# Topicality

## Reduce ≠ Eliminate

#### Interpretation:

#### Reduce is distinct from eliminate and has a limited application – prefer our evidence for specificity to WTO policy.

LAWASIA Moot Competition, 10

(IN THE INTERNATIONAL COURT OF ARBITRATION NEW DELHI, INDIA, GHC/GHC-MARU Claimant v INTELLECTUAL PROPERTY DEPARTMENT OF THE GOVERNMENT OF MARU Respondent, F3020-R)

The trade objectives support that TRIPS intervene in the national patent regime in order “to reduce distortions and impediments to international trade”. Thus, in cases where there is a distortion in trade, TRIPS should not intervene in the domestic patent regime. Furthermore, the use of the word “reduce”, instead of “eliminate”, means that TRIPS did not intend to intervene in every trade distortion, but only intervene in cases of severe trade distortion. Due to its limited application, the existence of equivalents do not severely disrupt a market, or distort trade49; and therefore, do not warrant any interference by TRIPS, such as obliging members to recognize NLI.

1. **Violation: the affirmative in cross x explained that they GET RID of IP protections**
2. **Reasons to prefer**

**Vote neg for limits – eliminating IP protections is an entirely different literature base and they obfuscate key neg ground like abolition. Extra topicality is a voting issue because it is unpredictable and allows the aff to fiat out of core neg arguments.**

#### D. Paradigm issues

**1. Drop the debater -- they skewed the debate from the 1AC and T indicts their advocacy**

**2. Competing interps -- you can't be reasonably topical and reasonability invites judge intervention**

**3. No RVIs -- forcing the 1NC to go all in kills substance education and discourages checking abuse**

# Pharma DA

**Pharma profits are up from COVID vaccines, patent waivers threaten this**

**Buchholz, 21**

(Katharina, https://www.statista.com/chart/24829/net-income-profit-pharma-companies/)

The profitability of coronavirus vaccines has been in the spotlight since U.S. President Joe Biden come out in support of temporarily lifting vaccine patents to make the production of the life-saving inoculations more financially feasible for poorer countries. EU leaders meanwhile remain divided over such a move. Company financial reports show that COVID-19 vaccine makers and developers like Johnson & Johnson, Pfizer, Moderna, AstraZeneca and BioNTech have seen their profits increase since the vaccine rollout, at times majorly. In early May, stocks of several companies that benefit from COVID-19 vaccine sales **took a nosedive on the news of Biden’s reversal**. Moderna stocks, for example, were still down more than 6 percent at close on May 5, the day of the announcement. Stocks recovered somewhat as German chancellor Angela Merkel came out against patent waivers the following day. While fluctuations in the stock market price have hurt drug makers in the **short term**, patent waivers would diminish the bottom line of companies involved with the development and production of COVID-19 **vaccines in the long term**. Pharma giants like Johnson & Johnson and Pfizer bring in billions of dollars of income every quarter from diverse sources, so the COVID bump was smaller for them. In the case of Pfizer, which has been a bigger producer than J&J, the year-over-year profit increase was a handsome 44 percent, however. For smaller AstraZeneca, the COVID year meant that its profits doubled. In the case of Moderna, the past year has turned a Q1 loss into a profit. The case is similar for German company BioNTech, which collaborated with Pfizer on its COVID vaccine. While Q1 2021 brought in a profit of $1.1 billion, the company ran a deficit since its founding in 2008 up until Q4 2020, when it posted a profit for the first time. The $446 million earned stood in contrast to losses of almost $428 million accrued in the first nine months of the year.

**Strong IP protection spurs innovation by encouraging risk-taking and incentivizing knowledge sharing -- prefer statistical analysis of multiple studies**

**Ezell and Cory, 19** [Stephen Ezell, vice president & global innovation policy @ ITIF, BS Georgetown School of Foreign Service. Nigel Cory, associate director covering trade policy @ ITIF, MA public policy @ Georgetown. "The Way Forward for Intellectual Property Internationally," Information Technology & Innovation Foundation, 4-25-2019, accessed 8-25-2021, https://itif.org/publications/2019/04/25/way-forward-intellectual-property-internationally] HWIC

Intellectual property rights power innovation. For instance, analyzing the level of intellectual property protections (via the World Economic Forum’s Global Competitiveness reports) and creative outputs (via the Global Innovation Index) shows that counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.46 IPR reforms also introduce strong incentives for domestic innovation. Sherwood, using case studies from 18 developing countries, concluded that poor provision of intellectual property rights deters local innovation and risk-taking.47 In contrast, IPR reform has been associated with increased innovative activity, as measured by domestic patent filings, albeit with some variation across countries and sectors.48 For example, Ryan, in a study of biomedical innovations and patent reform in Brazil, found that patents provided incentives for innovation investments and facilitated the functioning of technology markets.49 Park and Lippoldt also observed that the provision of adequate protection for IPRs can help to stimulate local innovation, in some cases building on the transfer of technologies that provide inputs and spillovers.50 In other words, local innovators are introduced to technologies first through the technology transfer that takes place in an environment wherein protection of IPRs is assured; then, they may build on those ideas to create an evolved product or develop alternate approaches (i.e., to innovate). Related research finds that trade in technology—through channels including imports, foreign direct investment, and technology licensing—improves the quality of developing-country innovation by increasing the pool of ideas and efficiency of innovation by encouraging the division of innovative labor and specialization.51 However, Maskus notes that without protection from potential abuse of their newly developed technologies, foreign enterprises may be less willing to reveal technical information associated with their innovations.52 The protection of patents and trade secrets provides necessary legal assurances for firms wishing to reveal proprietary characteristics of technologies to subsidiaries and licensees via contracts. Counties with stronger IP protection have more creative outputs (in terms of intangible assets and creative goods and services in a nation’s media, printing and publishing, and entertainment industries, including online), even at varying levels of development.

**Biopharmaceutical innovation is key to prevent future pandemics and bioterror**

**Marjanovic and Feijao, 20** [Sonja Marjanovic Ph.D., Judge Business School, University of Cambridge. Carolina Feijao, Ph.D. in biochemistry, University of Cambridge; M.Sc. in quantitative biology, Imperial College London; B.Sc. in biology, University of Lisbon. "How to Best Enable Pharma Innovation Beyond the COVID-19 Crisis," RAND Corporation, 05-2020, accessed 8-8-2021, https://www.rand.org/pubs/perspectives/PEA407-1.html] HWIC

