## Framing

## 1

#### CP: Member nations of the World Trade Organization should enter into a prior and binding consultation with the World Health Organization over reducing intellectual property protections by implementing a one-and-done approach for patent protection. Member nations will support the proposal and adopt the results of consultation.

#### WHO says yes – it supports increasing the availability of generics and limiting TRIPS

Hoen 03 [(Ellen T., researcher at the University Medical Centre at the University of Groningen, The Netherlands who has been listed as one of the 50 most influential people in intellectual property by the journal Managing Intellectual Property, PhD from the University of Groningen) “TRIPS, Pharmaceutical Patents and Access to Essential Medicines: Seattle, Doha and Beyond,” Chicago Journal of International Law, 2003] JL

However, subsequent resolutions of the World Health Assembly have strengthened the WHO’s mandate in the trade arena. In 2001, the World Health Assembly adopted two resolutions in particular that had a bearing on the debate over TRIPS [30]. The resolutions addressed:

– the need to strengthen policies to increase the availability of generic drugs;

– and the need to evaluate the impact of TRIPS on access to drugs, local manufacturing capacity, and the development of new drugs

#### Consultation displays strong leadership, authority, and cohesion among member states which are key to WHO legitimacy

Gostin et al 15 [(Lawrence O., Linda D. & Timothy J. O’Neill Professor of Global Health Law at Georgetown University, Faculty Director of the O’Neill Institute for National & Global Health Law, Director of the World Health Organization Collaborating Center on Public Health Law & Human Rights, JD from Duke University) “The Normative Authority of the World Health Organization,” Georgetown University Law Center, 5/2/2015] JL

Members want the WHO to exert leadership, harmonize disparate activities, and set priorities. Yet they resist intrusions into their sovereignty, and want to exert control. In other words, ‘everyone desires coordination, but no one wants to be coordinated.’ States often ardently defend their geostrategic interests. As the Indonesian virus-sharing episode illustrates, the WHO is pulled between power blocs, with North America and Europe (the primary funders) on one side and emerging economies such as Brazil, China, and India on the other. An inherent tension exists between richer ‘net contributor’ states and poorer ‘net recipient’ states, with the former seeking smaller WHO budgets and the latter larger budgets.

Overall, national politics drive self-interest, with states resisting externally imposed obligations for funding and action. Some political leaders express antipathy to, even distrust of, UN institutions, viewing them as bureaucratic and inefficient. In this political environment, it is unsurprising that members fail to act as shareholders. Ebola placed into stark relief the failure of the international community to increase capacities as required by the IHR. Guinea, Liberia and Sierra Leone had some of the world's weakest health systems, with little capacity to either monitor or respond to the Ebola epidemic.20 This caused enormous suffering in West Africa and placed countries throughout the region e and the world e at risk. Member states should recognize that the health of their citizens depends on strengthening others' capacity. The WHO has a central role in creating systems to facilitate and encourage such cooperation.

The WHO cannot succeed unless members act as shareholders, foregoing a measure of sovereignty for the global common good. It is in all states' interests to have a strong global health leader, safeguarding health security, building health systems, and reducing health inequalities. But that will not happen unless members fund the Organization generously, grant it authority and flexibility, and hold it accountable.

#### WHO is critical to disease prevention – it is the only international institution that can disperse information, standardize global public health, and facilitate public-private cooperation

Murtugudde 20 [(Raghu, professor of atmospheric and oceanic science at the University of Maryland, PhD in mechanical engineering from Columbia University) “Why We Need the World Health Organization Now More Than Ever,” Science, 4/19/2020] JL

WHO continues to play an indispensable role during the current COVID-19 outbreak itself. In November 2018, the US National Academies of Sciences, Engineering and Medicine organised a workshop to explore lessons from past influenza outbreaks and so develop recommendations for pandemic preparedness for 2030. The salient findings serve well to underscore the critical role of WHO for humankind.

The world’s influenza burden has only increased in the last two decades, a period in which there have also been 30 new zoonotic diseases. A warming world with increasing humidity, lost habitats and industrial livestock/poultry farming has many opportunities for pathogens to move from animals and birds to humans. Increasing global connectivity simply catalyses this process, as much as it catalyses economic growth.

WHO coordinates health research, clinical trials, drug safety, vaccine development, surveillance, virus sharing, etc. The importance of WHO’s work on immunisation across the globe, especially with HIV, can hardly be overstated. It has a rich track record of collaborating with private-sector organisations to advance research and development of health solutions and improving their access in the global south.

It discharges its duties while maintaining a dynamic equilibrium between such diverse and powerful forces as national securities, economic interests, human rights and ethics. COVID-19 has highlighted how political calculations can hamper data-sharing and mitigation efforts within and across national borders, and WHO often simply becomes a convenient political scapegoat in such situations.

International Health Regulations, a 2005 agreement between 196 countries to work together for global health security, focuses on detection, assessment and reporting of public health events, and also includes non-pharmaceutical interventions such as travel and trade restrictions. WHO coordinates and helps build capacity to implement IHR.

#### WHO diplomacy solves great power conflict

Murphy 20 [(Chris, U.S. senator from Connecticut serving on the U.S. Senate Foreign Relations Committee) “The Answer is to Empower, Not Attack, the World Health Organization,” War on the Rocks, 4/21/2020] JL

The World Health Organization is critical to stopping disease outbreaks and strengthening public health systems in developing countries, where COVID-19 is starting to appear. Yemen announced its first infection earlier this month, and other countries in Africa, Asia and the Middle East are at severe risk. Millions of refugees rely on the World Health Organization for their health care, and millions of children rely on the WHO and UNICEF to access vaccines.

The World Health Organization is not perfect, but its team of doctors and public health experts have had major successes. Their most impressive claim to fame is the eradication of smallpox – no small feat. More recently, the World Health Organization has led an effort to rid the world of two of the three strains of polio, and they are close to completing the trifecta.

These investments are not just the right thing to do; they benefit the United States. Improving health outcomes abroad provides greater political and economic stability, increasing demand for U.S. exports. And, as we are all learning now, it is in America’s national security interest for countries to effectively detect and respond to potential pandemics before they reach our shores.

As the United States looks to develop a new global system of pandemic prevention, there is absolutely no way to do that job without the World Health Organization. Uniquely, it puts traditional adversaries – like Russia and the United States, India and Pakistan, or Iran and Saudi Arabia – all around the same big table to take on global health challenges. It has relationships with the public health leaders of every nation, decades of experience in tackling viruses and diseases, and the ability to bring countries together to tackle big projects. This ability to bridge divides and work across borders cannot be torn down and recreated – not in today’s environment of major power competition – and so there is simply no way to build an effective international anti-pandemic infrastructure without the World Health Organization at the center.

