FAUX OUTRAGE: COUNTERFEIT DRUGS IN A GLOBALIZING ECONOMY

I. INTRODUCTION

With the many debates raging around healthcare in the United States and abroad, an often-overlooked aspect of the modern healthcare delivery regime is the shadow market that has emerged around counterfeit drugs. The World Health Organization (WHO) first noted the problem of counterfeit drugs at its 1998 World Health Assembly, and since then the problem has only successively worsened, culminating with the COVID-19 pandemic in 2020.[1]

By 2010, the WHO predicted the value of traded counterfeit drugs to be in excess of seventy-five billion dollars; by 2015 the Organization for Economic Cooperation and Development (OECD) estimated the trade had swelled to a value of $200 billion dollars.[2] For context, Pfizer, one of the largest pharmaceutical manufacturers in the world, reported an annual revenue in 2018 of roughly fifty-two billion dollars, representing only a quarter of the value of the counterfeit market.[3]

The market reach of counterfeit drugs is extensive, affecting both legitimate and illicit markets globally. The primary market for counterfeit drugs is largely thought to be for "lifestyle" medications including weight

1 *See Growing Threat from Counterfeit Medicines*, 88 BULLETIN OF THE WORLD HEALTH ORGANIZATION [WHO] 247 (2010), https://apps.who.int/iris/handle/10665/270662. For summary of assembly, see World Health Org., *Fifty-First World Health Assembly: Resolutions and Decisions Annexes*, WHO Doc. WHA51/1998/REC/1 (1998), https://apps.who.int/iris/bitstream/handle/10665/258896/WHA51-1998-REC-1-eng.pdf, and Sam Piranty, *Coronavirus Fuels a Surge in Fake Medicines*, BBC (Apr. 9, 2020), https://www.bbc.com/news/health-52201077. In 2020 during the early days of the COVID-19 pandemic, Interpol's global pharmaceutical crime fighting unit made over 121 arrests in just seven days, confiscating counterfeit medication worth in excess of fourteen million.

2 *See Growing Threat from Counterfeit Medicines*, *supra* note 1; Kristina M.L. Acri, Fraser Inst., née Lybecker, *Pharmaceutical Counterfeiting: Endangering Public Health, Society and the Economy*, at iii (2018), https://www.fraserinstitute.org/sites/default/files/pharmaceutical-counterfeiting-endangering-public-health-society-and-the-economy.pdf. For more of the OECD's assessment of the counterfeit drug trade see Chapter 4 in ORG. FOR ECON. COOP. & DEV., OECD REVIEWS OF RISK MANAGEMENT POLICIES: CONVERGING CRIMINAL NETWORK 79 (2016).

3 Pfizer's 2018 profit was reported at roughly 53.6 million dollars. *See* Press Release, Pfizer, Pfizer Reports Fourth-Quarter and Full-Year 2018 Results (Jan. 29, 2019), https://investors.pfizer.com/investor-news/press-release-details/2019/PFIZER-REPORTS-FOURTH-QUARTER-AND-FULL-YEAR-2018-RESULTS/default.aspx.

loss and popular erectile dysfunction medications.[4] However, with increasing healthcare costs, particularly pharmaceutical costs, in the United States and the relative lack of access to quality healthcare in poor and developing countries, the demand for counterfeits has extended into markets of lifesaving medications including those for HIV, malaria, and more recently COVID-19 tests and therapeutics.[5] The reach of counterfeit drugs is so great that it has even led to the counterfeiting of illicit controlled substances such as synthetic cannabis products and cocaine.[6]

While the profits for those willing to peddle in the unseemly trade of counterfeit drug distribution are extremely high, the costs can also be devastating for society.[7] The rise of the internet has magnified the problem exponentially, as the web provides a nexus for trafficking counterfeit pharmaceuticals from underground suppliers, largely concentrated in Asia, with pent up markets in Africa and the West.[8] Counterfeit medications can at a minimum undermine and cast uncertainty onto legitimate treatments and at worst lead to the distribution of lethal and defective products.[9] Furthermore, evidence suggests that counterfeit drug distribution is a

4 *See Growing Threat from Counterfeit Medicines*, *supra* note 1. "The study found that almost half the counterfeit drugs sold on the Internet were for weight loss, followed by influenza medicines. Another key market for counterfeits in Europe, as in Asia, is erectile dysfunction, nourished by the growth in online pharmacies that offer access to prescription-only medicines without the embarrassment of consulting a doctor. A Dutch study cited by the International Journal of Clinical Practice found that, of 370 seized Viagra samples, only 10 were genuine." *Id.*

5 *See id.* HIV antiretroviral therapies are increasingly being counterfeited and distributed HIV ravaged areas of Africa. *See* Joseph J. Amon, *Dangerous Medicines, Uproven AIDS Cures and Counterfeit Antiretroviral Drugs*, 4 GLOBALIZATION & HEALTH 5 (2008); *see also Counterfeit HIV Medication: Profitable For Criminals But Dangerous For Patients*, P'SHIP FOR SAFEMEDS., https://www.safemedicines.org/counterfeit-hiv-medication-profitable-for-criminals-but-dangerous-for-patients (last visited June 23, 2021); *see* Piranty, *supra* note 1; *supra* note 119. Particularly in the COVID-19 pandemic, malaria drug hydroxychloroquine took on a unique valence in the counterfeit drug discussion. Notably the drug was touted by U.S. President, Donald Trump, for its alleged therapeutic effects in the treatment of COVID-19. The evidence of these effects was largely anecdotal when President Trump began touting the drug; nonetheless, the value and demand for the drug skyrocketed. *See* Piranty, *supra* note 1 ("One producer in Pakistan said he used to buy the raw ingredients for an antimalarial drug called hydrochloroquine for about $100 a kilo." But today, the cost has increased to $1,150 a kilo."). This demand in turn has limited supply in traditional markets for hydroxychloroquine such as in the treatment of malaria that were already subject to counterfeit, further exacerbating problems pre-dating the COVID-19 pandemic.

6 *See* NAT'L CRIME PREVENTION COUNCIL, *Fake Drugs Are Bad Medicine*, https://www.ncpc.org/resources/ip-theft/counterfeit-drugs/ (last visited June 23, 2021) ("Easy-to-get fake illegal drugs can cause illness or death.").

7 *See* WHO, *supra* note 1. Profits in the counterfeit trade are predicted to be upwards of 200 billion dollars globally.

8 *See* Fiona Clark, *Rise in Online Pharmacies Sees Counterfeit Drugs Go Global*, 386 WORLD REP. P1327 (2015).

9 *See* Acri, *supra* note 2.

lucrative means by which global international terrorism and crime syndicates fund their operations, particularly in South Asia and Africa.[10]

Like many issues in today's complex world, the issue of counterfeit drugs is multifaceted, and the regulation thereof derive from a variety of legal sources. Criminal law plays a role in counteracting the distribution of counterfeits directly by prosecuting those engaged in the trade. Healthcare policy plays a role in shaping the markets for counterfeits. International law also plays a role in synchronizing networks of governments and NGO's in combating the spread of counterfeits.

Distinct yet uniquely stitched into the body of health policy and enforcement mechanisms is intellectual property law. Given the incredible importance of patent and trademark rights in the sphere of legitimate drug development and distribution, intellectual property provides a useful frame for addressing and considering the issue of counterfeit drugs. In particular, considering the varying regimes of intellectual property protections globally may elucidate why the counterfeiters have been able to develop and thrive in recent years.

This note will consider the implications of intellectual property protections regarding the proliferation of counterfeit drugs. The note will first explicate the scope of the issue of counterfeit drugs with specificity towards the relationship between counterfeits and intellectual property, then considering the defects within present intellectual property regimes permitting or encouraging the growth of counterfeits.

The note will then consider and propose solutions to resolve issues regarding the proliferation of counterfeit drugs. Criminal law, health law, international law, and broader health and economic policies will also be considered, as they are relevant to the underlying analysis of intellectual property regimes and the topic of counterfeit drugs.

10 *Id.*

II. BACKGROUND

Counterfeit medicine as described by the Food and Drug Administration (FDA) is "fake medicine."[11] This rather simplistic definition is inclusive of a wide range of products ranging from knock-offs with limited pharmacological action, tainted fakes that can cause toxic bodily harm, or mere mimicries of pharmaceuticals that may actually have active ingredients present.[12] The market for counterfeit extends to lifestyle medications, such as weight loss drugs and erectile dysfunction medication, to life saving drug regimes, such as retroviral HIV therapy and malaria treatment.[13] Included in the definition of counterfeit medicine are some types of illicit recreational drugs, but given the illegality of such substances, they are largely beyond the reach of intellectual property protections.[14]

While counterfeits have always been a component of illicit drug trades, the trade around counterfeit drugs has been buttressed and accelerated by the emergence of the internet.[15] Internet pharmacies have become a staple

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11 The exact definition of counterfeit drugs is actually hotly debated. Kristina Acri notes this contention in adopting the WHO's definition of counterfeits. Acri, *supra* note 2. Varying definitions can make enforcement quite difficult as some consider only counterfeit medicines which scam a pharmaceutical trademark (appearance) without providing any therapeutic benefit, *see infra* note 45, while others, including the WHO and the FDA, take more expansive definitions of counterfeits that leave open room for medicines that may have some therapeutic benefit, but for whatever reason were illegitimately manufactured or distributed. In fact, it is important to stress that counterfeits can come from legitimate manufacturers and even enter legitimate medication distribution streams, a result with harrowing consequences. *See* U.S. FOOD & DRUG ADMIN., *Counterfeit Medicine* (Jan. 5, 2021), https://www.fda.gov/drugs/buying-using-medicine-safely/counterfeit-medicine; *see also* WORLD HEALTH ORG., *Substandard and Falsified Medical Products* (Jan. 31, 2018), https://www.who.int/news-room/fact-sheets/detail/substandard-and-falsified-medical-products.

12 "There is a wide variation on how various nations define counterfeit drugs. The WHO defines counterfeit pharmaceutical product as a product which is deliberately and fraudulently mislabelled with respect to identity and/or source. Counterfeiting can apply to both branded and generic products and counterfeit drugs may include products with the correct ingredients but fake packaging, incorrect ingredients, no active ingredients, or insufficient active ingredients and toxins." Linus Mhando, Mary B. Jande, Anthony Liwa, Stanley Mwita & Karol J. Marwa, *Public Awareness and Identification of Counterfeit Drugs in Tanzania: A View on Antimalarial Drugs*, 2016 ADVANCES PUB. HEALTH 1.

13 *See supra* notes 2, 5.

14 However, see U.S. Patent No. 5,268,480 (filed Dec. 7, 1993), a cocaine analogue. Many fake illicit drugs are actually derived from patented and legitimately researched analogues. The counterfeit drug trade has also factored prominently in the present opioid crisis as many overdoses are caused by drugs with fentanyl, the distribution of which has been linked to counterfeiters. *See DEA Considers Fentanyl-Containing Counterfeit Medications a Global Threat*, P'SHIP FOR SAFEMEDS. (Aug. 1, 2016), https://www.safemedicines.org/2016/08/dea-considers-fentanyl-containing-counterfeit-medications-a-global-threat.html.

