# **Counterfeit medicines DA**

#### **IPP Law is essential for preventing the development of counterfeit medicines.**

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The protection of IP not only provides incentives to innovators to create, but also plays a crucial role in ensuring the safety of vaccines and helping to prevent the importation of fraudulent and dangerous goods. Unlike the typical pharmaceutical industry, the vaccine market is not a free and open market.69 Vaccines contain biological products made from living organisms and the risk of failure in vaccine development and production is high. 70 Moreover, the manufacturing process for vaccines is much more complex as it requires the use of facilities and equipment with a high degree of specialization.71 The complexity of vaccine products implies that more time and regulatory requirements are needed in order to make or “copy” the vaccine production process. Therefore, the innovator should be expected to make conscious and meticulous decisions as to when and to whom to issue licenses, as this is the most responsible way to bring their technologies to the world and safeguard global health. In addition, as the COVID-19 pandemic continues there has been a noticeable increase in the circulation of fake medicines around the world. According to the International Criminal Police Organization (Interpol), organized crime groups have been producing fake drugs and medical products and selling them for lucrative profits in developing countries.72 With the development of COVID-19 vaccines on the market, a rapid rise in the illegal sale of fake items is expected, according to the United Nations Office on Drugs and Crime (UNODC).73 Counterfeits of the legitimate products provide false promises of protection and could lead to disastrous consequences, including worsened illness and death for the individual and the retardation of herd immunity for the population at large. Effective and proactive IP procurement is essential and useful in mitigating the risks of counterfeit and substandard medicines. IP enforcement measures play a significant role in preventing these fake and illicit medicines from circulating in the market. While important during normal times, IP enforcement can take on an enhanced role of safeguarding the public during this critical period of time. Waiving all COVID-19 related IPRs raises the risk of unsafe or fake vaccines circulating in supply channels and being sold to unsuspecting governments, putting millions of human lives at risk and reducing trust in vaccines.

#### 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 catastrophic for individuals, producers, and governments

#### OECD/EUIPO (2020), Trade in Counterfeit Pharmaceutical Products, Illicit Trade, OECD Publishing, Paris,<https://doi.org/10.1787/a7c7e054-en>.//AK

#### Impact on individuals Bad quality counterfeit medicines can affect individuals in a variety of ways (WHO, 2017c): · Adverse effects (for example toxicity) from incorrect active ingredients. · Failure to cure or prevent future disease, thereby increasing mortality, morbidity and the prevalence of disease. · Contributing to the progression of antimicrobial resistance and drug-resistant infections. · A loss of confidence in health care professionals, health programmes and health systems. · Increasing out-of-pocket and health system spending on health care. · Lost income due to prolonged illness or death. · Lost productivity costs to patients and households when seeking additional medical care, the effects of which are felt by businesses and the wider economy. 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). While many incidences of patient harm will likely go undetected, numerous examples have nevertheless been recorded. 1 For example, a recent UK survey carried out by Sapio research and commissioned by a private company INCOPRO, concludes that almost one-third (32%) of those who have bought one or more counterfeit medicines have suffered a health issue as a result (INCOPRO, 2020). There are numerous other documented cases in which patients have died or suffered harm due to an online purchase. As just one example, in 2013 people died after taking a counterfeit diet pill bought through an online drug seller. The pill, sold as a weight loss aid through many illicit online pharmacies, is actually a pesticide with lethal consequences for humans.2 The impact of counterfeits on legitimate producers are multiple, including lost sales, costs of protecting brands, loss of reputation, the potential cost of managing the disposal of counterfeits and litigation costs involving counterfeiters and possibly people who were unknowingly victimised by counterfeits. The challenges are alluded to in corporate reports, albeit in a general manner. For example, one of the five largest pharmaceutical companies – Pfizer – mentioned counterfeiting in its 2019 annual financial report , although not in its general annual report. In the financial report, the company includes a section on counterfeit products, containing general information on the challenges it faces, and noting the efforts it has taken to address the situation (Pfizer Inc., 2019a; 2019b): Counterfeit pharmaceuticals can result in squandered health resources, not only for individual patients, but also for international humanitarian organisations, NGOs and national government programmes (OECD, 2016). Counterfeiters divert resources away from genuine treatment, robbing limited health budgets of already scarce resources. At the same time, counterfeits can mean losses in corporate taxes and VAT, increased regulatory and enforcement costs for securing the supply chain, and higher health care costs to treat the adverse effects of fake drugs. With respect to taxes, EUIPO (2016) estimates that the cost to EU governments of revenues foregone from counterfeit medicines was in the order of EUR 1.7 billion.

