## 1NC v TEJDrills Jordan Aff

## Offs

### 1

#### 1] Interp – the Affirmative must defend that all members of the World Trade Organization ought to reduce Intellectual Property for Medicines.

#### Actions regarding IP protections by member nations of the WTO must go through TRIPS.

Microsoft Academic No Date “Trips Agreement” <https://academic.microsoft.com/topic/2780454388/publication/search?q=TRIPS%20Agreement&qe=And(Composite(F.FId%253D2780454388)%252CTy%253D%270%27)&f=&orderBy=0> //Elmer

The Agreement on Trade-Related Aspects of Intellectual Property Rights (**TRIPS**) **is** an international **legal agreement** **between** all the **member nations of the** World Trade Organization (**WTO**). It **establishes** minimum **standards for** the **regulation** by national governments of different forms **of** intellectual property (**IP**) **as applied to** nationals of other **WTO member nations**. TRIPS was negotiated at the end of the Uruguay Round of the General Agreement on Tariffs and Trade (GATT) between 1989 and 1990 and is administered by the WTO.

#### TRIPS applies to all member states.

WTO No Date "Frequently asked questions about TRIPS [ trade-related aspects of intellectual property rights ] in the WTO" <https://www.wto.org/english/tratop_e/trips_e/tripfq_e.htm#Who'sSigned> //Elmer

Does the TRIPS Agreement apply to all WTO members? **All** the **WTO agreements** (except for a couple of “plurilateral” agreements) **apply to all WTO members**. The members each accepted all the agreements as a single package with a single signature — making it, in the jargon, a “single undertaking”. The **TRIPS** Agreement **is part of that package**. Therefore it **applies to all WTO members**. (More on the single undertaking.)

#### 2] Violation – they don’t, they specify [x country].

#### 3] Standards –

#### a] Limits – there are 164 countries in the WTO and the Aff’s model justifies single country Affs or permutation of country Affs literally unlimiting the Topic – this eviscerates a predictable stasis and shifts away from the core topic controversy of global medical access vs innovation.

CCA 21 "World Trade Organization" <https://advocacy.calchamber.com/international/trade/world-trade-organization/> (The California Chamber of Commerce is the largest broad-based business advocate to government in California, working at the state and federal levels for policies to strengthen California.)//Elmer

**The WTO and its 164 member nations** is the only global international organization dealing with the rules of trade between nations. At its heart are the WTO agreements, negotiated and signed by the bulk of the world’s trading nations and ratified or approved in their parliaments or legislatures. The goal is to help producers of goods and services, exporters and importers conduct their business.

#### b] Ground – Specifying Countries obliterates generics like Innovation that only apply to universal actions since their Link is scope-based – no generics spill-down to countries since the 1AR will say “other countries fill-in” which requires neg research on every possible Aff.

#### 4] TVA – Affirm all member nations reduce Data Exclusivity IP Protections for Medicines.

### 2

#### 1] Interpretation – Affs must defend a reduction in intellectual property protections that protect the medicines.

#### Medicines are physical substances

American Heritage Dictionary of Medicine 18 The American Heritage Dictionary of Medicine 2018 by Houghton Mifflin Harcourt Publishing Company <https://www.yourdictionary.com/medicine> //Elmer

"A **substance**, **especially a drug**, **used to treat** the signs and symptoms of a **disease**, condition, or injury."

#### 2] Violation - Data exclusivity protects clinical trial data, NOT MEDICINE. The plan doesn’t affect the actual production of Medical Substances, just the structural factors that influence it.

Thrasher 5-25 Rachel Thrasher 5-25-2021 "Chart of the Week: How Data Exclusivity Laws Impact Drug Prices" <https://www.bu.edu/gdp/2021/05/25/chart-of-the-week-how-data-exclusivity-laws-impact-drug-prices/> //sid

Data exclusivity is a form of intellectual property protection that **applies specifically to data from** pharmaceutical **clinical trials**. While innovator firms run their own clinical trials to gain marketing approval, generic manufacturers typically rely on the innovator’s clinical trials for the same approval. Data exclusivity rules keep generic firms from relying on that data for 5 to 12 years, depending on the specific law. Data exclusivity operates independently of patent protection and can block generic manufacturers from gaining marketing approval even if the patent has expired or the original pharmaceutical product does not qualify for patent protection. Although data exclusivity laws are matters of domestic legislation, the United States, the EU and others increasingly demand in their free trade agreement (FTA) negotiations that their trading partners protect clinical trial data in this way. Data exclusivity is just one of a host of “TRIPS-plus” treaty provisions designed to raise the overall level of intellectual property protection for innovator firms. Although the WTO’s Agreement on Trade-Related Intellectual Property Rights (TRIPS) does require Member states to protect clinical trial and other data from “unfair commercial use,” it does not require exclusivity rules that block the registration of generic products.

#### The 1AR will read a ton of cards saying Data Exclusivity is an IP Protection, THAT’S NOT SUFFICIENT since our argument is it has to protect the SUBSTANCE. The Aff is both Effects and Extra-T because they effect things unrelated to Medical IP – both of which are voters for Limits and Ground.

#### 3] The Standard is Limits – allowing Affs that relate to the factors and structures surrounding Medicines allows treatments, drug discovery techniques, computer programs, and production techniques that all have IP protections to be topical which eviscerate a stable locus of predictability.

#### 4] Paradigm Issues –

#### a] Topicality is Drop the Debater – it’s a fundamental baseline for debate-ability.

#### b] Use Competing Interps – 1] Topicality is a yes/no question, you can’t be reasonably topical and

#### c] No RVI’s - 1] Forces the 1NC to go all-in on Theory which kills substance education, 2] Encourages Baiting since the 1AC will purposely be abusive, and 3] Illogical – you shouldn’t win for not being abusive.

### 3

#### JFDA’s application of data exclusivity has encourages investment.

Obaidat 16 (, H., 2016. Hayel Obaidat Obaidat, JORDAN FOOD AND DRUG ADMINISTRATION — High-Level Panel on Access to Medicines. [online] High-Level Panel on Access to Medicines. Available at: <http://www.unsgaccessmeds.org/inbox/2016/2/28/dr-hayel-obaidat-obaidat> [Accessed 27 September 2021].)-rahulpenu

HAYEL OBAIDAT OBAIDAT, JORDAN FOOD AND DRUG ADMINISTRATION

ABSTRACT

The contribution is regarding Jordan Data Exclusivity in Pharmaceuticals Sector and their implementations at Jordan FDA, since joining World Trade Organization (WTO) in 2000, the adoption of the Unfair Competition and Trade Secrets Law, and signing a free trade agreement with the United States in 2001, **Jordan** has **strengthened** the **intellectual** **property** **protection** provides for pharmaceutical products.

JFDA is keen to bring new medications to the patients as quickly as possible to allow the worldwide therapeutic opportunities available in Jordan , so **by** **applying** the protection ( **data** **exclusivity**) this will **encourage** the international companies to **invest** **in** the **pharmaceutical** **sector** and the arrival of newer medicines, Nevertheless, JFDA has been implementing a standing operating policy and measures to accept receiving applications of generic version of an innovator during the last year protection in order to accelerate the registration of generic drugs and its affordability, also has included restricting market exclusivity to a narrow definition of “new” uses and limiting applications for data exclusivity to a short period 18 months following first market approval in worldwide..

This contribution contains some suggestion and recommendation taking in consideration human right in access to medicine

#### Especially from the US---empirics prove overwhelming investment attraction because of JUSFTA.

Chin et al. 08 (, J., Nasa’a, M., Leonard, S., Munoz, C. and Reilly, B., 2008. The Jordan-U.S. Free Trade Agreement: Eight Years Later. [online] Websites.umich.edu. Available at: <http://websites.umich.edu/~ipolicy/Policy%20Papers/jordanusfta.pdf> [Accessed 27 September 2021].)-rahulpenu

D. The Information and Communication Technology Industry

The other common effect discussed by officials when talking about the JUSFTA is a result of the agreement’s stringent IPR clauses. These officials often label the JUSFTA intellectual property rights clauses as ―TRIPS plus,‖ a reference to the fact that the agreement is stricter than the WTO’s Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS). They argue that, in combination with Jordan’s literate, educated workforce, the JUSFTA’s IPR clauses make Jordan an attractive opportunity for companies wishing to outsource IP-heavy information and communication technology (ICT) services and also for companies wishing to base pharmaceutical R&D and manufacturing services.

While ICT is currently a small part of Jordan’s economy, the country’s officials are not shy about stating their goal to have Jordan become an ICT hub for the region. In reality, however, there is little evidence that the JUSFTA contributes to this goal. Jordan is ranked 57th overall in the World Economic Forum’s 2006-07 Global Information Technology Report’s Networked Readiness Index. Its telecommunications exports to the United States decreased over the 2001- 2005 period, the most recent for which data is available (see Table 2 below). While many argue that the JUSFTA’s ―TRIPS Plus‖ conventions will attract foreign ICT investment and contracts, this has yet to be seen. Like U.S. exports, telecommunications exports to Great Britain, another country with a well-recognized IPR commitment, also decreased over the 2001-2005 period. The major export increases during this period were to China and South Korea. However, since China is perennially on the U.S. government’s ―Special 301‖ list, which identifies countries that inadequately protect IPR, it is unlikely that Jordan’s status as a ―TRIPS Plus‖ service provider drives these exports. South Korea is also on the 2007 Special 301 list.51

Table 2: Jordanian Telecommunications Exports, 2001-2005 (SITC 764)

[Table Omitted]

Even within the MENA region, it is unlikely that Jordan’s ―TRIPS Plus‖ status drives ICT trade and significantly contributes to Jordan’s development as a regional ICT hub. Of the 15 MENA countries for which telecommunications export data is available, 6 are on the Special 301 ―Priority Watch‖ or ―Watch‖ list. Therefore, the ability of the JUSFTA’s provisions to incentivize regional ICT development also appears minimal.