## 2

#### Cannabis industry will recover, but its tentative.

Patrick Mcgreevy ,6-3-2020, "California's legal pot industry faces year of decline because of coronavirus, Newsom warns," Los Angeles Times, <https://www.latimes.com/california/story/2020-06-03/california-legal-pot-industry-faces-decline-coronavirus-recession-gavin-newsom-budget//> WW AP

SACRAMENTO — California’s legal marijuana industry faces a year of declining sales as a result of the pandemic-induced recession despite an initial spike in consumer demand after dispensaries were deemed essential businesses, according to details outlined in Gov. Gavin Newsom’s proposed budget. Newsom projected in January that the state’s cannabis excise tax would bring in $479 million this year and $590 million in the fiscal year starting July 1, but his revised budget now forecasts just $443 million this year and a decline to $435 million next year. “While similar products like alcohol and tobacco tend to be recession-resistant, the forecast assumes that cannabis businesses will be more negatively impacted by the COVID-19 pandemic,” the budget says. “Cannabis businesses have less access to banking services that could provide liquidity, have a younger consumer base likely to be disproportionately affected by the COVID-19 recession, and still must contend with competition from the black market.” In an attempt to help the state’s legal pot industry weather a downturn, the Newsom administration has relaxed some restrictions on how cannabis firms operate, deferred license renewal fees and extended the deadline for filing first quarter tax returns. Industry leaders say they are bracing for economic turmoil caused by the coronavirus pandemic, which led Newsom more than two months ago to issue an order for California residents to stay at home to stem the disease’s spread. “It’s a pretty dire situation at this point,” said Jerred Kiloh, owner of the Higher Path cannabis store in Sherman Oaks, and president of the United Cannabis Business Assn., which represents many Los Angeles-based retailers. “The illicit market is just going to have another leg up this year,” he added. “When people have less disposable income they are going to look at the lowest cost option.” The darker projections are a setback for a market championed by Newsom, who was the leading proponent of Proposition 64, the 2016 ballot measure that legalized the sale of marijuana for recreational purposes in California. Since the state began licensing growing and selling cannabis in 2018, the legal industry has struggled to overcome impediments that include bans on sales by most California cities, high taxes and competition from a much larger illicit market that can offer lower prices. But when Newsom issued his [stay-at-home order](https://www.latimes.com/california/newsletter/2020-04-23/newsom-shutdown-newsletter-california-essential-california) that forced many businesses to close, he exempted marijuana sellers as “essential.” There was an immediate [run on cannabis products](https://www.latimes.com/california/story/2020-04-18/california-north-states-cannabis-industry-jackpot) as consumers stockpiled pot in anticipation of a possible future shortage amid concern pot shops might also be forced to close. “We initially saw a spike in sales that was attributed to panic buying,” said Josh Drayton, a spokesman for the California Cannabis Industry Assn., who noted that sales have “leveled out.” Drayton said the future is “very unpredictable” but that he has not seen enough data to support the idea of a downturn, and others say they think sales will continue to increase. BDSA, a firm that analyzes industry trends, still thinks California’s market will grow, from $2.9 billion last year to $3.6 billion this year. Illicit sales totaled $8.8 billion in 2019, according to Tom Adams, principal analyst of the financial research and consulting division of BDSA. “But slowly and surely we expect [legal sellers] to chip away at that enormous illicit market, which only has after-tax price as a competitive advantage,” Adams said. California retailers including Kiloh say the governor’s estimate of a decline in cannabis tax revenue is consistent with what they see in the severe, longer term damage the pandemic has inflicted on the state economy. While the number of individual purchases has climbed, the volume of products purchased is going down, Kiloh said. Newsom has estimated that the [state’s unemployment rate](https://www.latimes.com/california/story/2020-05-14/california-unemployment-federal-loans-gavin-newsom-budget-deficit) this year will be 18%, and Kiloh said one of the hardest hit groups is young people, including college students, who represent the largest demographic of cannabis customers. Some 60% of workers ages 16 to 24 have a high risk of unemployment compared with 42% of workers ages 45 to 54, according to a report last month by the Los Angeles nonprofit research group Economic Roundtable. While the state has begun [reopening many parts of the state economy](https://www.latimes.com/california/story/2020-05-26/hair-salons-barber-shops-can-reopen-this-week-newsom-plan), the governor’s budget proposal predicts that the cannabis industry will continue to struggle. That conclusion is based on assumptions “that recognize an economically fragile consumer base, a persistent illicit market and the continuing challenge the industry faces in accessing traditional banking liquidity solutions,” said Nicole Elliott, the governor’s senior advisor on cannabis. The industry has also been hurt by a large drop in visitors from outside the state. “Especially in places like San Francisco, San Diego and Los Angeles, 30% of our business is tourism,” Kiloh said. “When you see a 30% reduction in tourism, that’s big.” The impact of declining sales would be devastating for an industry that already faces unique challenges, Drayton said. “As with all businesses, if we do see a decline in sales we can anticipate layoffs, closures and an increased lack of access to regulated, tested, and taxed cannabis,” he said. Elliott said the state has begun taking steps to help the industry weather tough times. State agencies recently announced that licenses expiring in May and June can receive 60-day deferrals of their license fee payments, which can run into six figures. “The license fee deferrals are intended to provide immediate financial assistance to state cannabis licensees impacted by COVID-19,” said a statement by the state Bureau of Cannabis Control. Kiloh noted that the state action only delays the collection of license fees and that cannabis firms still have to come up with the money eventually, even as they struggle in a recession. State officials said the deferral was offered because the cannabis industry has so far been excluded from federal or banking-dependent assistance for small businesses because cannabis remains a Schedule I controlled substance under federal law. State agencies have also relaxed rules requiring sales in secured buildings so that pot shops can provide curbside pickup of purchases. Other rules that can be temporarily waived for businesses that apply include a requirement for a signature from customers when receiving deliveries, allowing retailers to accept expired drivers licenses after the DMV temporarily shuttered field offices due to the pandemic, and permitting the sale of non-cannabis products that are virus related, including hand sanitizer, that previously could not be sold in pot shops. The state tax agency has also offered payment plans for cannabis businesses struggling to pay sales and use taxes, and extended the deadline by which most operators must file their first-quarter 2020 tax returns. Elliott also said that if cannabis businesses can find an eligible lender, they may access the $50 million in the IBank’s Disaster Relief Loan Guarantee Program and a similar amount from the Small Business Loan Guarantee Program proposed in the governor’s budget for next year. Still, the industry is lobbying Congress to access some of the much larger pool of federal financial assistance being offered to other small businesses hurt by the pandemic. Without federal help, Drayton said, “Our businesses will continue to deal with the same hardships as other small businesses without access to financial relief programs nor the financial tools afforded to other industries.”