As key actors in the healthcare innovation landscape, pharmaceutical and life sciences companies have been called on to develop medicines, vaccines and diagnostics for pressing public health challenges. The COVID-19 crisis is one such challenge, but there are many others. For example, MERS, SARS, Ebola, Zika and avian and swine flu are also infectious diseases that represent public health threats. Infectious agents such as anthrax, smallpox and tularemia could present threats in a bioterrorism context.1 The general threat to public health that is posed by antimicrobial resistance is also well-recognised as an area in need of pharmaceutical innovation. Innovating in response to these challenges does not always align well with pharmaceutical industry commercial models, shareholder expectations and competition within the industry. However, the expertise, networks and infrastructure that industry has within its reach, as well as public expectations and the moral imperative, make pharmaceutical companies and the wider life sciences sector an indispensable partner in the search for solutions that save lives. This perspective argues for the need to establish more sustainable and scalable ways of incentivising pharmaceutical innovation in response to infectious disease threats to public health. It considers both past and current examples of efforts to mobilise pharmaceutical innovation in high commercial risk areas, including in the context of current efforts to respond to the COVID-19 pandemic. In global pandemic crises like COVID-19, the urgency and scale of the crisis – as well as the spotlight placed on pharmaceutical companies – mean that contributing to the search for effective medicines, vaccines or diagnostics is essential for socially responsible companies in the sector. 2 It is therefore unsurprising that we are seeing industry-wide efforts unfold at unprecedented scale and pace. Whereas there is always scope for more activity, industry is currently contributing in a variety of ways. Examples include pharmaceutical companies donating existing compounds to assess their utility in the fight against COVID19; screening existing compound libraries in-house or with partners to see if they can be repurposed; accelerating trials for potentially effective medicine or vaccine candidates; and in some cases rapidly accelerating in-house research and development to discover new treatments or vaccine agents and develop diagnostics tests.3,4 Pharmaceutical companies are collaborating with each other in some of these efforts and participating in global R&D partnerships (such as the Innovative Medicines Initiative effort to accelerate the development of potential therapies for COVID-19) and supporting national efforts to expand diagnosis and testing capacity and ensure affordable and ready access to potential solutions.3,5,6 The primary purpose of such innovation is to benefit patients and wider population health. Although there are also reputational benefits from involvement that can be realised across the industry, there are likely to be relatively few companies that are ‘commercial’ winners. Those who might gain substantial revenues will be under pressure not to be seen as profiting from the pandemic. In the United Kingdom for example, GSK has stated that it does not expect to profit from its COVID-19 related activities and that any gains will be invested in supporting research and long-term pandemic preparedness, as well as in developing products that would be affordable in the world’s poorest countries.7 Similarly, in the United States AbbVie has waived intellectual property rights for an existing combination product that is being tested for therapeutic potential against COVID-19, which would support affordability and allow for a supply of generics.8,9 Johnson & Johnson has stated that its potential vaccine – which is expected to begin trials – will be available on a not-for-profit basis during the pandemic.10 Pharma is mobilising substantial efforts to rise to the COVID-19 challenge at hand. However, we need to consider how pharmaceutical innovation for responding to emerging infectious diseases can best be enabled beyond the current crisis. Many public health threats (including those associated with other infectious diseases, bioterrorism agents and antimicrobial resistance) are urgently in need of pharmaceutical innovation, even if their impacts are not as visible to society as COVID-19 is in the immediate term.

**That causes extinction, which outweighs.**

**Millett & Snyder-Beattie, 17** Millett, Ph.D., Senior Research Fellow, Future of Humanity Institute, University of Oxford; and Snyder-Beattie, M.S., Director of Research, Future of Humanity Institute, University of Oxford. 08-01-2017. “Existential Risk and Cost-Effective Biosecurity,” Health Security, 15(4), PubMed

In the decades to come, advanced bioweapons could **threaten human existence**. Although the **probability** of human extinction from bioweapons **may** be low, the **expected value** of **reducing** the risk could **still** be **large**, since such risks jeopardize the existence of **all future generations**. We provide an overview of biotechnological extinction risk, make some rough initial estimates for how severe the risks might be, and compare the cost-effectiveness of reducing these extinction-level risks with existing biosecurity work. We find that reducing human extinction risk can be more cost-effective than reducing smaller-scale risks, even when using conservative estimates. This suggests that the risks are not low enough to ignore and that more ought to be done to prevent the worst-case scenarios. How worthwhile is it spending resources to study and mitigate the chance of human extinction from biological risks? The risks of such a catastrophe are presumably low, so a skeptic might argue that addressing such risks would be a waste of scarce resources. In this article, we investigate this position using a cost-effectiveness approach and ultimately conclude that the expected value of reducing these risks is large, especially since such risks jeopardize the existence of all future human lives. **Historically, disease events have been responsible for the greatest death tolls** on humanity. The 1918 flu was responsible for more than 50 million deaths,1 while smallpox killed perhaps 10 times that many in the 20th century alone.2 The Black Death was responsible for killing over 25% of the European population,3 while other pandemics, such as the plague of Justinian, are thought to have killed 25 million in the 6th century—constituting over 10% of the world's population at the time.4 It is an open question whether a future pandemic could result in outright human extinction or the irreversible collapse of civilization. A skeptic would have many good reasons to think that existential risk from disease is unlikely. Such a disease would need to spread worldwide to remote populations, overcome rare genetic resistances, and evade detection, cures, and countermeasures. Even evolution itself may work in humanity's favor: Virulence and transmission is often a trade-off, and so evolutionary pressures could push against maximally lethal wild-type pathogens.5,6 While these arguments point to a very small risk of human extinction, they do not rule the possibility out entirely. Although rare, there are recorded instances of species going extinct due to disease—primarily in amphibians, but also in 1 mammalian species of rat on Christmas Island.7,8 There are also **historical examples of large human populations being almost entirely wiped out** by disease, especially when multiple diseases were simultaneously introduced into a population without immunity. The most striking examples of total population collapse include native American tribes exposed to European diseases, such as the Massachusett (86% loss of population), Quiripi-Unquachog (95% loss of population), and the Western Abenaki (which suffered a staggering 98% loss of population).9 In the modern context, no single disease currently exists that combines the worst-case levels of transmissibility, lethality, resistance to countermeasures, and global reach. But many diseases are proof of principle that each worst-case attribute can be realized independently. For example, some diseases exhibit nearly a 100% case fatality ratio in the absence of treatment, such as rabies or septicemic plague. Other diseases have a track record of spreading to virtually every human community worldwide, such as the 1918 flu,10 and seroprevalence studies indicate that other pathogens, such as chickenpox and HSV-1, can successfully reach over 95% of a population.11,12 Under optimal virulence theory, natural evolution would be an unlikely source for pathogens with the highest possible levels of transmissibility, virulence, and global reach. But advances in biotechnology might allow the creation of diseases that combine such traits. Recent controversy has already emerged over a number of scientific experiments that resulted in viruses with enhanced transmissibility, lethality, and/or the ability to overcome therapeutics.13-17 Other experiments demonstrated that mousepox could be modified to have a 100% case fatality rate and render a vaccine ineffective.18 In addition to transmissibility and lethality, studies have shown that other disease traits, such as incubation time, environmental survival, and available vectors, could be modified as well.19-21 Although these experiments had scientific merit and were not conducted with malicious intent, their implications are still worrying. This is especially true given that there is also a **long historical track record** of**state-run bioweapon research** applying cutting-edge science and technology to design agents not previously seen in nature. The Soviet bioweapons program developed agents with traits such as enhanced virulence, resistance to therapies, greater environmental resilience, increased difficulty to diagnose or treat, and which caused unexpected disease presentations and outcomes.22 Delivery capabilities have also been subject to the cutting edge of technical development, with Canadian, US, and UK bioweapon efforts playing a critical role in developing the discipline of aerobiology.23,24 While there is no evidence of state-run bioweapons programs directly attempting to develop or deploy bioweapons that would pose an existential risk, the logic of deterrence and mutually assured destruction could create such incentives in more unstable political environments or following a breakdown of the Biological Weapons Convention.25 The **possibility of a war** between great powers could also increase the pressure to use such weapons—during the World Wars, bioweapons were used across multiple continents, with Germany targeting animals in WWI,26 and Japan using plague to cause an epidemic in China during WWII.27

# Framework - Util

#### The standard is maximizing expected well-being.

**My Value for the debate is utilitarianism. Util is a moral system where the rightness or wrongness of an action is judged by the outcome it produces. This is the best system for debating global actions for 3 reasons:**