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

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**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.

# Innovation DA

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

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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.

**TRIPS IP rights are key for innovation**

James **Bacchus 20**, adjunct scholar at CATO, “An Unnecessary Proposal: A WTO Waiver of Intellectual Property Rights for COVID-19 Vaccines,” December 16th, 2020, <https://www.cato.org/free-trade-bulletin/unnecessary-proposal-wto-waiver-intellectual-property-rights-covid-19-vaccines#does-novel-virus-present-novel-issues>

Technically, IP rights are exceptions to free trade. A long‐​standing general discussion in the WTO has been about when these exceptions to free trade should be allowed and how far they should be extended. The continuing debate over IP rights in medicines is only the most emotional part of this overall conversation. Because developed countries have, historically, been the principal sources of IP rights, this lengthy WTO dispute has largely been between developed countries trying to uphold IP rights and developing countries trying to limit them. The debate over the discovery and the distribution of vaccines for COVID-19 is but the latest global occasion for this ongoing discussion. The primary justification for granting and protecting IP rights is that they **are incentives for innovation**, which is the main source for long‐​term economic growth and enhancements in the quality of human life. IP rights spark innovation by “enabling innovators to capture enough of the benefits of their own **innovative activity** to justify taking considerable risks.”18 The knowledge from innovations inspired by **IP rights spills over** to inspire other innovations. The protection of IP rights promotes the diffusion, domestically and internationally, **of innovative technologies** and new know‐​how. Historically, the principal factors of production have been land, labor, and capital. In the new pandemic world, perhaps an even more vital factor is the creation of knowledge, which adds enormously to “the wealth of nations.” Digital and other economic growth in the 21st century is increasingly ideas‐​based and knowledge intensive. Without IP rights as incentives, **there would be less new knowledge and thus less innovation**. In the short term, undermining private IP rights may accelerate distribution of goods and services—where the novel knowledge that went into making them already exists. But in the long term, undermining private IP rights would **eliminate the incentives that inspire innovation**, thus preventing the discovery and development of knowledge for new goods and services that the world needs. This widespread dismissal of the link between private IP rights and innovation is perhaps best reflected in the fact that although the United Nations Sustainable Development Goals for 2030 aspire to “foster innovation,” they make no mention of IP rights.19

**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.

**Only pharma innovation solves global pandemics that risk extinction**

Jeffrey **Sachs 14**, Professor of Sustainable Development, Health Policy and Management @ Columbia University, Director of the Earth Institute @ Columbia University and Special adviser to the United Nations Secretary-General on the Millennium Development Goals) “Important lessons from Ebola outbreak,” Business World Online, August 17, 2014, http://tinyurl.com/kjgvyro

Ebola is the latest of many recent epidemics, also including AIDS, SARS, H1N1 flu, H7N9 flu, and others. AIDS is the deadliest of these killers, claiming nearly 36 million lives since 1981. Of course, even larger and more **sudden epidemics are possible**, such as the 1918 influenza during World War I, which claimed **50-100 million lives** (far more than the war itself). And, though the 2003 SARS outbreak was contained, causing fewer than 1,000 deaths, the disease was on the verge of deeply disrupting several East Asian economies including China’s. There are four crucial facts to understand about Ebola and the other epidemics. First, most emerging infectious diseases are zoonoses, meaning that they start in animal populations, sometimes with a genetic mutation that enables the jump to humans. Ebola may have been transmitted from bats; HIV/AIDS emerged from chimpanzees; SARS most likely came from civets traded in animal markets in southern China; and influenza strains such as H1N1 and H7N9 arose from genetic re-combinations of viruses among wild and farm animals. **New zoonotic diseases are inevitable** as humanity pushes into new ecosystems (such as formerly remote forest regions); the food industry creates more conditions for genetic recombination; and climate change scrambles natural habitats and species interactions. Second, once a new infectious disease appears, its spread through airlines, ships, megacities, and trade in animal products is likely to be **extremely rapid**. These epidemic diseases are new markers of globalization, revealing through their chain of death how vulnerable the world has become from the pervasive movement of people and goods. Third, the poor are the first to suffer and the worst affected. The rural poor live closest to the infected animals that first transmit the disease. They often hunt and eat bushmeat, leaving them vulnerable to infection. Poor, often illiterate, individuals are generally unaware of how infectious diseases -- especially unfamiliar diseases -- are transmitted, making them much more likely to become infected and to infect others. Moreover, given poor nutrition and lack of access to basic health services, their weakened immune systems are easily overcome by infections that better nourished and treated individuals can survive. And “de-medicalized” conditions -- with few if any professional health workers to ensure an appropriate public-health response to an epidemic (such as isolation of infected individuals, tracing of contacts, surveillance, and so forth) -- make initial outbreaks more severe. Finally, the required medical responses, including diagnostic tools and effective medications and vaccines, inevitably lag behind the emerging diseases. In any event, such tools must be **continually replenished**. This requires **cutting-edge biotech**nology, immunology, and ultimately bioengineering to create large-scale industrial responses (**such as millions of doses of vaccines or medicines** in the case of large epidemics). The AIDS crisis, for example, called forth tens of billions of dollars for research and development -- and similarly substantial commitments by the pharmaceutical industry -- to produce lifesaving antiretroviral drugs at global scale. Yet each breakthrough inevitably leads to the pathogen’s mutation, rendering previous treatments less effective. There is no ultimate victory, only a **constant arms race** between humanity and disease-causing agents.