#### Patents attract investors to the cannabis industry, allow for expansion and growth.

Chris Roberts, 5-28-2020, "Why Patent Cannabis? For Markets, Mostly.," Forbes, <https://www.forbes.com/sites/chrisroberts/2020/05/28/why-patent-cannabis-for-markets-mostly/?sh=1f424b0a14c3//> WW AP

On May 20, Charlotte’s Web, the Colorado-based CBD giant and arguably one of the biggest names in legal cannabis, [announced that the company](https://www.prnewswire.com/news-releases/charlottes-web-earns-us-patent-for-improved-hemp-variety-301062691.html) was awarded its second federal patent on a cannabis plant. Unlike the company’s 2018 plant patent on a Farm Bill-compliant high-CBD hemp cultivar—which was [the first hemp strain to receive](https://www.leafly.com/news/industry/this-is-the-first-hemp-strain-patented-in-the-us) federal intellectual property protection—[US Patent No. 10,653,085 is a utility patent](http://patft.uspto.gov/netacgi/nph-Parser?Sect1=PTO1&Sect2=HITOFF&d=PALL&p=1&u=%2Fnetahtml%2FPTO%2Fsrchnum.htm&r=1&f=G&l=50&s1=10,653,085.PN.&OS=PN/10,653,085&RS=PN/10,653,085). This means, after satisfying a more rigorous process, including dropping off thousands of seeds at an official United States depository, Charlotte’s Web now claims as its intellectual property both the cultivar of hemp the company calls CW1AS1 as well as “methods” of plant production and cannabinoid extraction. Okay! But so what? Why patent a hemp strain—why patent two? What does it all mean? Does Charlotte’s Web now have legal claim to the entire CBD game?To the last question, no. And as for what this means, for normal people and cannabis consumers, very little. For patent attorneys or competitors of Charlotte’s Web in the CBD industry, it portends a little more, but just a little. At least for now, cannabis patents like this one aren’t really intended to defend intellectual property in court—which is where a patent has its most practical value. No, this patent is probably meant for the market. Patents like this exist mostly for companies to satisfy and woo investors, for whom a company’s ability to say “Look! I have a patent” might be the difference between signing a check, or not. And like all publicly traded cannabis companies, Charlotte’s Web has a lot of spooked and angry investors who need pleasing. Whether Charlotte’s Web would enforce the patent, and how, “remains to be seen,” he added. Company officials were not available to discuss the matter. In a statement provided by Sylvia Tawse, the company’s director of communications, CEO Deanie Elsner said Charlotte’ Web “will continue to pursue patent protection for unique and novel hemp genetics developed by our horticulture division.” Whether that meant there are any pretenders the company plans to sue, she did not say. Though cannabis-related patent applications have been a thing since well before legalization and have tripled since 2015, [as IP Watchdog noted](https://www.ipwatchdog.com/2020/02/07/patenting-cannabis-possibilities-pitfalls/id=118615/), the mere phrase “cannabis patent” can still be triggering in cannabis circles. Patent talk can often lead to galaxy-brain thinking like the “Monsanto is supporting legalization in order to steal cannabis” or the “Philip Morris is buying up land in Humboldt County” conspiracy theories. In the case of Charlotte’s Web, the company’s already locked up what’s probably its most valuable asset: its name. Charlotte’s Web is named for Charlotte Figi, the sufferer of childhood epilepsy who enjoyed relief from her symptoms after taking an extract of high-CBD cannabis grown by the Stanley brothers (and who died earlier this month after contracting COVID-19). The world came to know Charlotte Figi and the Stanley brothers, [seven photogenic Coloradans](https://www.nytimes.com/2019/03/06/style/cbd-charlottes-web-seven-brothers.html) whose first names all begin with J, after they were prominently featured in a 2014 CNN special hosted by Sanjay Gupta. A very famous children’s book and a very famous and recognizable name, the company was sure lock down the name “Charlotte’s Web” with a trademark—[one the company is currently defending in federal court, after a rival company dared market CBD products called Charlotte’s Web.](https://news.bloomberglaw.com/ip-law/charlottes-web-cbd-maker-sues-rival-over-trademarks) That’s what patents are for in terms of the law. But markets are another matter—and it’s worth observing that the company went public after securing its first patent. Like almost all publicly traded companies in the cannabis sector, Charlotte’s Web is stuck in high-loss doldrums after hitting early peaks. For the past week, shares in Charlotte’s Web have been trading in the $7 to $9 range in the Toronto Stock Exchange. That’s a big gain from the $4.24 seen at the company’s mid-March nadir, but still far below last summer’s high-water mark of $28.21, set in August. Despite being sold in more than 11,000 stores, [the company still lost $1.7 million in 2020](https://investors.charlottesweb.com/press-releases/press-release-details/2020/Charlottes-Web-2019-Q4-and-Year-End-Results/default.aspx)—a hit smaller than other companies in the cannabis sector, but still in the red. Patenting hemp genetics and the processes to achieve them won’t be enough to rescue the rest of the company’s lost value. But if Charlotte’s Web wants to be a global CBD brand, with product in supermarkets and convenience stores all over the globe—and why wouldn’t it?—this means something. "Having this patent, that they can wave around and say, 'Hey, we've got coverage on it, and it's the best variety [of CBD rich hemp] that you're going to get,’ ” said Andrew Merickel, who holds a Phd in neuroscience and is also an attorney and partner at the San Francisco office of Knobbe Martens. “That’s pretty valuable.” How valuable? That’s all up to the logic of the market.

#### Medical marijuana has been proven to solve for opioid addiction.

Dwight K. Blake, 8-24-2021, "Can Medical Marijuana be A Solution to The Opioid Epidemic?," American Marijuana, <https://americanmarijuana.org/medical-marijuana-solution-to-opioid-epidemic/WW> AP