**1. Government/global organization actor—nations and trade organizations are not moral individuals so they can’t have Kantian intent.**

**2. Topic specific- debates about legal actions inevitably regress to consequences- the legal action is moral or immoral because of its ability to help or hurt the world.**

**3. Relational wording- Member nations in the resolution is plural, this implies we are debating about how the international community should be shaped and not what an individual’s moral obligations may be.**

#### Governments must use util since they can’t focus on every individual rights violation

Goodin, 95

Robert, 1995, Philosopher of Political Theory, Public Policy, and Applied Ethics. Utilitarianism as a Public Philosophy, Cambridge University Press, pg. 26-27

The great advantage of utilitarianism as a guide to public conduct is that it avoids gratuitous sacrifices, it ensures as best we are able to ensure in the uncertain world of public policy-making that policies are sensitive to people’s interests or desires or preferences. The great failing of more deontological theories, applied to those realms, is that they fixate upon duties done for the sake of duty rather than for the sake of any good that is done by doing one’s duty. Perhaps it is permissible (perhaps it is even proper) for private individuals in the course of their personal affairs to fetishize duties done for their own sake. It would be a mistake for public officials to do likewise, not least because it is impossible. The fixation on motives makes absolutely no sense in the public realm, and might make precious little sense in the private one even, as Chapter 3 shows. The reason public action is required at all arises from the inability of uncoordinated individual action to achieve certain morally desirable ends. Individuals are rightly excused from pursuing those ends. The inability is real; the excuses, perfectly valid. But libertarians are right in their diagnosis, wrong in their prescription. That is the message of Chapter 2. The same thing that makes those excuses valid at the individual level – the same thing that relieves individuals of responsibility – makes it morally incumbent upon individuals to organize themselves into collective units that are capable of acting where they as isolated individuals are not. When they organize themselves into these collective units, those collective deliberations inevitably take place under very different circumstances and their conclusions inevitably take very different forms. Individuals are morally required to operate in that collective manner, in certain crucial respects. But they are practically circumscribed in how they can operate, in their collective mode. And those special constraints characterizing the public sphere of decision-making give rise to the special circumstances that make utilitarianism peculiarly apt for public policy-making, in ways set out more fully in Chapter 4. Government house utilitarianism thus understood is, I would argue, a uniquely defensible public philosophy.

# On Case

## Circumvention

#### The plan gets circumvented through prioritization of bilateral trade agreements.

Durand and Milberg, 18

[Cédric, Associate Prof. Political Economy @ U-Geneva, member @ Paris Nord Economics Center; and William, Dean @ The New School for Social Research: “Intellectual Monopoly in Global Value Chains,” published in 2018, https://hal.archives-ouvertes.fr/hal-01850438]//AD

The contention over IPRs exemplified by the dispute between the US and China, reflects the heightened sensitivity of the US and other high-income economies to IPRs in an era where their governments and businesses consider innovation as their main competitive advantage. The US today is the leader of the movement toward stricter international IP norms, in contrast to its position in earlier periods (Peng, Ahlstrom, Carraher, & Shi, 2017). It is the most active complainant at the WTO under the TRIPS agreement but, as illustrated by the recent actions of the Trump administration, TRIPS is not enough (Sell, 2010). The US seeks other ways to extend internationally the standard of IP protection found in U.S. law and in particular to apply existing IP protection to digital media (Akhtar & Ferguson, 2011, p. 25). In order to circumvent the flexibility in the WTO TRIPS Agreement, and the reluctance of developing countries at the WTO to raise WTO standards of IP protection (Helfer, 2004), developed economies have relied increasingly on bilateral and regional preferential trade agreements (PTAs) to accomplish the objective of securing intellectual property related economic advantages (Abbott, 2006; Shadlen, 2008). The international intellectual property policymaking arena has grown ever more complex with overlapping transnational norms. For example, the 33 pages of the chapter dedicated to IPRs in the US-CAFTA agreement details the treaties and conventions that the parties shall ratify, which defines precisely and extensively the scope of IPRs concerned (copyrights, performance, patents, communication, trademarks, plants, microorganisms, industrial design, geographical indication, name domains…). Additionally, it describes enforcement mechanisms to be implemented in national legislation and considers supplementary protection of intellectual property under the investment chapter (CAFTA, 2004). IP provisions included in Japanese and EU international trade agreements are more general but they also provide supplementary coverage and additional obligations (Liberti, 2010). Moreover, investment treaties and chapters dedicated to investment protection in trade agreements open additional routes for IP protection, which can exercise a powerful chilling effect on government actions via the exposure to the risk of costly investor-state arbitration disputes (Ho, 2015, 2016; Kasolowsky & Leikin, 2017). The DESTA database (Dür et al., 2014) allows us to track this qualitative evolution in bilateral and regional trade agreements. IP provisions of trade agreements were nonexistent before the North American Free Trade Agreement (NAFTA) was signed in 1992. They became a standard feature of trade agreements in the 2000s. Figure 6 shows the number of PTAs signed each year and of those, the ones which included IPRs. It also shows the percentage of PTAs with an IP provision. By 2016, every PTA signed included an IP provision.

#### Turn--Bilateral trade agreements are worse than TRIPs – at least TRIPs allows for collective bargaining by the global south.

Kingston, 4

[William, School of Business Studies @ Trinity College (Dublin, Ireland): “Removing Some Harm from the World Trade Organization,” Oxford Development Studies, Vol. 32, No. 2, June 2004. http://www.tara.tcd.ie/bitstream/handle/2262/8696/Removing%20some%20harm.pdf?sequence=1]//AD

Also, now that TRIPS exists, it is better for the poorer countries that it should be maintained in existence, and reformed. This is because as an instrument of international law, it has the potential to enable them to withstand the power of the USTR in bilateral negotiations. As Cancu´ n showed, when a significant group of these countries act together, they can resist being bullied.

#### The aff forces countries to protect IP beyond TRIPs standards – turns case.

Bhala, 7

[Raj, Rice Distinguished Professor @ U- Kansas School of Law, J.D. Harvard, M.Sc. Oxford, M.Sc. London School of Economics, Marshall Scholar, Member @ Council on Foreign Relations, Royal Society for Asian Affairs, and Fellowship of Catholic Scholars, Author of Modern GATT Law (Sweet Maxwell 2005), International Trade Law: Theory and Practice (Lexis 2nd ed. 2000, 3rd ed. forthcoming 2008), and Trade, Development, and Social Justice (Carolina Academic Press 2003): “COMPETITIVE LIBERALIZATION, COMPETITIVE IMPERIALISM, AND INTELLECTUAL PROPERTY,” Liverpool Law Review (2007) 28:77–105. DOI: 10.1007/s10991-007-9017-2]//AD