E. The Pharmaceuticals Industry

U.S. and Jordanian officials commonly point to the **pharmaceuticals** **industry** **as** **another** that **benefit**s from the **JUSFTA**. While the nascent pharmaceuticals industry is directed to regional rather than U.S. markets, officials indicate that the **FTA’s** **TRIPS** Plus **provisions** **encourage** **investment** in this industry as well. Supporters point to the **successes** **of** the Arab Pharmaceutical Manufacturing Company (**APMC**), an active exporter that is listed on the Amman Stock Exchange. APMC manufactures, produces, markets and sells pharmaceuticals, compounds, and derivatives and also performs research and development activities. With almost 1000 employees and 2006 sales over $29 million, APMC is a large player in the regional and global pharmaceuticals market. International partners include the Takeda Pharmaceutical Company of Japan. 52

According to the Pharmaceutical Manufacturers Association of America (PhRMA), the **JUSFTA** **made** **Jordan's** **market** **more** **appealing** **for** **sales** **and** **licensing** **agreements**. This may be true; in 2006, the **U**nited **S**tates **export**ed $11.4 million in pharmaceutical products to Jordan, an almost **70** **percent** **increase** from 2001. Assuming that these pharmaceutical products provide real improvements over products previously offered in Jordan, this **provides** an **important** **health** **benefit** **to** the **Jordanian** **society**. However, it is less economically significant; $11.4 million in exports represented less than 2 percent of total U.S. exports to Jordan that year. Supporters who argue that the JUSFTA provides incentives for U.S. firms to contract research and development activities to Jordan face a similar challenge when trying to prove economic relevance. U.S. pharmaceutical imports from Jordan totaled only $7 million in 2006; a significant increase over 2001 numbers, but still less than one-half of one percent of Jordan’s total exports to the United States.

#### The plan would break a critical barrier for Chinese pharma investment into Jordan---strict control is key.

UNCTAD 11 (, 2011. Investment in Pharmaceutical Product ion in the Least Developed Countries A Guide for Policy Makers and Investment Promotion Agencies. [online] Unctad.org. Available at: <https://unctad.org/system/files/official-document/diaepcb2011d5\_en.pdf> [Accessed 27 September 2021].)-rahulpenu

4. Key policy determinants

The above sections indicate that there has been a clear trend towards diversification of the industry in terms of products, places of production and R&D, and target customers, in response to, inter alia, the pressures faced by the expiration of patents held by larger firms in developed countries. The landscape for pharmaceutical production has also been shaped by the policy environment, both at the international and national levels. This section examines the key policies that have demonstrably affected the pharmaceutical production and investment landscape.

Drug registration requirements. Pharmaceuticals are a heavily regulated industry, and for good reason. Products are ingested, injected, applied topically and so forth; they therefore need to be proven efficacious, safe and quality controlled. Drug regulatory authorities ensure that firms under their jurisdiction comply with these standards. They are also responsible for gauging the demand for and helping to ensure the supply of essential medicines in the country. Countries differ widely on how pharmaceuticals are regulated, however, and the scope of regulation may greatly affect the incentives for local and foreign firms. Selected examples of the impact of certain drug regulations on local production and foreign direct investment are examined below.

Drug regulatory authorities have the responsibility to register those drugs that will be allowed to be marketed in their specific countries, and depending upon the domestic law, also for export. They are also responsible for verifying compliance with good manufacturing practices by manufacturers. Those drugs that are not registered and produced in a good manufacturing practices-compliant facility cannot be distributed. Registration must satisfy certain requirements, including having met applicable laboratory, clinical and bioequivalence tests for safety, consistency, quality and the like. Good manufacturing practices approval should meet technical requirements with respect to the handling of raw materials, manufacturing and packaging processes, treatment of water for use in the production process, air-quality and quality-control equipment and systems. Changes in drug registration policies have often had a significant impact on the domestic landscape for pharmaceutical production in some developing countries. For example, the Bangladesh National Drug Policy of 1982 deregistered all medicines that had been classified as non-essential or useless, and introduced for the first time an essential medicines list. This action, however, ended up deregistering a significant part of the portfolio of products held by the R&D-based transnational corporations, relegating them to producing mainly injectable vitamins after 1982. Moreover, foreign companies that do not have their own production facility in Bangladesh are not allowed to market their products, even if they are manufactured in the country by contract manufacturing. As a result of this policy action, most of the R&D-based industry sold their factories to local investors, and local firms now control over 70 per cent of the local pharmaceutical market.44

Indonesia’s Ministry of Health issued in late 2008 Decree No. 1010, requiring every company to manufacture every one of its pharmaceutical products in Indonesia, failing which, their registrations would eventually be withdrawn. Foreign firms that are importing drugs will be classified as pharmaceutical wholesalers – they lost their registration rights for their products after a grace period of two years following the issuance of the Decree. Imported pharmaceuticals can be registered by local pharmaceutical companies with written consent from a foreign company, which must include technology transfer to allow local manufacturing within five years.45 Decree 1010 applies to all products earlier policies that required pharmaceutical firms to establish factories for local manufacture as a prerequisite for the right to distribute in Indonesia, subject to certain exceptions. The Indonesian policies have in part contributed to greater domestic investment in and the control of a predominant share of the pharmaceutical market by local firms. Given the size of Indonesia’s market and its potential for growth, however, many Western and Japanese R&D-based pharmaceutical transnational corporations have established factories in Indonesia and intend on staying in spite of the Decree.

Drug pricing. Pricing policies can have a major impact on the economic decisions of pharmaceutical firms, both in terms of trade and investment. Those prices are often determined by the drug regulatory authority, often in consultation with the industry. An interesting example of this is in **Jordan**, **where** **price** **controls** **target** certain essential **medicines**. For these medicines, the public price of imported medicines is determined according to the corresponding price at which the product is offered in the home market, plus cost and profit margins for those importers and distributors. While a profit margin has been factored into this equation, the **effect** **of** this **control**, together with a strong regulatory framework, **has** **been** generally **higher** **prices** in Jordan for pharmaceuticals. **Chinese** and Indian **manufacturers** have in large part **refrained** **from** **entering** the **Jordanian** **market**, as **they** **would** **have** **to** **meet** **strict** **Jordanian** **good** **manufacturing** **practices**, while offering their products at close to Chinese and Indian prices, respectively, **resulting** **in** **lower** **profit** **margins** than their Jordanian counterparts. 46 One should therefore be conscious about the possible effect that price controls may have, both on investment and on the competitiveness of domestic firms.

Intellectual property. With the adoption of the TRIPS Agreement in 1994 as part of the set of treaties to which aspiring WTO Members needed to adhere, most of the world became obliged to make available the possibility of obtaining a patent for pharmaceuticals. Countries that had excluded patent protection for pharmaceuticals, which included both developing countries such as India, and developed countries in the past such as Switzerland, could no longer continue not to offer the possibility of product patent protection for new chemical entities.

The TRIPS Agreement did not, however, lead to a completely uniform system of patents – nor was it designed to do so. Instead, by implementing the Agreement through national legislation, countries were allowed flexibilities to tailor the patent system to their particular needs. Additionally, developing countries that had heretofore not offered the possibility enjoyed a transition period until 1 January 2005 and LDCs, until 1 January 2006 – which has now been extended until 1 January 2016, to provide for the possibility to obtain patents for pharmaceuticals under the TRIPS Agreement. Thus, because of these disparities, patent systems remain nationally based to a large extent, and what is patentable in one country is not necessarily patentable in another.47, 48 Adding to the complexity is that R&D-based pharmaceutical firms have generally sought to seek patent protection for new chemical entities in jurisdictions where they have a potential market for good returns, but have generally not sought patent protection in other markets. The landscape for the production of generic medicines in developing countries has been heavily influenced by this complexity. India, for instance, had not offered patent protection for pharmaceutical products since the 1970 Patent Act and until the implementation of the TRIPS Agreement. It successfully nurtured a pharmaceutical industry that was home to some of the world’s largest manufacturers of generics, including giants such as Cipla, Dr. Reddy’s and Ranbaxy. In order to support the local generic industry, the Indians developed a capacity for reverse engineering. This enabled them to produce generic equivalents of even the more complex molecules produced by originator companies. They could then offer them for sale to markets where there was no patent protection for those molecules, either because protection was not available under the local patent law, the originator did not seek patent protection in that jurisdiction, or the originator filed an application for patent protection that eventually failed to obtain protection. The recent introduction of patent protection for pharmaceutical products in India is expected to change the landscape over the coming years, however. The local industry is currently in a state of flux, with the acquisition of major generic companies by R&D-based transnational corporations. Further, the development of both Argentina’s and Brazil’s generic industry is also attributable in part to the absence of pharmaceutical patents in the pre-TRIPS era.49

#### China is taking every opportunity for investment expansion---ensures US-China cold war.

Huang 9-16 (, Y., 2021. The U.S.-China Trade War Has Become a Cold War. [online] Carnegie Endowment for International Peace. Available at: <https://carnegieendowment.org/2021/09/16/u.s.-china-trade-war-has-become-cold-war-pub-85352> [Accessed 27 September 2021]. Huang is a senior fellow in the Carnegie Asia Program, where his research focuses on China’s economy and its regional and global impact.)-rahulpenu

The **U.S.-China Trade War** Has **Become** a **Cold** **War**

What began as a trade war over China’s unfair economic policies has now evolved into a so-called cold war propelled by differing ideologies. U.S.-China bilateral relations took a nosedive in 2018 when then U.S. president Donald Trump’s obsession with trade deficits led him to impose punitive tariffs on China. The tariffs were followed by restrictions on both China’s access to high-tech U.S. products and foreign investments involving security concerns and by allegations of unfair Chinese commercial practices.