Can Cannabis solve the opioid crisis? Short answer, to us, is it CAN be a part of the solution to the crisis. Marijuana is hailed for its high capability to cure plenty of untreatable diseases and illnesses such as cancer. With the opioid epidemic on the rise, is it possible for medical marijuana to also cure this problem? To answer this, let’s dive into the article as we compare the prescribing rate of opioid 1 year before and after medical marijuana is legalized. Marijuana contains many Cannabinoids including CBD or Cannabidiol and THC or Tetrahydrocannabinol. But contrary to the latter, topical CBD, particularly [CBD oil](https://americanmarijuana.org/best-cbd-oil/), manages and reduces pain, inflammation, discomfort, and a variety of other health conditions. As of 2020, medical marijuana is legal in over 20 states in the USA since it was first decriminalized in Nevada in 2001. But in 2017, it was found that [chronic pain was the most common qualification condition](https://www.healthaffairs.org/doi/full/10.1377/hlthaff.2018.05266) among patients who are licensed to use marijuana medically, accounting for almost 62% of nearly 1 million medical cannabis patients (representing an average of 33% to 73% each year from 1999 to 2016). Opioid is a group of chemically similar drugs containing prescription pain relievers and heroin. A good example of these includes hydrocodone (Vicodin®), oxycodone (OxyContin®), and morphine. This is what makes it one of the main contributing factors to the opioid crisis. According to [SAMHSA](https://www.samhsa.gov/data/sites/default/files/cbhsq-reports/NSDUHNationalFindingsReport2018/NSDUHNationalFindingsReport2018.pdf), approximately over in 2018, 10 million people aged 12 or older in 2018 have misused opioids. About 9.4 million of those have misused pain relievers exclusively while the remaining 506,000 have misused pain relievers and heroin use in the previous year. On a similar note, a little over 300,000 people have also misused heroin exclusively out of the 800,000 people who misused heroin in 2017 From 1999 to 2017, it was found that there were about [400,000 people who died from overdoses](https://www.cdc.gov/drugoverdose/data/analysis.html) of any, prescription, and illicit opioids. So how exactly is medical marijuana a potential solution to the opioid crisis? Here’s where things get really interesting… We’ve selected 19 states where medical marijuana is legal then compared the opioid prescribing rate 1 year before and after medical marijuana was legalized in the state. Here is what we found: Out of the 19 states, 15 have shown a fall of opioid prescribing rate 1 year after legalization of medical marijuana, and only 4 have increased in usage, namely: New Jersey, New Mexico, Michigan, and Arizona. Interestingly, the state with the highest fall of opioid prescribing rate among the 19 states was Ohio, from an average opioid prescribing rate of 82.7 down to 63.5, totaling 19.2 decreased prescribing rate after marijuana legalization. The state with the second-highest fall of opioid prescribing rate was Pennsylvania, from an average opioid prescribing rate of 75.5 down to 57.7, a total of 17.8 decreased prescribing rate after marijuana legalization. New Mexico and New Jersey had the least number of increase in opioid prescribing rate of the 4 mentioned states, with only 2.4 and 1.6 increase in usage after marijuana legalization, respectively. In an article published on [Harvard Health Publishing](https://www.health.harvard.edu/blog/access-to-medical-marijuana-reduces-opioid-prescriptions-2018050914509), M.D Peter Grinspoon has shown “access to medical marijuana can reduce opioid consumption”.​ A [study](https://jamanetwork.com/journals/jamainternalmedicine/article-abstract/2677000?redirect=true) conducted by Hefei Wen, Ph.D and Jason M. Hockenberry, Ph.D as of May 2018 showed that from 2011 to 2016, adult-use marijuana laws and medical marijuana laws were associated with lower opioid prescribing rates for Medicaid enrollees: 6.38% and 5.88% lower, respectively, compared with states without medical cannabis laws. In October 2014, Marcus A. Bachhuber, Brendan Saloner, Ph.D, Chinazo O. Cunningham, MD, MS, and Colleen L. Barry, Ph.D, MPP also conducted a study to determine [the association between the presence of state medical cannabis laws and opioid analgesic overdose mortality](https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/1898878). The report concluded: Between 1999 to 2010, states with medical cannabis laws (Alaska, Colorado, Hawaii, Maine, Michigan, Montana, Nevada, New Mexico, Rhode Island, and Vermont) had a 24.8% lower mean annual opioid overdose mortality rate compared with states without medical cannabis laws. Although they still claim “further investigation is required to determine how medical cannabis laws may interact with policies aimed at preventing opioid analgesic overdose.” It has to be noted that fewer annual drug doses were also being prescribed per physician in the U.S from 2010-2013: In the given period, there were 1,826 fewer doses of drugs per year per physician treating pain than in states without medical marijuana laws. Moreover, there were 562 and 541 fewer annual doses of drugs per year per physician to treat anxiety and nausea, respectively. In summary, 78% of the states (where medical marijuana is legal) have shown an average reduction rate of opioid consumption by 5.21. But what about licensed medical professionals such as physicians? What’s their take on this matter? This is where things start to make sense… To back our theory further, we’ve also gathered information from licensed medical cannabis patients and physicians. Surprisingly enough, in 2017, a [survey](https://www.statista.com/statistics/751359/opinions-of-us-patients-that-use-cannabis-and-opioids-for-select-issues/) interviewing 828 California patients revealed 74% of opioids and cannabis patients strongly agreed that the use of cannabis as a substitute with or in conjunction with opioids for select opioid-related issues can decrease opiate dose. They strongly agreed to this that 69% even prefers using cannabis to opiates and 72% would even use this more as substitute if available. 70% of the respondents also said cannabis side effects are more tolerable than opiates and that they handle pain more effectively than opiates. For 1684 surveyed medical cannabis and nonopioid using patients in California, [56% of them agreed that cannabis is more effective than their non opioid pain medication](https://www.statista.com/statistics/751412/opinions-of-us-patients-that-use-cannabis-and-nonopioids-for-select-pain/) while 67%would even prefer using cannabis to non opioid pain medication. Even more surprising, 68% would even use cannabis as a substitute if available. The effectiveness of cannabis vs opioid is so convincing that even physicians are starting to prescribe medical marijuana for their patients before opioids. Even though 23% are not prescribing it, 37% would consider prescribing it to their patients in 2017 while a surprising 40% are not yet sure as they need more research on medical marijuana. The data collected for this study relied on self-report. Some limitations that come with this include but are not limited to the following: selective memory, telescoping, and exaggeration. We can not be certain as to how close these data match up with reality.

#### Opioid overdoses killing half a million people yearly, happening right now in the squo.

WHO, 8-1-2021, "Opioid overdose," No Publication, <https://www.who.int/news-room/fact-sheets/detail/opioid-overdose/> WW AP