15 *See Fake Drugs on the Web*, INT'L INST. RSCH. AGAINST COUNTERFEIT MEDS. (2013), https://www.iracm.com/en/thematic-observatory/fake-drugs-on-the-web/. Noting the issues inherent in the internet and varying regulations therewith: "With the web, traffickers have found the opportunity to

of digital commerce, and such outlets can be witting and unwitting distributors of counterfeit medications.[16]

The National Association of Boards of Pharmacy identified in a 2013 report the internet as the primary supplier of counterfeit drugs.[17] Further the Board noted that ninety-seven percent of evaluated internet pharmacies were not compliant with either federal or state laws, or with industry standards.[18] Regardless of the potential risks associated with online pharmaceutical purchases, the FDA found in 2012 that roughly one in four internet users has utilized an online pharmacy.[19]

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sell their forged goods on a large scale, directly to patients, circumventing all secure distribution channels. One of the main difficulties encountered in the fight against the distribution of counterfeit drugs through the Internet lies in the fact that some countries have already legalized trade in online drugs, sometimes including mandatory prescription drugs. At stake for the international community: reconcile the ease of access offered by the internet with the need to control the quality and the origin of medicines." *Id.*

16 *See* Acri, *supra* note at 12. Further noting the modern status of counterfeits and the internet: "Since the end of the 1990s, the democratization of access to the internet has boosted sales of goods by correspondence, particularly in developed countries. Although it is highly regulated in most countries of the world, the marketing of medicines has not escaped this global phenomenon. Today, the web offers a particularly extensive choice of websites which distribute products from almost all families of medicines, and almost always illegally."

17 *See* Nat'l Ass'n of Bds. of Pharmacy, *Internet Drug Outlet Identification Program: Progress Report for State and Federal Regulators* (Apr. 2013), https://awarerx.s3.amazonaws.com/system/redactor_assets/documents/179/NABP_Internet_Drug_Outlet_Report_Apr2013.pdf.

18 *Id.* Note the National Association of Boards of Pharmacy is a trade group with member boards in the United States and a handful of other countries including Canada and Australia. *Id.* Some commentators have noted that weariness around internet pharmaceutical sales may in part be due to countervailing interests on behalf of American pharmaceutical manufacturers in protecting their profits domestically. "Enter the name of a popular prescription drug in an Internet search engine and you will quickly grasp just how big the Internet pharmacy market is in Canada. A large proportion of sales are to US customers, who are estimated to purchase upward of US$1 billion in drugs per year from Canadian pharmacies. Americans are turning to Canadian pharmacies with good reason: for many of them, Canadian retail prices for brand-name prescription drugs are a bargain. But, even in this era of free trade and regulatory harmonization, many American policymakers are opposed to such bargain hunting. Although their opposition generally revolves around a purported concern with public safety, the underlying objections are clearly rooted in protecting the industry's profitability. In doing so, policy-makers are supporting pricing strategies that ultimately harm uninsured and underinsured Americans." Steven Morgan & Jeremiah Hurley, *Internet Pharmacy: Prices on the Up-and-Up*, 170 CANADIAN MED. ASS'N J. 945 (2016).

19 *See* Erwin A. Blackstone, Joseph P. Fuhr, Jr. & Steve Pociask, *The Health and Economic Effects of Counterfeit Drugs*, 7 AM. HEALTH DRUG BENEFITS 216 (2014). With recent emphasis on the disparity between Canadian and American drug pricing, it is suspected that counterfeiters are preying on this weariness of American consumers by advertising their online outlets to sell "Canadian" Drugs. The FDA has responded by warning American consumers that they cannot validate the quality of anything sold abroad, even if sold legitimately in Canada. However, this has not dissuaded some Americans from physically traveling Canada to purchase medications or enter the hazy confines of the web to do so. *See* U.S. GOV'T ACCOUNTABILITY OFF., GAO-13-560, INTERNET PHARMACIES: FEDERAL AGENCIES AND STATES FACE CHALLENGES COMBATING ROGUE SITES, PARTICULARLY THOSE ABROAD 28 (2013).

The internet has long had a complicated relationship with intellectual property protections ranging from illicit downloads of art and music to the distribution of counterfeit goods.[20] The internet is particularly susceptible to the distribution of black-market goods for a variety of reasons not limited to instantaneity of communication, difficulty of monitoring networks, anonymity, and disparate legal regimes regarding the status of such goods. Counterfeit medicines are being plowed through the same digital channels as other black-market goods and have exposed the tensions of enforcing disparate intellectual property rights on a global platform.

Intellectual property protections cannot resolve internet distribution of black-market goods on the basis of qualities inherent in the online platform, but intellectual property regimes can help standardize which products are market worthy and which market actors may trade in certain products.[21] Such protections provide a guardrail beyond the mere enforcement arm of the criminal law and the abstractions of broader healthcare policy.[22] In fact, intellectual property law plays a key role in resolving the tensions in defining counterfeit drugs, generic drugs, and patent "branded" drugs.[23]

Patent branded pharmaceuticals describe drugs for which a patent has been issued and under which the patent protections still apply; generic drugs

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20 *See IP Issues in the Distribution of Content on the Internet*, WORLD INTELL. PROP. ORG., https://perma.cc/77DS-P6CD (last visited June 23, 2021); A&M Recs., Inc. v. Napster, 239 F.3d 1004 (9th Cir. 2001). Holding content providers liable for copyright infringement on Internet platforms.

21 *See* Richard B. Racine, *The Importance of Intellectual Property Rights in Business Deals*, FINNEGAN (2010), https://www.finnegan.com/en/insights/articles/the-importance-of-intellectual-property-rights-in-business-deals.html. Also worthy of note is that mere possession of intellectual property does not equate to a right to use, practice, or bring into tangible existence the rights conferred therewith. Still intellectual property serves as a useful guardrail for studying the scope of markets even if the furthest theoretical reaches of intellectual property are not coterminous with the bounds of legitimate marketplaces.

22 A key principle that runs through any intellectual property regime is the idea of the public knowledge. Such ideas run through copyright law through the idea of the public domain. *See Public Domain*, WORLD INTELL. PROP. ORG., https://www.wipo.int/copyright/en/activities/public_domain.html (last visited June 23, 2021). Similarly, in patent law the non-obviousness and novelty requirements for the issuance of patents are in some part designed to protect what is rightfully considered to exist within the public knowledge. *See* Alin Speriusi-Vlad, *Novelty, a General Condition for Intellectual Property Protection*, *in* RECENT ADVANCES IN FINANCIAL PLANNING & PRODUCT DEVELOPMENT 75 (2014), http://www.wseas.us/e-library/conferences/2014/Istanbul/FINANCE/FINANCE-10.pdf; *see also* Alan L. Durham, *Lost Art and the Public Domain*, 49 ARIZ. ST. L.J. 1257 (2017). The boundary between works worthy of intellectual property protections and those deemed to reside in the public's controls is a market guardrail of sorts that strengthens the state's ability control market actors. Given that counterfeit goods are often made by those with sufficient to skill to act in a market, weakening of market guardrails can allow illegitimate markets actors to infiltrate.

23 *See supra* note 11; *see also* Daniel C.K. Chow, *Three Major Problems Threatening Multi-National Pharmaceutical Companies Doing Business in China* (Ohio St. Pub. L. Working Paper, Paper No. 407, 2017).

describe drugs available for mass manufacture though not protected by patents; counterfeits describe, to use the FDA's pithy definition, "fake medicine" and in the broadest sense fail to meet some regulatory status associated with legitimately sold generic and patented pharmaceutical.[24] While generics do not maintain patent protections, they may still retain trademarks on the basis of the "brand" or pharmaceutical entity that produces them.[25] Accordingly, the term "branded" pharmaceutical may describe a patented drug for which the active ingredient is associated or any class of drug possessing a valid trademark.[26]

U.S. Patents are constitutionally dictated and enabled by Congressional statute.[27] The life of a patent is often twenty years, and though seemingly long in duration, due to the length of clinical trials and safety protocols, drugs generally do not come to market until 12 years after the original patent filing date.[28] Trademarks on the other hand are inhered by common law and registered through the U.S. Patent and Trademark Office and serve as the marker of a brand.[29] Trademarks in the case of pharmaceuticals may manifest as the brand name of a drug, the shape of a pill, or other characteristics that distinguish the product from other competing products.[30]

Another issue with counterfeit medications is that consumers are often confused as to the distinctions between generic and counterfeit medications, in which case they will unnecessarily opt for more expensive branded pharmaceuticals.[31] In fact it should be noted that most counterfeit

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24 *See Counterfeit Medicine*, *supra* note 11.

25 *Id.*; *see also* Nick de la Torre & Jennifer Theis, World Trademark Rev., Brinks Hofer Gilson & Lione, *Pharmaceutical Trademarks* (2012), https://www.brinksgilson.com/files/pharma_2012__selection_clearance_and_registration.pdf. "In the pharmaceutical context, nontraditional trademarks may include a particular pill shape or colour, or medication flavour. These marks may require threshold showings of non-functionality and/or secondary meaning (acquired distinctiveness) to be protectable." De la Torre & Theis, *supra*, at 62.

26 De la Torre & Theis, *supra* note 25, at 63.

27 *See* U.S. CONST. art. I, § 8 ([Congress shall have the power] "To promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries."); *see also* 35 U.S.C. (the title in the U.S. code concerned with patents).

28 Ingrid Torjesen, *Drug Development: The Journey of a Medicine from Lab to Shelf*, PHARM. J. (May 12, 2015), https://pharmaceutical-journal.com/article/feature/drug-development-the-journey-of-a-medicine-from-lab-to-shelf.

29 *See* U.S. Patent & Trademark Off., *Protecting Your Trademark: Enhancing Your Rights Through Federal Registration* (2020), https://www.uspto.gov/sites/default/files/documents/BasicFacts.pdf.

30 *See* Mylan, *supra* note 24.

31 *See Counterfeit, substandard and generic drugs: distinct definitions for distinctly different problems*, MEDECIN SANS FRONTIERES (Mar. 31, 2009), https://msfaccess.org/counterfeit-substandard-and-generic-drugs. The confusion between generics and counterfeits is also related to the more general problem of defining what constitutes counterfeit medication. *See also supra* note 10.

medications are not actually lethal.[32] Some counterfeits actually work and contain the specified formulation, while others contain inert or tainted substances.[33] In this manner counterfeits share an issue with the illicit recreational drug trade in that the issue with counterfeits is not that some counterfeits are not effective but that consumers are unaware of what they are buying. Accordingly, in some respects the fact that some counterfeits are effective make them more insidious. If counterfeits merely were ineffective people would quit buying them, but their potential effectiveness makes them attractive to those often faced with the prospect of going drugless absent the counterfeit.

III. ISSUE

A. The Supplier

According to a WHO study in 2017, 10.5 percent of pharmaceutical drugs in low and middle-income countries are phony or substandard.[34] China, India, and other countries in South and Southeast Asia are particularly affected by the problem of counterfeit drugs.[35] China is considered the largest source of counterfeit medications in the world with India tailing closely behind.[36] Precise rankings, however, are irrelevant; both countries suffer from lax intellectual property and enforcement

32 *See* Acri, *supra* note 2. Quoting Peter Pitts of the Center for Medicine in the Public Interest: "It's generally bad business to kill your consumer, and it's not in the interest of counterfeiters to hurt you outright."