\*FTA=Free Trade Agreement

Many of America’s newer FTAs, especially accords negotiated after the Uruguay Round, call upon partner countries to go beyond IP protection and enforcement measures set out in the TRIPs Agreement. In part, that reflects America’s bitter experience with lax IP enforcement in major markets like China. US trade negotiators relied, to the detriment of the American IP sector, on promises made by China of future implementation and enforcement during talks for Chinas accession to the WTO, which culminated in a November 1999 US–China bilateral agreement, and accession effective 11 December 2001.30 The subsequent history, from the US vantage point, was one of failure to adhere to the promises. One lesson learned by US trade negotiators was to insist on results – actual implementation and enforcement – before accession. They drilled the point in WTO accession talks with the Kingdom of Saudi Arabia, which culminated with a bilateral accord in the fall of 2005, and accession on 11 December 2005.31 A second lesson from the adverse experience with China was to use FTAs as a vehicle to go beyond the TRIPs Agreement, i.e., to demand TRIPs Plus commitments from a would-be FTA partner. Consider the following examples: In the U.S.–Jordan FTA, Jordan agreed to ratify and implement within two years two IP agreements that are not part of its TRIPs obligations: the World Intellectual Property Organization (WIPO) Copyright Treaty, and the WIPO Performances and Phonograms Treaty. The aim of these agreements, which are known as ‘‘Internet Treaties,’’ is to protect copyrighted works in a digital network environment. Thus, for example, they provide a creator with the exclusive right to make its creative works available online. The same TRIPs Plus provisions, incorporating the most up-to-date international copyright protection standards, exist in the U.S.–Morocco FTA. In the U.S.–Chile FTA and U.S.–Singapore FTA, Chile and Singapore agreed to TRIPs Plus commitments not only for patents, trademarks, and copyrights, but also for trade secrets. The two countries also accepted the obligation of ensuring its legal system contains meaningful penalties for piracy and counterfeiting. In negotiations for a U.S.–Australia FTA, the US had two key objectives concerning IP. First, it sought better IP protection, especially with respect to grey (parallel) market products. The US achieved this objective through provisions in the FTA that not only complement, but also enhance, existing international standards for both protection and enforcement of IP rights. These TRIPs Plus provisions include strong penalties for counterfeiting and piracy. Second, the US opposed the Australian pharmaceutical benefits scheme of pricing. On this point, agreement proved difficult and the end result – though TRIPs Plus – was nebulous. The two countries affirmed their shared objectives of (1) maintaining high quality healthcare and (2) improving public health standards. They agreed on three principles in pursuit of these objectives: (1) the importance of innovative pharmaceuticals, (2) the significance of research and development in the pharmaceutical industry, with appropriate governmental support including IP protection, and (3) the need for timely and affordable access to innovative pharmaceuticals through procedures that value objectively pharmaceuticals based on their therapeutic relevance. The sticking point was the procedures by which a federal health care program lists and prices new pharmaceuticals for reimbursement. Both sides agreed the procedures should demand transparency and accountability. But, how could the US be certain Australia would not discriminate against drugs from US pharmaceutical companies when listing and pricing medicines in its Pharmaceutical Benefits Scheme? From Australias perspective, how could its consumers be assured they would have access to effective US drugs at non-astronomical prices? The FTA establishes a Medicines Working Group to continue the conversation between the two countries on pharmaceutical issues, and creates in Australia an independent review process for listing decisions. The conversation indeed continues on this and other controversies. For example, when approving the FTA, the Australian Parliament added an ‘‘Anti-Evergreening’’ amendment to Australian law.32 This change blocks a pharmaceutical company from evergreening a patent or using the judicial process to preclude introduction of a generic medicine. The US opposes the amendment. In June 2006, NGOs – 416 of them, including the AFL-CIO, Citizens Trade Campaign, Communications Workers of America, Friends of the Earth, National Farmers Union, Sierra Club, and United Steel Workers – signed a letter urging Congress to reject the U.S.–Oman FTA (which Congress ultimately passed that summer.) They argued the accord not only lacked meaningful labor and environmental protections, but also would hurt poor and sick Omanis. The FTA IP provisions benefited large pharmaceutical companies by protecting their ‘‘unprecedented monopoly rights’’ of large pharmaceutical companies, forbidding for extended periods competition from generic products, and limiting access to affordable medicines.33 In the U.S.–Colombia FTA, signed in February 2006, but not implemented as of November 2006, Colombia agreed to join the WTO Information Technology Agreement (ITA).34 The ITA, an outgrowth of the Uruguay Round, lists a large number of computer and computer-related products subject to duty-free, quota-free treatment. However, it is a plurilateral accord, hence joining is required neither by TRIPs nor any other WTO accord. In January 2006, the US and Thailand were engaged in FTA negotiations, which commenced in June 2004. US insistence on TRIPs Plus IP commitments contributed to large-scale protests in Chiang Mai, Thailand, against an FTA, and brought talks to a halt.35 Four specific TRIPs Plus controversies arose:36 (1) The US insisted on 25-year span for patent protection, beyond the TRIPs Agreement norm of 20 years. (2) The US called for compensatory patent extensions by the Thai government to pharmaceutical companies, if the government ‘‘unreasonably’’ delayed either the grant of a drug patent, or approval of a drug for market use. The TRIPs Agreement does not contain this mandate. (3) The US sought a data exclusivity provision not found in the TRIPS Agreement. This provision would preclude manufacturers of generic drugs (which, of course, tended to be Thai companies) from using clinical trial data, or other scientific information, from any other company (e.g., an American pharmaceutical giant), to prove its generic product was safe and effective after the product had entered the market. Thailands Government Pharmaceutical Organization (GPO) objected. The GPO provides ‘‘first line’’ anti-retroviral medicines (i.e., older ones, some of which the patent had lapsed) to 80,000 AIDS patients (as of 2006), and sought to expand this program to 150,000 patients (by 2008). The GPO planned to offer generic ‘‘second line’’ drugs (i.e., newer, more sophisticated medicines still subject to a patent). Data exclusivity would inhibit its ability to do so. Further, data exclusivity would apply even to an unpatented drug, where no patent had been sought because the market for the drug was thought to be too small. (4) The US required tight language that would limit the terms and conditions under which the GPO could effect a compulsory license of a new drug. The US offered a side letter assurance that the language would be consistent with the November 2001 Doha Ministerial Conference Declaration on TRIPs and Public Health. Again, the GPO replied the language would adversely affect its ability to provide drugs to Thai AIDS patients. Thousands of Thai health care workers, AIDS victims, and activists – fearful of high-priced medicines should their government ‘‘cave’’ to the demands, demonstrated noisily, but peacefully (in front of the Sheraton Chiang Mai!) for about two days. Farmers, who were upset at US demands concerning agricultural trade (e.g., that Thailand reduce rice tariff barriers), joined them. The US team left the Sheraton as inconspicuously as possible, through a side door behind the concierge desk, into an unmarked van, and down a side street. The USTR blamed the ensuing stall in negotiations on Thai political unrest.37 Not surprisingly, some international trade law scholars offer persuasive arguments for the proposition that ‘‘TRIPs Plus’’ is ‘‘TRIPs Minus’’ for poor countries. For example, Dr Mohammed El-Said of the University of Central Lancashire cogently argues TRIPs Plus commitments in deals like the U.S.–Jordan and U.S.–Bahrain FTA end up doing greater harm than good to the US partners, hence rendering those countries worse off than under WTO disciplines.38 This line of argumentation would appear to be consistent with the competitive imperialism paradigm. In that paradigm, major trading powers race against one another to get the best possible deal for themselves. They neither intend to, nor hope to see, the IP provisions in their FTA and CU deals multilateralized. Obviously, if their provisions become WTO law, then their benefits no longer are specially tailored. All WTO Members, consisting of a not inconsiderable number of free riders (from the American or European perspective, at least), would enjoy whatever benefits they can realize for whatever IP industry they have.