The term “opioids” includes compounds that are extracted from the poppy seed as well as semisynthetic and synthetic compounds with similar properties that can interact with opioid receptors in the brain. Opioids have analgesic and sedative effects, and are commonly used for the management of pain. Opioid medicines such as methadone and buprenorphine are used for maintenance treatment of opioid dependence. After intake, opioids can cause euphoria, which is one of the main reasons why they are taken for non-medical reasons. Opioids include heroin, morphine, codeine, fentanyl, methadone, tramadol, and other similar substances. Due to their pharmacological effects, they can cause difficulties with breathing, and opioid overdose can lead to death. Their regular non-medical use, prolonged use, misuse and use without medical supervision can lead to opioid dependence and other health problems. Opioid dependence is a disorder of regulation of opioid use arising from repeated or continuous use of opioids. The characteristic feature of dependence is a strong internal drive to use opioids, which manifests itself by impaired ability to control use, increasing priority given to use over other activities and persistence of use despite harm or negative consequences. Physiological features of dependence may also be present, including increased tolerance to the effects of opioids, withdrawal symptoms following cessation or reduction in use, or repeated use of opioids or pharmacologically similar substances to prevent or alleviate withdrawal symptoms.(1) Worldwide, about 275 million people (or 5.5% of the global population aged 15-64 years) used drugs at least once in 2019. Among them, about 62 million people used opioids. About 36.3 million people suffered from drug use disorders in 2019.(2) Most people dependent on opioids used illicitly cultivated and manufactured heroin, but the proportion of those using prescription opioids is growing. Opioid use can lead to death due to the effects of opioids on the part of the brain which regulates breathing. An opioid overdose can be identified by a combination of three signs and symptoms: pinpoint pupils; unconsciousness; and difficulties with breathing. Worldwide, about 500 000 deaths are attributable to drug use. More than 70% of these deaths are related to opioids, with more than 30% of those deaths caused by overdose. According to WHO estimates, approximately 115 000 people died of opioid overdose in 2017. Opioid overdoses that do not lead to death are several times more common than fatal overdoses. The number of opioid overdoses has increased in recent years in several countries, in part due to the increased use of opioids in the management of chronic pain and increasing use of highly potent opioids appearing on the illicit drug market. In the United States of America (USA) the number of people dying from opioid overdose increased by 120% between 2010 and 2018, and two-thirds of opioid-related overdose deaths in 2018 in the USA involved synthetic opioids, including fentanyl and its analogues.(3) During the COVID-19 pandemic, a further substantial increase in drug overdose deaths was reported in the USA, primarily driven by rapid increases in overdose deaths involving synthetic opioids.(4) Fentanyl is a potent synthetic opioid that is used as a pain reliever and as an anaesthetic. It is approximately 50-100 times more potent than morphine. Fentanyl in various formulations is on the WHO Model List of Essential Medicines. However, fentanyl and its chemically-similar analogues (including carfentanil, acetylfentanyl, butyrfentanyl, and furanyl fentanyl) have been associated with a spike in deaths from opioid overdose. There is evidence that drug dealers may be adding fentanyl to increase the potency of their products (such as heroin) and selling fentanyl as counterfeit tablets, created to look like authentic prescription medications. Therefore, many users who test positive for fentanyl and its analogues do not realize that they took the substance.

## Case

### Vaccine imperialism

#### TRIPs waiver doesn’t solve- it doesn’t obligate countries to do anything, just makes it legal.

Mercurio 21 [Bryan; Professor of Law, The Chinese University of Hong Kong; "The IP Waiver for COVID-19: Bad Policy, Bad Precedent," 2021; 1-6. International Review of Intellectual Property and Competition Law.] Justin

It is not only the length of time which is an issue but also the ultimate impact of the waiver. A waiver simply means that a WTO Member would not be in violation of its WTO obligations if it does not protect and enforce the COVID-19-related IPRs for the duration of the waiver. The waiver would thus allow Members to deviate from their international obligations but not obligate Members to suspend protection and enforcement of the IPRs. Members like the US who support the waiver may not implement the necessary domestic legislation to waive IPRs within the jurisdiction. It is questionable whether the US could even legally implement the waiver given that IPRs are a matter of constitutional law.17

#### The aff doesn’t solve – access to medicine is not a one-way street and there are multiple other factors that they just can’t resolve

Motari 21, Marion Motari, [Jean-Baptiste Nikiema](javascript:;), [Ossy M. J. Kasilo](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Ossy_M__J_-Kasilo), [Stanislav Kniazkov](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Stanislav-Kniazkov), [Andre Loua](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Andre-Loua), [Aissatou Sougou](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Aissatou-Sougou), [Prosper Tumusiime](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#auth-Prosper-Tumusiime) are Adjunct Faculty, Daystar University School of Law, Nairobi, Kenya, “The role of intellectual property rights on access to medicines in the WHO African region: 25 years after the TRIPS agreement”, <https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y>, accessed apark 6/27/21

Although this paper focuses on the role of intellectual property rights on access to medicines, it is recognized that limited access to medicines in countries of the World Health Organization (WHO) African Region[Footnote3](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#Fn3) is a multidimensional problem. It is affected by other factors such as lack of public financing for health care and over-reliance on out of pocket expenditure[[7](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR7)], fragile logistics, storage challenges and high transport and distribution costs [[2](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR2)] and inadequate or inappropriate medicines regulatory frameworks [[8](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR8)]. These factors are further exacerbated by insufficient scientific, technological and local manufacturing capabilities in the Region [[9](https://bmcpublichealth.biomedcentral.com/articles/10.1186/s12889-021-10374-y#ref-CR9)].

#### 2] The first piece of Vanni evidence has no warrants for IP being the cause – rather it’s saying that lack of access to healthcare is what is causing disproportionate minority deaths.

#### A vaccine waiver greenlights counterfeit medicine – independently turns Case.

Conrad 5-18 John Conrad 5-18-2021 "Waiving intellectual property rights is not in the best interests of patients" <https://archive.is/vsNXv#selection-5353.0-5364.0> (president and CEO of the Illinois Biotechnology Innovation Organization in Chicago.)//Elmer

The Biden's administration's support for India and South Africa's proposal before the World Trade Organization to temporarily waive anti-COVID vaccine patents to boost its supply will fuel the **development of counterfeit vaccines and weaken the already strained global supply chain**. The proposal will not increase the effective number of COVID-19 vaccines in India and other countries. The manufacturing standards to produce COVID-19 vaccines are **exceptionally complicated**; it is unlike any other manufacturing process. To ensure patient safety and efficacy, only manufacturers with the **proper facilities and training should produce the vaccine, and they are**. Allowing a temporary waiver that permits compulsory licensing to allow a manufacturer to export counterfeit vaccines will **cause confusion and endanger public health**. For example, between 60,000 and 80,000 children in Niger with fatal falciparum malaria were treated with a counterfeit vaccine containing incorrect active pharmaceutical ingredients, resulting in more than **100 fatal infections.** Beyond the patients impacted, counterfeit drugs erode public confidence in health care systems and the pharmaceutical industry. Vaccine hesitancy is a rampant threat that feeds off of the distribution of misinformation. Allowing the production of vaccines from improper manufacturing facilities further opens the door for antivaccine hacks to stoke the fear fueling **vaccine hesitance**.

