for the results of investment in the development of new technology, thus giving the incentive and means to finance research and development activities (WTO, 1994). The fast growth of the **counterfeiting and piracy** as an intellectual property infringement in the last two decades, **have created** one of the biggest problems facing all sectors of the global economy (OECD, 2011). The **damage inflicted on the businesses** can be seen **through: loss of income, product withdrawal, loss of the brands’ value** etc. Counterfeiting also causes social problems like: **indirect tax rises, market destabilization,** **criminal activity, downsizing of foreign investments**, expenses for exercising of intellectual **property rights etc.** (OECD, 1998). **According to** the World Trade Organization (**WTO**), **counterfeiting is unauthorized representation of a registered trademark carried on goods identical or similar to goods for which the trademark is registered**, with a view to deceiving the **purchaser into** believing that he/she is **buying the original** good**s** (WTO, 1994). Reports from the **World Customs Organisation suggest that around 10% from every product**/service **sold** all **around the world are falsified**. The data on counterfeiting **and** piracy presented in the 2013/2014 Illicit trade report, indicate that **more than half** of the reported cases **were** illicit **pharmaceutical products**, followed by electronic appliances, food, toys, games and school supplies; products representing a potential health and safety risk for the consumers. Compared to the data from 2012 there is a significant increase (from 10.21% to 76.42%) in the reported cases of pharmaceuticals. The data regarding the falsified medicines include reported cases of many different types of medicines indicating that no medicine is safe from being counterfeited, including both innovative and generic, from life-style medicines to medicines that are indicated in life threatening diseases such as cancer, malaria and HIV. In the last years there is a sig- nificant increase in counterfeiting of dietary supplements (especially sliming dietary products) and medical devices. The phenomenon is increasing in the last few years, due to the growth of the sophistication of methods of falsification, and increased quantity of the imported products. According to the World Health Organization (WHO) around 10% of the medicines are falsified on a global level, 30% to 60% are in the developing countries, around 1% of the falsified medicines enter in the legitimate distribution chain in the developed countries, and around 50% from the medicines sold over internet are falsified. Counterfeiting of medicines is a highly profitable business with an estimated profit of more than 75 billion USD per year globally, resulting in a significant percentage of loss of the income of the pharmaceutical industry (WHO, 2010; WCO, 2013; WCO, 2014; WHO, 2014). Innovative pharmaceutical and biopharmaceutical companies usually spend an average of 15-17% of their annual incomes on the research and development fоr providing the quality, safety and efficacy of their products and for ensuring the best outcome of the use of the medicine, avoiding the risk to the health and lives of patients (Blackstone et al., 2014; OECD, 1998). Counterfeiting of medicines as an unauthorised use of the intellectual property of the pharmaceutical industry reduces the incentives for creation and innovation, resulting in the damage to the econ- omy, society and environment (Blackstone et al., 2014). From the other point of view, counterfeit medicines may include products with the correct ingredients or with the wrong ingredients, without active ingredients, with insufficient (inadequate quantities of ingredient(s) or with fake packaging and are often produced by unqualified personnel and in very poor and unhygienic conditions, and may con- tain toxic ingredients or unknown impurities, posing a serious treats to the health and safety of the patients. Consequently, counterfeiting of medicines has negative influence of the healthcare systems on an international level. Patients suffer from additional conditions due to the uncontrolled quality and quantity of the counterfeit medicine and there- fore must get additional care covered by the state’s min- istry of health, causing additional burden of the government’s funds (WHO, 2014). The counterfeiting of medicines compromises the le- gitimate activities performed during the production, trans- portation and distribution, such as, infringement of the pat- ent rights (unauthorised production, theft, selling and im- portation of patented active pharmaceutical ingredient), implementation of patented process or method for produc- tion of active pharmaceutical ingredients, excipients or fin- ished products, unauthorised use of the name or logo pat- ented for the medicine, the colour and shape of the dos- age form, the packaging or any other characteristic that are subject of patenting. Counterfeiting of the medicines may involve unauthorized manufacturers, brokers, illegal/un- regulated suppliers, wholesalers, and unregulated internet sale (MHRA, 2012; OECD, 2007). Anti-counterfeit regulatory activities on a global level Counterfeiting of medicines is an organized crime, reaching truly global proportions, which violates the law regarding the medicines and medical devices, but also in- cludes infringement of the intellectual property rights of the pharmaceutical industry. The greatest concern regard- ing the counterfeit medicines is the risk to public health, therefore this problem should be considered primarily from a public health perspective, and secondary as an intel- lectual property concern (Council of Europe, 2013; WHO, 2014). The real extent of the problem with occurrence and distribution of counterfeit medicines vary from country to country. The lack of resources/skills to detect counterfeit medicines, weak medicines regulatory systems, the differ- ent definitions of counterfeit medicines in different coun- tries worldwide, the variations in the distribution systems, high prices of the authentic medicines and insufficient co- operation between stakeholders are factors which facilitate counterfeiting activities (WHO, 1999). Since the problem with counterfeit medicines cannot be combated successfully with isolated measures, an inte- grated and multilateral approach is necessary; ensuring co- operation between the various authorities involved, such as public health authorities and medicines agencies, as well as customs and police authorities on national, regional and in- ternational level. The fight against counterfeiting of med- icines should also involve pharmaceutical manufacturers, distributors, health professionals, consumers and general public (Council of Europe, EDQM, 2013; MHRA, 2012; WHO, 1999). The World health organization (WHO) in February 2006 founded the International Medical Products Anti- Counterfeiting Taskforce (IMPACT), by joining together Maced. pharm. bull., 62 (1) 85 - 89 (2016) Counterfeiting of medicines as an infringement of the intellectual property rights 87 all of the stakeholders (international organizations, regu- latory agencies, associations of pharmaceutical manufac- turers, regulatory bodies) in the fight against counterfeit medicine