Despite pleas from the U.S. business community to ease tensions, U.S. President Joe Biden so far has amplified his predecessor’s policies by strengthening anti-China alliances and implementing additional sanctions. **Biden** now **characterizes** the **U.S.-China conflict** **as** “a **battle** **between** the utility of **democracies** in the twenty-first century **and** **autocracies**.”

But the logic underpinning the U.S. trade war was flawed, and the more recent, politically driven restrictions are counterproductive given the damaging long-term economic consequences for both sides. Nonetheless, there have been few signs to date that Biden is likely to change course. In the meantime, then, Europeans may be in a better position for productive give-and-take discussions with China on economic policymaking.

MISGUIDED U.S. TRADE POLICY

The Trump administration’s initial mistake in launching a trade war was to assume that U.S. trade deficits—which occur when a country imports more than it exports—were inherently bad and that China was to blame.

However, trade deficits are not a good indicator of the state of the economy, and U.S. trade balances largely are driven by soaring U.S. federal budget deficits, which have little to do with China. The irony is that three years after Trump’s tariffs were initiated to fix the U.S. trade deficit, bilateral trade between the United States and China has now rebounded to all-time highs, China’s trade surplus has increased, and the U.S. deficit has gotten worse.

Trump also echoed popular but misguided sentiments that U.S. firms had been overinvesting in China, resulting in a loss in competitiveness. But over the past two decades, only 1–2 percent of annual U.S. foreign investment has gone to China. By contrast, the EU, which is comparable to the United States in its economic size, has invested roughly twice as much as the United States has annually. The concern should be why the United States invests so little in China rather than so much.

CHINA’S INTELLECTUAL PROPERTY SAFEGUARDS

China’s alleged failure to protect intellectual property rights is also mischaracterized. At the extreme, **China** is **accused** **of** **stealing** **foreign** **i**ntellectual **p**roperty, especially technology. But after accounting for the size of China’s foreign transactions and research activities, such events may not occur unusually often or are possibly exaggerated.

Further, China’s patent courts have matured in dealing with this problem—foreign plaintiffs are now more likely to win their cases than domestic firms. In addition, theft is becoming less of a concern as payments for royalties and licenses by Chinese firms, according to one think tank scholar, have grown almost by a factor of four in the past ten years, making China the second-largest payer of such royalties globally.

The reality is that it takes **generations** **to** **develop** a **sound** **regime** **for** **i**ntellectual **p**roperty **rights**, as was the case for the United States. The foundation of China’s system was laid only two decades ago with reforms that accompanied China’s 2001 accession to the World Trade Organization. Progress has been notable in recent years as evidenced by the findings of the “2020 Business Climate Survey” by the American Chamber of Commerce in China; the survey indicated that nearly 70 percent of surveyed U.S. firms in China felt that China’s enforcement of intellectual property rights had improved, compared with only 47 percent in 2015.

CHINA’S PROTECTIONIST POLICIES

But there are also credible concerns that **China’s** **investment** **policies** **treat** **foreign** **firms** **unfairly**. One complaint is China’s use of subsidies. All countries provide subsidies to domestic companies and households, such as U.S. support to farmers, tax deductions to households to encourage clean energy use, and incentives to companies like Amazon to relocate. But in China, subsidies tend to be more focused on using the country’s banks and equity markets to support high-tech firms and strategic industries.

The U.S. government could choose to pressure China to better align its subsidy policies with Western norms, but instead, the Biden administration is copying China’s playbook by proposing its own subsidies to promote strategic industries.

China’s protectionist tendencies are also evident from the requirement that foreign firms form joint ventures with domestic Chinese firms as a condition for market entry in some economic sectors. This stipulation has been widely cited as a means of promoting so-called forced technology transfer, where foreign firms pass new technology on to their Chinese partners as a condition for being able to invest and produce in China.

But these Chinese requirements, too, have seemed to get less stringent in recent years, as exemplified by major foreign investments in chemical manufacturing (BASF), auto manufacturing (Tesla), and finance (BlackRock). These foreign companies have been allowed for the first time to enter key sectors without a Chinese partner.

China’s willingness to drop the joint venture requirement featured prominently in the EU-China Comprehensive Agreement on Investment negotiated in December 2020 (which has not yet been ratified). This experience suggests that policy differences can be addressed through consultations if both sides are willing to compromise.

#### Any conflict escalates---extinction.

Talmadge 18, [Caitlin Talmadge is Associate Professor of Security Studies at the Edmund A. Walsh School of Foreign Service at Georgetown University. "Beijing’s Nuclear Option, Why a US-China War Could Spiral Out of Control" Foreign Affairs, <https://www.foreignaffairs.com/articles/china/2018-10-15/beijings-nuclear-option> accessed 7-12-2019]

As China’s power has grown in recent years, so, too, has the risk of war with the United States. Under President Xi Jinping, China has increased its political and economic pressure on Taiwan and built military installations on coral reefs in the South China Sea, fueling Washington’s fears that Chinese expansionism will threaten U.S. allies and influence in the region. U.S. destroyers have transited the Taiwan Strait, to loud protests from Beijing. American policymakers have wondered aloud whether they should send an aircraft carrier through the strait as well. Chinese fighter jets have intercepted U.S. aircraft in the skies above the South China Sea. Meanwhile, U.S. President Donald Trump has brought long-simmering economic disputes to a rolling boil. A war between the two countries remains unlikely, but the prospect of a military confrontation—resulting, for example, from a Chinese campaign against Taiwan—no longer seems as implausible as it once did. And the odds of such a confrontation going nuclear are higher than most policymakers and analysts think. Members of China’s strategic community tend to dismiss such concerns. Likewise, U.S. studies of a potential war with China often exclude nuclear weapons from the analysis entirely, treating them as basically irrelevant to the course of a conflict. Asked about the issue in 2015, Dennis Blair, the former commander of U.S. forces in the Indo-Pacific, estimated the likelihood of a U.S.-Chinese nuclear crisis as “somewhere between nil and zero.” This assurance is misguided. If deployed against China, the Pentagon’s preferred style of conventional warfare would be a potential recipe for nuclear escalation. Since the end of the Cold War, the United States’ signature approach to war has been simple: punch deep into enemy territory in order to rapidly knock out the opponent’s key military assets at minimal cost. But the Pentagon developed this formula in wars against Afghanistan, Iraq, Libya, and Serbia, none of which was a nuclear power. China, by contrast, not only has nuclear weapons; it has also intermingled them with its conventional military forces, making it difficult to attack one without attacking the other. This means that a major U.S. military campaign targeting China’s conventional forces would likely also threaten its nuclear arsenal. Faced with such a threat, Chinese leaders could decide to use their nuclear weapons while they were still able to. As U.S. and Chinese leaders navigate a relationship fraught with mutual suspicion, they must come to grips with the fact that a conventional war could skid into a nuclear confrontation. Although this risk is not high in absolute terms, its consequences for the region and the world would be devastating. As long as the United States and China continue to pursue their current grand strategies, the risk is likely to endure. This means that leaders on both sides should dispense with the illusion that they can easily fight a limited war. They should focus instead on managing or resolving the political, economic, and military tensions that might lead to a conflict in the first place.

### 4

#### Counterplan text: The Hashemite Republic of Jordan ought to

#### Extend data exclusivity for patented medicines until the expiry of the medicine’s patent term

#### Require applicants for data exclusivity to demonstrate their data meets the conditions for protection

#### Allow the registration of generics when the product cost is unreasonably high, when the seller engages in anticompetitive practice, or when the seller cannot meet demand

Abughanm, S. (2012). The Protection of Pharmaceutical Patents and Data under TRIPS and US-Jordan FTA: Exploring the Limits of Obligations and Flexibilities: A Study of the Impacts on the Pharmaceutical Sector in Jordan.//sid