#### Vote neg on presumption, the squo solves all of their impacts – it provides less developed countries with access to patent protected drugs

Enrico Bonadio 15 [11-24-2015, "World's poorest countries allowed to keep copying patent-protected drugs," Conversation, <https://theconversation.com/worlds-poorest-countries-allowed-to-keep-copying-patent-protected-drugs-50799>] // WW DL

The World Trade Organisation has agreed to extend a waiver that allows poor countries to copy patented medicines. The waiver, which was due to expire in January 2016, has now been extended to 2033. The countries that will benefit from the waiver are the 48 poorest nations, classified by the United Nations as “Least Developed Countries” or LDCs, and include many African and some Asian countries. About half of the 900m population across these countries live on less than US$1.25 a day. All other countries, including developing countries such as India and China, are still bound by the WTO’s agreement on trade-related intellectual property rights (or TRIPS) with respect to drug patents. Higher disease burden The waiver is critical for the least developed countries. Compared with richer countries, they have a much higher disease burden, especially infectious diseases such as HIV and malaria. In 2011, about 9.7m people in these countries were living with HIV. We believe good journalism is good for democracy and necessary for it. Keeping antiretrovirals affordable. jonrawlinson/flickr Many of the drugs that treat these diseases are still under patent protection. Drug patents last for 20 years and allow drugs companies time to recoup their investment into research and development and turn a profit. Once the patent protection period ends, other drugs companies can then copy the drug and sell it as a generic medicine. These generics are much cheaper than branded drugs. Developing a local pharma industry Countries such as Uganda, Cambodia and Rwanda have already taken advantage of the WTO’s temporary waiver and begun to develop their own pharmaceutical industry. This has been helped by investments from drug companies in the developing world. For example, Uganda-based Cipla Quality Chemicals was originally a joint-venture between Cipla, a large Indian generics manufacturer, and the Ugandan government. It is the only company in Africa that makes triple-combination antiretroviral drugs. Developing and strengthening manufacturing capacities in LDCs is important as these countries are often unable to import cheap copies of patent protected drugs from countries like India. India has many large generics firms within its borders and, although it ratified TRIPS in 1995, it only brought its patent laws in line with the treaty in 2005. It too now has to respect international drug patents. So the extension of the waiver is important, but it is only temporary, which doesn’t please everybody. Least developed countries and some NGOs would have preferred an indefinite extension or at least an extension until a country is no longer classified as a least developed country, rather than the set date of 2033. This position is supported by the European Union, but not by the US. Patents don’t work for poor countries It costs pharmaceuticals companies about US$2.6 billioin to develop a new drug. If these companies were not allowed to protect their investment with patents, it is doubtful that any new drugs would be developed. So patents are an important incentive. But patent protection doesn’t work for poor countries. Intellectual property (IP) rights, like patents, aren’t an effective incentive in countries which have not reached an adequate level of economic development because they have no intellectual property to protect. IP rights might be effective over the long term, but only after a local and relatively strong pharmaceutical industry is developed. The exemption could be dropped once countries that have benefited from it have developed enough, and the industry reaches a self-sustaining size. Although building a home grown pharmaceuticals industry is not a requirement of the WTO waiver, a strong local industry would give poor countries direct access to much needed cheap medicines. The WTO’s transitional waiver makes sense. By temporarily allowing LDCs to ignore patents on drugs, it gives them time to develop their own pharmaceuticals industries. And we are already seeing evidence of this happening. According to the UN agencies, UNDP and UNAids, the proportion of people with HIV who are not receiving antiretrovirals reduced from 90% in 2006 to 63% in 2013 thanks to the availability of drugs made by LDCs. Despite some criticisms, the WTO’s decision to extend the waiver should be praised. It seems fair and reasonable, and it doesn’t excessively jeopardise companies that make branded (non-generic) drugs. They don’t seem to lose much from missed royalties. Overall, the poorest countries account for less than 2% of the world’s gross domestic product and about 1% of global trade in goods. Not a big business opportunity for big pharma.

#### **Current COVID-19 patent waivers will solve the pandemics advantage**

Pti 21 [6-10-2021, "India, South Africa’s patent waiver proposal in WTO achieved tremendous mileage, progression: Commerce Secretary," Hindu, https://www.thehindu.com/news/national/india-south-africas-patent-waiver-proposal-in-wto-achieved-tremendous-mileage-progression-commerce-secretary/article34778668.ece]

The proposal of India and South Africa on providing temporary patent waiver at the World Trade Organisation (WTO) to deal with the COVID-19 pandemic has achieved tremendous mileage and progression as the WTO member countries have agreed to commence text-based negotiations on it, a top government official said on June 10. The Trade-Related Aspects of Intellectual Property Rights (TRIPS) Council of the World Trade Organization (WTO) on June 9 agreed with consensus to start text-based negotiations on a proposal submitted by India and South Africa seeking patent waivers to deal with the COVID-19 crisis. Commerce Secretary Anup Wadhawan said that the text-based negotiations is the way forward and it means that the members have broadly and in-principle accepted the objective behind the waiver proposal. “India and South Africa’s proposal has achieved tremendous mileage and tremendous progression at a very fast pace,” he told reporters. “There is a deadline that by July-end, the members are expected to come to an agreed text. So it is a very positive development,” he added. How the objective will be given effect and to what extent and for how much duration, all that would happen though text-based negotiations, the Secretary noted. In October 2020, India and South Africa had submitted the first proposal suggesting a waiver for all WTO members on the implementation of certain provisions of the TRIPS Agreement in relation to the prevention, containment or treatment of COVID-19. In May this year, a revised proposal was submitted by 62 co-sponsors, including India, South Africa, and Indonesia. The agreement on TRIPS came into effect in January 1995. It is a multilateral agreement on intellectual property (IP) rights such as copyright, industrial designs, patents and protection of undisclosed information or trade secrets. According to the revised proposal of 62 co-sponsors, the waiver should be in force for at least three years from the date of the decision on the matter. The co-sponsors have stated that the duration has to be practical for manufacturing to be feasible and viable. The revised text has also proposed waiver for health products and technologies as the prevention, treatment or containment of COVID-19 which involves a range of things and “intellectual property issues may arise with respect to the products and technologies, their materials or components, as well as their methods and means of manufacture.”

**Evergreening is a myth – this card ends the debate.**

**Lietzan 20** [Erika; Professor of Law, University of Missouri School of Law, Research interests in Pharmaceutical Regulation, Device Regulation, Intellectual Property; “***The Evergreening Myth Claims that drug innovators extend their patents obscure a radical policy‐​making goal.***,” Cato Institute; Fall 2020; <https://www.cato.org/regulation/fall-2020/evergreening-myth>/] Justin

In recent years, U.S. policymakers have considered proposals intended to prevent — or at least reduce — “evergreening” by pharmaceutical companies. Some proposals would change the antitrust enforcement landscape, others the intellectual property landscape, and still others the regulatory framework that governs new medicines. Some proposals — such as those creating new causes of action under the antitrust laws or limiting the availability of patents for discoveries — are profound and their proponents cite a body of academic and policy literature that decries supposed “evergreening” by companies to justify their ideas.