# Case

**AT Extinction**

**1% rhetoric is the definition of threat construction – this is how states look to xt ! to justify deferring to policy with existential impact and reinforce realism - you should prefer probability in your calculus and have a low threshold for presumption**

**Sunstein 7** — Robert Walmsley University Professor at Harvard; was Administrator of the White House Office of Information and Regulatory Affairs; founder and director of the Program on Behavioral Economics and Public Policy at Harvard Law School (Cass, “Worst Case-Scenarios” 2007, 1-5, MT)

How do human beings and their governments approach worst- case scenarios? Do they tend to neglect them or do they give them excessive weight? Whatever we actually do, how should we deal with unlikely risks of catastrophe? In the aftermath of the attacks on 9/11, Vice President Dick Cheney set out what has become known as The One Percent Doctrine: “We have to deal with this new type of threat in a way we haven’t yet defined . . . With a low-probability, high-impact event like this . . . if there’s a one percent chance that Pakistani scientists are helping al Qaeda build or develop a nuclear weapon, we have to treat it as a certainty in terms of our response.”1 For especially horrific outcomes, it is tempting to think that a 1 percent chance should be treated as a certainty. In so suggesting, Vice President Cheney took the same position as many people who are confronting a low probability of disaster. No less than environmentalists who focus on species loss, climate change, and genetic modification of food, Vice President Cheney urged that governments should identify, and attempt to prevent, the worst-case scenario. Indeed, another vice president, Al Gore, implied a related principle for climate change—because the risk of a terrible catastrophe is real, we ought to respond aggressively to it. Many environmentalists enthusiastically embrace the Precautionary Principle, which is specifically designed for situations in which we cannot know that harm will occur. According to the Precautionary Principle, threats to the environment need not be established with certainty. Even a small risk of a catastrophic or irreversible harm is enough to require a serious response. But consider an obvious objection to this position. A 1 percent chance of a terrible outcome is a lot better than a certainty of a terrible outcome. In order to figure out what to do, **you should multiply the probability of the outcome by its magnitude**. If you face a 1 percent chance of losing $10,000, you should take fewer precautions than if you face a 90 percent chance of losing $10,000. Even with losses that do not involve money, and that are hard to turn into monetary equivalents, it is important to attend to both the probability of harm and the magnitude of harm. If you face a 1 percent chance of getting sick, you should act differently from how you would act if you faced a 90 percent chance of getting sick. People who are sensible, or even sane, do not treat a 1 percent risk of loss the same as a certainty of loss. Suppose that you have a health problem of some kind—serious heart disease, a brain tumor, failing eyesight, severe and chronic back pain—and your doctor tells you that an operation is 99 per- cent likely to solve the problem and to have no bad side-effects. Will you decline the operation if the doctor emphasizes that in 1 percent of cases things go quite wrong? Probably not. Whatever you do, you are most unlikely to treat a small chance of a bad out-come as equivalent to a certainty of a bad outcome. You will focus not just on the nature of the worst case but on the probability that it will come about. Perhaps you will decide to create a special “margin of safety,” or buffer zone, against the worst outcomes. But even if you do so, you will probably think a lot before deciding on the right margin of safety, and you will pay a great deal of attention to the probability of harm. The same point holds for governments. For public officials no less than the rest of us, the probability of harm matters a great deal, and it is foolish to attend exclusively to the worst-case scenario. Suppose there is a 99 percent chance that a new law will increase national security, and a 1 percent chance that it will decrease national security; a 99 percent chance that a reform of the health care system will improve both health and the economy, and a 1 percent chance that reform will significantly increase unemployment; a 99 percent chance that a voucher system for education will make schools better, and a 1 percent chance that schools will get worse. If government initiatives are rejected whenever they