Therefore, I strongly recommend that JFDA adopt in the “Drugs Registration Criteria” (DRC) the definitions of what constitutes a new chemical entity and new uses of old entities which were discussed in this chapter. It is further recommended that JFDA discontinue its current practice, whereby data submitted by sponsors of new drug applications are assumed to have met protection requirements; sponsors must be required to demonstrate that their data meet all conditions of, and requirements for, protection. This must be in addition to the incorporation of specific reasonable exceptions to and legitimate grounds for the revocation of protection under the relevant Jordanian legislation. Therefore, I recommend in particular the following reforms: (1) allow reliance on originators’ data to register drugs produced or imported under compulsory licenses or obtained via parallel importation. (2) Allow the registration of a generic drug by reliance on the originator’s data when the product associated with the latter is sold for an unreasonably high price, when the originator perpetrates anticompetitive conduct that directly or indirectly involves the data, when the originator ceases marketing its products locally, and when the quantities provided are insufficient for meeting local demand. If, however, originators’ data are used involuntarily, a reasonable payment should be made by the producer of the generics. The amount of the payment may be calculated on a cost- sharing basis. Yet no such remuneration should be made in cases of wrongdoing by the originator; for instance, if it engages in anticompetitive practices or an unjustifiable lack of, or insufficient, commercialization. Furthermore, with regard to the protection of data related to patented products, I recommend that the term of protection must be linked with and capped by the patent term of protection. This limitation is necessary to make timely use of the early working exception to patent rights. The objective underlying this exception is to market generic copies of a patented medicine right after its patent expires. If data protection is allowed beyond the expiry date of a patent, then the goal of this exception may be frustrated by unnecessary delay of generics’ entry to market. In addition, this thesis recommends that JFDA includes the following circumstances as grounds for the revocation of data protection in the Jordanian DRC: 343 (A) if, without a reasonable justification, a product is not marketed in Jordan within six months calculated from the local registration date, or if the marketed quantities are insufficient for meeting reasonable local demands, or, if available, the product is sold for unreasonably high prices; (B) if, without a reasonable cause, and after being actually marketed, a product ceases to be available in the local market for an uninterrupted six-month period, or if the same period results from multiple shorter durations throughout the entire term of protection; and (C) if an application to register a pharmaceutical product is abandoned before or after a sanitary approval for its marketing is issued by JFDA. Besides preventing abuses of data protection such as “evergreening”, these proposed measures should maintain the balance between the interest of the public at large and those of the originator. The measures should alleviate some of the economic burden of providing data protection by allowing more competition in the drug markets. Most of the forgoing recommendations with regard to the Jordanian protection of test data are equally applicable to other developing countries regardless of their developmental states or levels of income.

#### DTA on 1AR shells - They can blow up blippy 20 second shells in the 2AR but I have to split my time and can’t preempt 2AR spin which necessitates judge intervention

#### No new 1ar theory paradigm issues- A] New 1ar paradigms moot any 1NC theoretical offense B] introducing them in the aff allows for them to be more rigorously tested

#### Reasonability on 1AR shells – 1AR theory is very aff-biased because the 2AR gets to line-by-line every 2NR standard with new answers that never get responded to

#### 1AR theory bad, incentivizes intervention for 2ar responses to 2nr counterstandards and moots substantive education by allowing them to spam 20 second shells, inf abuse not possible nc was 7 minutes and skew is inevitable so just get more efficient

### 5

#### Yes tricks for me!

#### Permissibility and presumption negate

#### 1] Obligations- the resolution indicates the affirmative has to prove an obligation, and permissibility would deny the existence of an obligation

#### 2] Falsity- Statements are more often false than true because proving one part of the statement false disproves the entire statement. Presuming all statements are true creates contradictions which would be ethically bankrupt.

#### 3] Negating is harder – A] Aff gets first and last speech which control the direction of the debate B] Affirmatives can strategically uplayer in the 1ar giving them a 7-6 time skew advantage, splitting the 2nr C] They get infinite prep time

#### The role of the ballot is to determine whether the resolution is a true or false statement – anything else moots 7 minutes of the nc – their framing collapses since you must say it is true that a world is better than another before you adopt it.

#### They justify substantive skews since there will always be a more correct side of the issue but we compensate for flaws in the lit.

#### Scalar methods like comparison increases intervention – the persuasion of certain DA or advantages sway decisions – T/F binary is descriptive and technical.

#### a priori's 1st – even worlds framing requires ethics that begin from a priori principles like reason or pleasure so we control the internal link to functional debates.

#### The ballot says vote aff or neg based on a topic – five dictionaries[[1]](#footnote-1) define to negate as to deny the truth of and affirm[[2]](#footnote-2) as to prove true so it's constitutive and jurisdictional. I denied the truth of the resolution by disagreeing with the aff which means I've met my burden.

#### Negate –

#### **1] We’re in a hologram**

Stromberg 15[Joseph Stromberg- “Some physicists believe we're living in a giant hologram — and it's not that far-fetched” <https://www.vox.com/2015/6/29/8847863/holographic-principle-universe-theory-physics> Vox. June 29th 2015] War Room Debate AI

Some physicists actually believe that the universe we live in might be a hologram. The idea isn't that the universe is some sort of fake simulation out of The Matrix, but rather that even though we appear to live in a three-dimensional universe, it might only have two dimensions. It's called the holographic principle. The thinking goes like this: Some distant two-dimensional surface contains all the data needed to fully describe our world — and much like in a hologram, this data is projected to appear in three dimensions. Like the characters on a TV screen, we live on a flat surface that happens to look like it has depth. It might sound absurd. But when physicists assume it's true in their calculations, all sorts of big physics problems — such as the nature of black holes and the reconciling of gravity and quantum mechanics — become much simpler to solve. In short, the laws of physics seem to make more sense when written in two dimensions than in three. "It's not considered some wild speculation among most theoretical physicists," says Leonard Susskind, the Stanford physicist who first formally defined the idea decades ago. "It's become a working, everyday tool to solve problems in physics." But there's an important distinction to be made here. There's no direct evidence that our universe actually is a two-dimensional hologram. These calculations aren't the same as a mathematical proof. Rather, they're intriguing suggestions that our universe could be a hologram. And as of yet, not all physicists believe we have a good way of testing the idea experimentally.

#### 2] Paradox of tolerance- to be completely open to the aff we must exclude perspectives that wouldn’t be open to it which makes complete tolerance impossible.

#### 3] Decision Making Paradox- We need a decision-making procedure to enact the aff, but to choose a procedure requires another meta level decision-making procedure and so forth leading to infinite regress.

#### 4] The Place Paradox- if everything exists in a place, that place must have a place that it exists in and so forth. Therefore, identifying ought statements is impossible since it assumes the space-time continuum.

#### 5] Grain Paradox- One grain falling makes no sound, but a thousand grains make a sound. A thousand nothings cannot make something which means the physical world is paradoxical.

#### 6] Arrows Paradox- If time is divided into 0-duration slices, no motion is happening in each of them, so taking them all as a whole, motion is impossible.

#### 7] Bonini’s Paradox- As a model of a complex system becomes more complete, it becomes less understandable and vice versa; therefore, no model can be useful.

### 6

#### TJFs first –

#### a] Frameworks are essentially T debates about the word ought which proves the better model of debate is what matters. b] Turns substance – it doesn’t matter how true a philosophy is if it can’t be engaged or is impossible to learn from

#### c] Exclusionary rule – we cant engage which means all their substantive arguments should be presumed false

#### The standard is consistency with absolute sovereignty.

#### 1] Predictability – every individual engages within the social contract when going to school or using public infrastructure which means it’s the one political engagement everyone is aware of.

#### 2] Political Education – politicians have to understand the social contract in order to know what powers they have and what they have to provide citizens and debating about Hobbes helps us learn about that.

#### 3] Topic Ed – the Hobbesian approach is ideal for dealing with IP in the context of public health disaster.

Ashcroft 05 [Richard E. Ashcroft (MA, PhD Reader in Biomedical Ethics in the Department of Primary Health Care and General Practice at Imperial College London). “Access to essential medicines: a Hobbesian social contract approach”. Dev World Bioeth. 2005 May;5(2):121-41. Accessed 7/31/2021. <https://pubmed.ncbi.nlm.nih.gov/15842722/> //Xu]

The problems I have described in these concluding remarks are serious and difficult. I do not think they are decisive. None of these problems demonstrate either the falsity or incoherence of a Hobbesian approach. Rather, they show that a Hobbesian approach needs further detailed development. I think that the merits of the Hobbesian approach are plain, so far as it takes serious notice of the features of the state of war, the instrumental nature of states and their legal and civil institutions, and the overarching objective of states to preserve their citizens from misery and disaster. More obviously ‘moral’ theories (such as utilitarian theory, or natural rights theories such as Lockean theory or modern human rights theories) are less illuminating, in that they fail to construct compelling perfect obligations lying with specific agents. The Hobbesian account I have constructed here has many loose ends, but I hope I have shown in this paper how a powerful argument for a perfect duty lying on the state to protect its citizens from public health disaster can be constructed, and the foundations of legitimate sovereign enforcement of powers of compulsory license over intellectual property. Public health takes priority over private economic interest. The only question is whether private economic interest is the only, or indeed an, effective means for promoting the public health in conditions of disaster.

#### 4] Resource Disparities – philosophical frameworks ensure big squads don’t have a comparative advantage since debates become about quality of arguments rather than quantity and require a higher level of analytic thinking that small schools have.

#### 5] Resolvability – other debates create a mess of weighing and link turns, but using Hobbes is easily resolvable because it becomes a question of what the sovereign believes.

#### Negate –

#### 1] Sequencing – a sovereign can’t be obligated to do anything because they are the ones who choose what ethics and truth – the rez tries to coerce the sovereign to do something which challenges its authority.