33 *See Id.* Quoting Paul Toscano, "Counterfeiters are more likely to produce drugs containing inert substances," as opposed to drugs composed of lethal substances. Paul Toscano, *The Dangerous World of Counterfeit Prescription Drugs*, CNBC (Oct. 6, 2011, 11:10 AM), https://www.cnbc.com/id/44759526.

34 *See Growing Threat from Counterfeit Medicines*, *supra* note 1; *see also* Victoria Rees, *The Impact of Counterfeit Drugs in South and South-East Asia*, EUR. PHARM. REV. (July 3, 2019), https://www.europeanpharmaceuticalreview.com/article/92194/the-impact-of-counterfeit-drugs-in-south-and-south-east-asia/. "'If there is insufficient product on the market, within days, the vacuum is filled with falsified versions,' says Michael Deats, an expert on medicine safety and vigilance with WHO." *Id.*

35 *Id.*

36 *See infra* note 45 (noting China to be the largest producer of counterfeit pharmaceuticals). Contrast with findings from International Federation of Pharmaceutical Manufacturers & Associations, noting that India beats out China in only one domain of counterfeit goods, the domain of counterfeit medications. Thomas B. Cueni, *The Trade Routes of Counterfeits*, INT'L FED'N PHARM. MFRS. & ASS'NS (Sept. 18, 2017), https://www.ifpma.org/global-health-matters/the-trade-routes-of-counterfeits/.

regimes and, accordingly, both countries have incurred consequences of a rife counterfeit drug trade.[37]

The consequences of the manufacture of counterfeit drugs, though particularly localized in Asia, has global consequences. Half the deaths of the current opioid crisis are suspected to be a result of synthetic heroin fentanyl manufactured in China of a counterfeit formulation.[38]

Coincident with both countries is the fact that both countries have thriving counterfeit goods markets beyond pharmaceuticals. According to the OECD, China represented the source of 63.2 percent of all counterfeit goods in 2013, ranking first in the world, and India, at 1.2 percent, ranked sixth.[39] Aside from other economic considerations leading to counterfeit black markets, both countries have relatively young intellectual property regimes as opposed to more developed countries such as the United States. China joined the World Intellectual Property Organization (WIPO) in 1980 and passed its first law protecting patents in 1984 and trademarks in 1982.[40] The history of China also seems to indicate a relative intransigence around Western ideals of intellectual property protection prior to the economic

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37 *See* Rees, *supra* note 34. In 2009, Interpol seized over twenty million pills, bottles, and sachets throughout China and seven other Southeast Asian countries, resulting in the arrest of thirty-three people and the closure of one hundred retail outlets. *See Growing Threat from Counterfeit Medicines*, *supra* note 1.

38 *See id.* See also the discussion of opioid crisis and counterfeit drugs in *supra* note 5 and *infra* note 80. While counterfeit drug suppliers face a countervailing incentive to not kill their customers, as stated in the Background of this note, certain chemical compositions, such as fentanyl leave little room for error in dosing. The LD_{50} is a common metric for studying the potency of certain ingestible substances. A particular chemical composition's LD_{50} describes the threshold at which fifty percent of an animal population dosed with the composition dies as a result of ingestion. LD_{50} is measured as a concentration equaling the mass ingested divided per mass body weight. The LD_{50} of an extremely potent drug such as fentanyl is 62 mg/kg. To put in context, in a population of average American men weighing roughly two hundred pounds, fifty percent of the group would have consumed a lethal dose at a threshold of 5.62 grams of dosing of Fentanyl (roughly the mass of a nickel). By comparison a population of similarly weighing men would have to consume roughly 642 grams of ethanol to achieve a similar threshold. *See Safety Data for Ethyl Alcohol, Absolute (200 Proof)*, HSCI PROJ. (June 8, 2011), https://web.archive.org/web/20110714040451/http://msds.chem.ox.ac.uk/ET/ethyl_alcohol.html; *see also* U.S. Drug Enf't Agency, Diversion Control Div., *Acetyl Fentanyl* (2020), https://www.deadiversion.usdoj.gov/drug_chem_info/acetylfentanyl.pdf; Elizabeth Mendes, *In U.S., Self-Reported Weight Up Nearly 20 Pounds Since 1990*, GALLUP (Nov. 23, 2011), https://news.gallup.com/poll/150947/self-reported-weight-nearly-pounds-1990.aspx.

39 *See* OECD, *Global Trade in Fake Goods Worth Nearly Half a Trillion Dollars a Year* (Apr. 18, 2016), https://www.oecd.org/industry/global-trade-in-fake-goods-worth-nearly-half-a-trillion-dollars-a-year.htm.

40 *See* 1984 Patent Law (promulgated by Pres. People's Repub. China, Mar. 12, 1984, effective Apr. 1, 1985); Trademark Law (adopted by Standing Comm. Nat'l People's Cong., Aug. 23, 1982, amended Oct. 27, 2001). See also the information on Chinese intellectual property regime at WORLD INTELL. PROP. ORG., *Country Profiles: China*, https://www.wipo.int/directory/en/details.jsp?country_code=CN (last visited June 23, 2021).

demands of the late twentieth century resulted in greater consideration of espoused intellectual property rights by western actors.[41] India, by comparison, joined WIPO in 1975 and developed its first patent law in 1970 and trademark law in 1999.[42] India, by contrast to China, however, is infused with Common Law traditions, and the offense of "Passing Off" under Common Law was an analogue to trademark infringement prior to the formal passage of the Trademark law in 1999.[43]

The correlation between the strength of intellectual property rights and counterfeit drugs is twofold. Intellectual property rights must be established but also enforced. The WHO has stated that when:

> 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.[44]

Patent and trademark rights are most relevant to pharmaceutical companies in preventing counterfeits. The effective assertion of patent rights prevents manufacturers from stealing the means of production and

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41 Noting the long tradition of Chinese society differing from Western norms around intellectual property, see WILLIAM P. ALFORD, TO STEAL A BOOK IS AN ELEGANT OFFENSE: INTELLECTUAL PROPERTY LAW IN CHINESE CIVILIZATION 1 (1995) ("To steal a book is an elegant offense.").

42 For access to the 1970 Patents Act and the 1999 Trade Marks Act, see *India IP Laws*, WIPO IP PORTAL, https://wipolex.wipo.int/en/legislation/profile/IN (last visited June 23, 2021).

43 Jaclin Cassios, *"Passing Off" a Trademark: A Discussion of Common Law, Statutory Codification, and Civil Law*, JD SUPRA (June 28, 2018), https://www.jdsupra.com/legalnews/passing-off-a-trademark-a-discussion-of-98446/. "A successful passing off claim requires a plaintiff owner or licensee to demonstrate that it has acquired a commercial reputation in the geographical area where it seeks to enforce its rights through use of its particular indicium or mark, such as a registered or unregistered trademark, or trade name. A reputation is acquired if the mark has become publicly known, and goodwill exists with respect to the mark (namely, the benefits and advantages of the good name and connection of a business that attracts customers). The length of time an owner has used the mark in question to identify its goods, services or business in the market will factor into the extent of the reputation of that mark. The amount of time necessary to prove a reputation is dependent upon, among other things, the inherent distinctiveness of the mark. The greater the distinctiveness of a particular mark, the broader the scope of protection afforded, and, hence, the greater the likelihood of confusion when similar indicia are used within that scope of protection. Further evidence that a mark has acquired a reputation is significant advertising and marketing utilizing the mark. The existence of significant sales is an additional factor to be considered when establishing the reputation of a mark." *Id.*

44 *See* Kristina M. Lybecker, *Keeping It Real: Anticounterfeiting Strategies in the Pharmaceutical Industry*, 29 MANAGERIAL & DECISION ECON. 5, 389–405 (2008).

thereby creating an unregulated product.[45] Trademark rights may work to allow drug manufacturers to place distinctive markers on their products that, if misappropriated, should grant them legal recourse.[46]

In the case of China, both patent and trademark rights are dubious in the pharmaceutical sphere. However, pressures regarding patent rights place particular stress on the counterfeit drug market.[47] In 1994 the Agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS) was adopted by the World Trade Organization (WTO).[48] This agreement attempted to standardized certain intellectual property rights especially with respect to pharmaceuticals.[49] In the course of applying for drug licensing, the application for a patent is only the first step.[50] Drugs undergo extensive

45 *See* Chow, *supra* note 23. Also note, "effective assertion" does imply enforcement regimes capable of enforcing the letter of the law.

46 Trademark rights may be easier to assert in the pharmaceutical space, because trademarks involve outward affects that are designed to inform consumers of the products origin. In fact, a justification for the grant of trademark protections is that trademarks serve a "quality assurance" function by allowing consumers to develop brand loyalties and be conscious of the sourcing of products. Further, producers have greater ability to manipulate trademarks such that the public can receive sufficient notice of the products validity as opposed to patents. The patented aspects of products often go "unseen" to the consumer, even if the consumer is implicitly demanding or purchasing the product on behalf of the patented components. The balance of these IP regimes has already led to drug manufacturers to use certain watermarks on their products in order to distinguish legitimately produced pharmaceuticals from counterfeits. *See* Elmer William Hanak, III, *The Quality Assurance Function of Trademarks*, 43 FORDHAM L. REV. 363, 363 (1974) ("Today virtually every writer on trademark law accepts the quality assurance function."); Antoinette Konski, Foley & Lardner LLP, *IP Strategies to Combat Distribution of Counterfeit Drugs* (2008), https://perma.cc/P22Q-3QUW.

47 China has made some efforts to strengthen its intellectual property enforcement as its economy shifts from merely being the manufacturer of the world to one built more on homegrown innovation and entrepreneurship. *See* Yukon Huang & Jeremy Smith, *China's Record on Intellectual Property Rights Is Getting Better and Better*, FOREIGN POL'Y (Oct. 16, 2019, 9:52 PM), https://foreignpolicy.com/2019/10/16/china-intellectual-property-theft-progress/. For a slightly more biased view from an organ of the Chinese state, see Tao Kaiyuan, *China's Commitment to Strengthening IP Judicial Protection and Creating a Bright Future for IP Rights*, WIPO MAG. (June 2019), https://www.wipo.int/wipo_magazine/en/2019/03/article_0004.html. For critiques of developments specifically of China's new trademark law, see Xuan-Thao Nguyen, *The World's Trademark Powerhouse: A Critique of China's New Trademark Law*, 40 SEATTLE U. L. REV. 901 (2017).

48 *See* WORLD TRADE ORG., *Overview: the TRIPS Agreement*, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited June 23, 2021). For the full text of the agreement, see Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, annex 1C, 1869 U.N.T.S. 299 [hereinafter TRIPS Agreement]. Introductory Objectives: "*Desiring* to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade . . . *Desiring* to establish a mutually supportive relationship between the WTO and the World Intellectual Property Organization (referred to in this Agreement as "WIPO") as well as other relevant international organizations." *Id.* pmbl. (emphasis in original).

49 *See* TRIPS Agreement, *supra* note 48.

