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#### Current TRIP-plus data exclusivity standards in Jordan devastate healthcare accessibility and the economy.

Barqawi 19 “The access to medicine puzzle: scaling back the negative effects of the Jordan–US Free Trade Agreement” Laila Barqawi [Lecturer of University of Central Lancashire, Preston (UCLAN)]. Journal of Intellectual Property Law & Practice, Volume 14, Issue 9, September 2019, Pages 678–686, <https://doi.org/10.1093/jiplp/jpz080> SM

Jordanian officials have started to recognize the negative impact of data exclusivity as can be seen through the Jordan’s food and drug administration’s (JFDA) submissions to the UN High Level Panel below. We explore their workability in an attempt to scale back the negative effects of TRIPS-plus and data exclusivity.

Data exclusivity operates as a ‘wholly distinct form of intellectual property rights and could not be overcome by a compulsory license.’2 Furthermore, TRIPS protects only ‘undisclosed data’ to prevent ‘unfair commercial use’; it does not confer either exclusive rights or an automatic period of marketing monopoly.3 TRIPS does not define what constitutes ‘commercial use’.4 There have been arguments for data exclusivity in that it incentivizes innovation in the field of pharmaceutical drugs and assists pharmaceutical companies in recouping the costs of clinical trials and clinical trial data transparency.5 These arguments have been refuted on the basis that a few years of patent protection is adequate to recover the cost of clinical trials as US companies, for example, have made an excess of USD 1 billion on 55 ‘blockbuster’ drugs in 2013.6

As part of Jordan’s WTO’s accession package, Jordan agreed to block registration and marketing approval of generic medicine for five years, ‘even when no patents exist’.7 This has been implemented through the Trade Secrets and Unfair Competition Draft Law, which had been referred to Parliament in November 19998 and is now Article 8 of Jordan’s Law No 15 of 2000 on Unfair Competition and Trade Secrets (UCTS).9 This is clearly TRIPS-plus in nature.

Moreover, restrictions by JUSFTA also require three further years for data exclusivity for new uses, which clearly is an e xcessive form of protection for an existing TRIPS-plus condition.

The effect of this restricted use of data exclusivity is evidenced by the 103 registered medicines which were launched since 2001 and had no patent protection in Jordan; of these, at least 79 per cent had no competition from a generic equivalent as a consequence of data exclusivity.10 This suggests that data exclusivity limits competition. Beyond implications for competition, there are financial effects as well. For example, an analysis funded by the Medicines Transparency Alliance estimated that the delayed market entry of generics resulting from TRIPS-plus requirements in JUSFTA cost consumers in Jordan’s retail market US$ 18 million in 2004.11

#### Data exclusivity is the key internal link to blocking generic competition, economic growth, and affordable healthcare – case study proves.

Malpani 09 “All costs, no benefi ts: How the US – Jordan free trade agreement affects access to medicines” Rohit Malpani [a senior campaigns advisor at Oxfam America. He currently manages Oxfam International’s access-to-medicines campaign]. 2009 Palgrave Macmillan 1741-1343 Journal of Generic Medicines Vol. 6, 3, 206–217 <https://citeseerx.ist.psu.edu/viewdoc/download?doi=10.1.1.851.5138&rep=rep1&type=pdf> SM

HOW TRIPS-PLUS RULES HAVE RESTRICTED GENERIC COMPETITION IN JORDAN SINCE 2001

Since the US – Jordan FTA was formally enacted on 17 December 2001, TRIPS-plus rules have given multinational pharmaceutical companies more tools to prevent generic competition with their products. In fact, most pharmaceutical companies have not bothered to apply for patent protection for medicines launched onto the Jordanian market. Instead, multinational drug companies rely on TRIPS-plus rules, in particular, data exclusivity, to prevent generic competition for many medicines.

A. Patenting practices of foreign drug companies in Jordan since 2001

Numerous medicines marketed in Jordan after enactment of the FTA were not patented by multinational pharmaceutical companies. Working with the Jordan Patent Office and a local patent law fi rm, Oxfam analysed 108 medicines launched onto the Jordanian market since 2001. These medicines represent 42 per cent of all new medicines with no generic equivalent launched from 2002 until mid-2006, and more than 70 per cent of sales of new medicines with no generic equivalent. Of 108 medicines registered and launched by 21 multinational pharmaceutical companies since 2001 that currently enjoy a market monopoly in Jordan, only five medicines have product patent protection. 1

According to local industry and government officials, most multinational companies decided not to file patent applications after the US – Jordan FTA was signed because: (1) Jordan is not a member of the Patent Co-operation Treaty (PCT), thereby making patent filings expensive, complicated and time-consuming for new medicines; (2) many medicines without a generic equivalent would have qualified for little or no patent protection in Jordan owing to the original patent filing date; and (3) pharmaceutical companies concluded that data exclusivity effectively prevents generic competitors from entering the market for 5 years following registration of the originator medicine. In fact, of the 21 multinational drug companies, only three bothered to patent medicines that they launched onto the Jordanian market by mid-2006. The other multinational drug companies chose to rely on data exclusivity to enforce at least a 5-year market monopoly for medicines that were launched onto the Jordanian market by mid-2006. 2

Data exclusivity creates a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines for 5 or more years, even when no patent exists. Drug regulatory authorities are prevented from using the clinical trial data developed by the originator company to establish the safety and efficacy of a medicine in order to approve the marketing of a generic medicine that has already been shown to be equivalent to the original one. This delays or prevents generic competition. The TRIPS Agreement protects only ‘undisclosed data ’to prevent ‘ unfair commercial use ’ ; it does not confer either exclusive rights or a period of marketing monopoly. Earlier studies indicate that enforcing data exclusivity results in significant price increases for medicines. 3

Data exclusivity prohibits generic competition for a specified period of time. The alternative would be for generic manufacturers to repeat clinical trials of medicines to prove their safety and efficacy. However, doing this would violate medical ethics because clinical trial methodologies would require some patients to be given placebos. Giving placebos when the safety and clinical validity of the medicine being tested is already established and is unethical. In recent years multinational drug companies have started to file patent applications for drug precursors that will eventually be launched on the Jordanian market. It generally requires between 8 and 10 years to obtain a medicine to the market from the time the patent application is fi led. Data exclusivity will ensure that even if a patent application is rejected, the pharmaceutical company can secure at least 5 years of monopoly protection.

Data exclusivity prevents generic competition independent of patent protection

Multinational pharmaceutical companies have prevented generic competition for many medicines by solely enforcing data exclusivity provisions in Jordan ’ s IP law. This is because companies can rely upon data exclusivity more easily than patent protection to deny generic competition. Patent offices apply rigorous standards and impose safeguards to ensure that only innovative medicines are granted a monopoly. On the contrary, a pharmaceutical company merely has to submit clinical trial data to obtain a 5-year market monopoly.

According to Oxfam ’ s analysis of 103 medicines registered and launched since 2001 that currently have no patent protection in Jordan, at least 79 per cent have no competition from a generic equivalent as a consequence of data exclusivity. Jordanian generic manufacturers expressed frustration at the data exclusivity law because multinational pharmaceutical companies can rely upon data exclusivity to preclude generic competition. A generic competitor could replicate these medicines, in the absence of a data exclusivity law, shortly after the medicine’s launch on the domestic market.

Although data exclusivity was imposed as a result of the US – Jordan FTA and WTO accession, the TRIPS-plus measures benefit many other countries ’multinational drug companies. At least 21 US, European Union (EU), and Swiss drug companies have taken advantage of the benefits of data exclusivity. TRIPS-plus rules, although imposed by the US FTA, benefit all drug companies because developing countries must alter their national IP laws to fully implement TRIPS-plus rules. Thus, all pharmaceutical companies marketing medicines in a developing country, including European companies, benefit from these changes, and benefit from US efforts to impose TRIPS-plus rules elsewhere.

Consequences of data exclusivity on public health

Generic competition drastically reduces medicine prices. Multinational pharmaceutical companies that enforce data exclusivity for their clinical trial data in Jordan can prevent the onset of generic competition for 5 years, even without a patent on the medicine.

In contrast, nearby Egypt has not introduced data exclusivity and other TRIPS-plus rules, and multinational pharmaceutical companies have only received patent protection for medicines from 2005 onwards. Thus, most medicines currently sold on the Egyptian market have no form of monopoly protection (and therefore may have multiple generic competitors).

Heart disease and diabetes are serious public health problems in both Jordan and Egypt. Jordan had approximately 195,000 cases of diabetes in 2000, while Egypt, a more populous country, had an estimated 2.6 million cases. Similarly, according to 2002 WHO (World Health Organization) estimates, heart disease is one of the leading causes of death in both countries.

A comparison of prices for five best-selling medicines that treat diabetes and cardiovascular disease in Jordan and Egypt illustrates the enormous disparity between the costs of the originator medicine in Jordan (with no generic competitor available solely because of data exclusivity) against the lowest-priced generic equivalent in Egypt (where price reductions owing to generic competition are unrestricted) (see Table 1 ).

These new medicines are significantly more expensive in Jordan than in Egypt. If TRIPS-plus rules had been present in Egypt, local manufacturers could not have driven down the prices for these medicines through generic competition, and the prices for these medicines would have been much higher. The result would have been increased healthcare costs and less medical treatment, especially for poor people.