#### 2] IP rights are implicit in the creation of the sovereign in expressing creativity.

Ghosh 04 [Shubha Ghosh (B.A., Amherst College; Ph.D., University of Michigan; J.D., Stanford Law School; Professor of Law, University at Buffalo, SUNY, Law School; Visiting Professor, SMU Dedman School of Law). “PATENTS AND THE REGULATORY STATE: RETHINKING THE PATENT BARGAIN METAPHOR AFTER ELDRED”. BERKELEY TECHNOLOGY LAW JOURNAL. 2004. Accessed 9/3/21. <https://lawcat.berkeley.edu/record/1119327/files/fulltext.pdf> //Xu]

As illustration of the limits of social contract theory,46 particularly the malleability of the notions of consent and promise, consider a social contract theory of intellectual property based on the thoughts of Thomas Hobbes rather than that of John Locke. No scholar has expressly developed a Hobbesian theory of patent or of copyright, but as a challenge to social contract theory, it may be useful to imagine what such a theory would look like.47 For Hobbes, humans created the leviathan-the sovereign state-to protect themselves from each other in the state of nature. 48 Without the leviathan, the state of nature was not an idyllic paradise but a condition of savagery and brutality. In the state of nature, to the extent that any creative activity occurred, the objects of creation would be cannibalized, thoughtlessly copied, adapted, distributed, and performed or used, sold, offered to sell, and made by others. Thus, intellectual property law under the leviathan would protect individuals from this state of nature by making them absolute, immutable, bountiful, and unlimited. Humans would consent to these terms if they were enforced equally for all creations, and each author and inventor would promise to all others to abide by this form of the intellectual property social contract.

## Case

### Advantage

#### Jordan Pharma high now – that’s 1AC Salih – flips Uniqueness negative – either a] Jordan pharma isn’t enough and can’t solve your impacts or b] Jordan pharma is already solving – it’s high even with Data Exclusivity which disproves your causal analysis.

#### Jordan Pharma is shifting to innovation – most recent analysis proves – IPR is key – specifically solves Economic Growth.

* Note – I used date last updated since it reflects most recent info

WIPO 8-25 8-25-2021 "Evolving Towards IP-Fueled Innovation" <https://www.wipo.int/ipadvantage/en/details.jsp?id=2647> (World Intellctual Property Organization)//Elmer

Background Operating out of the capital of Amman, **Hikma** is **transforming** the **Jordanian pharmaceutical industry** (Photo: Manni Manae) Ever since its inception, the Jordanian pharmaceutical industry has s**teadily grown into the country’s highest value-added export industry.** By 2010, sixteen pharmaceutical companies were exporting 81% of their production per year to over sixty countries, with high quality products and affordable pricing driving demand. In 2008, sales of the top ten pharmaceutical companies exceeded US$ 500 million. For much of its history, Jordan’s pharmaceutical industry has focused on producing affordable generic drugs. **Jordan’s** accession to the World Trade Organization (WTO) in 2000 and a free trade agreement with the United States in 2001 strengthened its intellectual property (**IP) system**, and the Jordanian pharmaceutical industry **has been evolving as a result.** Leading this evolution is Al Hikma Pharmaceuticals (Hikma), the largest pharmaceutical company in Jordan. Founded in the capital of Amman in 1978 by Mr. Samih Darwazah, Hikma’s initial focus was to develop a branded pharmaceuticals business across the Middle East and North Africa region (MENA), which it did by manufacturing patented pharmaceutical products under license. In 1991, the company’s success led it to establish a presence in the United States through the acquisition of West-Ward Pharmaceuticals (West-Ward). In only three years Hikma became compliant with United States Federal Drug Administration (USFDA) regulations, and in 1996 it became the first Arab company to receive USFDA approval. Shortly after its early successes in the United States, Hikma established an innovative injectable pharmaceutical manufacturing venture in Portugal targeting the MENA and Portugal markets. By the late 1990s, Hikma’s organic innovation and presence in Europe, MENA and North America led to significant expansion of the company. Licensing and Partnerships Hikma’s early success came through the manufacturing and marketing of branded generic drugs. While this continues to be an important part of the company’s overall strategy, **Jordan’s comprehensive economic reforms**, its accession to the Trade-Related Aspects of Intellectual Property Rights (TRIPS) agreement and the country’s increased level of IP protection **brought** many **new opportunities** for Hikma. The greatest of these was the **increased confidence of international partners**, which brought even more licensing and partnership opportunities. Prior to Jordan’s IP reforms, companies in the country would use slightly different formulas to manufacture a patented product for the generic market. While this was not considered to be IP infringement, it proved difficult to attract foreign investment in the industry. Under the new IP laws, Jordanian companies seeking to make generic versions of patented products cannot use different formulas or ingredients; they must use the exact, patented formula. To do so would require licensing and partnership agreements with the patent holder, and this change brought an opportunity that Hikma was quick to seize upon. Obtaining products under license has always been a part of Hikma’s strategy, and the new IP laws helped the company capitalize on the increased appeal of the country’s pharmaceutical industry generated for foreign investors. The company’s strong market position and established infrastructure made it a clear partner for multinational pharmaceutical companies seeking access to fast growing MENA markets. By the time IP laws in Jordan changed, Hikma already had a proven track record of working with global licensing partners, and its USFDA approved facilities combined with its highly skilled workforce and existing production capabilities made the company even more attractive to multinational partners. In 2007, the company’s successful utilization of new domestic IP laws through increased licensing agreements and partnerships yielded profits of US$ 198 million. As of 2010, it manufactured and marketed 40 licensed branded products through partnerships with multinational corporations such as LG Life Sciences of the Republic of Korea, Sinclair of the United Kingdom and MonoSolRx of the United States. Licensing deals and partnerships have also given Hikma unique acquisition opportunities, which in turn have brought the company access to new markets. In 2007, Hikma acquired Arab Pharmaceutical Manufacturing (APM), which was the third largest pharmaceutical company in Jordan, through which it significantly increased its presence in Saudi Arabia, as APM gets over one third of its revenue from Saudi Arabia. That same year, it entered the Egyptian market through the acquisition of Alkan Pharma, which became Hikma Egypt, and also entered Germany through acquiring two well known pharmaceutical companies in the injectable oncology market: Ribosepharm and Thymoorgan. These acquisitions, along with new licensing agreements, allowed the company to launch 28 new products, receive 167 approvals and submit 74 regulatory filings in Europe, Jordan and the United States in 2007. Injectable products are one of Hikma's three major business segments (Photo: Adrian Clark) Commercialization Hikma commercializes its products under three major segments: branded, injectable and generic pharmaceuticals. The branded segment manufactures branded generic pharmaceutical products for sale across the MENA region and Europe. The company has been involved in branded pharmaceuticals since its start, and as such enjoys a very good reputation in this area. The company’s injectable segment manufactures injectable generic pharmaceutical products in powder, liquid and lyophilized forms for sale in MENA, Europe and the United States. Lastly, the generic segment produces non-branded generic pharmaceutical products. This segment is focused primarily on the United States, as it is the largest market for the company’s non-branded generic products. The company’s business in this segment is operated by West-Ward, and as of late 2010 it sold 49 generic compounds in 108 dosage forms and strengths. The company has twelve world class manufacturing facilities which provide it with the flexibility to select the most appropriate manufacturing strategy for a particular product, taking into account factors such as cost, regulatory requirements and capacity. Manufacturing facilities are located in Jordan and Saudi Arabia, five of which have been approved by the USFDA, which provides the company with the capability to produce products for the United States market at a lower cost. Maintaining a local manufacturing presence in the MENA region is essential for the company’s growth, as some markets restrict the range of products that can be imported from outside the region. Research and Development Sparked by Jordan’s new IP framework, Hikma has secured the resources it needs to continue and expand its research and development (R&D) activities through licensing agreements, partnerships and acquisitions. The company’s R&D team is spread throughout Europe, Jordan and the United States, and focuses on developing technically challenging products such as injectables, complex formulations, unstable compounds and sustained release tablets and capsules. The R&D team aims to continually increase the number of approvals that it receives from regulatory authorities in its markets for newly developed products which have a strong market potential. Hikma’s R&D division is in charge of product formulation, process design and monitoring of bio-equivalency testing for all of its business segments. Beyond developing new products, it also improves existing products and manufacturing techniques, as well as performing R&D activities related to the manufacture of chemical synthesis, fermentation and purification. To accelerate its R&D efforts, Hikma aims to invest up to six percent of its total annual revenue in R&D, and also cooperates with leading R&D organizations through its collaborative partnerships. All of these factors have **allowed Hikma to transform** into a company that not only produces generics, but **into a company that innovates new products**, **making a substantial impact to** the growth of the company and the **Jordanian pharmaceutical industry**. At the end of 2009, Hikma’s R&D department contributed to a total of 116 compounds and 190 dosage forms and strengths pending regulatory approval, giving the company **a significant pipeline of innovative new products.** The Hikma trademark is protected in Europe (OHIM trademark No.005727425) Patents and Trademarks In 2007, Hikma filed its first Patent Cooperation Treaty (PCT) international patent application for a nanoparticle pharmaceutical carrier invention made in collaboration with the Queen’s University of Belfast. By 2010, the company has also filed three patent applications with the European Patent Office (EPO). Because branded products are an important part of Hikma’s business, the company has protected several of its brand names through registering trademarks. The company has utilized the international Madrid system to register a trademark for its Cefofix antibiotic in 1992, which was granted in 1995. It has also registered its name and slogan, “Hikma Quality,” with the Trademarks and Designs Registration Office of the European Union (OHIM). Business Results As the IP landscape in Jordan has changed, so has Hikma’s approach to its future growth and success. **Foreign investment, licensing, partnerships and acquisitions** **have all contributed to Hikma’s rapid growth**. The company’s success was recognized internationally in 2005 when it was **listed on the London Stock Exchange**. In 2007, it had an increase in revenue of 41.6% from the previous year. By 2009, Hikma was the fifth largest pharmaceutical company in the MENA region, enjoying a 3.7% market share, 12.4% annual growth rate and over US$ 400 million in sales. For the six months ended June 30, 2010, revenue was up 11.3% and operating profit was up by 20.2% on the previous year. The company is one of the top twenty generic prescription providers in the United States, has a geographic footprint spanning 49 countries, and is the licensing partner of choice for multinational companies looking to expand into the MENA region. An Effective IP System for Economic Growth **Jordan’s** **strengthened IP system** has **helped** **put** the **Jordanian pharmaceutical industry on the path of innovation**. While many Jordanian companies were previously focusing on manufacturing generic drugs, Hikma is an example of a company that is now creating its own patentable drugs and innovations. Inspired by Hikma’s success, Jordanian pharmaceutical companies have expanded their distribution networks to over sixty countries worldwide. Jordan has evolved into a leading knowledge economy in the region, and the pharmaceutical industry is just one example how **IP can lead the growth of an entire economy.**