50 *See supra* note 45.

clinical trials and regulatory checks before being released to the market.[51] The data collected in this process is not patented but is generally protected by data, exclusivity laws, some form of which is required by TRIPS.[52] The protection of this data prevents other manufacturers from relying on an initial drug developer's clinical trial results for a specified period (five years in the United States).[53] While this data is not essential in the manufacture of chemical entities, it is often a procedural hurdle for prospective follow-on manufacturers.[54] In effect the release of such data creates a larger potential pool of manufacturers and general deregulatory regime that increases the likelihood that substandard and counterfeit drugs enter in the legitimate drug supply.[55] In this manner, such protections can also be used in lieu of patent protections for chemical entities that may not meet the standards of novelty or non-obviousness demanded by patent protections.[56]

China, in accordance with TRIPS, borrowed language from the treaty when it passed its own data exclusivity law, specifying exclusivity only for "new chemical entities."[57] This law, however, did not explain the meaning of a "new chemical entity," and as such the Chinese have exploited the ambiguity of the language as not all drugs constitute "new chemical entities," effectively allowing the Chinese government to release clinical trial data and procedural data for certain non-"new chemical entity" drugs into the public domain in contravention to the spirit of TRIPS.[58] The release

51 *See id.*

52 *See* TRIPS Agreement, *supra* note 48, art. 39.3. In relevant part: "Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use." *Id.*

53 "In cases like this, the data exclusivity mechanism fills the need, such that potentially beneficial drugs—though ones that may not be eligible for patent protection—can be given protection by another kind of intellectual property and brought to market. Therefore, for drugs involving improvements that are not significant enough to allow patent protection, seeking data exclusivity may be the way to go." Crystal J. Chen, *Patents vs. Data Exclusivity in Pharmaceuticals*, LEXOLOGY (Jan. 29, 2015), https://www.lexology.com/library/detail.aspx?g=5fe621cd-4372-49af-933f-714b3e8e7a02.

54 *See id.*

55 *See id.*

56 *See id.*

57 Drug Administration Law (promulgated by Standing Comm. Nat'l People's Cong., Dec. 1, 2019), art. 35. "The State exercises special control over narcotic drugs, psychotropic substances, medicinal toxic drugs and radioactive pharmaceuticals. Measures for the control in this respect shall be formulated by the State Council."

58 *See supra* note 45.

of this data requires all drugs to be sold in China be clinically tried in China, so this lever is omnipresent for any drug brought to market in the country.[59]

In effect China has structured a regime that channels post-patent data into the public domain in a far less restrictive manner than in the United States. This data in turn can be used by counterfeit manufacturers.[60]

In greater contravention to American standards and views around patent protections, both India and China maintain compulsory licensing provisions in their patent laws.[61] Compulsory licensing involves the ability of

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59 *See id.*

60 While the American norms around clinical trial data are generally more on the restrictive side, increasingly debates around healthcare reform have considered the impact of data transparency in improving delivery of healthcare, lowering drug prices, and encouraging innovation. *See* Judy Stone, *Why Transparency and Data Sharing in Clinical Trials Matters*, FORBES (Jan. 15, 2015, 7:00 AM), https://www.forbes.com/sites/judystone/2015/01/15/why-transparency-and-data-sharing-in-clinical-trials-matters/#4e4d6a187752. "There have been many attempts at ensuring clinical trial transparency and sharing more data. This began with the Food and Drug Administration Modernization Act of 1997, which mandated registration of studies on ClinicalTrials.gov. Later, in 2004, the International Committee of Medical Journal Editors provided support for the goal of trial registration by requiring it as a condition for publication. In 2007, the Food and Drug Administration Amendments Act (known as FDAAA 801) required reporting of summary results from most trials. Some journals pushed this effort along, most notably the Annals of Internal Medicine, with its Reproducible Research initiative and the British Medical Journal. Both journals required data sharing statements from the authors. . . . There are now 182,168 trials registered on ClinicalTrials.gov. While there has been a gradual increase in reporting of results, only 15,845 registered trials posted results in 2014. Estimates are that the results from half of all clinical trial results have never been published; positive trials are twice as likely to be published as others, whether these are industry sponsored or not." *Id.* Canada also presents a model of data transparency that has been looked to by American observers. Increasingly, given the costs of conducting clinical trials and the broader demands of pharmaceutical research, data sharing on a global scale is seen as a way to improve efficiency of costs and speed of drug approval. *See* Barbara Mantel, *Canada's Decision to Make Public More Clinical Trial Data Puts Pressure on FDA*, NPR (Oct. 11, 2019, 2:18 PM), https://www.npr.org/sections/health-shots/2019/10/11/769348119/canadas-decision-to-make-public-more-clinical-trial-data-puts-pressure-on-fda. "It is important to have multiple regulators making the data public, says Peter Doshi, an associate editor at the BMJ, an international medical journal, and an associate professor of pharmaceutical health services research at the University of Maryland School of Pharmacy. As it stands now, 'If FDA approves first, which often it does, we won't know anything until Health Canada or the EMA makes a decision,' says Doshi. 'And not every drug, device, biologic out there is going to be approved by these other regulators or even submitted to these other markets.'

In addition, redundancy lessens the impact if one regulator changes policy. The EMA, for example, earlier this year moved its operations from London to Amsterdam because of Britain's anticipated exit from the European Union. Clinical data publication "was one of the activities suspended until we are more settled in Amsterdam," says Anne-Sophie Henry-Eude, head of documents access and clinical data publication. No date has yet been announced for its resumption. Sandy Walsh, a spokesperson for the FDA, says the agency does not have the same freedom as Canadian and European regulators to release clinical study reports. "U.S. laws on disclosure of trade secret, confidential commercial information, and personal privacy information differ from those governing EMA and Health Canada's disclosure of clinical study reports," she wrote in an email." *Id.*

61 *See* Chow, *supra* note 23; *see also* Yanzhong Huang, *The Compulsory Licensing of Pharmaceuticals: Will China Follow in India's Footsteps?*, COUNCIL ON FOREIGN RELS. (Oct. 1, 2012,

governments to demand patentees license their property if they do not act on their patent rights in a "timely" manner.[62] In China, if "the patentee fails to give good reason for failing to fully or sufficiently implement the patent right three years from the date of the patent being granted, and that it has been four years from the date of applying for the patent," then the licensing may be implemented.[63] This provision is not inherently objectionable, and in fact such provisions are authorized by TRIPS and were given greater endorsement and liberality in the Doha Declaration of 2001.[64] However, in the context of a massive counterfeit market, compulsory licensing provides yet another route to pry open information to potentially untoward manufacturers.[65]

10:44 AM), https://www.cfr.org/blog/compulsory-licensing-pharmaceuticals-will-china-follow-indias-footsteps. "Between 2001 and 2010, twenty-four compulsory licensing episodes in seventeen countries were reported. Most of these episodes ended in a price reduction for the specific drug in question through a compulsory license (CL), a voluntary license, or a negotiated discount. Also, most of the episodes involved drugs for HIV/AIDS and other communicable diseases, with only five cases involving drugs for NCDs such as cancer. In 2006, India announced it would issue a CL for the anti-cancer drug Imatinib Mesylate (Gleevec), although it ended up not doing so . . . . In March 2012, the Indian Patent Office issued its first ever CL for Bayer AG's blockbuster cancer drug sorafenib tosylate (Nexavar), authorizing a domestic generic drug-maker (Netco) to produce a low-cost version of the drug. This move is significant for three reasons. First, it would lead to a generic drug that is 97 percent less than the patented drug thus effectively ending the German pharmaceutical company's monopoly over the drug in the Indian market. Second, it may signal other Indian generic producers to follow suit if the patent holders fail to supply drugs in large quantities at affordable prices. Third, it could encourage other developing countries such as China to issue compulsory licenses for drugs that treat NCDs." *Id.*

62 Chow, *supra* note 23 (defining compulsory licensing as "when a government allows someone else to produce a patented product or process without the consent of the patent owner or plans to use the patent-protected invention itself"); *see also* WORLD TRADE ORG., *Compulsory Licensing of Pharmaceuticals and TRIPS*, https://www.wto.org/english/tratop_e/trips_e/public_health_faq_e.htm (last visited June 23, 2021).

63 *See* Chow, *supra* note 23.

64 *See id.*; *supra* note 48. "The Doha Declaration reaffirmed that '*the TRIPS Agreement does not and should not prevent Members from taking measures to protect public health*' . . . The Doha Declaration refers to several aspects of TRIPS, including the right to grant compulsory licenses and the freedom to determine the grounds upon which licenses are granted, the right to determine what constitutes a national emergency and circumstances of extreme urgency, and the freedom to establish the regime of exhaustion of IP rights." TRIPS AND DEVELOPING COUNTRIES: TOWARDS A NEW IP WORLD ORDER?, at 55 (Gustavo Ghidini, Rudolph J.R. Peritz & Marco Ricolfi eds., 2014).

65 A theme running through the counterfeit market is the way in which the strength of regulatory regimes creates an environment more or less favorable to potential untoward actors. The strength of intellectual property protections and enforcement in some ways directly counteracts certain manufacturers from manufacturing or making use of certain products/product likenesses. The manufacturers directly targeted by such regulations, however, are not always those who would be engaged in counterfeiting. Since counterfeiting is an unlawful enterprise, by the act's criminal nature, counterfeiters are undeterred by the direct legality of use of certain information. Rather, strong intellectual property regimes seem place stricter controls on information flow useful to counterfeiters, such as brand formulations and likenesses that in looser regulatory regimes are more available to legitimate manufacturers. Such looseness, while unintended in result, creates greater opportunities for counterfeiters to obtain misbegotten information.

Fundamentally counterfeited drugs necessarily infringe a trademark as counterfeits usually resemble the shape and color of either a branded generic or patented drug.[66] Trademarks in China are subject to some of the forced transfer of property as described with respect to patents, but more so suffer from a lack of enforcement. Incentives in low/middle income countries favor economic productively and potentially increasing supply of otherwise unobtainable medications. Further, many regional leaders in China face pressures to increase economic output such to ignore potential intellectual property violations.[67]

Trademarks, as opposed to patent protections, have inherent counters to the issue of counterfeiting. Pharmaceutical manufacturers maintain great leeway in creating a trademark, and thusly can watermark or imbue their products in a such a manner as to make counterfeiting extremely difficult or easily noticeable.[68] In fact, many countries including India have started requiring drugs to be marked with 2D barcodes or radio-frequency identification (RFID).[69] These mechanisms can help to prevent the misidentification of drugs that allow counterfeits to enter legitimate streams of commerce or lead to unsuspecting consumers to ingest counterfeit medications. However, such mechanisms are unlikely to deter buyers aware of the fact that they are engaged in a black-market transaction.[70]

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66 *See* Chow, *supra* note 45.

67 *See id.*; Dan Harris, *China Trademark Theft. It's Baaaaaack in a Big Way*, CHINA L. BLOG (Aug. 16, 2018), https://www.chinalawblog.com/2018/08/china-trademark-theft-its-baaaaaack-in-a-big-way.html ("Though troublesome, the damage from domain name usurpation is typically small, particularly as compared to what can happen if someone hijacks your trade name or trademark in China. We have seen this happen countless times, mostly to American companies who are unfamiliar with the 'first to file' trademark law, as opposed to the U.S., British, and Canadian, 'first to use' systems.").

68 *See supra* note 46.