## Insulin

#### Patents are not the limiting factor – 95% of insulin patents expired in 2016

Kaplan, 16

Warren A. Kaplan, (MA works in Department of Global Health), 7-19-2016, "The global intellectual property ecosystem for insulin and its public health implications: an observational study," Journal of Pharmaceutical Policy and Practice, [https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8 //](https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8%20//) AW

Global insulin patents Most patents on insulin products in the world have already expired by 2015 yet many markets continue to be dominated by the brand-name versions marketed by original patent-holders. Figure [1](https://joppp.biomedcentral.com/articles/10.1186/s40545-016-0072-8#Fig1) plots the percentage of all OB/HC granted patents on insulin remaining in force in any given year (based on a 20 year-from-filing patent life (black markers), and shows how relatively quickly the Eli Lilly, Novo and Pfizer insulin OB/HC patents are expiring compared to Sanofi. We confirm that after 2016, between about 5–20% of Pfizer, Eli Lilly and Novo Nordisk patents listed in the OB/HC remain un-expired and these percentages rapidly dimish, except for those of Sanofi who appears to have listed OB/HC patents whose expirations would extend well into 2030 and beyond (i.e., derived from a patent application filed in 2010).

#### It is not IP that is limiting insulin’s availability, it is corrupt trial processes

Peccoud, 18

Jean Peccoud (professor at colorado state), 9-13-2018, "After a century, insulin is still expensive – could DIYers change that?," Conversation, [https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822 //](https://theconversation.com/after-a-century-insulin-is-still-expensive-could-diyers-change-that-99822%20//) AW

Patents don’t make insulin expensive [Discovering and developing drugs is expensive](https://www.scientificamerican.com/article/cost-to-develop-new-pharmaceutical-drug-now-exceeds-2-5b/). Patents help drug companies recoup the costs from their investments by granting them a monopoly for a limited time. Once the patent expires, competing companies can begin producing generics: off-brand versions of a patented drug. This healthy competition drives [prices down](https://www.fda.gov/downloads/Drugs/ResourcesForYou/Consumers/BuyingUsingMedicineSafely/GenericDrugs/UCM609808.pdf). So why, with the original patent long-expired, is there still no affordable generic insulin? Don’t let yourself be misled. The insulin for purchase today is not the same insulin used to treat diabetic patients nearly 100 years ago. That insulin came primarily from animals. Today, insulin is brewed up by microbes that have been [genetically engineered](https://www.fda.gov/downloads/AboutFDA/WhatWeDo/History/ProductRegulation/UCM593496.pdf) with the gene for human insulin. Insulin pumps are one of the newer ways to administer the drug to diabetic patients. [AP Photo/Mark Zaleski](http://www.apimages.com/metadata/Index/Insulin-Legislation/75bd28fc8ed840c3802727306873cce0/1/0) And insulin is seldom injected with an old-fashioned syringe and needle anymore. Now there are insulin pens, pumps, test strips and other devices that improve the quality of life for diabetic patients. Pharmaceutical companies have also modified the chemical formula to produce faster-acting or longer-lasting insulins. With each of these inventions came a new patent. But the benefits of these “improved” insulins [are debatable](https://doi.org/10.2337/dc13-2915), and there’s nothing preventing competing companies from selling older, long off-patent versions of insulin. So [what’s the holdup](https://doi.org/10.1016/j.tibtech.2018.07.009)? Regulations keep insulin expensive Insulin is a [biologic drug](https://theconversation.com/biologics-the-pricey-drugs-transforming-medicine-80258), which means it’s produced by a living organism, not a chemical reaction. This process, called biomanufacturing, is [more inconsistent](https://doi.org/10.1177/1932296813516958) than chemical synthesis of non-biologic drugs like aspirin. Making reliable biologic drugs is a little like winemaking. Even though the winemaker carefully follows a well-established process, minute differences will affect the final product. It’s always wine, but some vintages are better than others and tasting the wine is the only way to evaluate the final product. So if a new company wants to make insulin, that insulin has to be tested on patients in expensive clinical trials. Bringing a biologic drug to market can cost as much as [$250 million](https://doi.org/10.4161/mabs.3.2.15005). No company can afford that lump if it can’t file for a patent to recoup the investments. That’s why there’s only [one “generic” insulin](https://www.businessinsider.com/insulin-cheaper-generic-2016-12) available so far. It’s [made by a company](https://www.basaglar.com/en/) that was already a major player in the insulin market, and it’s only 15 percent cheaper than the patented version. By comparison, most non-biologic generic drugs cost [80 percent less](https://doi.org/10.1056/NEJMms1411398) than the original. Obviously, regulations are important for keeping insulin safe, but at what cost? [Ten percent of people](https://doi.org/10.2337/dc12-0257) living with diabetes in the U.S. are uninsured, and there are nearly 10,000 crowdfunding campaigns related to insulin on the site GoFundMe alone. Stories about diabetic patients ending up hospitalized or worse because they [tried to ration their insulin](https://www.cbsnews.com/news/the-rising-cost-of-insulin-horror-stories-every-day/) are all-too common. Could big pharma eventually be cut out of the process by home brewers cooking up their own medications? [Sanofi Pasteur](https://www.flickr.com/photos/sanofi-pasteur/5283263633), [CC BY-NC-ND](http://creativecommons.org/licenses/by-nc-nd/4.0/) Democratizing insulin production Some people are taking matters [into their own hands](https://doi.org/10.1016/j.tibtech.2018.07.009), tinkering to meet their medical needs. In 2015, patients and hobby scientists launched an initiative known as the [Open Insulin Project](http://openinsulin.org/about-the-project/). As in winemaking, the specific know-how required for insulin production is a guarded secret. The goal of the Open Insulin Project is to figure out a patent-free method and release the information, so that competing companies can manufacture “generic” insulin. Given the cost of regulatory approval, it is more likely that the project could enable patients to “home brew” their own diabetic treatments. There is currently no structure for regulating drugs that are not produced commercially. One report estimates that as many as [2,000 patients have already reverse engineered](https://www.bloomberg.com/news/features/2018-08-08/the-250-biohack-that-s-revolutionizing-life-with-diabetes) their own insulin pumps and electronic monitoring systems. The insulin itself could be next. Is it possible to make biologic drugs like insulin more affordable without compromising safety? One suggestion that has been gaining steam is to [scale down biomanufacturing](https://doi.org/10.1038/nbt.3888). Right now, biologic medicines like insulin are cooked up in giant batches. Ensuring that those batches are consistent and free of contamination is a major challenge. Think about the meat department in your grocery store. Many big-box stores stock hamburger that was ground in a central processing plant and then distributed. If an E. coli outbreak occurs in the plant, it’s going to spread to all of the stores downstream, potentially infecting hundreds or thousands of people. The meat is also exposed to more potential contamination events through storage and transport. And, if contaminated meat is identified in one store, it won’t be immediately clear whether or not all the others are safe. Industrial-scale production – whether of hamburger or drugs – makes it harder to zero in on the source of problems when they occur. [David Tadevosian/Shutterstock.com](https://www.shutterstock.com/image-photo/meat-grinder-industry-775823329) Now, consider a small local butcher who grinds meat in-house. Any safety risk is going to be isolated to the customers of that one store and the source will be obvious. Similarly, producing medications in smaller batches reduces the potential impact of any one safety event. Pharmacy compounding provides [an example](https://doi.org/10.1038/nbt.3888). In compounding, drugs are specially mixed or produced for a very small number of patients. Compounded medications are not subject to clinical trials. If insulin were made in smaller batches, manufacturers might be able to forego clinical trials and use simpler and [less expensive tests](https://doi.org/10.1208/s12248-016-9908-z) to confirm that each batch of insulin produced is safe and comparable to previously approved insulins. It would be like using chemical tests to identify important flavor compounds in two vintages of wine instead of organizing taste tests. [This model](https://doi.org/10.1016/j.tibtech.2018.07.009) could also apply to other expensive biologic drugs such as those that treat cancer, HIV and rheumatoid arthritis. The technology necessary for small-batch insulin production [already exists](http://news.mit.edu/2016/portable-device-produces-biopharmaceuticals-on-demand-0729). [Future research](http://peccoud.org/insulin/) could help automate and streamline small batch medicine production in order to minimize safety risks. The authors describe how biohacking insulin and other biologic drugs have important implications for the future of pharmaceutical drug regulation. The future of medicine The pharmaceutical industry is [ripe for disruption](https://doi.org/10.1016/j.tibtech.2018.07.009). In the coming decades, drugs might be produced in very different settings. Hospitals have already begun [plans to make their own medicines](http://www.latimes.com/business/la-fi-generic-drugs-hospitals-20180906-story.html). DIY biologists could provide patients with the knowledge needed to produce for themselves the drugs their lives depend on. As the industry and regulatory agencies gain more experience with biologic drugs, it is also possible regulations will ease up, lowering the cost of approval. This would enable the emergence of small-scale drug manufacturers that could provide off-brand drugs at a lower cost. One thing is certain, the future of medicine will not be “business as usual.” Biomanufacturing technologies will continue to evolve. These changes could enable [decentralized production of life-saving drugs](https://doi.org/10.1016/j.tibtech.2018.07.009). How the regulatory system and pharmaceutical industry will adjust to that future is yet to be determined.