#### Data Exclusivity is key to Pharma Innovation Investment.

Gangil, J, et al 10. “Do Intellectual Property Rights and Data Exclusivity Encourage Innovation in the Pharmaceutical World?” Systematic Reviews in Pharmacy, vol. 1, no. 2, 22 Dec. 2010, p. 190., doi:10.4103/0975-8453.75088. //sid

The purpose of data exclusivity is to ensure that the initial registrants of a new drug can recover the costs of testing the drug for efficacy and safety. Extensive testing directly translates into considerable costs for generating the data necessary to obtain approval of each new active ingredient. Drug developers challenge that they cannot afford to bring drugs to market without data exclusivity because later registrants, who did not have to invest in the high cost of obtaining marketing approval, can free-ride on the initial registrant’s approval and sell the same or similar drug at a lower price.[7] Experts argue that data exclusivity offers benefits to domestic innovators in developing countries and, in particular, that it provides incentives for research to identify new uses for the existing unpatented product. Data exclusivity is likely to have the largest effect in countries where for historical or other reasons there are many products with no current patent protection that may gain rights to exclusivity. Today in many developing countries, there are numerous medicines that are not patented. This is often the case in developing countries where TRIPS-based laws have only recently been introduced. In addition, even where there are patent laws, companies may not have considered the market sufficiently valuable to justify the expense and administrative cost of securing patents. In that case, the introduction of data exclusivity laws may bring into exclusivity drugs that would otherwise be open to generic competition. The perceived absence of strong patent protection in India, even after the law was revised in 2005, and the presence of a large number of products without patent protection due to the absence of product patent protection before 2005, is a major reason why the international pharmaceutical industry lobbied very hard for a strong data exclusivity regime in India. In contrast, Indian companies focusing principally on generics argued for a weaker data protection regime.[8] In certain cases it is observed that “data exclusivity” helps innovator companies to recover investments made on discovering and developing a new drug; for example, according to a published article, Aventis’s innovative drug Leflunomide for rheumatoid arthritis took 17 years from discovery to commercialization.[9] Data Exclusivity Plays a Key Role for Biologics New Economics Research supports **13–16 years of data exclusivity for biologics**. A new working paper by Duke University economist Dr. Henry Grabowski, “Data Exclusivity for New Biological Entities,” identifies 12.9–16.2 years or about 13–16 years of data exclusivity as necessary to sustain investment in the research and development (R and D) of new biologics in any approach to creating an abbreviated pathway for follow-on biologics (FOBs). The Duke University working paper states that without sufficient data exclusivity, there would be little incentive to develop and market new biologics with uncertain or few remaining years of patent protection. Under this scenario, innovators would be less likely to pursue the development of a molecule if there were uncertainty regarding the possibility of recouping their investments and achieving a positive return.[10]

#### Data Exclusivity ­does not prevent competitive products.

GaBi Online 11 “Data Exclusivity Is Not the Same as Market Exclusivity.” GaBi Online, 26 Jan. 2011, www.gabionline.net/policies-legislation/Data-exclusivity-is-not-the-same-as-market-exclusivity. //sid

Furthermore, Mr Quinn states that it is fiction that 12 years of data exclusivity would extend innovators’ monopoly power. “Data exclusivity does not give it any sort of monopoly”, he writes. “You would be hard pressed to find a term that is used more and understood less than the term ‘monopoly’. “Patents don’t give monopolies, and neither would data exclusivity. If patents gave monopolies then how is it possible that anyone other than Apple could sell a portable MP3 player? Apple has the iPod and iPhone locked up tight, but not so tight that other companies are prohibited from selling similar products. Look at all the iPhone wanna-bes that are on the market now. Seriously! You have to stop thinking that patents grant monopolies. What they do is make it difficult for others to copy an innovation, but if you can make something that does the same thing that isn’t a copy, then patent law does not prevent that”. He explains that similarly, products that compete with innovative biologicals **can still be introduced during the period of data exclusivity.** A period of data exclusivity merely means that those who do not innovate cannot piggyback off the hard work of innovators and rely on the research conducted by the innovator company. They must conduct their own safety and efficacy research and testing to obtain FDA approval and, obviously, not infringe the patents owned by the innovator. “So can we please stop using the world ‘monopoly’? No matter how many times it is used it will never accurately describe the protections provided. If you doubt that do a patent search and you will see in every industry numerous patents that all purport to cover similar things. How else, for example, could Microsoft and Apple both have patent portfolios? How else could Motorola and Nokia have patent portfolios? How else could AMD and IBM have patent portfolios? And so on” Mr Quinn states. (see also [Minimal 12 years of biologicals data exclusivity required](http://www.gabionline.net/Biosimilars/News/Minimal-12-years-of-biologicals-data-exclusivity-required), [12 years exclusivity workable for patients; not anticompetitive](http://www.gabionline.net/Generics/General/12-years-exclusivity-workable-for-patients-not-anticompetitive) and [Innovative biologicals development must be preserved](http://www.gabionline.net/Pharma-News/Innovative-biologicals-development-must-be-preserved))

#### AT Wolf 21 - Multiple Alt Causes to Instability – coups, COVID econ issues, refugees, water scarcity – zero reason Pharma can overcome – your ev

1AC Wolf 4-14 “A Hashemite Family Reunion Can’t Hide Jordan’s Woes” Albert B. Wolf, an associate research fellow at Johns Hopkins SAIS and an assistant professor of political science at the American University of Central Asia. April 14, 2021 <https://foreignpolicy.com/2021/04/14/jordan-abdullah-hamzah-hashemite-family-reunion-cant-hide-economic-woes/> SM //Re-cut by Elmer

­­A Hashemite Family Reunion Can’t Hide Jordan’s Woes Making nice after **an alleged coup** attempt obscures serious challenges, including **water scarcity, a refugee crisis, and unhelpful neighbors**. The Hashemite Kingdom of Jordan is no stranger to royal intrigues and attempted coups. The first 20 years of the late King Hussein’s rule was wracked with coup plots, assassination attempts, and **a civil war** with the country’s large Palestinian population. Most recently, the former crown prince and half-brother of King Abdullah II, Prince Hamzah, was accused of engaging in sedition and placed under the “protection of the king” (i.e., house arrest) until the two made a joint appearance on Sunday. On Monday, the prince pledged his allegiance to the incumbent monarch and seemingly defused the latest royal tempest. But his display of deference doesn’t mean the end of **instability** in Jordan.This episode is a symptom of the challenges Abdullah has faced **since the outbreak of the Arab Spring**, not the problem itself. It is **unlikely to be the last challenge** the king faces to his rule unless Jordan’s economy undergoes significant economic reforms—quickly. Jordan has experienced multiple bouts of protests that were brought on by **economic downturns** (including **during the Arab Spring and** the **COVID**-19 pandemic) and were met with a combination of changes in economic tactics and giveaway programs, repression, and government reshuffles. This plot supposedly came from within the royal court, giving a tabloid quality to a security threat, especially after the **prince** made his **house arrest** all the more unusual by issuing a personal statement online. However, Hamzah’s alleged **plan to overthrow Abdullah** is a distraction from Jordan’s ongoing strategic and economic problems that do not have readily apparent solutions. Bruce Riedel, a senior fellow at the Brookings Institution, described the latest royal feud as the “most serious political crisis” Jordan has faced in 50 years. Regional experts have heard these warnings before. However, Abdullah’s combination of political savvy and luck in negotiating the challenges he has faced since the outbreak of the Arab Spring does not mean he will continue be lucky in the future. Domestic stability cannot be taken for granted. Tourism, Jordan’s biggest industry, ground to a halt after the emergence of the COVID-19 pandemic. It had accounted for $5.8 billion in revenues in a $43 billion economy in 2019, but Jordan could not allow tourists back into the country as COVID-19 spread. Furthermore, remittances, which had accounted for $3.7 billion in 2018, were estimated to drop by nearly 20 percent for the entire region in 2020. Two weeks ago, protests broke out in Amman along with other cities because of the deaths of six people from COVID-19 at government hospitals. The cause was low oxygen supplies. However, the literature on comparative authoritarianism shows that protests may provide elites with opportunities to reveal their preferences and split from the incumbent regime. Should more protests occur due to the worsening economic situation, water shortages, the coronavirus crisis, or the strains of hosting a large refugee population, a window of opportunity may open for Prince Hamzah or another opportunistic contender for the throne. (According to Jordan’s Ministry of Planning and International Cooperation, 34 percent of the population are refugees, most of whom are Palestinian. The U.N. refugee agency counts 663,210 Syrians who have registered as refugees—while the Jordanian government counts more than 1.3 million.) Many commentators and Jordan watchers have expressed shock and surprise at Hamzah’s open criticism of Abdullah. However, the more shocking display has been the public outpouring of criticism of the incumbent monarch. Popular radio programs have reported regular call-ins criticizing Abdullah, blaming him for the country’s poor economic performance and corruption. Prior to the pandemic, the country had less than 2 percent annual growth, and nearly 1 in 4 adults were unemployed. Some Jordanians who have been left behind economically felt that Hamzah used the language of the Arab street to speak to people’s needs in order to advance his own interests. Even Jordanian Finance Minister Mohamad al-Ississ reportedly said, “Unemployment is this country’s greatest problem.” Official figures put unemployment at 24 percent currently. Jordan’s supposed regional allies are not helping. The kingdom is surrounded by “frenemies” like Israel and Saudi Arabia, which, despite benefiting from the stability and cooperation of the Hashemite royal family, tend to engage in behaviors that undermine its steadiness. These frenemies’ behaviors exacerbate Jordan’s domestic political tensions. One of the most significant issues is water. Access to water is a problem for many Jordanians—and water theft is a big business that the state has failed to address. While water consumption continues to rise, an agreement with Israel’s government over providing an additional 8 million cubic meters remains elusive. Because of these problems, ordinary Jordanians are at the mercy of water thieves who drill untapped reservoirs without the permission of the state and charge what they want to people currently unserved and underserved by the state. Jordan has made clear it hopes to build a canal to the Red Sea or Dead Sea to ameliorate these problems, but, so far, it has been unable to cut a deal with Israel. There are rumors—and this time they are just that, rumors—that Saudi Arabia was involved in the alleged plot to overthrow Abdullah. It is important to note that once details of the arrests of Hamzah and others had leaked, most countries issued statements of support for Abdullah. However, some in Jordan fear that the Saudis are interested in a peace deal with Israel in order to displace the Hashemites as the guardians of Al-Aqsa Mosque and take over custodianship of Jerusalem’s holy places. The royal family’s latest feud is an allegory for Jordan’s ongoing economic and strategic problems. Should they continue, it is highly likely that this moderate ally of the United States and the West will find itself convulsed by domestic challenges again in the future. This could come in at least two forms: The first is another civil conflict with Jordan’s large Palestinian population. The second could be another challenge for the throne, possibly from Hamzah or from another royal rival who has yet to reveal himself.