69 *See id.*; *see also* Dipika Bansal, Swathi Malla, Kapil Gudala & Pramil Tiwari, *Anti-Counterfeit Technologies: A Pharmaceutical Industry Perspective*, 81 SCIENTIA PHARMACEUTICA 1 (2012) ("An ideal anti-counterfeit technology should possess a high level of security (non-clonable), higher product application and authentication speed, proven standards, be difficult to remove and reapply, easy to check, have automatic authentication, be useable by consumers, and must be legally compliant by the industries. However, the FDA recommends the use of multiple, periodically changing, authentication measures on a product-specific basis.").

70 *See infra* note 113. Trademark may have ancillary role in the intermediate marketplace, namely at the point of sale in pharmacy. Currently a large swath of the counterfeit market is online. The demand for drugs online is robust and unlikely to be stemmed through mere prohibition. Further, prohibition would likely just lead to dark web sales as occurs in the case of illicit drugs. *See* Nathaniel Popper, *Dark Web Drug Sellers Dodge Police Crackdowns*, N.Y. TIMES (June 11, 2019), https://www.nytimes.com/2019/06/11/technology/online-dark-web-drug-markets.html. Proposed solutions to the online pharmacy issue have included better standardizing the identification of legitimate outlets as opposed to counterfeit outlets. This process could involve the application of Trademark law, particularly analogous to brand associations such as Walgreens and CVS. The determination of

Concludingly, supplier governments (China, India, etc.) in this analysis could be said to not necessarily be actively encouraging a counterfeit regime for the sake of counterfeits. Rather, supplying jurisdictions could be responding to conditions in their own countries that balance, in the government's view, in favor of accepting the downsides of a thriving counterfeit black-market for potential economic growth and increased access to and manufacture of medication. The intellectual property regulations discussed herein are not specifically tailored towards eliminating counterfeits, rather it is the relaxation of such regulations that relaxes market guardrails that creates an environment that allows counterfeit suppliers to act. Counterfeit suppliers in some cases are sophisticated manufacturers with specialized technical manufacturing knowledge. This knowledge makes prospective counterfeit manufacturers particularly nimble in a lax regulatory environment to capitalize on weakness or loopholes in enforcement in countries where counterfeiting is rife. In conclusion, strengthening intellectual property protections in supplier countries can darken the line between black and legitimate market spheres, keeping potential black-market suppliers from garnering the intellectual property and other market knowledge reserved for the legitimate markets.

B. The Buyer

Counterfeit drugs necessitate not only a seller but also a buyer. While *laissez faire* intellectual property enforcement and policy regimes present in China and India may contribute to bolstering the supply for counterfeit drug markets, countervailing forces are present. In global markets, including healthcare markets in the United States, that encourage looser controls on intellectual property and drug production more generally.

A common critique of TRIPS and western values around intellectual property is that American and European norms around intellectual property may stifle innovation and access in developing countries.[71] In studying the

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legitimate outlets is particularly important in the American and Canadian context as American consumers are often duped into purchasing counterfeit medication from outlets sporting themselves as Canadian pharmacies selling drugs as discounted rates. *See infra* note 106; *supra* note 18.

71 JOSEPH E. STIGLITZ, MAKING GLOBALIZATION WORK, W.W. Norton & Company (2006). *See also* GILLIAN J. BUCKLEY AND LAWRENCE O. GOSTIN, COUNTERING THE PROBLEM OF FALSIFIED AND SUBSTANDARD DRUGS, The National Academies Press (2013) ("TRIPS imposed on the entire world the dominant intellectual property regime in the United States and Europe, as it is today. I believe that the way that intellectual property regime has evolved is not good for the United States and the EU; but even more, I believe it is not in the interest of the developing countries."). *See also* Emmanuel Hassan, Ohid Yaqub, Stephanie Diepeveen, *Intellectual Property and Developing Countries*, RAND Europe, https://www.rand.org/content/dam/rand/pubs/technical_reports/2010/RAND_TR804.pdf.

effects of TRIPS on developing countries, the RAND (Research AND Development) Corporation, a policy think tank, found that strengthening intellectual property rights in developing countries may serve to create market channels for licensing and innovation that improve the overall economic situations in such countries.[72] This effect was observed in certain industries, however it was not as pronounced in the healthcare space, where the capital costs of research are generally higher.[73]

Constraints on legitimate healthcare in developing countries seem to be a potent driving force for the market of counterfeits. The British International Policy Network predicts that seven hundred thousand deaths a year are caused by fake malaria and tuberculosis drugs, diseases that disproportionately affect poor and developing countries.[74] Further according to the WHO in developing parts of Asia, Africa, and Latin America, more than thirty percent of the medicines on sale can be fake.[75] The consequence of counterfeits in such areas may not just result in harm to the individual in possession of the drugs; rather since many counterfeits are not pure fakes or death tonics, but merely just substandard or slightly altered versions of the branded pharmaceutical, improper treatment regimens brought about by substandard drugs is thought to contribute to drug resistant strains of tuberculosis and other such diseases.[76]

In noting why the proliferation of counterfeits is so common in Africa, the UN notes weak regulatory regimes.[77] In recent years investment by the WHO and many African governments have attempted to develop a home-grown pharmaceutical manufacturing base on their continent.[78] Weak regulatory controls, however, have contributed to situations where

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72 *See* RAND Europe *id.*

73 *See id.*

74 *See* Jocelyne Sambira, *Counterfeit Drugs Raise Africa's Temperature*, AFR. RENEWAL (May 2013), https://www.un.org/africarenewal/magazine/may-2013/counterfeit-drugs-raise-africa%E2%80%99s-temperature. "About 100,000 deaths a year in Africa are linked to the counterfeit drug trade, according to the World Health Organization (WHO). The British think-tank, International Policy Network, estimates that globally, 700,000 deaths a year are caused by fake malaria and tuberculosis drugs—comparing the death toll to the equivalent of 'four fully laden jumbo jets crashing everyday.' The WHO defines counterfeit medicine as 'one which is deliberately and fraudulently mislabelled with respect to identity and/or source.' Both branded and generic products are faked. In some parts of Africa, Asia and Latin America, more than 30% of the medicines on sale can be fake, notes the organization." *Id.*

75 *See id.*

76 *See id.* Controlled delivery of medication is particularly important in the treatment of HIV and malaria.

77 *See id.*

78 *See id.*

substandard drugs sometimes inadvertently, but many times intentionally enter the stream of commerce.[79]

Even in the face of stronger regulatory regimes than in certain African countries where counterfeits are rife, counterfeit drugs still proliferate in American markets even if not produced domestically.[80] In fact, in a 2018 symposium the Partnership for Safe Medicines stated that up to 19 million Americans purchased counterfeits in the previous year.[81] In the United States, counterfeits have even found their way into legitimate supply chains.[82] The demand could be tied to above-inflation rises in drug pricing.[83] Further, uninsured Americans who are already outside of the legitimate healthcare system may be more predisposed to shopping around in less legitimate sources.[84]

The proliferation of counterfeits in the United States serves to show the truly global problem of counterfeit drugs, even if the vast majority of sufferers (and beneficiaries) of the counterfeit drug trade reside outside the United States.

IV. SOLUTIONS

As mentioned at the outset of this note, the issue of counterfeit drugs is multifaced and complicated. The COVID-19 pandemic has, further, turned many global and domestic public health systems on their proverbial head. Accordingly, adapting solutions to the issue of counterfeit medications is likewise a complicated process. Likely no single solution would be sufficient to completely stifle the trade. In fact, looking to an analogous

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79 *See id.* Observers have actually recommended that the WHO develop a "three-strikes-and-you-are-out rule" for companies making low-quality drugs. Since the WHO often oversees the dissemination of formulation and manufacturing rights to home-grown African pharmaceutical distributors, the organization has some levers of control over misbehaving manufacturers.

80 *See* P'ship for Safe Medicines, *Counterfeit Medicine In America: 2018* (Oct. 29, 2018), https://www.in.gov/bitterpill/files/Safdar-Counterfeit-IN-AG-Opioid-Summit-2018-10-29-FINAL.pdf.

81 *See id.* The symposium notes how counterfeits fit into the opioid crisis as many fake medicines are found to be laced with fentanyl. Fentanyl is extremely potent and miniscule amounts (2–3 milligrams) can lead to overdoses. Fentanyl laced drugs have been found in the illicit recreational drug trade and in some cases, legitimate streams of drug commerce. The symposium notes that a sixty-year-old Georgia resident took some of her husband's Percocet following surgery and ended up in treatment for an overdose of fentanyl.

82 *See id.* The symposium also notes a famous counterfeit drug tragedy in which counterfeit Avastin, a drug used in the treatment for cancer, was found in circulation containing no active ingredient.

83 On ever increasing drug prices, see KAISER HEALTH NEWS, *Drug Prices Still Jumped Four Times the Rate of Inflation Despite Public, Congressional Outrage Over Increases* (July 2, 2019), https://khn.org/morning-breakout/drug-prices-still-jumped-four-times-the-rate-of-inflation-despite-public-congressional-outrage-over-increases/.

84 *See* Blackstone et al., *supra* note 19.

situation, if the widely publicized issues of combatting the illicit recreation drug trade ("War on Drugs") has taught us any lessons, it is that no matter the circumstance, drugs will invariably find a way to meet a buyer.[85]

A. Access to Drugs in Developing Economies

Perhaps the most obvious and important solution, especially in the face of strengthening intellectual property protections more broadly in developing countries, is that the availability of generic and patented drugs in developing countries should be made broader in order to facilitate the strengthening of regulatory regimes necessary to stamp out counterfeits. Developing countries face dueling incentives in the case of counterfeit drugs: while counterfeit drugs are detrimental on a societal level, some counterfeit medications contain active ingredients that possess effectiveness to consuming individuals. More importantly, the effective regulation of counterfeits may hinder the production of much needed legitimate drugs.

In Nigeria for example: the country's Food and Drug Administration found that forty-one percent of pharmaceuticals in the country were counterfeit, and seventy percent were unregistered.[86] This statistic may seem astoundingly high, but in a county in which ninety-seven percent of the population lives at risk of malaria and in which average annual income as measured by Gross National Income equated to $1,960 per year, the fact

85 In 1970, Congress passed the Comprehensive Drug Abuse Prevention and Control Act (CDAPC). Two years late the Drug Enforcement Agency (DEA) initiated operations. In tracking a period between 1980 and 2008 the CDC found that overdose deaths per 100,000 people did not in fact decline in the period following CDAPC's and the DEA's activity. In fact the overdose rate went from roughly 2 per 100,000 people to 12 per 100,000 people in 2008. Further, from 2010 to 2017, the CDC and NIH tracked the raw number of overdoses. In 2010 the raw number of overdoses of any drug was roughly 40,000 nationwide; by 2017, the number was close to 72,000. While some debate concerns whether government policy has contributed to overdose deaths, the relative increase of overdoses seems to indicate the alluring market power of drugs even under strict market controls. *See* Ctrs. for Disease Control, *Data Brief 81: Drug Poisoning Deaths in the United States, 1980–2008*, https://www.cdc.gov/nchs/data/databriefs/db81_tables.pdf#4 (last visited June 23, 2021); *see also Overdose Death Rates*, NIH NAT'L INST. ON DRUG ABUSE (Jan. 29, 2021), https://www.drugabuse.gov/related-topics/trends-statistics/overdose-death-rates; Jeffrey A. Singer, *Harm Reduction: Shifting from a War on Drugs to a War on Drug-Related Deaths*, CATO INST. (Dec. 13, 2018), https://www.cato.org/publications/policy-analysis/harm-reduction-shifting-war-drugs-war-drug-related-deaths; Christopher J. Coyne & Abigail R. Hall, *For Decades and Counting: The Continued Failure of the War on Drugs*, CATO INST. (Apr. 12, 2017), https://www.cato.org/publications/policy-analysis/four-decades-counting-continued-failure-war-drugs.