Three years of additional data exclusivity for new uses of old medicines

Article 4 of the US – Jordan FTA requires Jordan ’ s drug regulatory authority to provide three additional years of data exclusivity when a drug manufacturer discovers a new use for a previously known chemical entity. There is considerable disagreement between the multinational pharmaceutical industry and the Jordanian government about which medicines can receive additional monopoly protection. Pharmaceutical companies have argued that a ‘ new use ’would broadly include new therapeutic indications, formulas, dosage forms and formulations. Therefore, companies have attempted, including through use of litigation and lobbying of the US Trade Representative ’ s office, to extend data exclusivity to trivial modifications of a medicine, such as arguing that a higher dosage of an existing medicine would qualify as a ‘ new use ’ . On the contrary, the government argued that a ‘ new use ’only extends, at a maximum, to new indications for old medicines. Despite this narrow definition, at least 25 medicines have received an additional 3 years of monopoly protection for new indications. 4

#### Data exclusivity creates monopolies that guts access to affordable medicine – reverse causal data proves.

Armouti and Nsour 16 “Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S.- Jordan Free Trade Agreement?” WAEL ARMOUTI [LL.M in intellectual property law, Faculty of Law, the University of Jordan (Amman, Jordan), Legal Affairs Director at Jordan Food and Drug Administration (JFDA).] AND MOHAMMAD F.A. NSOUR [Lawyer and associate law professor at the University of Jordan.] OREGON REVIEW OF INTERNATIONAL LAW [Vol. 17, 259 2016] <https://scholarsbank.uoregon.edu/xmlui/bitstream/handle/1794/20019/Nsour.pdf?sequence=1&isAllowed=y> SM

In order to control diseases, people must be able to access affordable medicines. International human rights have stated that access to affordable medicine, health facilities and services should be accessible to all without discrimination.240 Instead of enabling this internationally mandated access to affordable medicines, the data exclusivity approach operates by delaying the entrance of generic (affordable) medicines into the market, which has the consequence of increasing the monopoly duration of the originator companies.241 Under this regime, prices of medicine will increase by 20%, according to the pricing regulations which give the generic product a maximum of 80% of the originator product’s price. Also, after the entrance of the generic product, some originators decrease their prices.242 According to an Oxfam report, data exclusivity has contributed to the problem by comparing the prices of selective medicines between Jordan and Egypt. This comparison illustrates the fact that prices in Jordan are much higher than Egypt, which is not currently implementing data exclusivity protection.243 Dr. Michael P. Ryan has responded to this Oxfam report, indicating that Jordanian prices are similar to prices in Saudi Arabia, and the pricing is according to the pricing regulation at the JFDA.244 Dr. Ryan did not take into account, however, the fact that for more than five years only the originator product will be present on the market.

Another proponent of data exclusivity, the former PhRMA chairman in Jordan, posits that data exclusivity has helped the originator companies to provide people around the world with new molecules and has ultimately led to better health.245

Jordanians obtain medicine through either the public or private system. The public insurances cover 55% of the Jordanian population,246 and this system buys the medicines through tenders announced by the Joint Procurement Department (JPD). Data exclusivity’s effect on the prices is very obvious when one looks at the assigned prices for the tenders. The government is obliged to buy the originator product for almost six years with no competition from the generic product.247 After the approval of a generic product, the originator product price will come down. The JAPM has conducted an analysis study of the official tender (JPD) prices in 2009, 2010 and 2011.248 This study showed the cost savings for the government after the availability of the local generic products.249 The prices of the local generic products in 2009 and 2010 JPD tenders for ten therapeutic groups were less than the second bidders, at $25 million JPD. Table 1 illustrates the savings that resulted from buying local generic products, as compared to the originator prices for these two years.250

After the introduction of the local generic products in the JPD tender, the originator companies have reduced their products prices. The originators price reduction in twelve therapeutic groups was around 14 million JD in 2010 tender and around 1.7 million JD in 2011 tender compared to their prices for the year before local generic products were introduced.

Table 2 illustrates the difference in prices bid by originator companies before and after the participation of Jordanian pharmaceutical companies in tenders of the same products.252

The study concluded that there was a reduction in the government’s spending on pharmaceuticals in the public health sector after the generic product was made available.254 This will lead to better utilization of our limited resources.255

Also, the JAPM has conducted an analysis of the price of a cancer product in public tenders. The 2009 tender price of this drug was 170.960 JD, while in the same year the generic product was registered with a public price of 86.700 JD. Thus, the price of the generic product was half the tender price. In 2010 tender, the originator product’s tender price was 56.000 JD, nearly 33% of the previous year’s tender price.

Additionally, the JAPM has analyzed the prices of six products from the same therapeutic category in the 2010 tender. Here, the originator product’s price was 3128290 JD while the local generic product’s price for the same category was 1084806. That is, the percentage reduction on government spending due to the availability local generic product is more than 71%, with a 2 million JD saving.258 Chart 2 represents this saving.

#### Data exclusivity stymies the generic market which is key to the Jordanian pharmaceutical industry. That spills over to neighboring countries and the Jordanian economy writ large.

Armouti and Nsour 16 “Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S.- Jordan Free Trade Agreement?” WAEL ARMOUTI [LL.M in intellectual property law, Faculty of Law, the University of Jordan (Amman, Jordan), Legal Affairs Director at Jordan Food and Drug Administration (JFDA).] AND MOHAMMAD F.A. NSOUR [Lawyer and associate law professor at the University of Jordan.] OREGON REVIEW OF INTERNATIONAL LAW [Vol. 17, 259 2016] <https://scholarsbank.uoregon.edu/xmlui/bitstream/handle/1794/20019/Nsour.pdf?sequence=1&isAllowed=y> SM

Since 2001, no real foreign investments from originator companies in Jordan have materialized. There are two types of investment that have been introduced. The first is the expansion of originator companies’ scientific offices, which has had a negative impact on the local industry due to the aggressive sales tactics employed by these companies, those with which the local industry cannot compete.

The other type of investment is contract manufacturing with local industry, manifested as secondary packaging only without any transfer of product know-how. The reason for this was to obtain a higher public price for the originator product, based on considering Jordan as country of origin. This is evident when we compare the Jordanian situation with that in neighboring country Egypt, which has many originator companies with manufacturing sites therein.261 Dr. Ryan has responded to the dearth of investment in the country by claiming that Jordan is a small pharmaceutical market in the region and that there is no reason to invest in manufacturing capacity. Additionally, he claims that medical tourism had grown due to implementation strong IPR.262 This position was confirmed by the ex-chairman of PhRMA in Jordan, who insisted that hospitals, doctors and pharmacies have benefited from health tourism due to drug availability.263

Furthermore, Originator companies are now conducting clinical trials in Jordan Research Centers because of the availability of a strong IPR environment.264

3. Promotion of Pharmaceutical Local Industry

The pharmaceutical industry is one of the leading industries in Jordan. There are sixteen private companies.265 The number of employees includes approximately 5,500 directly employed workers and 5,000 indirectly employed workers, with 99% of this employment being Jordanian. The percentage of females employed is 37%, 67% of which have university degrees.266 This sector is characterized as the highest-paid sector in Jordan.267 The investment in this sector is around $1 billion U.S. dollar and another $1 billion U.S. dollar in branches which are 17 branches in 8 countries.268

Eighty-one percent of local production is exported to 60 countries because of the high quality reputation of the local pharmaceutical industry, and it is considered number one between the Arab countries.269 Chart 3 represents the export of the local industry between 2004-2013.270

Five companies have either a European GMP or U.S. FDA approval.271 Pharma ex-chairman has stated that after data exclusivity, the local companies have upgraded their quality levels and they are now exporting their products to the European Union and United States.272 The JAPM has replied to this point that the local companies have taken this step regardless data exclusivity.273

The Jordanian pharmaceutical industry is considered to be a generic industry, one which does not involve innovation products. Few Jordanian companies have patents in this field, and the existing patents are mostly related to new techniques of old chemical entities, rather than to a new chemical entity. This lack of patents issued on the basis of innovation is due to insufficient financial resources for conducting the clinical trials that are required for new chemical entities, and also due to there being no foreign investment to support the local research and development or to strengthen the companies’ infrastructure.274

Additionally, the local pharmaceutical industry faces many obstacles in their bid to export to countries such as Saudi Arabia, Algeria, and Egypt; these countries tend to protect their own local industry.275 Additionally, as per the Secretary General of the JAPM, the enforcement of the data exclusivity approach has compounded the problem faced by Jordan’s pharmaceutical industry. Delaying the registration of the local generic product in Jordan, the country of origin, to around six years after the registration of the originator product consequently delays the generic product’s registration in export countries as well. Some countries request the marketing of the product in its country of origin for at least one year before submission of its registration file like Saudi Arabia. Additionally, other countries like Saudi Arabia price the generic products in descending order, so delaying the registration file submission will lead to a lower price, a price which might be untenable. Adding to this conundrum, a late market entry also has the effect of decreasing market share.

Contrary to the situation in Jordan, the generic pharmaceutical industries of other countries like Israel and India have evolved to counter the effects of data exclusivity. These countries have set legislation in such a way as to promote their generic industry.276 For example, Israel registers a generic product during the exclusivity period of the originator product for the purposes of export.277

Beyond merely stymieing the growth of the Jordanian pharmaceutical industry, the constraints of the data exclusivity approach could have farther-reaching economic implications. Consequently, the decrease in pharmaceutical industry export will affect the Jordanian economy.278

#### Pharma growth is under-performing and unsustainable now – only a strong generic market can underpin long-term success. Data exclusivity hinders market development and broader Middle East healthcare – Jordanian exports are key.

Cochrane 16 “Jordan's Pharmaceutical Sector Punches Above Its Weight” June 6, 2016 [Paul Cochrane is an independent journalist. He has written for over 80 publications worldwide, covering business, media, politics and culture in the Middle East, Africa and the Indian subcontinent. He is the co-director of a documentary on the political-economy of water in Lebanon - We Made Every Living Thing from Water (on Vimeo). He is also a media commentator, and has appeared on Al Jazeera Arabic, Al Jazeera English, CBS-NYC radio, Canada's CTV and CBC Radio, Press TV, Etejah TV, Future TV, Al Manar, Sahar TV, Today FM Ireland, and South Korea's TBS eFHM radio. Paul has a BA in International History and International Politics from Keele University, UK, and a MA in Middle Eastern Studies from the American University in Beirut (AUB), Lebanon.] <http://backinbeirut.blogspot.com/2016/06/jordans-pharmaceutical-sector-punches.html> SM

Jordan may be small in population terms, but it packs a hefty punch in the Middle East pharma manufacturing sector

With a population of just 6.6 million, Jordan may be a small country but it is one of the largest pharma manufacturers in the Middle East. A key reason for this is that production is export focused, particularly in the generics sector.

The country’s manufacturing sector, with an annual turnover of US$500m, had been steadily growing at 8–10% per year until 2012, according to the Jordanian Association of Pharmaceutical Manufacturers and Medical Appliances (JAPM). But since the ‘Arab Spring' of 2011, exports have slowed due to instability in the region, notably the conflict in neighbouring Syria.

Development is also being hindered because Jordan, unlike some of its regional competitors, notably Iraq and Iran, abides by the World Trade Organisation (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and data exclusivity. Since becoming a member of the WTO in 2000 and signing a free trade agreement with the USA in the same year, Jordanian companies have not developed any significant new medicines.