#### Counterfeit medicines related to insulin are prevalent in the squo and disproportionately affect oppressed people.

Cheng, 09

May M. Cheng (BA LLB), Nov 2009, "Is the Drugstore Safe? Counterfeit Diabetes Products on the Shelves," PubMed Central (PMC), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b12> // AW

Deaths caused by counterfeit medication often do not make the news in developing countries due to how commonplace such occurrences have become. Back in 1988, Dr. Dora Nkem Akunyili, a distinguished professor of pharmacology in Nigeria, witnessed the death of her 21-year-old sister due to hyperglycemia. However, it was not diabetes that killed her; it was the fake insulin supplied to her for treatment.[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b11) A survey published in 2001 by the Nigerian Institute of Pharmaceutical Research indicated that some 80% of the drugs distributed in major pharmacies in Lagos, Nigeria, were counterfeit. Upon her appointment as head of the Nigerian National Agency for Food and Drug Administration and Control (NAFDAC) that same year, Dr. Akunyili became a crusader against counterfeit medicines, getting the police to raid premises, publicly burning mountains of fake drugs and putting suppliers behind bars. Her actions drew the wrath of the fake drug barons who firebombed NAFDAC's offices, and in a December 2003 ambush, six gunmen opened fire on her car. Undeterred, she has continued with a strong grassroots campaign that starts with educating consumers and involving all stakeholders, yielding impressive results. In 2006, the NAFDAC published a new survey showing a 90% decrease in the incidence of counterfeit drugs in circulation and a take of $100 million in counterfeit drugs seized and destroyed over a 5-year period.[11](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b11) In February of 2009, it was reported that police in China had arrested four suspects on charges of selling fake diabetes drugs that killed two patients in the remote Northwest region of Xinjiang. The fatal drugs were falsely labeled with a known local brand name and contained illegal quantities of the chemical ingredient glibenclamide, which, while used in the treatment of diabetes, in excessive quantities can cause serious low blood glucose and consequent brain damage.[12](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b12) Examples from developing countries are too numerous to recount. However, increasingly, the sale of counterfeit medical products in pharmacies is no longer isolated to developing countries. In recent years, there have been a number of incidents involving counterfeit blood glucose test strips for use with glucose meters being sold in licensed pharmacies in the United States. There are over 10 million Americans who measure blood glucose, many of whom rely on at-home diabetes tests to take sensitive measurements of blood sugar levels to monitor insulin requirements. OneTouch® Test Strips, manufactured by LifeScan, a Johnson & Johnson company, the world's largest consumer-health products maker, were the most successful of these products in the United States. In 2006, about one million phony OneTouch test strips turned up in at least 35 states and in a number of countries in Europe, the Middle East, and Asia. These counterfeit test strip kits, manufactured in China, were found to give incorrect readings, with the potential to cause patients to inject dangerous levels of insulin.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b13) The counterfeiters had accurately copied many elements of the test strip packaging, with the important exception of the lot number on the carton, which was incorrect, enabling the company to identify the fakes and issue public warnings.[13](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b13) The Chinese businessman responsible for their distribution was apprehended and convicted in a Shanghai court in August 2007 and sentenced to 3.5 years in prison, among other penalties.[14](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b14),[15](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b15) Also in 2006, Johnson & Johnson and Lifescan successfully brought civil actions in a number of countries arising from these events [for example, Johnson & Johnson et al. v. Butt et al. (2007) 162 A.C.W.S. (3d) 232 (Ont. S.C.) and Johnson & Johnson et al. v. Alexander Vega et al. (2006) QCCS 5883 (Que. S.C.)]. The counterfeit test strips were sold via two Canadian companies to a number of U.S. distributors, which in turn ended up in over 700 U.S. pharmacies.[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b16) The case underscores the burgeoning number of fake medical products entering the North American market and the danger of their infiltrating the legitimate supply chain through “gray market” channels that may act as a cover for dealing in illicit counterfeits.[16](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b16) In another case involving defective blood glucose test strips in the United States, criminal charges led to a guilty plea in January 2009 by the president of a recycling company in Knox, Indiana.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b17) Bayer had discovered that Nor AmPlastics Recycling Inc. fraudulently sold previously recalled test strips on eBay for $3700 in profits, while Bayer was paying $8000 to recycle the diabetic glucose strips that were recalled by Bayer.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b17) Officials confirmed that over 100 people had purchased the bogus strips, but there were no reports of injuries.[17](https://www.ncbi.nlm.nih.gov/pmc/articles/PMC2787054/#b17)

#### Counterfeits for hormones like insulin have the wrong amount of API – literally killing patients who think they are being treated

Williams, 14

Lakeisha Williams, Pharmd, Msph Drug Information Specialist Xavier University Of Louisiana College Of Pharmacy New Orleans, Louisiana Ellen Mcknight Pharmd Candidate, 2017 Xavier University Of Louisiana College Of Pharmacy New Orleans, Louisiana, 6-19-2014, "The Real Impact of Counterfeit Medications," No Publication, <https://www.uspharmacist.com/article/counterfeit-meds%20/> // AW