86 *See How to Combat Counterfeit Drugs in Nigeria*, BERKELEY MDP, https://mdp.berkeley.edu/how-to-combat-counterfeit-drugs-in-nigeria/ (last visited June 23, 2021).

that some non-trivial portion of the population reaches for *some* form of treatment, even if faulty, comes much clearer into view.[87]

Notable methods for building up pharmaceutical supply in developing economies include: 1) build up domestic pharmaceutical production and research capacity, and 2) provide foreign pharmaceuticals at a discount.[88] The problem with the first solution is that the pent up demand in struggling countries often leads to much greater emphasis on manufacturing than research. Further, in countries with loose regulatory controls, the domestic homegrown pharmaceutical industry can become a complicit player in the counterfeit trade.[89] American pharmaceutical companies have attempted to embark on solution two, however, the results of such are mixed.[90] Some argue that the cuts in price the pharmaceutical companies offer are not great enough to actually meet the demand. Further pharmaceutical companies face tough questions in shifting cost burdens onto consumers in wealthier countries, as many wealthy countries already complain of high drug prices.[91]

A secondary consideration in certain countries relates to compulsory licensing and sharing of clinical data.[92] While compulsory licensing in the

87 *See Data: Nigeria*, WORLD BANK, https://data.worldbank.org/country/nigeria (last visited June 23, 2021); United States Embassy in Nigeria, *Nigeria Malaria Fact Sheet*, U.S. EMBASSY IN NIGERIA, https://photos.state.gov/libraries/nigeria/231771/Public/December-MalariaFactSheet2.pdf.

88 *See* Sambira, *supra* note 74.

89 *See id.*

90 *See* Tina Rosenberg, *H.I.V. Drugs Cost $75 in Africa, $39,000 in the U.S. Does It Matter?*, N.Y TIMES (2018), https://www.nytimes.com/2018/09/18/opinion/pricing-hiv-drugs-america.html. "What does it cost to make each year's supply of that $39,000 therapy? Well, the generic manufacturers Aurobindo and Mylan, which supply the drug in Africa, make a profit when they sell it to the United States' President's Emergency Plan for AIDS Relief and to the Global Fund to Fight AIDS, Tuberculosis and Malaria—two organizations that buy drugs for low-income countries. So, logic says it must cost less than $75." *Id.* Further, a recent Supreme Court decision regarding patent exhaustion may alter the drug pricing calculus of pharmaceuticals abroad. *See* Impression Prods., Inc. v. Lexmark Int'l, Inc., 137 S. Ct. 1523 (2017). In *Lexmark*, the court held that the common law doctrine of patent exhaustion has no territorial limit, and thus the sale of patented items abroad exhausts the patentee's interest in the item such that patent rights cannot be invoked to restrain the purchaser's consumption or transfer of the item. (Patent exhaustion is constrained to the particular item sold. A buyer cannot merely buy one pill and open a pill factory based on the doctrine of patent exhaustion, but a buyer could resale the purchased pill assuming such a resale does not violate any other law.). A potential outcome of the decision is an inability of patentees to sell products for different prices in different territorial limits. In the pharmaceutical context this means the discounting of drugs in certain countries may become untenable depending on the structure of other legal regimes and market forces.

91 *See The Price of Africa's Cheap Drugs*, ECONOMIST (Apr. 19, 2001), https://www.economist.com/unknown/2001/04/19/the-price-of-africas-cheap-drugs.

92 Sharing of clinical data is actually gaining some traction in the United States, despite profit stakes of domestic pharmaceutical companies in not providing such data. Jennifer Miller, Joseph S. Ross, Marc Wilenzick, Michelle M. Mello, *Sharing of Clinical Trial Data and Results Reporting Practices Among*

context of China has been alleged to be at worst a scheme by the government to steal American intellectual property, compulsory licensing is implicitly recognized even in TRIPS (a pro-western Intellectual Property reform) to have some value in opening up developing economies.[93] Furthermore, compulsory licensing has been used to some avail in countries such as Brazil and South Africa to address HIV/AIDS.[94] Like any tool, compulsory licensing has the potential for abuse. However, judicious use for truly exigent circumstances may prove quite fruitful for populations in need.

B. Drug Pricing in the United States

Addressing drug pricing may be somewhat in tension with addressing the concerns abroad with drug access. This solution also does not address the more global problem of counterfeit drugs, because while the United States is affected by counterfeit drugs, developing countries bear far more of the brunt of the problem. However, it must be acknowledged that Americans pay far more in drug prices than their peers abroad.[95] This

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Large Pharmaceutical Companies: Cross Sectional Descriptive Study and Pilot of a Tool to Improve Company Practices, 2019 BMJ 366. "Public expectations for transparency in the conduct and reporting of clinical trials continue to evolve. In the late 1990s, US law required only that clinical trials relating to life threatening conditions be registered. In 2007, the Food and Drug Administration Amendments Act (FDAAA) expanded registration requirements to trials for all conditions and mandated the posting of results for many phase II and phase III trials for FDA approved drugs. A decade later the Department of Health and Human Services' Final Rule expanded trial registration and results reporting requirements to still more types of trials, including those for unapproved drug indications and phase I trials funded by the National Institutes of Health." *Id.*

93 See the discussion of Doha Declaration, *supra* note 64. See also Brazil and South Africa's use of compulsory licensing to address the AIDS crisis, William W. Fisher III & Cyrill P. Rigamonti, *The South Africa AIDS Controversy A Case Study in Patent Law and Policy*, HARV. L. SCH. L. & BUS. PATENTS (2005), https://cyber.harvard.edu/people/tfisher/South%20Africa.pdf. "Fearing a domino effect in the developing world, the U.S. pharmaceutical industry, backed by the U.S. government, vigorously opposed the enactment of Section 15C [compulsory licensing provision], arguing that it was tantamount to a complete abrogation of patent rights and that it violated the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). As a representative of Bristol-Myers Squibb put it, 'Patents are the lifeblood of our industry. Compulsory licensing and parallel imports expropriate our patent rights,' adding that the only beneficiary of the erosion of patents would be the generic drug industry. Nevertheless, the planned modifications, including Section 15C, were signed into law by President Nelson Mandela on December 12, 1997." *Id.* at 5.

94 *See id.*

95 *See* U.S. Dep't of Health & Hum. Servs., Off. of Assistant Sec'y for Planning and Evaluation, *Comparison of U.S. and International Prices for Top Medicare Part B Drugs by Total Expenditures* (Oct. 25, 2018), https://aspe.hhs.gov/system/files/pdf/259996/ComparisonUSInternationalPricesTopSpendingPartBDrugs.pdf. "Overall, prices and reimbursement rates for Part B drugs are significantly higher for U.S. providers than purchasers outside the U.S. Except in a few outlier cases, this conclusion holds for each drug, and regarding each international comparator. Medicare could achieve significant savings if prices in the U.S. were similar to those of other large market-based economies." *Id.* at 10.

pricing scheme likely drives some of the demand for counterfeits stateside, which in turn buttresses markets overseas.[96]

Solutions to this problem may include implementing government cost controls on prescription drugs, or embracing greater subsidies, or government regulation in the healthcare marketplace. Greater clinical trial data transparency in the United States and developed world may also be of use in this space.[97] Of secondary concern, however, is that the American consumers account for sixty-four to seventy-eight percent of total pharmaceutical profits and the United States accounted for fifty-seven percent of the world's new medicines between 2001 and 2010.[98] That said,

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96 "Pharmaceuticals play a more prominent role in American health care than in any other nation. The North American market today comprises 47% of the global prescription drug market, which now exceeds half a trillion dollars, with Americans spending approximately $251.8 billion annually on pharmaceuticals . . . Why is there such unfortunate growth in counterfeit pharmaceuticals . . . the demand of prescription drugs; the cost of prescription drugs." David C. Wyld, *RFID Tagging of Pharmaceuticals*, *in* ENCYCLOPEDIA OF HEALTHCARE INFORMATION SYSTEMS 1199 (Nilmini Wickramasinghe & Eliezer Geisler eds., 2008).

97 Inst. of Med., *Clinical Data as the Basic Staple of Health Learning: Creating and Protecting a Public Good* (2010), https://www.ncbi.nlm.nih.gov/books/NBK54290/. "Because of their potential to enable the development of new knowledge and to guide the development of best practices from the growing sum of individual clinical experiences, clinical data represent the resource most central to healthcare progress (Arrow et al., 2009; Detmer, 2003). Whether captured during product development activities such as clinical research trials and studies, or as a part of the care delivery process, these data are fundamental to the delivery of timely, appropriate care of value to individual patients—and essential to building a system that continually learns from and improves upon care delivered. The opportunities for learning from practice are substantial, from improved understanding of the effects of different treatments and therapies in specific patient subpopulations, to developing and refining practices to streamline or tailor care processes for complex patients, to the development of a delivery system that can advance the evidence base on novel diagnostic and therapeutic techniques (Hrynaszkiewicz and Altman, 2009; Nass et al., 2009; NRC, 2009; Safran, 2007). Furthermore, U.S. per capita healthcare costs are now nearly double that of comparable nations (Health care spending in the United States and OECD countries, 2007), and broader access and use of existing and future clinical data may be a key opportunity to better understand and address system-wide factors—such as waste and inefficiencies—that contribute to rising healthcare expenditures." *Id.*

98 *See* Peter Pitts, *How Other Countries Freeload on U.S. Drug Research*, WALL ST. J. (Feb. 21, 2017, 7:16 PM), https://www.wsj.com/articles/how-other-countries-freeload-on-u-s-drug-research-1487722580; *see also* Dana Goldman & Darius Lakdawalla, *The Global Burden of Medical Innovation*, BROOKINGS (Jan. 30, 2018), https://www.brookings.edu/research/the-global-burden-of-medical-innovation/. "American consumers may feel some philanthropic pride about the benefits they have spurred for the world's poorest HIV patients. But similar benefits are also enjoyed by German, British, and French HIV patients, and were financed by the same revenues generated, in large part, by high American drug prices. Whether one sees this as philanthropy on the part of American drug buyers, or free-riding on the part of other wealthy countries who pay much less for the same drugs, America clearly contributes more to pharmaceutical revenue, and hence incentives for new drug development, than its income and population size would suggest. . . . U.S. consumers spend roughly three times as much on drugs as their European counterparts. Even after accounting for higher U.S. incomes, Americans spend 90 percent more as a share of income. Indeed, North American consumers spend about 3.5 times the price per dose of medicine taken, including generics, compared to their European counterparts, even

the more innovative aspects of pharmaceutical research are disproportionately borne on American healthcare patients. While the fairness of such a regime may be debated, shifting costs away from American consumers without recompense may be detrimental to overall innovation.[99]

Accordingly, a solution in this vein is by no means simple, and likely involves considerations and resolutions of other complicated distinctly American healthcare topics.