That said, Jordan’s domestic pharma market is growing. According to UK- based BMI Research, the total market, including imports, reached Jordanian Dinars JOD643m ($905m) in 2014, and is forecast to grow by 6.4% in 2015, to JOD683m ($962m). Samer Al-Ansari, Marketing Director for the Middle East and North Africa (MENA) at Hikma, one of the region’s leading pharma manufacturers and exporters, established in Jordan and listed on the London Stock Exchange, says the total market grew by 9.4% in 2014, while according to BMI generic growth was 10.5%.

Driving sales is burgeoning population growth, at 4.2%, further boosted by the influx of Syrian refugees: 937,830 were registered as of 2015, according to the United Nations High Commission for Refugees (UNHCR). Demand comes from the UN and other agencies supporting the refugees, and the market’s value is increasing due to the entry of patented products with high prices as well as an increase in generics, said Al-Ansari.

However, aid agencies import medicines and individual refugees have low purchasing power. ‘Bluntly, demand for pharmaceuticals did not reflect the 15% rise in the population. Refugees are buying in small quantities, and only the essentials,’ said Mohammad Shahin, CEO of the Jordan Sweden Medical and Sterilisation Company (JOSWE), and Chairman of JAPM.

The Jordanian healthcare sector is heavily supported by the government, with the ministry of health providing insurance to 40% of the population, followed by state health services organisation Royal Medical Services (RMS) covering 27.5%, according to the Jordan Journal of Pharmaceutical Sciences (JJPS). Government healthcare spending is on the rise, projected to go from JOD1.86bn ($2.62bn) in 2014, to JOD1.97bn ($2.78bn) in 2015, a 6.2% increase, according to BMI Research.

In 2016, compulsory health insurance is scheduled to be introduced to cover all Jordanians. If such a move happens, it is expected to be a boost for pharmaceutical sales. ‘The goal is to have local insurance companies support the private sector, but so far it has been only discussions, nothing has been agreed on yet. But you see that Jordan is moving towards the privatisation of healthcare, and wants to boost medical tourism,’ said Al-Ansari.

Jordan has 16 pharmaceutical firms, which manufacture mostly generics or branded generics, bulk antibiotics and cancer-related treatments. The market is dominated by Hikma, followed by Dar Al Dawa, Arab Pharmaceutical Manufacturing, JOSWE, Pharma International and United Pharmaceutical Manufacturing. ‘Local companies supply around 20% of total domestic consumption, and the rest is imported,’ said Shahin. More than 70% of Jordanian pharma production is for export, to more than 65 countries, primarily in the Middle East, Africa and Asia.

Regional instability has had a negative impact on exports, affecting the country’s overall economy, which is expected to grow by just 2.5% in 2015, according to the International Monetary Fund. ‘Our export markets are challenged to Iraq, Syria, Egypt and Saudi Arabia, as well as to Yemen and Sudan. You can anticipate issues in one or two countries but not four surrounding countries all having problems,’ said Hana Uraidi, CEO of the Jordan Enterprise Development Corporation (JEDCO).

Financing has also been complicated by the instability, while credit lines are under pressure. ‘It’s hard to get extended credit lines as insurance companies are seeing Jordan as higher risk, so traders have to pay up front, and we have a cash problem. If we take out loans it affects overall costs and profits. Before, we thought the situation would calm down after two or three years, but the government is now forecasting problems for 10 years,’ she added.

The closure of the Syrian border has hit the pharmaceutical sector particularly hard, as it was a major transit route for exports to Lebanon, and on to Turkey and northern Iraq, while the western Iraqi border has also been closed due to the presence of Islamic State. Companies are managing, however, to export to Kurdish Iraq and Baghdad, avoiding areas controlled by IS, while the central Iraqi government is still delivering drugs.

‘Overall exports are down by around 10–15% on 2014. It is not only neighbouring countries that have affected us, the whole region is affected, and in certain countries it is not clear who is in control. Payments are another problem,’ said Shahin. JOSWE expects a drop of 10% in its sales this year, with its business evenly split between local sales and exports.

Syria was not an export market for Jordanian manufacturers prior to the conflict as the country was practically self-sufficient in pharmaceutical production. But although the Syrian sector has been ravaged by war it has started exporting to the Arab Gulf and north Africa, according to Shahin, which has detracted from Jordan’s export competitiveness due to low prices.

Looking ahead, it may be generics that really underpin the Jordanian pharma sector’s success. WTO membership and its US trade deal have forced the country’s pharma sector to be transparent about producing generics and original research is still at an emerging stage due to a lack of investment, according to a 2015 article in the JJPS. The Jordanian Scientific Research Support Fund inked four agreements with public and private universities to develop pharmaceutical and medical research projects, worth $479,660 in September 2015, but it is not expected to cause any major upturn in the overall sector given the large investments elsewhere in the world.

‘We had hoped when we signed the WTO and IPR agreements that there would be a transfer of technology and know-how from multinationals to the local industry, but it’s been an unfulfilled promise,’ said Shahin.

Currently, local producers engage in contract manufacturing for global majors, which contributes to less than 5% of the sector’s overall revenue, according to the JJPS. The rest of production is generics under licence, with most licensing agreements still in effect signed before 1999.

Heightened competition

Due to data exclusivity and a lack of diversification, there is heightened competition among manufacturers, while JAPM estimates that few companies are operating at more than 40% of installed capacity. ‘Pharmaceutical companies are all making the same product, and each product has 15 or 20 competitors, while some have 50 or even 100 if we include imports as well,’ said Shahin. Such products include second-, third- and fourth-generation generics. To bolster business, JOSWE has started producing generics not in the market, but few others have followed the same route.

‘JAPM is trying to advise companies not to add more similar generic products but to create variety and products not in the market,’ added Shahin. The overcrowded generics market has led to a domestic price war, with companies trying to sell the same generics at a price 20% lower than the originator drug.

Companies are also having to make their generic products known in the market. ‘In the EU or the US you can sell a generic by its scientific name, but in the Middle East and North Africa (MENA) it is branded generics, so you have to build up a brand name,’ said Al- Ansari.

The fact that the writ of TRIPS does not run across Jordan’s region is a problem: ‘You find firms in such countries registering more products than us as they are not as strict in protecting IPR agreements,’ said Shahin. Egypt, for instance, has no TRIPS-Plus provisions, mandating more data exclusivity in its IPR law, yet it has had more foreign investment in its pharma industry, boosting competition for Jordan.

Price controls in Saudi Arabia to protect domestic production, and protectionism in Algeria to encourage pharmaceutical manufacturing are also affecting Jordanian exports.

The JJPS noted that data exclusivity related to TRIPS affected Jordanian exporters, as they ‘will be out of their export markets for at least seven years – five years’ protection due to data exclusivity, one year registration time in Jordan and at least one year registration in the export market’.

#### Economic stagnation structurally locks in instability in Jordan.

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

­­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.

#### Economic dependency on the US is a ticking time bomb – it makes instability structurally inevitable absent a domestic economic boost.

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

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.

The economic crunch that squeezes the country will be particularly acute this year, after Jordan’s Gulf Cooperation Council (GCC) allies – Saudi Arabia, UAE, and Kuwait – did not renew a five-year financial assistance programme with Amman worth $3.6bn that ended in 2017.

The United States is now the only donor that has committed itself to support Jordan. On Wednesday, US Secretary of State Rex Tillerson signed a five-year $6.375bn ($1.275bn a year) aid deal with Foreign Minister Ayman al-Safadi.

This surpassed the previous agreement of about $1bn a year, signed with the previous US administration, by about 27 percent, and increased in length from three years to five.

A US State Department statement said $750m was earmarked annually for economic support funds and $350m for the military. It was unclear what the remaining $175m would be used for.

“As part of this bilateral understanding, Jordan has committed to prioritise economic and security sector reforms that aim to support Jordanian self-reliance,” it said.

During a joint press conference in Amman, Tillerson said the increase would support Jordan’s security roles in fighting terrorism and the conflict in Syria.

However, even with the increased flow of US aid that has funded budgets and projects since the 1950s, it remains to be seen if Jordan’s economy will stabilise, according to analysts.

Hussam Abdallat, a political activist and former government official, told Al Jazeera the American assistance won’t benefit ordinary Jordanians.

“American aid to Jordan is useless to the average Jordanian; most of it goes to support the Jordanian military – which serves American interests, not Jordan’s – and the rest goes back to the US through US companies working in Jordan,” Abdallat said.

Any US aid that is not directly budgeted for economic development is “meaningless”, he added.

Regional stability

Journalist Salameh Aldarawi, editor of Maqar online newspaper, told Al Jazeera that Jordan’s economic problems are directly related to political stability in the region.

Aldarawi, who writes on the Jordanian economy, said devastating wars in neighbouring Syria and Iraq – the country’s biggest trading partners – have curtailed economic growth.

The harsh measures taken by the government will not improve economic stability and will only hurt the most vulnerable people in Jordanian society, he said.

“Prices and tax hikes are only hurting the poor and the middle class, especially in the absence of wage increases or social safety nets,” Aldarawi said. “These measures will only provide temporary quick fixes, not a long-term, strategic solution.”

He said tackling corruption was imperative, along with fixing the “collapsed education and healthcare systems.

“The government must start with fighting entrenched and endemic corruption within its ranks, recover billions of dollars of embezzled public funds, [and] create equality among the different segments of the population, especially towards those who pay more taxes but get fewer services and privileges,” said Aldarawi.

‘Economic disaster’

Abdallat, who leads several activist groups demanding political and economic reform, said Jordan’s political elite must be held accountable for their actions that have driven the country to the edge of financial ruin.

“People are protesting in several areas in the country and demanding the resignation of the government and the parliament, who are responsible for the economic disaster we are in now,” he said.

In Amman, where nearly half of Jordan’s 9.9 million population resides, criticism of government policies has spread over social media, but, so far, not significantly to the streets.

Analysts say that, unlike residents of the capital, people in the southern and northern provinces are more dependent on government largesse and employment and will suffer greater hardship when the government is no longer able to meet their needs.

“At this rate, I am afraid that we will end up with a revolt of the hungry,” said Abdallat.

Hussein Mahadeen, a professor of social development at Mutah University in Kerak, south of Amman, said Jordan has a foreign aid dependency problem because of its political and social structure.