on a global level, with the main purpose to pro- vide the main principles and elements of the national leg- islation for combating this problem. IMPACT is focused on the establishment, implementation and enforcement of the legislation and regulatory infrastructure, development of the technology to prevent and to detect counterfeit med- icines and communication strategy for rising public aware- ness (WHO, 2008). The Medicrime convention of the Council of Europe is a powerful tool against the counterfeiting of medicines, from the perspective of protection of the patients’ health. The Medicrime convention provides the guidance for in- troduction of common minimal standards for safety, effica- cy and quality of medicinal products, essential and proce- dural criminal law; administrative procedures and preven- tive measures as well as provisions directed towards im- proving the cooperation and exchange of information be- tween the entitled organs in the fight against counterfeit medicines (Council of Europe, 2013). The intellectual property rights are mostly regulat- ed on the national level, but additionally from an interna- tional perspective, the Trade related Aspects of Intellectu- al property rights (TRIPS) Agreement is also applicable. The TRIPS agreement is a document that guides the im- plementation of a global system for protection of the intel- lectual property rights, developed by the WTO and estab- lishes minimal standards for legal protection of intellectu- al property rights (sanctions for criminal activities are not harmonized). The TRIPS agreement introduced intellec- tual property law into the international trading system for the first time and remains the most comprehensive interna- tional agreement on intellectual property to date. Specifi- cally, **TRIPS requires WTO members to provide copyright rights, geographical indications, industrial designs, patents, trademarks and undisclosed or confidential information. TRIPS specifies enforcement procedures, remedies, and dispute resolution procedures.** According to TRIPS, the protection and enforcement of all intellectual property rights will contribute to the promotion of technological in- novation and to the transfer and dissemination of technolo- gy, to the mutual advantage of manufacturers and users of technological knowledge, while maintaining the social and economic welfare, and balancing the rights and obligations of the holders if intellectual property rights (WTO, 1994). Protection of the brand of the pharmaceutical industry In order to protect their brands, many pharmaceuti- cal companies take measures for prevention of counterfeit- ing and for rapid and effective response to counterfeited products including: development of the strategy for pro- tection from counterfeit, establishment and protection of Макед. фарм. билт., 62 (1) 85 - 89 (2016) their intellectual property rights, developing standards for traceability of the authenticity of their products, and there- fore providing larger transparency of the distribution chain and early detection of counterfeited products. The compa- nies should continuously implement new anti counterfeit- ing technologies for securing the distribution chain and to protect their brands by using track and trace systems, se- rialization and by keeping electronic records for all stages of the distribution of their products. Many different anti- counterfeit technologies are applied by the pharmaceutical companies including human readable (overt) and machine readable (covert) safety features, use of sophisticated print- er inks and track and trace software (Abel, 2010; OECD, 2007). EU Directive 2011/62 provides for measures to pre- vent the entry into the legal supply chain of falsified me- dicinal products by requiring the placing of safety features consisting of a unique identifier and an anti-tampering de- vice on the packaging of certain medicinal products for hu- man use for the purposes of allowing their identification and authentication (Council of Europe, 2011). The new EU regulation 2016/161 sets out the system for identifica- tion and confirmation of the authenticity of the medicines (Unique Identifier, UI and Anti tampering device, ATD) in the distribution chain in order to in order to verify the le- gitimacy of the manufacturer (Council of Europe, 2015). The pharmaceutical companies should establish test- ing laboratory units in different countries for examination of suspected counterfeit samples. Additionally, in the fight against counterfeit medicines the pharmaceutical industry should participate trough organizing trainings (for law en- forcement, government officials, pharmacists and official testing laboratories), but also attending educational pro- grams for detection, monitoring and reporting of counter- feit medicines; leading and supporting networks against counterfeiting for promoting knowledge and experience exchange, development of activities for communication, informing, education and awareness increase of the gen- eral public; establishment of cooperation between private and public institutions (Abel, 2010; OECD, 2007). The wholesalers has also an important role in preven- tion of counterfeiting of medicines, by verifying the au- thenticity of the medicinal products in his physical posses- sion and in cases where the verification of the safety fea- tures of the medicinal product indicates that the product may not be authentic or its packaging has been tampered, to report it to the relevant competent authorities (Council of Europe, 2015). The marketing authorisation holder, parallel importers or parallel distributors are also an important link in secur- ing the distribution chain of medicines and should share the responsibility with other stakeholders in the fight against counterfeiting medicines (Council of Europe, 2015). 88 F. Cvetanovski, K. Brezovska, A. Poceva Panovska, J. Acevska, J. Tonic Ribarska, Z. Sterjev, A. Grozdanova, K. Ancevska Netkovska Conclusion Counterfeiting of medicines is a crime carried out us- ing deception and other techniques typical of organized crime, posing a significant danger to global public health in developing as well as developed countries. Additional- ly, counterfeiting of medicines has negative influence to the health care systems as well as to the pharmaceutical industry, causing financial problems, loss of the value of the brands and reduced confidence in their products. Solv- ing this problem and preventing counterfeiting of med- icines require establishment legislation that will identify the counterfeiting of medicines as a serious crime and en- forcement of effective penalties proportional with the con- sequences of this crime, strengthening the regulatory ac- tivities for securing the distribution chain of the medicines, establishment and improvement of collaboration between health authorities, police, customs and judiciary and de- velopment of communication strategy for raising public awareness for the risk of using counterfeit medicines. The role of the pharmaceutical manufacturers, wholesalers and retailers in the fight against counterfeited medicines is essential for both securing the supply chain to provide quality, safety and efficacy of the medicines that reach the patients from one side and to protecting their brands and their profit from the other side.