#### AT Younes 18:

#### 1] The fact that Pharma is high now disproves their ability to access 1AC Younes since Econ instability is happening despite thriving Pharma – no quantification of why some more generics would solve – U/Q overwhelms the Link – multiple Alt Causes – here’s your ev.

1AC Younes 18 “Jordan’s economic crisis threatens political stability” Ali Younes, 14 Feb 2018 <https://www.aljazeera.com/economy/2018/2/14/jordans-economic-crisis-threatens-political-stability> SM//re-cut by Elmer

Jordan’s economic crisis threatens political stability **Anger simmers after** the **government hiked taxes** between 50-100 percent **on** key food staples such as **bread**. Angry at the decision to **increase food prices** last month, restive Jordanians are demanding the government’s resignation and the dissolution of parliament. Last month, the government implemented a tax rise of between 50-100 percent on key food staples such as bread, in order to decrease its $700m budget deficit. Jordan’s **debt has now reached $40bn** and its debt-to-gross-domestic-product ratio has reached a record 95 percent, up from 71 percent in 2011.

#### 2] The line about Jordan Econ being connected w/ Middle East is mis-highlighted – it says Middle East issues cause Jordan Instability NOT the other way around.

#### AT Al-Shami – No I/L – the Economic Instability they’ve identified comes from the Crown Prince trying to start a coup – it’s perception-based which domestic production from Pharma can’t solve – here’s your ev

1AC Al-Shami et al 4/13 “Jordan’s Thorny Spring Spells Trouble for the Middle East” Farah Al-Shami, Research Fellow, Arab Reform Initiative (ARI), Tuqa Nusairat, Deputy Director, Rafik Hariri Center for the Middle East - Atlantic Council, Paolo Maggiolini, Associate Researcher, Italian Institute for International Political Studies (ISPI) and Lecturer in History of Islamic Asia, Catholic University of Milan, Bruce Riedel, Senior Fellow, Foreign Policy, Center for Middle East Policy, Center for Security, Strategy, and Technology, Director - The Intelligence Project, Brookings, April 13, 2021 <https://www.ispionline.it/en/pubblicazione/jordans-thorny-spring-spells-trouble-middle-east-30024> SM//Re-cut by Elmer

**Jordan's** image, painstakingly built by the country’s authorities as an oasis of relative **stability** within a turbulent Middle East, **took a hit** on April 3, **when** former **Crown Prince** Hamzah bin Hussein was **accused of cooperating with** “**foreign entities” to destabilize the state.** The incident, widely presented as a family disagreement, resulted in the arrest of eighteen people and Hamzah's oath of allegiance to the Crown and the Constitution two days later. While investigations are still ongoing, the recent controversy comes as an unexpected novelty for the country. Since the Hashemite kingdom's origins, Jordan has always been seen as an island of stability in an otherwise unstable neighbourhood. At the same time, King Abdullah II has long been held in high regard in the United States, as Washington has relied on his steadying influence and views him as a highly reliable partner. Today, Amman remains one of the United States’ closest allies in the region, especially in counterterrorism operations and intelligence-sharing in the fight against al-Qaeda and the Islamic State. Nevertheless, despite its apparent stability, the country faces substantial socio-economic challenges. Jordan has been hard hit by the coronavirus (it ranks among the highest COVID-19 infection and death rates per capita in the region), while its unemployment rate reached one-fourth of the population in 2020. Furthermore, the country is currently home to over 660,000 Syrian refugees while also hosting a large community of Palestinian refugees. Hence, coming at a particularly uncertain moment for the country and combined with pre-existing structural problems, the tensions within the ruling family risk detracting attention from long-needed socio-economic reforms. Jordan’s uneasy geopolitical position “The kingdom of Jordan has so far been spared a visit by the Arab Spring, apart from several random and discontinuous waves of protests. For years now, **economic** demands have been growing and calls for less **corruption**, and more **transparency** have been rising. Against this backdrop, the ruling family is not only facing challenges on the economic front but also subtle opposition from the Muslim Brotherhood, which has been very active in other countries visited by the Arab Spring as well. Moreover, Iran and its hegemony over Iraq, Syria, and Lebanon puts Jordan in a difficult geopolitical position that requires close collaboration with GCC countries to counterbalance, especially that these countries are also ruled by monarchies. Thus, at the moment, the ruling family is trying to avoid having these geopolitical challenges spill into the local political scene and cause a serious threat to its rule via a combination of chaos and uprisings.” Farah Al-Shami, Research Fellow, Arab Reform Initiative (ARI) Amman’s economy needs less foreign loans and more support for structural reforms “One positive spill-over from the incident might be bringing Jordan back to the radar of its foreign allies, who tend to take the stability in the country for granted and have been ignoring quieting of Jordanians dissatisfied with dire economic situation in the country, further exacerbated by the Covid-19 pandemic. What Jordan needs, however, is not more loans – its foreign debt already amounts to over 90% of its GDP – but development aid and technical assistance in implementation of wise economic reforms that would not further harm the already impoverished population. Austerity is not an answer at a time when the cost of living is growing, remittances – falling, and officially one in four (and realistically more) Jordanians is out of work.” Katarzyna Sidło, Director of the Middle East and North Africa Department, Center for Social and Economic Research (CASE) Jordan’s social mobilization limbo and the risk of a security clampdown “Jordan, a resource-poor country that was initially lauded for containing COVID-19, has struggled to manage the economic fallout. Remittances and tourism have declined as has assistance from neighboring Gulf countries. With many businesses in ruins due to COVID-19 lockdowns, the government has to do more to ensure social safety net programs help vulnerable populations climb out of economic despair. The government is also struggling to support the nearly one million refugees in the country. While Jordanians have been protesting for months, recent events involving Prince Hamzah are likely to make Jordanians think twice before going out into the streets. The government must act fast to address economic challenges while avoiding a security clampdown that could make matters worse.” Tuqa Nusairat, Deputy Director, Rafik Hariri Center for the Middle East - Atlantic Council Jordan-Israel relations must refocus on shared interests and avoid political calculus “While it is still difficult to establish the extent of the alleged coup plot in Jordan, what seems particularly intriguing are the allegations of foreign meddling. Ten years ago, while protests and dissents were mushrooming, Amman was counting on Saudi aid and Israel’s implicit support. Today, while regional powers, including both countries, are voicing support for the king, Amman is becoming increasingly concerned that the Tel Aviv can be to the detriment of its legitimacy. The recent incident at the Israeli-Jordan border and the rapprochement between Riyadh and allegations pointing to Israel and Saudi Arabia are only the most recent episodes in a stream of tensions developing since 2017. These are like a wake-up call. Jordan-Israel relations have always been based on solid shared interests and not on political calculus. It is of utmost importance to recognize this for the future of the region and the security of both countries.” Paolo Maggiolini, Associate Researcher, Italian Institute for International Political Studies (ISPI) and Lecturer in History of Islamic Asia, Catholic University of Milan The US and international support for Amman is essential to preserve the region’s stability “The Biden administration is facing an unexpected crisis in Jordan where King Abdallah faces unprecedented divisions within the **ruling family exacerbated by foreign meddling**, the pandemic and recession. **At risk is the stability of the lynchpin of the region**. Saudi support for Prince Hamzah’s challenge to the King raises serious questions about the reckless and dangerous behaviour of the Crown Prince Muhammad bin Salman. Biden has moved quickly to signal support for Abdallah. He needs to rally international help for Jordan’s weak economy and deep structural problems. Keeping Jordan stable is critical to survival of the Israel-Jordan peace treaty which is deeply unpopular.”