Mahadeen said Jordan is still transitioning from its tribal society roots into a semi-modern state.

“Lacking solid legal and civic institutions, to safeguard the rights and liberties of citizens and their ability to contest government decisions, is a major impediment towards its political and economic development,” he told Al Jazeera.

“The Jordanian society, for several reasons, is not mature enough socially and politically to be able to mount a serious challenge to the state’s ability to impose strict economic measures.”

‘Violent revolt’?

For many decades, foreign aid and remittances from expatriate Jordanians in the Gulf region were the mainstays of the Jordanian economy that kept the country afloat.

This, however, created dependency, and a succession of Jordanian governments failed to take measures to wean the country off foreign assistance and become self-reliant, according to Mahadeen.

Jordan’s main problem is it hasn’t progressed and developed beyond its “functional state” roots,that is a state created to perform certain functions on behalf of others, after its creation by the British, after defeating the Ottoman Empire in World War I, he said

Abdallat – who has been imprisoned several times for his criticism of the government – said he was concerned the economic situation facing Jordan could result in an uprising.

“If the current economic crisis persists, it might lead to a revolt, and I am afraid it will be a violent one,” he said.

#### Jordan instability due to economic failure spills over regionally – independently ruins Israel-Jordan peace treaty.

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

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 rapprochement between Riyadh and Tel Aviv can be to the detriment of its legitimacy. The recent incident at the Israeli-Jordan border and the 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.”

#### Instability spills over to Israeli security crises specifically.

Solomon 4/6 “Instability in neighboring Jordan is ‘bad news’ for Israel” Ariel Ben Solomon [Middle East Correspondent for the Jerusalem Post], Apr 6, 2021 <https://www.jns.org/instability-in-neighboring-jordan-is-bad-news-for-israel/> SM

Instability in neighboring Jordan is ‘bad news’ for Israel

For the past several years, Jordan has come under increasing strain due to wars in bordering Iraq and Syria, which has led to many refugees resettling in Jordan. Combine a population holding divergent loyalties with a poor economic situation, and the result has been unrest.

(April 6, 2021 / JNS) The arrest last weekend of nearly 20 people, including former Crown Prince Hamza bin Hussein, by Jordanian authorities in what is being viewed by some as a coup attempt has led to fears over the stability of the strategic Arab state.

Jordan, a key U.S. and Israeli ally, is important for Israel’s national security because it serves as a buffer against radical forces from within the country as well as those further east, Israeli Middle East experts told JNS.

“The border with the Hashemite Kingdom is Israel’s longest, and Jordan serves as a friendly buffer on the east,” affirmed Efraim Inbar, president of the Jerusalem Institute for Strategic Studies. “We should not forget that the territories east of Jordan until the border of India are in the hands of rulers under Islamist influence.”

On Saturday, Jordan’s official media outlet denied reports that Prince Hamza had been arrested, claiming that the prince had instead been asked to stop “movements and activities that are used to target” the kingdom’s stability and security. Other key figures were also detained, including at least one other Jordanian royal, as well as tribal leaders and members of the country’s political and security establishment.

Prince Hamza, the eldest son of the late King Hussein and his American-born fourth wife, Queen Noor, and the half-brother of King Abdullah, said he would defy his house arrest conditions, adding to the intrigue behind what was reported as an attempt to destabilize the country.

“For sure, I won’t obey when they tell you that you cannot go out or tweet or reach out to people but are only allowed to see the family. I expect this talk is not acceptable in any way,” Hamza said on Monday in a recording released by Jordan’s opposition, reported Reuters.

According to the report, Prince Hamza had visited tribal gatherings in recent weeks, where the government and the king had been openly blasted.

Middle East expert Hillel Frisch, a professor at Bar-Ilan University in Ramat Gan, told JNS, “I don’t think this is the beginning of the fall of King Abdullah. All the key actors are behind him.”

“Nevertheless, this is the first serious fissure in the royal family, which if it did not enjoy total unity was always sufficiently disciplined to keep major differences within the family,” he said. “What happened in Jordan seems to be a result of dynastic struggles within the ruling royal family.”

“A mainstay of Hashemite rule always lay in that it was more united than any other political actor in Jordan,” added Frisch. “This may no longer be the case.”

Indeed, Abdullah has ruled the country since King Hussein’s death in 1999 and has cultivated a very close relationship with the United States.

Hamza has had a strained relationship with his half-brother, who stripped him of his title in 2004 and later appointed his own son as crown prince. Nevertheless, Hamza has held multiple positions within the monarchy, including in the army, and commands a loyal following in Amman, where he often styles himself after his late father.

At the same time, for the past several years, Jordan has come under increasing strain due to wars in bordering Iraq and Syria, which has led to many refugees resettling in Jordan. The country has most recently has been hard-hit by the coronavirus pandemic.

The United States is “closely following” the situation in Jordan following reports of an alleged coup plot involving the former Jordanian crown prince, U.S. State Department spokesperson Ned Price said on Sunday.

The action against Hamza comes a few weeks after the Jordanian government publicly acknowledged a new defense agreement with the United States that allows free entry for American forces. It boosts Israel’s unstable eastern neighbor, providing a base from which U.S. forces can potentially act in Syria, Iraq and Iran.

The defense pact’s timing—coming soon before the government crackdown—shows how dependent Jordan is on outside support.

Weak national identity leads to instability

Jordan is estimated to have more than half of its population of Palestinian origin, with many from the West Bank, which Jordan occupied between 1949 and 1967, in addition to a significant Muslim Brotherhood presence. These are ingredients for instability.

Add to this the fact that the Jordanian state has a weak sense of national identity, as it and other Arab states were created by Western European powers after the breakup of the Ottoman Empire.

A journal article by Linda L. Layne titled “The Dialogics of Tribal Self-Representation in Jordan,” published in 1989 in the American Ethnologist, explains how the state sought to cultivate a national identity around disparate tribes.

“The symbolization of tribes has been facilitated by the Jordanian government’s policy over the last several decades to unify and integrate individual tribal identities into one broad tribal identity, that is, to promote Bedouinism in a general way rather than encouraging each tribe to maintain and develop its own individual identity,” she wrote.

One question that gets to the root of the matter is how “Jordanian” its citizens actually feel. Palestinian, tribal and Islamist elements are less loyal to the state than their ideology or kinship networks. In the Middle East, loyalty tends to be to one’s family and tribe.

The Jordanian regime keeps its grip on power thanks to military and economic aid, mainly by the United States and the Gulf states.

Indeed, America is Jordan’s biggest supporter with more than $1.5 billion in aid in 2020, including $425 million in military assistance.

The poor economic situation combined with a heterogeneous population with divergent loyalties has led to frequent unrest among a vehemently anti-Israel population.

As Frisch noted, “even though the rise of a radical regime was not in the offing, instability in Jordan is bad news for Israel.”

#### Collapse of Israel-Jordan Peace Treaty causes Middle East war.

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

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.

#### Middle East turmoil goes nuclear.

Silverstein 4/23 “Iran-Israel tensions: The threat of nuclear disaster looms large,” Richard Silverstein [writes the Tikun Olam blog, devoted to exposing the excesses of the Israeli national security state], 23 April 2021 <https://www.middleeasteye.net/opinion/iran-israel-tensions-threat-nuclear-war-looms-large> SM

Israel had a near-miss of potentially catastrophic proportions on Thursday. As it has done hundreds of times in the past decade, the Israeli air force attacked Iranian bases inside Syria. In response, Syrian forces fired anti-aircraft missiles of a rather primitive Soviet model, one of which overflew its target and landed some 30 kilometres from Israel’s Dimona nuclear reactor. Israel said recently that it was bolstering its defences around Dimona for just such an eventuality.

Although an Iranian general taunted Israel, implying that Iran had some responsibility for the attack, that doesn’t appear to be the case. But the missile landing inside Israel does show that if Iran wanted to attack Dimona, it has the capacity. And despite Israel’s best efforts, an Iranian missile could hit its target.

With that, one of the worst nuclear disasters in the region’s history could unfold, including a Chernobyl-type radioactive leak that could endanger not only all of Israel, but also many of its neighbours.

A US general has assured a Senate committee that the Syrians weren’t intending to attack Israel. Rather, a misguided missile meant to target an Israeli warplane overshot its target. He blamed it on “incompetence”, as if that was supposed to be somehow reassuring; rather, it only reinforces how easy it is even for a mistake to cause a nuclear disaster.

Campaign of terror

Certainly, if either Israel or Iran wanted to bomb each other’s nuclear facilities, they could do so successfully. An Israeli attack would probably cause less catastrophic damage, but only because Iran’s nuclear programme is not nearly as developed as Israel’s. An Iranian direct hit on Dimona would cause incalculable damage due to the plutonium reactor at the facility.

Nor does this happen in a vacuum: Israel has maintained a decade-long campaign of terror attacks on Iranian military bases and nuclear scientists. Most recently, it bombed the Natanz nuclear facility, destroying the power generation source and damaging older-generation centrifuges. It also attacked an Iranian Revolutionary Guard spy ship off the Yemeni coast this month.

Iran has responded in its own limited way, restrained by its need to maintain good relations with nuclear-deal signatories.

For Israel, the attacks are a low-risk proposition. It defies US opposition (if there is any) with a wink and a nod, and the attacks look good on Prime Minister Benjamin Netanyahu’s résumé. To weather his corruption trial and retain public support, he needs external enemies (and internal enemies, but that’s a different story). Iran provides these in spades.

Eliminating Israeli leverage

The US could exert control over this scenario by eliminating Israeli leverage. If it agreed to lift sanctions in exchange for Iran’s return to low levels of uranium enrichment, as designated in the nuclear deal negotiated by the Obama administration, Israel’s rejectionist approach would become moot. The problem is that US President Joe Biden is running scared from Republican opposition to any nuclear deal with Iran. Besides, he has designated the Middle East a low priority for his administration.

There is some faint hope in the US announcement that it is ready to lift a partial set of sanctions. However, the list on offer is quite limited, and will certainly not satisfy the Iranians. Such half-measures present an example of the limitations of the Biden approach. He should instead make a full-throated commitment to end this dithering once and for all.