entail a 1 percent chance of a bad outcome, we will have far too few initiatives. In many contexts, governments, just like ordinary people, take their chances on the worst-case scenario—and they are entirely right to do so. These points create real problems for any one percent doctrine. Ordinarily it is a big mistake to ignore the difference between a 1 percent chance and a certainty. But pause over what it would mean if Al Qaeda were able to acquire nuclear weapons for use against the United States and its allies. For a truly catastrophic outcome, a 1 percent chance may not be so radically different from a much higher chance—and it is tempting to consider responding as if it were a certainty. To see the point, imagine a 1 percent chance that New York City, or the entire East Coast, would be completely destroyed. Or imagine a 1 percent risk of worldwide calamity from climate change—with hundreds of millions of deaths from malaria and other climate-related diseases, countless extinctions, the melting of the polar ice sheets, catastrophic flooding in Florida, New York, Paris, Munich, and London. Or imagine a 1 percent chance of a devastating collision between a large asteroid and our planet. If the worst-case scenario is awful enough, we might well treat a small probability as if it were much larger. But on reflection, is this really wise? One problem is that responses to worst-case scenarios can be both burdensome and risky—and they can have worst-case scenarios of their own. We need to investigate the burdens and risks of the responses, not simply the scenarios. In the context of national security, an aggressive response to a 1 percent threat may create a new threat, perhaps higher than 1 percent, of producing its own disaster. **A preemptive war, designed to eliminate a small risk of a terrible outcome, might create larger risks of a different but also terrible outcome**. If the United States attacked an unfriendly nation to eliminate the (low probability?) danger that it poses, the attack would likely create a certainty of many deaths, and a (low?) probability of many more. The Bush administration resisted significant steps to halt climate change, pointing to the burdens and costs of the regulatory actions that some people believe to be required. Suppose that cli- mate change does, in fact, create a 1 percent risk of catastrophe at the very least—and that an aggressive response to climate change, calling for massive changes in energy policy, creates a significant chance of imposing serious hardships on many nations, including not just the United States but India and China as well. Perhaps those hardships would entail significant increases in unemploy- ment and hence poverty. If the world devotes resources to climate change, perhaps it will not be able to use those resources to com- bat more serious problems.2 To take another example: We could easily imagine responses to the AIDS crisis, such as quarantines, that would impose unacceptable burdens on people who are infected or who are at risk of becoming infected. To know whether and how to respond, we must look at the consequences of possible responses—not only at the existence, probability, and size of the danger. In this book, I try to make progress on issues of this kind. I have three specific goals. The first is to understand people’s responses to worst-case scenarios and in particular their susceptibility to two opposite problems: excessive overreaction and utter neglect. As we shall see, both problems affect individuals and governments alike. The second goal is to consider how both individuals and public of- ficials might think more sensibly about situations involving low- probability risks of disaster. Insisting on a wide viewscreen, one that emphasizes the likelihood and magnitude of the risks on all sides, would be a good place to start. The third goal is to explore the uses and limits of cost-benefit analysis, especially when dealing with harms that will not come to fruition in the near future. Cost-benefit analysis is at best a proxy for what really matters, which is well- being rather than money; but sometimes proxies can be helpful. Throughout I shall use climate change as a defining case, both because it has immense practical importance and because it pro- vides a valuable illustration of the underlying principles. But I shall also refer to other sources of very bad worst-case scenarios, includ- ing terrorism, depletion of the ozone layer, genetic modification of food, hurricanes, and avian flu. My hope is that the basic analysis can be adapted to diverse problems, including many not yet on the horizon. The discussion is organized around five general themes.