Only IPRs can check back against counterfeit production – key to solving crisis

FIFARMA 4/28. “This Is How We Fight Counterfeit Medicines with Intellectual Property.” FIFARMA, 28 Apr. 2021, fifarma.org/en/this-is-how-we-fight-counterfeit-medicines-with-intellectual-property/.

This is how we fight counterfeit medicines with Intellectual Property 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). The role of 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. In 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

# **Innovation will be destroyed - negative effect of Aff plan.**

#### **The status quo is rolling, innovation at a high**

Daniel **Cohen,** [**Laura Furstenthal**](https://www.mckinsey.com/our-people/laura-furstenthal)**, and Leigh Jansen(et al) 20**

https://www.mckinsey.com/industries/pharmaceuticals-and-medical-products/our-insights/healthcare-innovation-building-on-gains-made-through-the-crisis#

While **the COVID-19 pandemic** has **placed** unparalleled **demands on** modern healthcare **systems**, **the industry’s response** has vividly **demonstrated** its **resilience and ability to bring innovations** to market **quickly**. But the crisis is likely far from over and **the sector’s innovation** capabilities **must continue** to rise to the challenges presented both by COVID-19 and the economic fallout from its spread. While many industries are facing unprecedented disruption, medicine and healthcare are uniquely affected given the nature of this crisis. **For example, pharmaceutical companies racing to develop vaccines** must also manage complex supply chains, **new models for engagement** with healthcare professionals, a largely **remote workforce**, and disruption to many clinical trials. Similarly, hospitals are caring for COVID-19 patients with evolving protocols while maintaining continuity of care for others, often against the backdrop of vulnerable staff, supply and equipment shortages, and, for some, accelerating financial headwinds.