Israel is mounting a full-court press this coming week as it sends its Mossad and military intelligence chiefs, along with its army chief of staff, to Washington in an attempt to influence nuclear negotiations as they enter what may be a final stage. According to Haaretz, army chief of staff Aviv Kochavi “will also raise other issues, including Iran’s military expansion in Syria and the instability of Lebanon. Israel is concerned about the possibility that Hezbollah will try to … [foment] conflict with Israel.”

The hypocrisy of Israel’s refusal to acknowledge its own massive military interventions in Lebanon, Syria, Gaza and even Iraq, while decrying Iran’s involvement in Syria, is almost breathtaking.

There is next to no chance that any of this will enter into the considerations of negotiators in Vienna. Unlike Israel, they are interested in doing a nuclear deal, not engaging in wishful thinking.

Combustible Middle East mix

Returning to the Biden administration’s global goals, the Middle East doesn’t care about presidential priorities. It contains a combustible mix of corrupt elites and overbearing dictators who do not shirk from causing mayhem in their domains. And one of them, perhaps a desperate Israeli prime minister or an ageing ayatollah eager to preserve his honour and legacy, could inadvertently (or intentionally) set the entire region aflame.

If Biden doesn’t act quickly and decisively, there is a sizeable risk that another missile from one country or the other will hit a target and cause devastation. That would mark a point of no return, like the assassination of Archduke Franz Ferdinand in Sarajevo in 1914, which led to World War One. The difference is that in 1914, armies fought with guns, bayonets and artillery. Today, they will fight with F-35s, ballistic missiles and possibly nuclear weapons.

#### Regional war escalates quickly and draws in Russia and the US.

Hour 18 (Maj. Nadav Ben Hour, a visiting military fellow with The Washington Institute, “The Great Middle Eastern War of 2019,” 8/20, <https://www.washingtoninstitute.org/policy-analysis/view/the-great-middle-eastern-war-of-2019>)

MULTIPLE ACTORS, FRONTS, AND DOMAINS The potential for yet another war—one of unprecedented scope and complexity—is an outcome of the Syrian civil war, which has enabled Iran to build a military infrastructure in Syria and to deploy its Shi’a “foreign legion” to Israel’s borders. War is now possible on multiple fronts and in far-flung theaters, fought on land, in the air, at sea, and in information and cyber domains by fighters from Hezbollah, Iran, Syria, Iraq, Afghanistan, Pakistan, and even Yemen. The widened scope of a possible war will create new military options for Iran and Hezbollah, and stretch Israeli capabilities to their limits. Hezbollah Secretary General Hassan Nasrallah said as much, though perhaps with some exaggeration, when he warned in June 2017 that “if an Israeli war is launched against Syria or Lebanon it is not known that the fighting will remain Lebanese-Israeli, or Syrian-Israeli,” and “this could open the way for thousands, even hundreds of thousands of fighters from all over the Arab and Islamic world to participate.” Likewise, IRGC Commander Mohammad Ali Jafari stated in November 2017 that, “The fate of the resistance front is interwoven and they all stand united, and if Israel attacks a part of it, the other component of the front will help it.” Such a war is most likely to occur as a result of unintended escalation, after another Iranian action against Israel from Syria, or after an Israeli strike in Lebanon or Syria (for example, against missile production facilities). It could start as a result of a U.S. and/or Israeli strike on Iran’s nuclear program. It might even come about as a result of a conflict that starts in the Gulf but that reaches Israel’s borders—perhaps as a result of Iranian diversionary moves (much as Saddam Hussein tried in 1991 to derail the U.S. military campaign to expel Iraqi forces from Kuwait by launching missiles at Israel). A new northern war could resemble one of several scenarios: Lebanon War Plus. A war between Israel and Hezbollah in Lebanon, in which Iranians, thousands of foreign Shi’a fighters, and even Hamas (which has established a limited military presence in southern Lebanon) also participate. The Syrian front remains relatively quiet, with Israel acting there on a limited basis to interdict the movement of fighters and capabilities into Lebanon. War in Syria. A war between Israeli and Iranian forces, Shi’a militias (including Hezbollah fighters), and perhaps even elements of the Syrian military, fought on Syrian territory. The Lebanese front remains relatively quiet. Should Syrian ground forces get drawn into combat, however, Russia might intervene to protect its client. A Two-Front War. A war in Lebanon and Syria between Israeli and Iranian troops, Hezbollah, Shi’a militias, and perhaps even elements of the Syrian military, in which both sides treat Lebanon and Syria as a single, unified theater of operations. All three of these scenarios entail a potential for escalation or spillover into secondary fronts or theaters, and the involvement of additional actors: Additional Fronts/Theaters. A war in Lebanon and/or Syria might prompt: attacks on Israel from Gaza, unrest in the West Bank, or terrorist attacks in Israel; Houthi attacks on Israeli interests (such as Israeli maritime traffic in the Bab al-Mandeb Strait), or Israeli strikes on Houthi targets in Yemen; missile attacks on Israel by Shi’a militias in Iraq, and Israeli counterstrikes. Some of these militias have already warned that the latter could trigger attacks on U.S. personnel in Iraq. Israel vs. Iran. During fighting in Syria or Lebanon, Israel attacks Iran to strike a blow against the central pillar of the enemy coalition, and to thereby influence the course of the war. Alternatively, Iran augments attacks on Israel from Syria or Lebanon with attacks from its own territory, perhaps after suffering heavy losses in Syria. These could take the form of air or missile strikes and/or destructive cyberattacks on military targets and critical infrastructure. A Regional War? A low-probability/high-impact scenario in which a conflict in the Levant morphs into a regional war involving Saudi Arabia and perhaps the United Arab Emirates as well. Israel responds to attacks on its critical infrastructure with air strikes or cyberattacks on Iran’s oil industry or even its nuclear facilities—with the encouragement and perhaps logistical assistance of Gulf Arab states. Iran retaliates against Israel, but also conducts missile strikes, sabotage, or cyberattacks on Arab oil facilities across the Gulf, leading to escalation there, and perhaps even military intervention by the United States.

#### Nuke war causes extinction – Ice Age, famines, and war won’t stay limited

Edwards 17 [Paul N. Edwards, CISAC’s William J. Perry Fellow in International Security at Stanford’s Freeman Spogli Institute for International Studies. Being interviewed by EarthSky. How nuclear war would affect Earth’s climate. September 8, 2017. earthsky.org/human-world/how-nuclear-war-would-affect-earths-climate] Note, we are only reading parts of the interview that are directly from Paul Edwards -- MMG

In the nuclear conversation, what are we not talking about that we should be?

We are not talking enough about the climatic effects of nuclear war. The “nuclear winter” theory of the mid-1980s played a significant role in the arms reductions of that period. But with the collapse of the Soviet Union and the reduction of U.S. and Russian nuclear arsenals, this aspect of nuclear war has faded from view. That’s not good. In the mid-2000s, climate scientists such as Alan Robock (Rutgers) took another look at nuclear winter theory. This time around, they used much-improved and much more detailed climate models than those available 20 years earlier. They also tested the potential effects of smaller nuclear exchanges. The result: an exchange involving just 50 nuclear weapons — the kind of thing we might see in an India-Pakistan war, for example — could loft 5 billion kilograms of smoke, soot and dust high into the stratosphere. That’s enough to cool the entire planet by about 2 degrees Fahrenheit (1.25 degrees Celsius) — about where we were during the Little Ice Age of the 17th century. Growing seasons could be shortened enough to create really significant food shortages. So the climatic effects of even a relatively small nuclear war would be planet-wide. What about a larger-scale conflict? A U.S.-Russia war currently seems unlikely, but if it were to occur, hundreds or even thousands of nuclear weapons might be launched. The climatic consequences would be catastrophic: global average temperatures would drop as much as 12 degrees Fahrenheit (7 degrees Celsius) for up to several years — temperatures last seen during the great ice ages. Meanwhile, smoke and dust circulating in the stratosphere would darken the atmosphere enough to inhibit photosynthesis, causing disastrous crop failures, widespread famine and massive ecological disruption. The effect would be similar to that of the giant meteor believed to be responsible for the extinction of the dinosaurs. This time, we would be the dinosaurs. Many people are concerned about North Korea’s advancing missile capabilities. Is nuclear war likely in your opinion? At this writing, I think we are closer to a nuclear war than we have been since the early 1960s. In the North Korea case, both Kim Jong-un and President Trump are bullies inclined to escalate confrontations. President Trump lacks impulse control, and there are precious few checks on his ability to initiate a nuclear strike. We have to hope that our generals, both inside and outside the White House, can rein him in. North Korea would most certainly “lose” a nuclear war with the United States. But many millions would die, including hundreds of thousands of Americans currently living in South Korea and Japan (probable North Korean targets). Such vast damage would be wrought in Korea, Japan and Pacific island territories (such as Guam) that any “victory” wouldn’t deserve the name. Not only would that region be left with horrible suffering amongst the survivors; it would also immediately face famine and rampant disease. Radioactive fallout from such a war would spread around the world, including to the U.S. It has been more than 70 years since the last time a nuclear bomb was used in warfare. What would be the effects on the environment and on human health today? To my knowledge, most of the changes in nuclear weapons technology since the 1950s have focused on making them smaller and lighter, and making delivery systems more accurate, rather than on changing their effects on the environment or on human health. So-called “battlefield” weapons with lower explosive yields are part of some arsenals now — but it’s quite unlikely that any exchange between two nuclear powers would stay limited to these smaller, less destructive bombs.

#### Plan: The Hashemite Kingdom of Jordan ought to reduce data exclusivity for medicines.

Barqawi 19 “The access to medicine puzzle: scaling back the negative effects of the Jordan–US Free Trade Agreement” Laila Barqawi [Lecturer of University of Central Lancashire, Preston (UCLAN)]. Journal of Intellectual Property Law & Practice, Volume 14, Issue 9, September 2019, Pages 678–686, <https://doi.org/10.1093/jiplp/jpz080> SM

We now examine each of the JFDA’s recommendations:

1. ‘Shortening the term of data exclusivity for new chemical entity: neither TRIPS nor Jordan-US FTA request the five years.’14

As mentioned above, Jordan has gone beyond its TRIPS obligations to provide five years of protection for data exclusivity.15 To this effect, Jordan should repeal Article 8 of Jordan’s Law No 15 on Unfair Competition and Trade Secrets Law, which reduces data exclusivity protection to 3 years as per JUSFTA.