Counterfeit drugs have been defined as products deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product.1-4 Counterfeit medications include drugs that contain no active pharmaceutical ingredient (API), an incorrect amount of API, an inferior-quality API, a wrong API, contaminants, or repackaged expired products.1,5 Some counterfeit medications may even be incorrectly formulated and produced in substandard conditions.5 Counterfeiting can apply to both branded pharmaceuticals and their less expensive generic counterparts.6 In fact, generic drugs are sometimes confused with counterfeit medications, which may pose an obstacle to the widespread use and acceptance of generic medications. This may create a particular challenge for pharmaceutical industries in places such as India, Europe, and Japan—countries in which generic drugs are manufactured. Moreover, any impact on generic-drug use is potentially far-reaching. It is estimated that half of all prescriptions in the United States, for example, are now filled with approved generic drugs, with expenditures estimated in the billions.6 Counterfeit Drugs: A Global Problem For years, the number of counterfeit medications that have made their way into trusted pharmacies and subsequently to patients’ medicine cabinets has been on the rise. Imagine the scenario in which a patient takes a medication for a life-threatening illness, only to become aware later that the doses contained no APIs. It is estimated that this misfortune has occurred with thousands of people worldwide and continues to happen. The growing issue of counterfeit medications is a concern not only for the patient, but also for pharmacists and pharmaceutical companies. Wertheimer et al state that the magnitude of the drug-counterfeiting problem is difficult to gauge.7 Since the crimes of producing and selling counterfeit drugs generally become known only when the perpetrators are caught, any accurate determination of prevalence is difficult.7 The World Health Organization (WHO) has estimated that 10% of global pharmaceutical commerce, or $21 billion worth, involves counterfeit drugs.7,12 Drug counterfeiting, although not a new phenomenon, has provoked greater concern because it has become so widespread in recent years.8,9 A WHO study revealed that nearly one-half (48.7%) of the documented cases of drug counterfeiting were reported in developing countries of the Western Pacific (China, the Philippines, and Vietnam), followed by developing countries grouped within WHO’s Regional Office for Africa, with 18.7%. The industrialized areas of WHO’s Regional Office for Europe came in third, with 13.6% of reported cases.10,11 It is estimated that approximately 1% of counterfeit medications are sold in the U.S, but the numbers are increasing annually.1 Most U.S. counterfeit medications are purchased online; however, others have infiltrated legitimate supply chains. Drugs Most Often Counterfeited High-demand, expensive medications such as various chemotherapeutic drugs, antibiotics, vaccines, erectile dysfunction drugs, weight loss aids, hormones, analgesics, steroids, antihistamines, antivirals, and antianxiety drugs are common counterfeiting targets.1,3,4 Among those deceived into buying counterfeit drugs are consumers who use medicines inappropriately or who seek to purchase medications at discounted prices. In addition to being very cheap to make, counterfeit medicines often closely resemble actual medications, with nearly identical labels and tablets, thus duping unsuspecting pharmacists and patients. It has been reported that oftentimes drug counterfeiters use cheap and sometimes harmful materials such as brick dust, sheetrock, and flour to create their bogus tablets.13 Pfizer reported discovering 14 of its counterfeited pharmaceutical products in at least 36 countries, including the U.S., in the first 9 months of 2009 and reportedly seized more than 11 million counterfeit tablets, capsules, and vials that year.1,14,15 Also in 2009, a U.S. government crackdown uncovered some 800 packages of counterfeit medications, including Viagra (sildenafil citrate), Vicodin (hydrocodone bitartrate and acetaminophen), and Claritin (loratadine).16 Mui and Ylan state that some of the drugs had as much as three times the amount of API than is typically prescribed, while others contained no API at all or harmful substances.16 Internet Sites the Largest Suppliers Increasing access to the Internet coupled with new methods of manufacturing and distributing illegal pharmaceuticals have created new challenges to safeguarding the legitimate pharmaceutical supply chain.2 Thousands of websites openly sell unapproved and/or counterfeit drugs, as well as prescription drugs without requiring a valid prescription, all in violation of federal and state laws. Many of these sites are hosted by U.S. registrars, accept payment by U.S. payment processors, and ship their products via U.S.-based express courier companies or the U.S. Postal Service (USPS).2 Counterfeit Drugs: A Public Health Concern Counterfeiting drugs is not only illegal, but it is also a major public health concern. Counterfeit drugs often contain the correct ingredients in incorrect quantities; however, they may also contain either a wrong API—which may even be toxic—or no active substance at all.15 Treatment with ineffective counterfeit drugs such as antibiotics can lead to the emergence of resistant organisms and may have a deleterious effect on a wide section of the population. In extreme cases, counterfeit drugs may even cause death.3 For example, it has been estimated that between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing only chloramphenicol, an antibiotic that is generally combined with another medication, which may have resulted in more than 100 fatal infections.17, 18 As a consequence of such damaging effects, counterfeit drugs may erode public confidence in healthcare systems, healthcare professionals, the suppliers and sellers of genuine drugs, the pharmaceutical industry, and national drug regulatory authorities.4 Taking Legal Action To disrupt and dismantle illicit networks trading these harmful counterfeit drugs in the U.S. and countries such as Africa and Asia, the White House’s Counterfeit Inter-Agency Working Group has collaborated with the FDA; the Departments of Justice, State, and Commerce; and the Agency for International Development as well as both foreign and domestic law enforcement partners such as U.S. Customs and Border Protection and U.S. Immigration and Customs Enforcement. In order to eliminate the distribution of counterfeit drugs, the combined efforts of these agencies have implemented strategies that include partnerships with the private sector to secure supply chains and share intelligence; identify, seize, forfeit, and destroy products that infringe trademarks and copyrights; and levy monetary penalties and enforce laws at the U.S. border.2 The FDA is working with law enforcement agencies and USPS inspectors to secure the global drug-supply chain by identifying drugs that are most likely to be counterfeited, contaminated, or adulterated and targeting shipments of these drugs for additional inspection.1 In addition, anticounterfeiting initiatives in other countries have been launched, including the Anti-Counterfeiting Trade Agreement—an initiative between the European Union, Japan, the U.S., and Switzerland. Other efforts to thwart counterfeiting include the World Customs Organization’s Provisional Standards Employed by Customs for Uniform Rights Enforcement, G-8 Countries’ Initiatives on Counterfeits, World Intellectual Property Organization’s Advisory Committee on Enforcement, and Security and Prosperity Partnership, an initiative between Canada, Mexico, and the U.S.6 Anticounterfeiting Technologies Many anticounterfeiting technologies are being utilized by pharmaceutical companies to ensure distribution of the authentic product from the manufacturing site to the pharmacy.1 Among these technologies used by pharmaceutical manufacturers are holograms, color-shifting inks, and embedded codes, images, and dyes.1 These anticounterfeiting features allow pharmacists to identify suspicious medications as possible counterfeits. Protecting Consumers According to the Pharmaceutical Research and Manufacturers of America, consumers who purchase medications online should avoid the following: sites that are located outside of the U.S. that do not indicate any physical address; sites that do not have a license by the relevant State Boards of Pharmacy; sites without a licensed pharmacist to answer questions; and websites that do not require a prescription.8,10 Consumers who wish to purchase drugs over the Internet should look for websites that have the Verified Internet Pharmacy Practice Sites seal. These sites, which are created by the National Association of Boards of Pharmacy, are licensed pharmacies selling FDA-approved medications to discourage the sale of counterfeit drugs from illegitimate online sources.5 Role of the Pharmacist Pharmacists are vital in ensuring the safety of medications used by patients. Furthermore, they are responsible for the integrity of the supply chain, ranging from manufacturer to distributor and, ultimately, to the patient. Specifics on how pharmacists, pharmacy students, and technicians can combat counterfeit medications are shown in TABLE 1.1,11 Conclusion Counterfeit medications may be detrimental to a patient’s health status. The use of substandard drugs may result in adverse side effects, treatment failure, resistance, toxicity, and even death. It is important that pharmaceutical companies, healthcare professionals, pharmacists, and patients be educated about counterfeit medications and the laws being enforced to prevent this crime. With increased awareness and the promotion of global health, the growing threat of counterfeit medications may begin to decline.