Waiving IPP would significantly hinder innovation

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The IP system is designed to encourage and reward creativity and innovation while benefiting society as a whole. The idea is that IPRs stimulate innovation by “enabling innovators to capture enough of the benefits of their own innovative activity to justify taking considerable risks.” 23 Therefore, while in the short term waiving IPRs may arguably accelerate the distribution of goods and services – i.e. access to COVID-19 vaccines – in the long term undermining IPRs would eliminate the incentives that spark innovation, thus hindering the discovery and development of knowledge for new products or technologies that the world needs.24 An example that illustrates the significance of IP protection is the technology of synthetic mRNA, a genetic technology behind the COVID-19 vaccines of both Pfizer and Moderna. Synthetic mRNA is a genetic technology that has long held huge promise but has so far run into biological roadblocks. The concept of tweaking specific strands in synthetic mRNA to deliver desired results was first introduced in the 1990s, but at that time while it made sense in theory it often failed in the real world as synthetic RNA was notoriously vulnerable to the body’s natural defences and the synthetic RNA was very often destroyed before reaching its target cells. In some situations, the foreign materials even elicited an immune response that poses health risks for some patients. The solution, substituting one of the nucleosides (building blocks of mRNA) for a slightly tweaked version to bypass the body’s defence, was not discovered until 2005 and did not reach commercialization stage for another 15 years. Without the prospect of IP protection, it is simply unimaginable that scientists would devote the human and monetary resources into such R&D as there would have been no incentive to spend the time and effort on a promising but extremely challenging technology. Likewise, venture capitalists would refuse to invest billions of dollars into any research effort knowing that any other company could simply take the successful result and produce a medicine without paying for the R&D costs; in such a scenario, it would be virtually impossible to recoup the initial investment. Thus, without the promise of IP protection the technology underpinning the most advanced and promising COVID-19 vaccines would likely never have been developed. This point is of such importance that it is worth stating the obvious: IPRs have played a large role in the response to COVID-19; a response which has led to an incredible feat of humanity – the identification of the genome of a new pathogen and development of several treatments and promising vaccines within the space of a year. Without the promise of financial gain, the level of R&D into the novel coronavirus would have been greatly reduced and innovation hampered and delayed. In short, the IP system encouraged a robust response to the threat from innovator companies and worked as designed. It would be unwise (if not reckless) to place the innovation system which has delivered results in record time in jeopardy only in exchange for what is at best short-term benefits.

**The alternative to a patent system is trade secrecy which chills innovation**

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**What would our innovation system look like without patents?** It’s hard to imagine that it would be much to look at given that the primary alternative would be **trade secrecy**. But the high cost of seeking patent protection overseas, among other reasons, is elevating the status of trade secrecy as an IP tool of choice, despite its chief shortcoming. As the NIH points out, “trade secret protection lasts for as long as the secret is kept confidential. If the secret is never publicly disclosed, it will never lose its protection. If the secret is uncovered by means of industrial espionage, disloyal employees, theft, or the like, the owner of the secret has legal recourse against those who misappropriated the secret, or anyone who procured it through such impropriety.”35 Protection is not afforded, however, “in the event that someone managed to successfully duplicate the recipe by legitimate means.”36 A trend toward greater trade secrecy to avoid the pitfall of an insufficient patent regime poses two significant problems. For companies, **it’s unsustainable** because today’s technology makes inimitability exceedingly difficult to maintain. For society, it’s undesirable because secrecy deeply undermines the scientific process that feeds on the kind of transparency and collaboration that the patent system was conceived to deliver. Opting for **trade secrecy** over patent protection **will have a chilling effect on innovation** and threatens to undermine broad-ranging scientific advancement. The quality of innovation touches our lives and enterprises in so many ways. Thus, we are all stakeholders in the patent debate and, in particular, the life science patent debate.

#### **OVERVIEW:**

The aff triggers two negative effects,and also doesn’t ensure solvency. These two negative effects are medicines being counterfeited which outweighs the supposed benefits of the aff because there’s no purpose in having access if there’s not a guarantee that people will have quality and safe medicines. In reality reducing IP isn’t going to do anything good if it triggers the risk that people may die from consuming counterfeit medicine. For example Malaria takes as much as 1m lives every year,and ⅕ of those deaths is due to counterfeit medicine. Another negative effect is that innovation will be destroyed because IP protects and rewards the innovation of many individuals.By reducing IP, if looked at in the long term undermining IPRs would eliminate the incentives that spark innovation,ruining the chance of new products that we all need, to not be discovered. In addition to that, the AFF may sound good but the truth is that it doesn’t have any real solvency according to my **Bonadio and Chandler card,**  an IP waiver won’t solve and that proves aff is a bad idea which is enough to vote neg.