Jordan should continue its efforts to redefine what constitutes a New Chemical Entity (NCE), started with a circular dated 16 June 2009 by the JFDA’s director general:

A New Chemical Entity is the pharmaceutical product that contains active moiety or moieties that is responsible for physiological or pharmacological effect whereby no more than eighteen months have elapsed from the date of first registration of any of its ingredients (components) singly or collectively in any country in the world irrespective of any difference in, including but not limited to, type of salt, ester, isomer, complex or other derivative. A pharmaceutical product shall be considered to have the same chemical entity even if there is a difference in polymorph, metabolite, enantiomer, solvate, size of particles, formulation, combination, or method of use, pharmaceutical dosage form or concentration.16

Jordan has also excluded isomers and new crystalline forms from its NCE definition.17 Further suggestions on how to restrict the definition of an NCE are offered below.

2. ‘Start date of data exclusivity: a country can consider that the start date for granting data exclusivity is the first registration of the product worldwide.’18

Jordan’s start date of data exclusivity is the date of first registration of a medicine in Jordan. This is pursuant to Article 4.22 of JUSFTA. Jordan could amend its laws to reflect the above recommendation, as other countries have done. For instance, Peru’s Legislative Decree allows five-year term of data exclusivity protection ‘to start concurrently from the date the product is approved in other countries with high sanitary monitoring or approval regime.’19

Jordan could attempt to go farther in decreasing the existing negative effect of data exclusivity specifically as per the Chilean example by amending its national laws to limit pharmaceutical data protection availability to the year following grant of marketing approval, which means that the drugs’ test data not marketed within the year are not protected so that the period of protection for the pharmaceutical test data starts early.20

3. ‘JFDA should examine the test data protection conditions before granting data exclusivity: Then, JFDA can issue a protection certificate confirming complaint of data exclusivity conditions’21

The JFDA, in its capacity to register drugs,22 does not scrutinize test data protection and check whether it has been granted previously or not,23 instead relying on the applicant’s declaration.24 This recommendation requires specialized patent examiners that will be able to assess and examine test data protection conditions to grant data exclusivity.

4.‘Undisclosed test data: this should be defined in the registration criteria and JFDA should examine this condition by requesting a certificate from the originator company declaring that the submitted test data have not been published by any means or in any way. If the data become non-confidential, then the JFDA has the right to end the data exclusivity period.’25

The JFDA, currently, requests that clinical trials of phase III be published. This does not fulfil the requirement of data confidentiality under Article 39.3 of TRIPS.26 To this effect, JFDA grants five years of data exclusivity without checking ‘whether data submitted for regulatory approval has been previously disclosed.’27 The JFDA, however, assesses ‘the published data of Phase III’.28

Undisclosed clinical trial data is a universal issue and various initiatives have been put in place to tackle this.29 A study conducted recently has shown that only ‘57% of clinical trial results for a new drug are made publicly available’.30

Jordan may implement national laws to state that if a summary of clinical studies ‘or of information in scientific literature’ is publicly available then this is ‘sufficient to consider the test data as disclosed’.31 For instance, in accordance with a policy applied since January 2015 by the European Medicines Agency, the information about clinical studies cannot be considered ‘commercial confidential information’.32

While ‘clinical reports may not be used to support a MAA [marketing authorisation application]/ extensions or variations to a MAA nor to make any unfair commercial use of the clinical reports’,33 the restriction does not change the nature of the information as disclosed to the extent that it is publicly available.34 In this context, Jordan could argue that such disclosures are sufficient to negate data exclusivity to a drug.

5. ‘Considerable efforts: this should be defined in the registration criteria and JFDA should examine this condition by requesting evidence from the originator company to show that the generation of the submitted test data involved considerable efforts by reporting the cost and the period involved in the generation of the submitted test data.’35

Jordan does not examine the considerable effort element36 or have a definition37 for it despite it being a requirement of Article 39.3 TRIPS. The JFDA should define this and require the originator company to submit a declaration or certificate stating how conditions are fulfilled. This recommendation is straightforward and is in line with other countries policies such as Peru. Peru’s Legislative Decree protects cases if ‘generating it has involved considerable efforts’ and therefore the submission of undisclosed test data is ‘necessary to determine the safety and efficiency of such product’.38

This has been applied by Colombia’s Decree 2085 of 2002, which introduced seven exceptions. The most relevant to this recommendation states that ‘protection does not apply to: 1. Test data that are already in the public domain or have not involved considerable effort from the patent applicant to produce’.39

The benefit of fulfilling this recommendation is that Jordan will be able to ‘protect information against unfair commercial use’ as stipulated in Article 4.22 of JUSFTA,40 finally giving useful meaning to an ambiguous term. Achieving this will be in line with Article 39.3 of TRIPS as well as an advantage to use Article 4.22 of JUSFTA.

6. ‘Data exclusivity term should not extend beyond the patent term’. 41

A study on medicine affordability in Jordan concluded that medicine prices required review to provide inexpensive medication to the poor.42 Almost 32 per cent of the Jordanian population is not insured and will have to finance its own needs.43 A further issue highlighted in the study is that ‘the government is purchasing originator brands where lower-priced generics are available, which points to a lack of efficiency’.44

This clearly warrants a reviewing exercise by the JFDA to examine existing patented medications. JFDA should then produce a list of available alternatives.

JFDA has been implementing a ‘standing operating policy’ which welcomes generic applications from an innovator during the final year of protection to allow prompt registration of affordable generic drugs.45 This policy, if applied effectively, could also ensure that data exclusivity terms will not extend beyond the patent term.

7. ‘Allow registration of the generic product for the purposes of export’.46

This recommendation is straightforward and is self-explanatory. Israel, for example, has removed its trade barriers and now allows for a generic product to be registered during the exclusivity period of the originator product for the purposes of export.47

8. ‘Grounds for revocation of the data exclusivity period: such as anti-competitive practices of the originator company: high prices, delay in marketing the product more than six months from approval date, stop marketing for more than six months or insufficient marketing of the product’.48

As mentioned previously, JUSFTA is the only FTA which does not stipulate grounds for pre-grant or limit grounds of revocation.49 This should be defined within Jordan’s national legislation because the status quo means that originator companies will not be penalized for various unlawful acts. The author would add to the recommendation that grounds of revocation should include acts of inequality, misrepresentation and fraud, as per the Bahrain-US FTA (BUSFTA). 50

9. ‘Waive data exclusivity protection in cases of compulsory licensing: in case of the issuance of a compulsory license, the generic company is still required to submit clinical trials. Therefore, data exclusivity should be waived in such cases’. 51

Jordan’s regulations could provide that ‘data exclusivity shall have no effects against a compulsory licensee granted for any of the grounds established under the applicable patent law, or against persons authorized to undertake a governmental non-commercial use of the patented product’.52

Furthermore, Malaysia adopted similar stances to mitigate the effects of data exclusivity as per section 5 of Malaysia’s 2011 Directive of data exclusivity, entitled ‘Non-Application of Data Exclusivity’, according to which:

‘Nothing in the Data Exclusivity shall:

apply to situations where compulsory licenses have been issued or the implementation of any other measures consistent with the need to protect public health and ensure access to medicines for all; or

prevent the Government from taking any necessary action to protect public health, national security, non-commercial public use, national emergency, public health crisis or other extremely urgent circumstances declared by the government.’53

10. ‘Waive data exclusivity in cases of emergency and public interest.’54

Colombia succeeded in including a clause in its Decree 2085 of 2002 which states that ‘protection does not apply to: […] 4. Information whose disclosure is necessary to protect the public interest’.55

This is an important waiver to include in Jordanian legislation because access to medicine is a human right, as stipulated within various international documents, such as the Universal Declaration of Human Rights 1948 at Article 25,56 the preamble57 and Article 158 of 1946 Constitution of the World Health Organisation and the 1966 International Covenant on Economic, Social, and Cultural Rights.59 It is arguable that TRIPS and TRIPS-plus clauses are in conflict with human rights clauses; however, this issue is beyond the scope of this article.

11. ‘Waive data exclusivity for products intended for the treatment of life-threatening diseases.’60

The above waivers in the JFDA’s recommendations could be included in Jordan’s national legislation laws as exceptions to limit the effects of data exclusivity.61

Similar waivers are embodied within the Chilean legislation, which excluded certain areas from the scope of protection. One example is Article 91 of the Chilean Industrial Property Law, which states:

The protection of this Paragraph shall not apply when:

[…]

(b) For reasons of public health, national security, non-commercial public use, national emergency or other circumstances of extreme urgency declared by the competent authority, ending the protection referred to in Article 89 shall be justified.

#### Reducing data exclusivity revives the generic market which boosts accessible healthcare and the economy.

Alawi and Alabbadi 15 Investigating the Effect of Data Exclusivity on the Pharmaceutical Sector in Jordan Rand Alawi [Pharmacist, MBA, Faculty of Business, The University of Jordan] and Ibrahim Alabbadi [ Associate Professor, MBA, PhD, Biopharmaceutics and Clinical Pharmacy Department, Faculty of Pharmacy, The University of Jordan Jordan Journal of Pharmaceutical Sciences, Volume 8, No. 2, 2015 <https://journals.ju.edu.jo/JJPS/article/view/9377/4480> SM

On the other hand, medicines prices have continued to rise in Jordan after IP rules, but Jordan was not able to use TRIPS safeguards to reduce their cost. Also, Jordanian generic companies have not developed any new medicines since the Free Trade Agreement (FTA). While new medicines were frequently unavailable or unaffordable in Jordan(14).

The research-based pharmaceutical industry claims that data exclusivity provides incentives for companies to generate the necessary data, since without marketing exclusivity, brand-name companies would not want to conduct expensive preclinical tests and clinical trials(15). The argument that data exclusivity laws will encourage the introduction of new medicines into the market betrays a misunderstanding of their implications. In fact, there is a possibility that data exclusivity would actually provide incentives to delay the entry of new products for multinational companies would prefer to keep prices high in developed markets by delaying their entry into the developing world at lower prices(16).