The term “evergreening” is a metaphor, meant to remind audiences of evergreen trees, which have green foliage year‐​round. It implies that something has been extended, and users of the metaphor view this extension as improper or undesirable. When offering descriptions and examples of evergreening, they focus on drug companies continuing to innovate after first introducing a new molecule, and on the broader marketplace for medicines after subsequent innovations have been introduced to the market. But proponents are ***frustratingly inconsistent and unclear*** about ***what, exactly, has been “extended”*** in these situations. A close look at the regulatory landscape in which continuing pharmaceutical innovation occurs shows that arguments for reform are grounded in ***myths***, such as the myth that pharmaceutical companies continuing to innovate somehow “***extend” their patents.***

Once the myths of “evergreening” are laid bare, it becomes apparent that proponents of these proposals really want for the government to limit medical innovators to one medical product in the marketplace for each useful new molecule discovered. They are arguing that an innovator should not enjoy an exclusive market — and the resulting advantageous pricing — for innovations that, though discrete and independently satisfying the standard for a patent under U.S. law, stem in some fashion from an earlier innovation for which that innovator separately enjoyed exclusivity and the resulting pricing advantages. Or, at least, that drug innovators should not. This is a radical proposal that merits careful reflection and discussion, and it is not ripe for action. Understanding that this is the true policymaking objective requires unpacking the regulatory landscape and market more carefully, and paying closer attention to word choice, than proponents of reform often do. The Evergreening Allegation In the United States, every new medicinal product requires premarket approval from the Food and Drug Administration. The drug statute refers to approval of a “new drug,” and ambiguity in the term “drug” provides fertile ground for confusion and rhetorical mischief, as discussed later in this article. A firm that wants to market a new drug must prove to the FDA that the drug is safe and effective. Generating this information takes years, beginning with work in the laboratory and on animals, and progressing through several rounds of “clinical” testing in humans. For new molecules, the clinical portion of this research and development program averages six years. The process is also expensive: the Tufts Center for the Study of Drug Development now estimates the average cost of developing a new molecular entity at $2.6 billion. That figure includes average out‐​of‐​pocket costs of $1.4 billion and reflects the cost of unsuccessful projects. Most research and development programs fail. When new drugs are first launched by innovators, they tend to be sold under brand names and protected by patents as well as statutory rights in the data that supported FDA approval (known as “data exclusivity”). Although the pricing of these products may reflect competitive pressure from other branded products, it also reflects the fact that patent rights and statutory data exclusivity delay the launch of cheaper copies. But no more than five years later, and often earlier, the innovator’s competitors may file applications seeking approval of their own products based on the innovator’s research, rather than performing their own. They file what are known as “abbreviated applications” — abbreviated because they omit some, or all, of the research needed to prove safety and effectiveness. Abbreviated applications are much less expensive and time‐​consuming to assemble, and the competitors’ drugs correspondingly much less expensive than the original drugs they copy. When a competitor seeks to market an exact copy through an abbreviated application, we call its drug a “generic” drug. Pharmacists usually dispense generic copies even when doctors prescribe the corresponding branded products by name. Some people use the “evergreening” label when an innovator holds more than one patent protecting its product, especially if some patents expire later than others. More often, though, these people use the label when an innovator introduces a ***newer version of its own product*** that is already on the market. These newer products tend to be ***sold under brand names*** and ***protected by their own patents*** and statutory data exclusivity. Sometimes the innovator also stops selling its older product. If purchasers shift to the innovator’s newer product rather than purchasing cheap copies of the innovator’s older product, some say the innovator has engaged in evergreening. Although the term “evergreening” is a metaphor and signifies an extension of something, proponents of reform proposals do not agree on the particulars of the term’s use. Some say the company has evergreened its invention, its drug, or its product. Others say the company has evergreened the drug’s patent or patent life, or its exclusivity. Some say it has extended the drug’s patents, or the drug’s patent coverage or patent life, or the drug’s exclusivity period. Some say the company has evergreened the drug’s price, or its own profits or monopoly, or the company has extended its market power. Many argue that through evergreening — whatever the term means — the innovator has improperly blocked other firms from competing with it. On this basis, they seek government intervention. For instance, one recent proposal would allow the Federal Trade Commission to bring antitrust actions against innovators who introduced newer products to replace their older products. Three Myths of Evergreening The circumstances that trigger the “evergreening” label occur at the intersection of several complex bodies of law: the federal framework requiring premarket approval of new medicines and their copies, federal intellectual property laws, federal and state laws governing promotion of medicines, and federal laws and practices and state laws relating to prescribing and dispensing medicines. Many who propose aggressive government intervention because of evergreening give short shrift to this landscape, which allows the perpetuation of three myths that distort policymaking discussions. Before reviewing the myths, it will help to understand two points about the framework in which innovators compete with the companies that submit abbreviated applications. First, the FDA approves products, not active ingredients. And second, patents protect inventions, not products. Federal law states that every “new drug” requires an ***approved application***. But at the FDA the term “drug” has more than one meaning. It includes a medicine’s active ingredient, to be sure. But it also includes drug products. A drug product is a medicine in its finished form, meaning the form that will be sold in the market and administered to patients. And the FDA approves a particular product described in a particular application — the specific combination of active and inactive ingredients (often called a drug’s “formulation”), in a particular dosage form (such as capsule or tablet), for a particular route of administration (such as oral or topical), at a particular strength, for particular medical uses (also known as the product’s “indications”), manufactured as described in the application, and accompanied by labeling written for prescribers based on the data in the application. Federal law allows a patent to issue for any new, ***useful, non‐​obvious invention***, including a ***process***, a ***composition*** of ***matter***, and an ***improvement*** to an ***existing*** ***process*** or ***composition*** of matter. The patent usually expires 20 years after its application date. For any particular drug product approved by the FDA, the innovator might own patents on various types of inventions. The innovator usually owns a patent claiming the product’s active ingredient, and because the innovator generally files this patent before starting clinical trials, it is usually the first to expire. Other inventions protected by patent might include the product’s formulation or a dosage form and dosage of the active ingredient (or formulation). These inventions may emerge later in the premarket development process. If the resulting patent applications refer to the active ingredient patent, the patents will expire when the active ingredient patent expires, but otherwise they will expire later. The innovator may also own other patents claiming inventions embodied in the product, such as a patent claiming methods of using or administering the product, a patent claiming the manufacturing process, or a patent claiming a metabolite of the active ingredient. These, too, could expire later than the first patent — sometimes much later. These two points work together. A single active ingredient associated with a single brand name might be the subject of a half dozen, dozen, or more discrete products. Suppose an active ingredient was formulated into tablets and the innovator sold six strengths. Suppose the innovator also formulated an injectable version, which it sold in two strengths. Suppose it also developed a disintegrating tablet for oral administration, which it sold in four strengths. This innovator would sell 12 discrete products with the same active ingredient and probably (though not necessarily) the same brand name. And because a single product might incorporate many discrete inventions, the patents relevant to one product might differ from the patents relevant to another. Failure to realize this — and its regulatory significance — leads to three myths, as follows.

Myth of evergreening patents / The first **myth** is that innovators ***extend their patents***. This is ***legally impossible***. In the United States, a patent expires 20 years after its application date.