#### AT Lazaroff – This is not about the Plan OR collapse of Israel-Jordan – it’s about Netanyahu’s plan to annex the West Bank – zero Internal Link since it’s not causal – here’s your ev.

1AC Lazaroff 20 “Will annexation destroy Israeli-Jordanian peace, set kingdom aflame?” Tovah Lazaroff is the Deputy Managing Editor of The Jerusalem Post May 1, 2020 <https://www.jpost.com/middle-east/will-annexation-destroy-israeli-jordanian-peace-set-kingdom-aflame-626104> SM //Re-cut by Elmer

The possible **collapse of the Israel-Jordan Peace Treaty** and potential destruction of a stable regional ally, the Hashemite Kingdom, **is** one of the **stronger** **arguments** **against** Prime Minister Benjamin **Netanyahu’s plan to annex West Bank settlements** this year. The 1994 peace treaty with Jordan, as well as the 1979 treaty signed with Egypt, have been a foundation cornerstone of Israeli regional security and gateway to the Arab world. The value of the two treaties, in an otherwise hostile region, has only increased in relation to the growing threats from Iran and ISIS and other Islamic fundamentalist terrorist groups. So **the idea of an Israeli plan**, either unilateral or in conjunction with the US, that **would risk those treaties** and the stability of Israel, after a decade of regional turmoil, has to give one pause. “Unilateral annexation will damage stability in the Middle East” and harm Israel, said former Shin Bet (Israel Security Agency) director Ami Ayalon. “The peace treaty with Egypt and the peace treaty with Jordan are in a way the two cornerstones of our [regional] policy and our security for the last 30 to 40 years,” he said. A retired admiral, Ayalon is among a group of more than 220 former security officers who have embarked on a campaign against the move through the group Commanders for Israel’s Security. Last week, he and two other high-level former security officials, Maj.-Gen. (ret.) Gadi Shamni and former Mossad director Tamir Pardo, published an article in US-based Foreign Policy magazine, warning about the implications to Jordan and Egypt. There are many rational reasons for the two countries to maintain ties with Israel, Ayalon told The Jerusalem Post. Egypt relies on Israel for intelligence and security cooperation when it comes to fighting al-Qaeda and ISIS in Sinai. Jordan has water and gas deals with Israel. Both countries also rely heavily on financial assistance from the United States, which is tied to the peace deals. Still, those factors would not be enough to offset the danger to the Kingdom from the street, Ayalon said. In the aftermath of the Arab Spring, however, regional leaders cannot afford to ignore public opinion, particularly on a topic where emotions run high, such as the Israeli-Palestinian conflict, he said. Rulers in both Egypt and Jordan “have to listen to the voices of the street because they understand that power,” he said. Egyptian President Egyptian President Abdel Fattah el-Sisi has more flexibility than Jordan’s King Abdullah, Ayalon said. Jordan is home to a large number of Palestinians, and there are also many young people who are radicalized, Shamni said. “They will never accept Jordanian silence with regards to annexation,” he said. “To survive, the king will have to take extreme steps that might even severely damage the Israeli-Jordanian peace agreement.” Throughout the years, **Israeli actions in the West Bank**, Jerusalem and **Gaza have had a destabilizing influence**, Ayalon said. “But there is a huge difference between incremental change” and a large unilateral act, such as **annexation**, particularly one that is against the declared will of all Arab leaders, he said. Shamni, who was also Israel’s former military secretary to the US and a military adviser to former prime minister Ariel Sharon, said the plan **creates unnecessary turmoil and security problems**. At issue is Israel’s eastern border, which is its calmest out of the five borders, he said. There are hostilities along the Lebanese, Syrian and Gaza borders, and even the Egyptian border can be problematic because of terrorist groups in the Sinai Desert, he said. But the combined efforts of Israeli and Jordanian security forces have kept violence at bay, Shamni said. Jordan acts as an additional security buffer for Israel and provides a strategic safeguard against terrorism and other security threats, he said. Jordan’s location, bordering Iraq on the other side, makes peaceful relations with Israel particularly significant, he added. Coordination with Jordan is crucial for Israel’s safety along this critical stretch, Shamni said.

#### 1] No Israel-Jordan spill-over card – they can only solve regional Water Issues but their Impact is about the broader region and 2] Nowhere near enough for a Nuclear War Impact – just says tensions or flashpoint – those are constrained and they have no draw-in warrant – they can’t even say they access regional war since their ev doesn’t say war – flashpoints refers solely to Palestine flare-ups.

#### No Jordan key to health care argument, 1ar’s too late

#### AT Silverstein –

#### 1] No Risk of this – this card is about Israel-Iran – 1AC doesn’t have a Jordan key card and 1AC Alaaldin doesn’t mention Israel OR Iran once – I’ll insert a re-highlighting.

#### 2] It’s about Israel-Iran miscalc – an internal link the Aff doesn’t resolve since it’s structural past pandemics.

#### 3] Says Netanyahu treats Iran as existential – makes Middle East War instability and escalation either a] inevitable or b] all-hype so no impact.

#### AT Hour – No Mid East escalation

Imran 19 2/6/19 [Myra Imran, writer for The News International. Citing the international seminar on “Strategic Dimensions of Peace and Conflict in South Asia and the Middle East”. Seminar on ‘Strategic dimensions of peace and conflict in South Asia, Middle East’. 2/6/19, https://www.thenews.com.pk/print/428298-seminar-on-strategic-dimensions-of-peace-and-conflict-in-south-asia-middle-east]

Islamabad : There is a need to study the causes of proxy wars, and what are the potential impacts of such wars on the overall conflict. These thoughts in a daylong international seminar on ‘Strategic Dimensions of Peace and Conflict in South Asia and the Middle East,’ organised by Pak Institute for Peace Studies (PIPS), an Islamabad-based think tank, participated by prominent national and international scholars. Prof. Shahram Akbarzadeh, Deakin University, Australia, argued there is significant gap in the literature on non-state actors. He called for empirical research, along with concrete policy suggestions, on the topic, so as to mitigate the conflicts in the region, in particular South Asia and Middle East. Speakers grappled at the notion of non-state actors and proxy wars: PIPS director Muhammad Amir Rana said non-state actors often evoke memories of violent elements. This despite that as per definition, non-state actors include organizations working for human rights. Prof. Syed Rifaat Hussain, Department of Government and Public Policy, NUST, said the term “proxy wars” is a contested notion. There is no universal agreement on its definition, nor on the set of circumstances behind such wars. Interestingly, he said, proxy wars are as old as the phenomena of conventional war itself. Speakers noted proxy wars are instruments of state power. As to why states go for it, it was argued, it is because they are often cheap undertaking to change the status quo. Participants noted over the decades, much of the conflict involves non-state actors. Interstate conflict, on the other hand, has declined. In recent times, he said tit-for-tat tactics on behalf of such actors have reduced their appeal. Dr. Ibrahim Fraihat, Doha Institute of Graduate Studies, Doha, termed proxy war as an arms conflict between two parties, though one of them is not directly involved. This way, domestic conflicts are escalated by external power intervention. At the same time, proxy war, if unresolved, can take the shape of conventional war, the most significant example was of Vietnam War. In contemporary times, he lamented, the Middle East has been rendered a stock market of proxy organizations. William Gueriache, Associate Professor American University in the Emirates Dubai, said on surface, all states support open diplomacy and multilateralism. Yet the survival of patronage has paved the way for foreign intervention during conflicts in the whole Middle East. Dr. Marwan Kablan, Director Policy Analysis at the Arab Center for Research and Policy Studies Doha, also hinted multiplicity of actors involved in Syrian conflict, calling it as mother of conflicts in the region. It was said that wars cannot be ended unless patron states achieve their interests. Dr. Shaheen Akhtar, Professor National Defence University Islamabad focused on the apprehension of Pakistan about India’s involvement in Afghanistan. She said Pakistan’s uneasy relationship with Kabul reinforces a perception of encirclement while growing US-India strategic cooperation further aggravates these apprehensions. Dr. Muhammad Riaz Shad, National University of Modern Languages (NUML) Islamabad, said fighting through proxies gives states an opportunity of deniability.

1. <http://dictionary.reference.com/browse/negate>, <http://www.merriam-webster.com/dictionary/negate>, <http://www.thefreedictionary.com/negate>, <http://www.vocabulary.com/dictionary/negate>, <http://www.oxforddictionaries.com/definition/english/negate> [↑](#footnote-ref-1)
2. *Dictionary.com – maintain as true, Merriam Webster – to say that something is true, Vocabulary.com – to affirm something is to confirm that it is true, Oxford dictionaries – accept the validity of, Thefreedictionary – assert to be true* [↑](#footnote-ref-2)