C. Trans-Pacific Partnership and Trade Deals

The Trans-Pacific Partnership was a trade deal drafted among a variety of Pacific Rim countries including Australia, the United States, Vietnam, Mexico, Chile, and Japan in order to forge a strategic economic alliance.[100] The trade agreement was originally signed and subsequently withdrawn, following the 2016 election, by the United States.[101] TPP provided in turn a

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though their income is only 60 percent higher. Prior research suggests that a substantial share of this gap is due to greater use of newer and higher-strength medicines in the U.S. The rest is due to lower prices for the identical drug overseas." *Id.*

99 *See id.* A variety of proposals have been made to the effect of reducing pharmaceutical costs for American consumers while preserving the purported innovation that results from their disproportionate expenditures. Generally, arguments have been made that other wealthy countries should step up and pay more for pharmaceuticals. *See* Pitts, *supra* note 98 ("Increasing European prices by 20 percent— just part of the total gap — would result in substantially more drug discovery worldwide, assuming that the marginal impact of additional investments is constant."). Other measures include harmonizing global regulatory standards. This could include standardizing IP protections globally. While these proposals in general terms offer some way forward, little concrete policy has been offered to undergird them. Other sources of innovation include China, whose rapid ascent to the global stage economically has coincided with a rapidly growing biotech sector. *See* Jacky Wong, *China's Drug Market Is Opening Up*, WALL ST. J. (Nov. 11, 2019, 5:30 AM), https://www.wsj.com/articles/chinas-drug-market-is-opening-up-11573468202; *see also* Peter K. Yu, *China's Innovative Turn and Changing Pharmaceutical Landscape* (Tex. A&M U. Sch. of L. Legal Stud. Research Paper, Paper No. 19-32, 2019) ("For more than a decade, China has been the world's leading supplier of active pharmaceutical ingredients. Today, it has become not only the world's second largest pharmaceutical market, behind only the United States, but it also produces about four percent of the world's new pharmaceutical products."). Some dissenters to the correlation between American drug pricing and innovation have argued that certain other countries such as the United Kingdom and Switzerland have innovated at a pace greater than their relative GDP would suggest compared to the United States. *See* Salomeh Keyhani, Steven Wang, Paul Herbert, Daniel Carpenter & Gerard Anderson, *US Pharmaceutical Innovation in an International Context*, 100 AM. J. PUB. HEALTH 1075 (2010).

100 James McBride, Andrew Chatzky & Anshu Siripurapu, *What Is the Trans-Pacific Partnership (TPP)?*, COUNCIL ON FOREIGN RELS. (Feb. 1, 2021, 7:00 AM), https://www.cfr.org/backgrounder/what-trans-pacific-partnership-tpp. For full text of TPP *See TPP Full Text*, OFF. U.S. TRADE REPRESENTATIVE, https://ustr.gov/trade-agreements/free-trade-agreements/trans-pacific-partnership/tpp-full-text (last visited June 23, 2021).

101 *See* Adam Taylor, *A Timeline of Trump's Complicated Relationship with the TPP*, WASH. POST (Apr. 13, 2018, 9:59 AM), https://www.washingtonpost.com/news/worldviews/wp/2018/04/13/a-timeline-of-trumps-complicated-relationship-with-the-tpp/.

range of pharmaceutical intellectual property protection upgrades in much of geographic reach including, notably, data protection for new pharmaceutical products, a stricture stronger than the similarly worded TRIPS provision, the language of which facilitates a key loophole in Chinese patent law protections.[102] Further the deal adopted more American intellectual property artefacts such as a twelve-month prior art disclosure grace period before the patent filing date.[103]

Perhaps in addressing counterfeit drugs through intellectual property channels, TPP is the best solution of all proposed herein. If the outcry by critics of imposing stiff intellectual property protections in developing countries is any indication, their opprobrium of the deal likewise testifies to the strength of the deal's strictures involving intellectual property protections.[104]

Following President Trump's withdrawal from TPP however, the remaining signatories stripped the trade arrangement of many of its key intellectual property amendments.[105] TPP, contrarily, shows that proper negotiations may be able to strengthen intellectual property protections and accordingly provide mechanisms to stem counterfeit drug markets even in places in which such protections may have valid contestations.[106]

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102 See Chow's discussion of China's "new chemical entity" data protection loophole, in Chow, *supra* note 23. *See also* TRIPS Agreement, *supra* note 48; Knowledge Ecology Int'l, *TPP and IP Pharmaceuticals* (2015), https://www.keionline.org/sites/default/files/Obama-TPP-will-raise-drug-prices.pdf.

103 *See id.* This period gives inventors the opportunity share and present research for one year prior to the patent filing date in order to prevent their art from prematurely entering the public domain. This provision reinforces the strength of the "property" right vested to patentees.

104 For strong critiques of the TPP intellectual property provisions, see Susan K. Sell, *TRIPS Was Never Enough: Vertical Forum Shifting, FTAS, ACTA, and TPP*, 18 U. GA. L. J. OF INTELL. PROP. L. 447 (2011). Other criticisms of TPP also include its pro-free trade provisions and its protections (or lack thereof) protections for workers. *See* Charlie Fanning, *How TPP Trades Away Migrant Rights*, AFL-CIO (Oct. 27, 2016), https://aflcio.org/2016/10/27/how-tpp-trades-away-migrant-rights.

105 *See* Shoko Hino, Kevin M. O'Brien & Kensaku Takase, *Reconsidering the Trans-Pacific Partnership and Impact on Intellectual Property*, LEXOLOGY, https://www.bakermckenzie.com/en/insight/publications/2018/04/reconsidering-the-tpp-and-impact-on-ip (last visited June 23, 2021). For the full text of the revised TPP, The Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP), see *CPTPP Text and Associated Documents*, AUSTRALIAN GOV'T DEP'T FOREIGN AFFS. & TRADE, https://www.dfat.gov.au/trade/agreements/in-force/cptpp/official-documents (last visited June 23, 2021).

106 Vietnam, one of the trade deal's signatories, is one of the largest counterfeit markets in the world after China and India. The presence of other Southeast Asian signatories including Malaysia, Singapore, and Brunei may have also served to bolster the United States' interests in the region. On Southeast Asia's role in the counterfeit drug trade, see Jakkrit Kuanpoth, *Combatting Counterfeit Drugs: Case Studies of Cambodia, Vietnam and Thailand*, 2017 J. GENERIC MEDS.

D. Trade War

President Trump's trade war with China poses an interesting dilemma in this analysis. In a way the trade war could be seen as a route to strengthen American interests in China if played properly. One could foresee forcing both the China and the United States to negotiate over trade could lead to strengthening American intellectual property rights in the region, which could in term help curtail some of the counterfeit drug manufacture in China. This objective has been made all but explicit by the United States.[107] However, the trade war has already gained much skepticism, and some believe targeting legitimate trade out of China will just lead to a flourishing of illegitimate counterfeit trade in the region.[108] Further, stressing the wallets of the vast Chinese populace may in turn further amplify demand for counterfeit medications in a country that still retains a fair amount of low- and middle-income earners.[109]

A trade war may not be an effective solution to facing the issues of counterfeit goods in China and India, but indisputably, to address the issue of counterfeit pharmaceuticals, both locales must be dealt with in some form. Through the power of diplomacy, India has shown willingness to barcode and strengthen trademarks in its own markets.[110] China may similarly be prompted by certain diplomatic tacks to do more to curtail the problem within its own borders. Further China has shown tremendous improvement in recent years in strengthening its own intellectual property protections and attempting to root out corruption that may allow counterfeiters to flourish.[111] Overall, solutions in this vein should emphasis the diplomatic even if negotiating partners may, on occasion, need to resort to stiffer trade tactics.

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107 *See China to Raise Penalties on IP Theft in Trade War Compromise*, BLOOMBERG (Nov. 24, 2019, 5:21 PM), https://www.bloomberg.com/news/articles/2019-11-24/china-to-raise-penalties-on-ip-rights-violations.

108 Jennifer Schlesinger & Andrea Day, *Here's How the Trade War Could Lead to a Boom in Counterfeit Goods*, CNBC (Mar. 13, 2019, 2:07 PM), https://www.cnbc.com/2019/03/13/heres-how-the-trade-war-could-lead-to-a-boom-in-counterfeit-goods.html.

109 China's GDP per capita is $8,827 compared with $1,940 in India, $38,428 in neighboring Japan, and $59,532 in the United States. *See World Development Indicators*, WORLD BANK, http://datatopics.worldbank.org/world-development-indicators/ (last visited June 23, 2021).

110 *See supra* note 61.

111 *See supra* note 47.

E. Internet

Given the internet's prominent role in the sale of counterfeit medications, any solution will likely have to address one of the market's biggest middlemen.[112] The online sale of medicine is legal in the United States, Canada, and in Europe.[113] Rather than bemoan the state of laissez-faire internet marketplace, a solution to counterfeiting may be to acknowledge the limitations of the internet marketplace and do more to make it a fruitful destination for the purchase and sale of medicine. [114] Further, improving the quality and standardizing the internet marketplace

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112 *See* Blackstone et al., *supra* note 19. Data suggests in fact that the internet is the counterfeit drug marketplace's biggest middleman. "According to a 2009 report, online pharmacy sales were an estimated $11 billion that year, up from an estimated $4 billion in 2007.23 Early on, counterfeit drugs involved primarily so-called lifestyle drugs, especially sildenafil (Viagra), but the market has expanded to include all types of therapeutic medicines, including insulin, cancer medications, and cardiovascular drugs. Although counterfeit drugs sometimes end up in the pharmaceutical supply chain, the primary source of counterfeit drugs is online pharmacies. The National Association of Boards of Pharmacy found that 97% of the Internet pharmacies it examined were not compliant with either federal or state laws, or with industry standards." *Id.*

113 *See Fake Drugs on the Web*, INT'L INST. RSCH. AGAINST COUNTERFEIT MEDS. (2013), https://www.iracm.com/en/thematic-observatory/fake-drugs-on-the-web/. On relevant US laws: "The online sale of medicines is permitted, but strongly regulated. However, each State is susceptible to establish its own laws in this matter." *Id.* On Canadian laws: "A number of pharmacies in Canada have legitimate Web sites that offer a limited range of products and services, particularly information to consumers. Pharmaceutical practice in Canada is regulated by the provinces, and any authorized pharmacy that offers services on the Internet must comply with the standards of practice in its province. (Source: Federal Ministry of Health, Canada). *In parallel to these legitimate sites, it should be noted that there are a large number of illegal pharmacies flying the Canadian flag*." *Id.* (emphasis added). On European laws: "the legal websites commercialising prescription drugs online must all display a common logo and a link that will redirect the user to the website of the competent authority in each Member State, the latter also being obliged to display a list of persons authorized to sell drugs on the Internet." *Id.*