There are only two ways a patent’s expiration date can shift later in time: (1) When it issues a patent, the U.S. Patent and Trademark Office (PTO) adjusts the expiry date later to compensate for routine delays at the PTO. And (2), if the marketing application proposed a new active ingredient, then if the company asks the PTO for a ***patent term extension*** within 60 days of FDA approval, the PTO will use a statutory formula to extend one patent claiming the product to compensate partially for the lapse of patent life during premarket testing and regulatory review. There is no other mechanism by which a patent might be extended. In particular, a patent on one invention — no matter when it expires — does ***not extend the patent on another invention.***

Myth of ***blocked competitors*** / The second myth is that when an innovator holds patents that expire after its active ingredient patent, or when it introduces newer products to market, it can prevent its competitors from bringing their copies to market. Instead, once the initial patent and (if applicable) statutory exclusivity on the innovator’s active ingredient have expired, its ***competitors have substantial freedom to operate***. This freedom reflects two facts that are often overlooked.

First, the innovator’s competitor does not have to ***propose an exact copy***. Federal law permits the competitor to rely on the ***innovator’s research but propose competing products*** that are not identical. To be sure, a competitor may submit an ANDA for a product that essentially duplicates the innovator’s product — that is, a generic. Ordinarily, the company shows in the ANDA that its product has the same active ingredient, route of administration, dosage form, strength, and labeling as the innovator’s product. The generic must also be “bioequivalent” to the original drug that it references, meaning that its active ingredient must reach the site of action in the body to the same extent and at the same rate as the active ingredient of the referenced product. But even a generic can be a little different. For example, it usually does not need the same inactive ingredients in the same quantities. And the generic competitor need not use the same manufacturing process.

If a competitor wants to offer a different ***route of administration, dosage form, or strength*** — for instance, to avoid infringing a patent — it may still be able to use the ***generic drug approval pathway***. It simply files a “suitability petition” asking the FDA’s permission. The agency will approve the petition unless more data are needed to establish the proposed product’s safety and effectiveness. And at this point, the competitor may file an ANDA. More significantly, though, a competitor can always use a different abbreviated application pathway: a “505(b)(2)” application for a product that differs more substantially from the innovator’s product. Although the changes proposed in this hybrid application must be supported by new data, the competitor otherwise relies on the innovator’s data, avoiding the expensive and time‐​consuming research and development process the innovator went through. In addition to using this mechanism to propose modifications that avoid a patent, a competitor might use the mechanism to propose innovations that will offer an advantage in the market — such as changes to the active ingredient and new medical uses.

Second, an abbreviated application cites a ***specific innovative product***, not the active ingredient or brand writ large. The competitor selects one innovative product as the reference product on which it relies — for instance, one of the 12 products in the hypothetical above. Its regulatory burden is tied to that ***specific*** ***product alone***. The requirement to show sameness and bioequivalence (for an ANDA) and, critically, the obligation to contend with patents and wait for statutory exclusivity to expire are linked to the one specific product, alone. (In rare circumstances, when filing a hybrid application, a competitor might cite two innovative products, but the same point applies.)

To be sure, the patents associated with the cited innovative product affect when the FDA may approve the abbreviated application. Whether it files an ANDA or a hybrid application, a competitor must address the unexpired patents listed in the FDA’s “Orange Book” for the specific innovative product it has chosen to cite. For each listed patent, it has two choices, and its selection dictates the timing of FDA approval as far as that patent is concerned. The competitor may state the date on which the patent will expire, signaling that it does not plan to market its product until expiry. This precludes final approval of its product until patent expiry. Or it may assert that the patent is invalid or will not be infringed by its product, notifying the innovator of this position. If the innovator sues within 45 days, the drug statute stays final approval of its abbreviated application for 30 months. Under changes to the law made in 2003, though, unless the competitor changes its position on a patent after filing its abbreviated application, approval of its application is stayed only once. At the end of the 30 months, the FDA must approve the abbreviated application if the approval standard is met, even if there is ongoing patent litigation.

Although a competitor using the abbreviated application pathway must contend with the innovator’s patents and approval of its product may be delayed because of those patents, this is true of ***only the patents associated with the specific product that it references***. The competitor does not have to contend with ***patents associated with other products that happen to contain the same active ingredient*** or bear the same brand name. Similarly, the competing applicant grapples with only the statutory exclusivity associated with the product it references. The drug statute provides five years of exclusivity in the data supporting new chemical entities and three years of exclusivity for most new products that are not new chemical entities. Separately, if an innovator introduces what the FDA calls a new “condition of approval” — such as a new strength or dosage form — the drug statute may provide three years of exclusivity. This delays approval of abbreviated applications proposing products with the same active ingredient for the same condition of approval. But a competitor that proposed a different strength or dosage form — or that cited a product with a different strength or dosage form (such as the innovator’s original product) — would not need to grapple with that exclusivity.

This ***debunks the myth that an innovator with later‐​expiring patents and an innovator that introduces newer products*** can ***prevent*** its competitors from bringing copies to market. Instead, competitors have several options. For instance, empirical studies show that competitors file abbreviated applications as early as the law permits them to do so, arguing that the innovator’s patents are invalid or, if applicable, not infringed by the new drug. They tend to lose these arguments when the active ingredient patent is at issue, but they tend to win if a formulation patent is at issue. If a competitor believed it would infringe a patent or feared it would lose the patent infringement suit brought by the innovator, it could ***seek a license***. Settlements of patent litigation between innovators and competitors seeking to market generic copies usually include a license allowing the competitor to bring its product to market earlier than the date of patent expiry. There are also ***other options.***

Once the patent on the active ingredient expires, a competitor can use the ingredient in its own product and file an abbreviated application, relying on the research performed and submitted by the innovator. Even in an ANDA, a true generic application, only the active ingredient must be the same. A ***competitor may be able to design around patents claiming other aspects of the innovator’s product*** (such as its strength and route of administration) and still file a true generic application. The competitor would simply file a suitability petition and, upon approval of that petition, a generic application proposing the difference that allowed it to avoid patent infringement. Then it would assert non‐​infringement in its application. If it could not file a generic application (for instance, because the FDA requested data to support the changes made), it could always file a hybrid application. It would still rely on the innovator’s research and it would similarly assert non‐​infringement in its application. In either case, the innovator might not sue if the competitor clearly avoided its patents.

It is thus misleading for advocates of intervention to complain about the number of “patents” associated with a “drug.” A competitor filing an abbreviated application does not copy a “drug” in the broad sense of the term. Accurately describing a company’s freedom to operate in the market would require focusing on discrete products that can serve as references for abbreviated applications and on the number, scope, and breadth of the patent claims held by the innovator for those products. This would tell policymakers more about the market effects of a firm’s innovation and patenting practices than the number of patents associated with a particular brand name or the number of patents associated with the many finished products containing a particular active ingredient.