#### IP is the single effective preventative measure against counterfeit medicine, removal would explode the counterfeit drug market hurting diabetes prevention globally

Konski, 08

Antoinette Konski, 2008, “Ip Strategies to combat distribution of counterfeit drugs”, Foley and Lardner LLP, [https://www.foley.com/-/media/files/insights/publications/2008/04/ip-strategies-to-combat-distribution-of-counterfei/files/ip-strategies-to-combat-distribution-of-counterfei/fileattachment/combatcounterfeitdrugs\_a-konski.pdf //](https://www.foley.com/-/media/files/insights/publications/2008/04/ip-strategies-to-combat-distribution-of-counterfei/files/ip-strategies-to-combat-distribution-of-counterfei/fileattachment/combatcounterfeitdrugs_a-konski.pdf%20//) AW

A number of international government initiatives have been established to combat the growing problem of counterfeits. The World Health Organization (WHO) and the U.S. Food and Drug Administration have specific programs to make it more difficult to manufacture and distribute counterfeit pharmaceuticals.7 Criminal actions by governmental entities also help impede counterfeiting and can provide a powerful deterrent. For example, on August 31, 2007, Johnson & Johnson, Inc. announced that a Shanghi Court fined and sentenced Su Zhiyong, Chinese business man, to 3 ½ years in prison for selling approximately 1 million counterfeit OneTouch™ test trips. The counterfeit strips were found in 35 U.S. States, Canada, Greece, India, Pakistan, the Philippines, Saudi Arabia and Turkey.8 Such governmental efforts reduce the public health threat of counterfeit drugs but will not provide economic redress to those whose products are being copied. Enforcement of privately held intellectual property rights can however, address economic harm while at the same time, remove the copies from the market. Proactive procurement of intellectual property is the first step toward seeking private redress for economic harm. Patents, trademarks and copyrights, collectively referred to as intellectual property (IP), vary in scope, duration, geographical reach, as well as the investment of time and money required to obtain and enforce.9 It is useful at the outset for businesses to assess which form of IP protection is appropriate for a product and anticipate how illicit copying of their products and/or packaging may occur. Important considerations in this initial assessment include the type of product, the nature of the likely copying, the geographical scope of intended distribution and the duration of the exclusivity period needed to protect against copiers.10 Patents A patent allows the patentee to exclude third parties from making, using, importing, selling, or offering for sale patented products or methods of manufacture or use for a finite period of time, typically no more than 20 years from the date of initial patent filing. Patent protection must be obtained on a country-by-country basis. It is used to prevent others, for that geographical area and without the consent of the patent holder, from manufacturing and/or selling exact and close copies of the patented technology. Pharmaceutical patents are usually considered the first line of defense in protecting intellectual capital because patents can prevent others from manufacturing, using, selling and/or importing products that have the same or equivalent active ingredient or formulation. However, as compared to other intellectual property, patent rights are expensive to enforce and a final, enforceable judgment may only be obtained years after a lawsuit is filed. Patent holders must prove in civil litigation that the alleged copier is making or selling a product that is described in the patent. This requires a detailed review of the patent document and correspondence between the patent applicant and the patent office. Frequently, technical experts are retained to opine on technical terminology and the meaning of phrases or terms during this phase of the lawsuit. Only after this initial review is the alleged infringing technology compared to the property right defined during the initial phase of the proceeding. Thus, the patent can only prevent others from manufacturing, using, selling or importing products that are exact or close copies of the patented technology. Rarely, however, are counterfeit medicines close copies of the original. For example, counterfeit medicines often do not contain the same, or perhaps the same amount of the genuine, patented formulation. Therefore, a patent will not prevent the making or selling of a look-alike counterfeit drug that does not contain the same or similar active compound or formulation. In addition, a patent is granted to an “innovator” and therefore manufacturers of generic drugs, frequently manufactured after drugs have gone off-patent, cannot use patents to prevent distribution of counterfeited generics. 9 Under appropriate circumstances, misappropriation of trade secrets can provide economic redress. For a general discussion of trade secret protection, and its comparison to other forms of intellectual property, see Medd and Konski, Workplace Programs to Protect Trade Secrets, Nature Biotechnology (2003) Vol. 21:201-203. 10 Id. ©2008 Foley & Lardner LLP 4 Copyrights Copyrights prevent others from copying and claiming authorship of original works. Copyright protection is granted to original works of authorship that have been fixed in a tangible form of expression. Works of authorship include literary, musical, dramatic, pictorial, graphic, sculptural, cinematic, and architectural works. Titles, names, and short phrases are generally not copyrightable. Ownership of a copyright is secured from the time of creation and the work need not ever be published. Similar to patent protection, copyright protection is available on a countryby-country basis and requires a registration process to enforce the right against third parties. In terms of the use of copyrights to secure protection from counterfeiters, copyrights on package inserts may be useful but is of limited effectiveness in preventing the counterfeit from reaching the public or providing redress for economic harm. Trademarks Because trademarks seek to prevent exactly what counterfeiters seek to obtain, i.e. the economic benefit and investment in product integrity of the manufacturer, a strong trademark is the most valuable type of intellectual property that can be used to combat counterfeiting. Similar to patents, trademarks are enforceable on a country-by-country basis, and therefore trademark protection must be obtained in each country where the product is made or distributed.11 However, in contrast to patents, trademarks are not limited to a finite period of time but can extend as long as the trademark is used in commerce in connection with the product. Trademarks are used to identify the source of goods or services. Words, names, numbers, symbols, devices, designs, sounds, and colors that function as brands to distinguish the source of goods and their packaging may be registered as trademarks. The colors of pills as well as their shape may be trademarked. In contrast to patents, a trademark cannot be obtained on the process of making the product or medicine and does not protect the innovation of the underlying product. However, trademarks are available to generic manufacturers who identify their products with a unique logo or other identifying mark or property. Misappropriated trademarks mislead consumers by copying the unique name, logo, product packaging, shape and/or color used by the manufacturer on the genuine product or packaging, thus confusing consumers as to the actual source, and quality, of the product. Therefore, all unique aspects of the product and packaging should be considered as worthy of trademark protection and the company’s trademark should be applied as frequently as possible, e.g., on the pill itself, on both inner and outer packaging, etc. All modifications of the label, such as the product logo or other unique identifying descriptive marks should be protected in the language of the country where the product is to be sold. 11 Unlike patents, some countries recognize a trademark right without a formal application and review process, although other procedural requirements typically must be met in such cases as demonstrating proof of sale of the product within the relevant jurisdiction. ©2008 Foley & Lardner LLP 5 As compared to patents, obtaining and enforcing trademark rights are typically less costly, and a final enforceable judgment is usually obtained faster than in a patent infringement action. Indeed, evaluation of whether a trademark is likely to be infringed can be limited to a visual inspection rather than a complicated analysis of the patented technology. Most significantly, however, in many countries trademark owners can have the counterfeit goods and accompanying documents, and even sometimes manufacturing equipment immediately seized at the outset of the lawsuit. Such powerful preliminary remedies are generally not available in patent lawsuits and can lead to swift resolution of the action. Conclusion The rise of counterfeit medicines is a threat to public health and the economic investment made by innovators and generic manufacturers in the pharmaceutical industry. All manufactures of medicines can limit their economic harm by proactively assessing their product and available intellectual property options and anticipating counterfeit designs and products. After this initial assessment, appropriate intellectual property protection can be pursued in the relevant markets and countries. Although patents and to a lesser extent copyrights can be useful in combating counterfeiting and addressing economic harm, a strong trademark is the strongest intellectual property tool for combating counterfeiting.