The tension between patent law and public health concerns such as access to medicine has long been an issue of much debate. The requirement of patent protection for pharmaceutical products and various other relevant provisions under the TRIPS agreement signifies this tension as they have created considerable difficulties for developing countries acquiring the medicines needed to address their public health concerns, despite the flexibilities that had been built into the agreement. Hence, the Doha Declaration on the TRIPS agreement and public health has been adopted in 2001 to address this issue, hoping to provide relief to this tension between public health policies and intellectual property rights legislations. Nevertheless, this tension seems to have been further heightened with the proliferation of the FTAs, through which developed countries such as the US and the EU have introduced TRIPS-plus obligations that go beyond the minimum standards set by TRIPS, further exacerbating the tension. Over the years, these TRIPSplus FTAs have been much criticized for their possible conflict with TRIPS norms and their potential negative impact on access to medicines.

Data exclusivity did not affect only Jordan, but also its export market, as the local Jordanian manufacturers will be out of their export markets at least for 7 years;(5 years protection due to data exclusivity, 1 year registration time in Jordan and at least one year registration in export market).

One of the perceived gains of data exclusivity is an increase in foreign direct investment in the pharmaceutical sector and the arrival of newer medicines for Jordanian patients, but in reality this did not happen, most licensing agreements in effect today were signed before 1999, and transfer little know-how to local manufacturers. Furthermore, Egypt, in contrast to Jordan, has no TRIPS-Plus provisions in its IPR law yet still enjoys a significant amount of foreign investment in its pharmaceuticals industry.

Conclusion

This study indicated that data exclusivity for the pharmaceutical products seems likely to generate negative impacts on Jordan in terms of higher drug prices. It is also suggested that data exclusivity, on one hand, would have no relation whatsoever to the rate of R&D and foreign investment, but, on the other hand, is likely to impede the industrial development process of the country. Additional expenditure for medicine with no generic equivalent was resulted from the enforcement of data exclusivity.

#### FW—

Standard is consistency with hedonic act utilitarianism.

#### Evolution – only a naturalistic understanding of the world explains it.

**Lutz and Lenman 18.** Lutz, Matthew and Lenman, James, "Moral Naturalism", The Stanford Encyclopedia of Philosophy (Fall 2018 Edition), Edward N. Zalta (ed.), URL = <https://plato.stanford.edu/archives/fall2018/entries/naturalism-moral/>. //Massa

The second argument against moral non-naturalism concerns moral epistemology. **According to**evolutionary debunking arguments**, our moral beliefs are products of evolution**, and this evolutionary etiology of our moral beliefs serves to undermine them. Exactly why evolution debunks our moral beliefs is a matter of substantial controversy, and the debunking argument has been interpreted in a number of different ways (Vavova 2015). Sharon Street, whose statement of the evolutionary debunking argument has been highly influential, holds that debunking arguments make a problem for all versions of moral realism—her paper is entitled “A Darwinian Dilemma for Realist Theories of Value.” But according to another popular line of argument, these debunking arguments are only problems for moral non-naturalism. **The fundamental worry is that our moral beliefs are the product of evolutionary facts rather than moral facts**. If this is so, **this would serve to debunk our moral beliefs, either because it is a necessary condition on justified belief that you take your beliefs to be explained by the facts in question** (Joyce 2006, Ch. 6; Bedke 2009; Lutz forthcoming) **or else because the non-naturalist is left with no way to explain the reliability of our moral beliefs** (Enoch 2009, Schechter 2017).

**But if moral naturalism is true, the realist needn’t grant the skeptic’s premise** that our moral beliefs are the product of evolutionary facts rather than moral facts. **If moral facts are natural, then we needn’t see moral facts as being contrary to natural, evolutionary facts.** The **moral facts might be among these evolutionary facts that explain our moral beliefs.** If, for instance, **to be good** just **is** to be **conducive to social cooperation, then an evolutionary** account that says that we judge things to be good only when they are conducive to social cooperation **would not debunk any of our beliefs about goodness. This** account **would**, instead, **provide a deep vindication of those beliefs** (Copp 2008).

#### Pleasure and pain are intrinsic value and disvalue – everything else regresses – robust neuroscience proves

Blum et al. 18 Kenneth Blum, 1Department of Psychiatry, Boonshoft School of Medicine, Dayton VA Medical Center, Wright State University, Dayton, OH, USA 2Department of Psychiatry, McKnight Brain Institute, University of Florida College of Medicine, Gainesville, FL, USA 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA 5Department of Precision Medicine, Geneus Health LLC, San Antonio, TX, USA 6Department of Addiction Research & Therapy, Nupathways Inc., Innsbrook, MO, USA 7Department of Clinical Neurology, Path Foundation, New York, NY, USA 8Division of Neuroscience-Based Addiction Therapy, The Shores Treatment & Recovery Center, Port Saint Lucie, FL, USA 9Institute of Psychology, Eötvös Loránd University, Budapest, Hungary 10Division of Addiction Research, Dominion Diagnostics, LLC. North Kingston, RI, USA 11Victory Nutrition International, Lederach, PA., USA 12National Human Genome Center at Howard University, Washington, DC., USA, Marjorie Gondré-Lewis, 12National Human Genome Center at Howard University, Washington, DC., USA 13Departments of Anatomy and Psychiatry, Howard University College of Medicine, Washington, DC US, Bruce Steinberg, 4Division of Applied Clinical Research & Education, Dominion Diagnostics, LLC, North Kingstown, RI, USA, Igor Elman, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, David Baron, 3Department of Psychiatry and Behavioral Sciences, Keck Medicine University of Southern California, Los Angeles, CA, USA, Edward J Modestino, 14Department of Psychology, Curry College, Milton, MA, USA, Rajendra D Badgaiyan, 15Department Psychiatry, Cooper University School of Medicine, Camden, NJ, USA, Mark S Gold 16Department of Psychiatry, Washington University, St. Louis, MO, USA, “Our evolved unique pleasure circuit makes humans different from apes: Reconsideration of data derived from animal studies”, U.S. Department of Veterans Affairs, 28 February 2018, accessed: 19 August 2020, <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6446569/>, R.S.

**Pleasure** is not only one of the three primary reward functions but it also **defines reward.** As homeostasis explains the functions of only a limited number of rewards, the principal reason why particular stimuli, objects, events, situations, and activities are rewarding may be due to pleasure. This applies first of all to sex and to the primary homeostatic rewards of food and liquid and extends to money, taste, beauty, social encounters and nonmaterial, internally set, and intrinsic rewards. Pleasure, as the primary effect of rewards, drives the prime reward functions of learning, approach behavior, and decision making and provides the **basis for hedonic theories** of reward function. We are attracted by most rewards and exert intense efforts to obtain them, just because they are enjoyable [10].

Pleasure is a passive reaction that derives from the experience or prediction of reward and may lead to a long-lasting state of happiness. The word happiness is difficult to define. In fact, just obtaining physical pleasure may not be enough. One key to happiness involves a network of good friends. However, it is not obvious how the higher forms of satisfaction and pleasure are related to an ice cream cone, or to your team winning a sporting event. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure [14].

Pleasure as a hallmark of reward is sufficient for defining a reward, but it may not be necessary. A reward may generate positive learning and approach behavior simply because it contains substances that are essential for body function. When we are hungry, we may eat bad and unpleasant meals. A monkey who receives hundreds of small drops of water every morning in the laboratory is unlikely to feel a rush of pleasure every time it gets the 0.1 ml. Nevertheless, with these precautions in mind, we may define any stimulus, object, event, activity, or situation that has the potential to produce pleasure as a reward. In the context of reward deficiency or for disorders of addiction, homeostasis pursues pharmacological treatments: drugs to treat drug addiction, obesity, and other compulsive behaviors. The theory of allostasis suggests broader approaches - such as re-expanding the range of possible pleasures and providing opportunities to expend effort in their pursuit. [15]. It is noteworthy, the first animal studies eliciting approach behavior by electrical brain stimulation interpreted their findings as a discovery of the brain’s pleasure centers [16] which were later partly associated with midbrain dopamine neurons [17–19] despite the notorious difficulties of identifying emotions in animals.

Evolutionary theories of pleasure: The love connection BO:D

Charles Darwin and other biological scientists that have examined the biological evolution and its basic principles found various mechanisms that steer behavior and biological development. Besides their theory on natural selection, it was particularly the sexual selection process that gained significance in the latter context over the last century, especially when it comes to the question of what makes us “what we are,” i.e., human. However, the capacity to sexually select and evolve is not at all a human accomplishment alone or a sign of our uniqueness; yet, we humans, as it seems, are ingenious in fooling ourselves and others–when we are in love or desperately search for it.

It is well established that modern biological theory conjectures that **organisms are** the **result of evolutionary competition.** In fact, Richard Dawkins stresses gene survival and propagation as the basic mechanism of life [20]. Only genes that lead to the fittest phenotype will make it. It is noteworthy that the phenotype is selected based on behavior that maximizes gene propagation. To do so, the phenotype must survive and generate offspring, and be better at it than its competitors. Thus, the ultimate, distal function of rewards is to increase evolutionary fitness by ensuring the survival of the organism and reproduction. It is agreed that learning, approach, economic decisions, and positive emotions are the proximal functions through which phenotypes obtain other necessary nutrients for survival, mating, and care for offspring.

Behavioral reward functions have evolved to help individuals to survive and propagate their genes. Apparently, people need to live well and long enough to reproduce. Most would agree that homo-sapiens do so by ingesting the substances that make their bodies function properly. For this reason, foods and drinks are rewards. Additional rewards, including those used for economic exchanges, ensure sufficient palatable food and drink supply. Mating and gene propagation is supported by powerful sexual attraction. Additional properties, like body form, augment the chance to mate and nourish and defend offspring and are therefore also rewards. Care for offspring until they can reproduce themselves helps gene propagation and is rewarding; otherwise, many believe mating is useless. According to David E Comings, as any small edge will ultimately result in evolutionary advantage [21], additional reward mechanisms like novelty seeking and exploration widen the spectrum of available rewards and thus enhance the chance for survival, reproduction, and ultimate gene propagation. These functions may help us to obtain the benefits of distant rewards that are determined by our own interests and not immediately available in the environment. Thus the distal reward function in gene propagation and evolutionary fitness defines the proximal reward functions that we see in everyday behavior. That is why foods, drinks, mates, and offspring are rewarding.