114 *See id.* "The constraints governing the creation of online pharmacies are currently much less restrictive than those regulating the opening of a physical pharmacy. It is for this reason that the International Pharmaceutical Federation (FIP) requests that the standards applied to online pharmacies be identical to those required for all pharmacies: registration and inspection by a competent national authority; use of quality labels; source of supply of drugs. . . ." *Id.* "Despite the risks involved, the online trade in drugs appears to satisfy an important and inevitable consumer/patient expectation. Some players even believe that the deficit of legal offers on the internet (less than 5% of e-pharmacies) leaves the field open to traffickers and promotes the proliferation of fake drugs on the web. It therefore seems that a measure to consider would be to encourage licensed pharmacists to invest in e-commerce by creating pharmacies on the Web that would be made accessible to the public through a national Web portal. Such is the opinion of the European Council, for example, who in 2007 adopted the resolution on: 'good practices for the distribution of medicines sold by correspondence to protect the security of patients and the quality of the medicines issued.' Its text stated: 'the criticism concerning the sale of drugs by mail mainly relates to the dangers arising from the illegal sale on the internet of drugs that may be counterfeit, but the legal sale of drugs by mail is often forgotten'. And recognizing that the consumer demand was unavoidable, the resolution considered that 'the only way to protect the public against illegal offers is to help it to make the distinction between these offers and the properly identifiable legal offers and to ensure that the web sites of pharmacies give comprehensible, reliable and precise information'." *Id.*

may help assuage some of the aforementioned drug pricing issues in the United States, as making the internet a safer, more viable and legitimate market for the purchase of drugs could allow for greater competition and pricing battles that ultimately lead to falls in drug prices.[115]

115 Consumer Reports notes that drug prices can vary by large margins from pharmacy to pharmacy. "Our secret shoppers called more than 150 pharmacies in six metropolitan regions around the U.S. asking for their retail cash prices for a one-month supply of five commonly prescribed drugs—basically the prices a consumer would pay without insurance. The range in prices they found was stunning. The five-drug 'market basket' cost just $66 at the online pharmacy HealthWarehouse.com but $105 at Costco. The two highest-priced national retailers—CVS and Rite Aid—had prices closer to $900 for the five drugs." *See* Lisa L. Gill, *Shop Around for Lower Drug Prices*, CONSUMER REPS. (Apr. 5, 2018), https://www.consumerreports.org/drug-prices/shop-around-for-better-drug-prices/. In its *Strategies for Improving the Affordability of High-Quality Health Care and Coverage* report, the National Coalition on Healthcare identified "Barriers to transparency and competition in pharmaceuticals" as one of its primary cost drivers. The report notes that such barriers create: "unsustainable launch prices in new biologic and specialty drugs, year-over-year price increases for on-market brand name drugs, and price spikes in certain low-volume generic and brand name drugs." *See also supra* note 19. Data transparency, the internet, and drug/healthcare pricing converge in meaningful respect, especially regarding the transparency of drug prices. Transparency of drug pricing as a means of lowering American healthcare costs has been forwarded a solution to encourage greater competition in the pricing of drugs. American health consumers are often unaware that pharmacies can charge drastically different prices for the same medication. These price disparities are thought in part to lead to lead to significant costs. *See* Joel Ario & Kevin McAvey, *Transparency in Health Care: Where We Stand and What Policy Makers Can Do Now*, HEALTH AFFS. (July 11, 2018), https://www.healthaffairs.org/do/10.1377/hblog20180703.549221/full/. "Transparency is vital to opening up our at-times opaque health system and fostering a more competitive health care Marketplace, so it's welcome news that the Department of Health and Human Services (HHS) secretary Alex Azar has embraced the cause. We are transparency advocates with battle scars to prove it: Joel as insurance commissioner in Pennsylvania and Oregon plus a stint at the Centers for Medicare and Medicaid Services on the exchanges, and Kevin as an expert in the use of data in health care, helping states across the country to develop effective strategies to connect all-payer claims databases (APCDs) to actual data needs." *Id.* APCDs, or All-Payer Claims Databases are systems for monitoring and collecting data relating to medical, pharmacy, and dental claims, and the files collected from public and private payers. *See* All-Payer Claims Databases, Agency for Healthcare Research and Quality, https://www.ahrq.gov/data/apcd/index.html. "APCD data are reported directly by insurers to States, usually as part of a State mandate. In terms of their capacity to produce price, resource use, and quality information for consumers, APCD data have three potential advantages over other datasets:

> - They include information on private insurance that many other datasets do not.
> - They include data from most or all insurance companies operating in any particular State, in contrast to some proprietary datasets.
> - They include information on care for patients across care sites, rather than just hospitalizations and emergency department visits reported as part of discharge data systems maintained by most States through State governments or hospital associations. They also include large sample sizes, geographic representation, and capture of longitudinal information on a wide range of individual patients." *Id.*

F. COVID-19 (SARS-CoV-2 Coronavirus)

On January 30, 2020, the WHO declared a novel coronavirus first detected in Hubei Province in China a "public health emergency of international concern."[116] The 'SARS-CoV-2' coronavirus responsible for the 'COVID-19' disease was officially declared a pandemic on March 11, 2020, and led to an unprecedented global health response in many countries, including mass closures of businesses and public buildings, cancelations of large gatherings, and restrictions on movement.[117]

The pandemic has been a major boon to the counterfeit drug market.[118] Early on, lacking a vaccine to the virus, many opportunistic scam artists took to peddling fake "cures" to COVID-19.[119] Further fake coronavirus

116 *Coronavirus Disease 2019 (COVID-19)*, CDC (2020), https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/summary.html.

117 *Id.*

118 Piranty, *supra* note 1. In many ways the pandemic was the perfect stew for opportunistic counterfeiters. The pandemic itself is a frightening disease without a cure, which creates a void for fake cures even the most low-level counterfeiter could fill. The disease, given its relationship to China, greatly disrupted pharmaceutical supply chains, many of which are run through China. Several pharmaceutical companies reported to the BBC that supply chains were operating at 50-60% of their normal capacity at the start of the pandemic. These disruptions in supply chains, not only create a void for coronavirus fake cures, but create a void for all medications affected. These voids thusly find fillers from the black market.

119 *See id.*; *see also* Marius Schneider & Nora Ho Tu Nam, *Africa and Counterfeit Pharmaceuticals in the Times of COVID-19*, 2020 J. INTELL. PROP. L. & PRAC. 1 ("Africa with the highest prevalence (18.7 per cent) of falsified and substandard medicines (page 31) is particularly at risk from counterfeit medical supplies and fake coronavirus 'cures'. Already, in the first week of April 2020, Cameroon seized fake chloroquine, a much-touted possible remedy to the COVID-19, from at least 300 pharmacies and hospitals."). Hydroxychloroquine, a drug used to treat conditions including malaria, rheumatoid arthritis, and lupus, offers interesting insights into the dynamics of the nature of pandemic counterfeit medicine. The drug was not only peddled by counterfeiters as a cure, but high-profile endorsements of the drug's efficacy treatment of COVID-19 from nonother than the President of the United States, Donald Trump, have boosted demand of the drug to the point that the drug began to face shortages. These shortages in turn create pressures in the legitimate markets for hydroxychloroquine, which may allow opportunistic counterfeiters entry. For example, a Lupus patient unable to get hydroxychloroquine begins looking to black market. *See* Robert Preidt, *Shortages of Hydroxychloroquine for Lupus Patients*, WEBMD (June 2, 2020), https://www.webmd.com/lung/news/20200602/shortages-of-hydroxychloroquine-for-lupus-patients ("One patient finally filled her prescription after three weeks of calling different pharmacies. Yet another said her physician advised halving her regular dose until there was no longer a supply shortage."); *Hydroxychloroquine Sulfate Tablets*, ASHP (Aug. 4, 2021), https://www.ashp.org/drug-shortages/current-shortages/drug-shortage-detail.aspx; Piranty, *supra* note 1 ("The antimalarial chloroquine is normally sold for about $40 for a pot of 1,000 tablets. But pharmacists in the DRC were found to be selling them for up to $250. The medicine being sold was allegedly manufactured in Belgium, by 'Brown and Burk Pharmaceutical limited'. However, Brown and Burk, a pharmaceutical company registered in the UK, said they had 'nothing to do with this medicine. We don't manufacture this drug, it's fake.'").

tests and therapeutics increasingly seeped into legitimate markets.[120] More recently, in light of approval of vaccines effective against the SARS-CoV-2 virus, instances of fake vaccine distribution have also been reported.[121]

The spread of SARS-Cov-2 is also tied to a larger theme of the counterfeit drug trade, namely global multinational, multilateral responses to public health crises. The pandemic has highlighted the difficulty of coordinating massive global (and even domestic) health responses.

The fallout from the spread of the disease is unlikely to be fully understood for quite some time but could ultimately be an impetus for strengthening global responsiveness to global public health crises that could improve overall responsiveness to the counterfeit drug issue.

V. CONCLUSION

The issue of counterfeit drugs is nothing short of a global health crisis. While the problem is multifaceted, its toll is too grave to ignore. While there is no silver bullet for the problem, levers exist to address the issue. By strengthening intellectual property protections, fostering productive trade relationships, and investing in developing economies, the issue can be tackled.

Recent events including the recent U.S.-China trade war and the outbreak of the novel coronavirus, COVID-19, may conspire to force the issue to greater prominence and measures taken in tandem with those geopolitical controversies may coincide, by happenstance, with policy

120 *See Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments*, U.S. FOOD & DRUG ADMIN. (Mar. 1, 2021), https://www.fda.gov/consumers/consumer-updates/beware-fraudulent-coronavirus-tests-vaccines-and-treatments; *Scams and Counterfeit Medicines – People Need to Be Informed*, COUNCIL OF EUR., https://www.coe.int/en/web/portal/covid-19-scams-counterfeit-medicines (last visited June 23, 2021).

121 Fake COVID-19 vaccines are already present on the internet. "Both Interpol and Europol issued warnings of a coming onslaught of underworld activity as criminals seek to exploit global pandemic paranoia. There are already doses for sale on the dark web for between $250 and $750 that Europol says could be fatal if used." Barbie Latza Nadeau, *Fake COVID-19 Vaccines are Already Being Sold Online*, Daily Beast (Dec. 18, 2020, 6:09 PM), https://www.thedailybeast.com/fake-covid-19-vaccines-are-already-being-sold-online. Instances of fake COVID-19 vaccinations are starting to be reported beyond just internet scams. "Police in the UK are searching for a man who allegedly injected a 92-year-old woman with a fake Covid-19 vaccine -- and charged her £160 ($217) for it." Sara Spary, *Police Hunt for Man Who Allegedly Injected Woman, 92, with 'Fake Covid-19 Vaccine'*, CNN (Jan. 8, 2021, 8:19 AM), https://www.cnn.com/2021/01/08/uk/fake-vaccine-appeal-scli-intl-gbr/index.html. Europol and various government agencies have started warning about counterfeits. *Early Warning Notification: Vaccine-Related Crime During the COVID-19 Pandemic*, EUROPOL (Dec. 4, 2020), https://www.europol.europa.eu/early-warning-notification-vaccine-related-crime-during-covid-19-pandemic-0; *Beware of Fraudulent Coronavirus Tests, Vaccines and Treatments*, *supra* note 120.

solutions for the counterfeit drug crisis. The potential upshot of these crises is that they could improve global level responses to other global public health concerns. As the economy becomes increasingly global, digital, and interconnected, the counterfeit drug issue is likely to remain a major global health issue and an indicator of the world's ability to combat foes that are truly global in scale.

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