There have been theories linking pleasure as a required component of health benefits salutogenesis, (salugenesis). In essence, under these terms, pleasure is described as a state or feeling of happiness and satisfaction resulting from an experience that one enjoys. Regarding pleasure, it is a double-edged sword, on the one hand, it promotes positive feelings (like mindfulness) and even better cognition, possibly through the release of dopamine [22]. But on the other hand, pleasure simultaneously encourages addiction and other negative behaviors, i.e., motivational toxicity. It is a complex neurobiological phenomenon, relying on reward circuitry or limbic activity. It is important to realize that through the “Brain Reward Cascade” (BRC) endorphin and endogenous morphinergic mechanisms may play a role [23]. While natural rewards are essential for survival and appetitive motivation leading to beneficial biological behaviors like eating, sex, and reproduction, crucial social interactions seem to further facilitate the positive effects exerted by pleasurable experiences. Indeed, experimentation with addictive drugs is capable of directly acting on reward pathways and causing deterioration of these systems promoting hypodopaminergia [24]. Most would agree that pleasurable activities can stimulate personal growth and may help to induce healthy behavioral changes, including stress management [25]. The work of Esch and Stefano [26] concerning the link between compassion and love implicate the brain reward system, and pleasure induction suggests that social contact in general, i.e., love, attachment, and compassion, can be highly effective in stress reduction, survival, and overall health.

Understanding the role of neurotransmission and pleasurable states both positive and negative have been adequately studied over many decades [26–37], but comparative anatomical and neurobiological function between animals and homo sapiens appear to be required and seem to be in an infancy stage.

Finding happiness is different between apes and humans

As stated earlier in this expert opinion one key to happiness involves a network of good friends [38]. However, it is not entirely clear exactly how the higher forms of satisfaction and pleasure are related to a sugar rush, winning a sports event or even sky diving, all of which augment dopamine release at the reward brain site. Recent multidisciplinary research, using both humans and detailed invasive brain analysis of animals has discovered some critical ways that the brain processes pleasure.

Remarkably, there are pathways for ordinary liking and pleasure, which are limited in scope as described above in this commentary. However, there are **many brain regions**, often termed hot and cold spots, that significantly **modulate** (increase or decrease) our **pleasure or** even produce **the opposite**

of pleasure— that is disgust and fear [39]. One specific region of the nucleus accumbens is organized like a computer keyboard, with particular stimulus triggers in rows— producing an increase and decrease of pleasure and disgust. Moreover, the cortex has unique roles in the cognitive evaluation of our feelings of pleasure [40]. Importantly, the interplay of these multiple triggers and the higher brain centers in the prefrontal cortex are very intricate and are just being uncovered.

Desire and reward centers

It is surprising that many different sources of pleasure activate the same circuits between the mesocorticolimbic regions (Figure 1). Reward and desire are two aspects pleasure induction and have a very widespread, large circuit. Some part of this circuit distinguishes between desire and dread. The so-called pleasure circuitry called “REWARD” involves a well-known dopamine pathway in the mesolimbic system that can influence both pleasure and motivation.

In simplest terms, the well-established mesolimbic system is a dopamine circuit for reward. It starts in the ventral tegmental area (VTA) of the midbrain and travels to the nucleus accumbens (Figure 2). It is the cornerstone target to all addictions. The VTA is encompassed with neurons using glutamate, GABA, and dopamine. The nucleus accumbens (NAc) is located within the ventral striatum and is divided into two sub-regions—the motor and limbic regions associated with its core and shell, respectively. The NAc has spiny neurons that receive dopamine from the VTA and glutamate (a dopamine driver) from the hippocampus, amygdala and medial prefrontal cortex. Subsequently, the NAc projects GABA signals to an area termed the ventral pallidum (VP). The region is a relay station in the limbic loop of the basal ganglia, critical for motivation, behavior, emotions and the “Feel Good” response. This defined system of the brain is involved in all addictions –substance, and non –substance related. In 1995, our laboratory coined the term “Reward Deficiency Syndrome” (RDS) to describe genetic and epigenetic induced hypodopaminergia in the “Brain Reward Cascade” that contribute to addiction and compulsive behaviors [3,6,41].

Furthermore, ordinary “liking” of something, or pure pleasure, is represented by small regions mainly in the limbic system (old reptilian part of the brain). These may be part of larger neural circuits. In Latin, hedus is the term for “sweet”; and in Greek, hodone is the term for “pleasure.” Thus, the word Hedonic is now referring to various subcomponents of pleasure: some associated with purely sensory and others with more complex emotions involving morals, aesthetics, and social interactions. The capacity to have pleasure is part of being healthy and may even extend life, especially if linked to optimism as a dopaminergic response [42].

Psychiatric illness often includes symptoms of an abnormal inability to experience pleasure, referred to as anhedonia. A negative feeling state is called dysphoria, which can consist of many emotions such as pain, depression, anxiety, fear, and disgust. Previously many scientists used animal research to uncover the complex mechanisms of pleasure, liking, motivation and even emotions like panic and fear, as discussed above [43]. However, as a significant amount of related research about the specific brain regions of pleasure/reward circuitry has been derived from invasive studies of animals, these cannot be directly compared with subjective states experienced by humans.

In an attempt to resolve the controversy regarding the causal contributions of mesolimbic dopamine systems to reward, we have previously evaluated the three-main competing explanatory categories: “liking,” “learning,” and “wanting” [3]. That is, dopamine may mediate (a) liking: the hedonic impact of reward, (b) learning: learned predictions about rewarding effects, or (c) wanting: the pursuit of rewards by attributing incentive salience to reward-related stimuli [44]. We have evaluated these hypotheses, especially as they relate to the RDS, and we find that the incentive salience or “wanting” hypothesis of dopaminergic functioning is supported by a majority of the scientific evidence. Various neuroimaging studies have shown that anticipated behaviors such as sex and gaming, delicious foods and drugs of abuse all affect brain regions associated with reward networks, and may not be unidirectional. Drugs of abuse enhance dopamine signaling which sensitizes mesolimbic brain mechanisms that apparently evolved explicitly to attribute incentive salience to various rewards [45].

Addictive substances are voluntarily self-administered, and they enhance (directly or indirectly) dopaminergic synaptic function in the NAc. This activation of the brain reward networks (producing the ecstatic “high” that users seek). Although these circuits were initially thought to encode a set point of hedonic tone, it is now being considered to be far more complicated in function, also encoding attention, reward expectancy, disconfirmation of reward expectancy, and incentive motivation [46]. The argument about addiction as a disease may be confused with a predisposition to substance and nonsubstance rewards relative to the extreme effect of drugs of abuse on brain neurochemistry. The former sets up an individual to be at high risk through both genetic polymorphisms in reward genes as well as harmful epigenetic insult. Some Psychologists, even with all the data, still infer that addiction is not a disease [47]. Elevated stress levels, together with polymorphisms (genetic variations) of various dopaminergic genes and the genes related to other neurotransmitters (and their genetic variants), and may have an additive effect on vulnerability to various addictions [48]. In this regard, Vanyukov, et al. [48] suggested based on review that whereas the gateway hypothesis does not specify mechanistic connections between “stages,” and does not extend to the risks for addictions the concept of common liability to addictions may be more parsimonious. The latter theory is grounded in genetic theory and supported by data identifying common sources of variation in the risk for specific addictions (e.g., RDS). This commonality has identifiable neurobiological substrate and plausible evolutionary explanations.

Over many years the controversy of dopamine involvement in especially “pleasure” has led to confusion concerning separating motivation from actual pleasure (wanting versus liking) [49]. We take the position that animal studies cannot provide real clinical information as described by self-reports in humans. As mentioned earlier and in the abstract, on November 23rd, 2017, evidence for our concerns was discovered [50]

In essence, although nonhuman primate brains are similar to our own, the disparity between other primates and those of human cognitive abilities tells us that surface similarity is not the whole story. Sousa et al. [50] small case found various differentially expressed genes, to associate with pleasure related systems. Furthermore, the dopaminergic interneurons located in the human neocortex were absent from the neocortex of nonhuman African apes. Such differences in neuronal transcriptional programs may underlie a variety of neurodevelopmental disorders.

In simpler terms, the system controls the production of dopamine, a chemical messenger that plays a significant role in pleasure and rewards. The senior author, Dr. Nenad Sestan from Yale, stated: “Humans have evolved a dopamine system that is different than the one in chimpanzees.” This may explain why the behavior of humans is so unique from that of non-human primates, even though our brains are so surprisingly similar, Sestan said: “It might also shed light on why people are vulnerable to mental disorders such as autism (possibly even addiction).” Remarkably, this research finding emerged from an extensive, multicenter collaboration to compare the brains across several species. These researchers examined 247 specimens of neural tissue from six humans, five chimpanzees, and five macaque monkeys. Moreover, these investigators analyzed which genes were turned on or off in 16 regions of the brain. While the differences among species were subtle, **there was** a **remarkable contrast in** the **neocortices**, specifically in an area of the brain that is much more developed in humans than in chimpanzees. In fact, these researchers found that a gene called tyrosine hydroxylase (TH) for the enzyme, responsible for the production of dopamine, was expressed in the neocortex of humans, but not chimpanzees. As discussed earlier, dopamine is best known for its essential role within the brain’s reward system; the very system that responds to everything from sex, to gambling, to food, and to addictive drugs. However, dopamine also assists in regulating emotional responses, memory, and movement. Notably, abnormal dopamine levels have been linked to disorders including Parkinson’s, schizophrenia and spectrum disorders such as autism and addiction or RDS.

Nora Volkow, the director of NIDA, pointed out that one alluring possibility is that the neurotransmitter dopamine plays a substantial role in humans’ ability to pursue various rewards that are perhaps months or even years away in the future. This same idea has been suggested by Dr. Robert Sapolsky, a professor of biology and neurology at Stanford University. Dr. Sapolsky cited evidence that dopamine levels rise dramatically in humans when we anticipate potential rewards that are uncertain and even far off in our futures, such as retirement or even the possible alterlife. This may explain what often motivates people to work for things that have no apparent short-term benefit [51]. In similar work, Volkow and Bale [52] proposed a model in which dopamine can favor NOW processes through phasic signaling in reward circuits or LATER processes through tonic signaling in control circuits. Specifically, they suggest that through its modulation of the orbitofrontal cortex, which processes salience attribution, dopamine also enables shilting from NOW to LATER, while its modulation of the insula, which processes interoceptive information, influences the probability of selecting NOW versus LATER actions based on an individual’s physiological state. This hypothesis further supports the concept that disruptions along these circuits contribute to diverse pathologies, including obesity and addiction or RDS.