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All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines

The USA continues to impose TRIPS-plus rules on developing countries, thus preventing poor people from accessing inexpensive, generic medicines. Jordan was required under the terms of its WTO accession package and its free trade agreement (FTA) with the USA to introduce TRIPS-plus rules. Medicine prices have increased drastically, and TRIPS-plus rules were partly responsible for this increase. Furthermore, stricter levels of intellectual property protection have conferred few benefits with respect to foreign direct investment, domestic research and development, or accelerating introduction of new, effective medicines. Medicine prices will continue to rise in Jordan, but the country will be unable to use TRIPS safeguards to reduce their cost. Other developing countries implementing or considering FTAs with TRIPS-plus rules should consider the consequences for public health.

Summary

Since enactment of the TRIPS (Trade Related Aspects of Intellectual Property Rights) Agreement in 1995, the USA has imposed progressively higher levels of intellectual property protection (TRIPS-plus rules) on developing countries, which undermines access to affordable medicines. The US-Jordan free trade agreement (FTA) introduced a rigid framework of TRIPS-plus rules that the USA continues to impose on developing countries, although subsequent FTAs have even stricter levels of intellectual property (IP) protection. Jordan was also required to increase the level of IP protection under the terms of its accession to the World Trade Organization (WTO).

Medicine prices in Jordan have increased 20 per cent since 2001. Higher medicine prices are now threatening the financial sustainability of government public health programmes.¹ TRIPS-plus rules contributed to the increase in medicine prices, and will delay or prevent use of public health safeguards to reduce the price of new medicines in the future. In particular, data exclusivity has delayed generic competition for 79 per cent of medicines newly launched by 21 multinational pharmaceutical companies between 2002 and mid-2006, that otherwise would have been available in an inexpensive, generic form. Data exclusivity is a TRIPS-plus rule that creates a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines for five or more years, even when no patent exists.

Additional expenditures for medicines with no generic competitor, as a result of enforcement of data exclusivity by multinational drug companies, were between \$6.3m and \$22.04m. These expenditures have required that both public health system and individuals pay higher prices for many new medicines that are needed to treat serious non-communicable diseases (NCDs), such as hypertension, asthma, diabetes, and mental illness. For example, new medicines to treat diabetes and heart disease cost anywhere from two to six times more in Jordan than in Egypt, where there are no TRIPS-plus barriers.

Furthermore, there have been no benefits from introducing strict IP rules in Jordan, despite positive assertions made by the United States Trade Representative (USTR) and other US government officials ever since the agreement was enforced. In particular, there has been nearly no foreign direct investment (FDI) by drug companies into Jordan since 2001 to synthesise or manufacture medicines in partnership with local generics companies, which also has serious implications for public health. Patients in Jordan pay from two to ten times more for some new medicines compared with patients in Egypt, where new medicines are manufactured locally through licensing agreements and partnerships. The only FDI into Jordan by multinational drug companies has been to expand scientific offices, which use aggressive sales tactics to ensure that expensive patented medicines are used instead of inexpensive generics.

Furthermore, stricter intellectual property rules have not encouraged Jordanian generic companies to engage in research and development (R&D) for medicines since passage of the FTA; these companies have not

developed any new medicines. Finally, new product launches in Jordan are only a fraction of total product launches in the USA and the EU; many new medicines launched in Jordan are exorbitantly priced and unaffordable for ordinary people, and few or no units of these recently launched medicines have actually been purchased on the local market, due to their cost.

In the future, an increasing burden of non-communicable diseases will require even greater expenditure on health care and medicines. Higher medicine prices will put a strain on the public health system, and for those Jordanians without health insurance, the higher prices will require significant out-of-pocket expenditure that disproportionately harms the poorest. Yet Jordan has fewer options now that TRIPS-plus rules are in place, and the government will be unable to mitigate higher medicine prices through the use of public health safeguards.

To reduce the burden of the US TRIPS-plus agenda and its effects on access to medicines, Oxfam recommends:

Jordan

- Resist entry into the Patent Co-operation Treaty (PCT);
- Introduce exceptions to data exclusivity that reduce its impact on generic competition;
- Severely restrict scope of patentability in its IP law, and in particular, consider replicating India's definition of scope of patentability;
- Repeal its stringent restrictions on parallel importation

USA

- Stop coercing developing countries into adopting TRIPS-plus IP protections through bilateral and regional trade agreements and through other forms of pressure and inducement.

Other developing countries

- Prevent introduction of TRIPS-plus rules in national legislation, and fully implement TRIPS safeguards to ensure production of generic medicines for domestic consumption and for export to other developing countries.

Introduction

As part of the global trade agreement negotiated in the Uruguay Round, WTO member countries signed up to the Trade Related Aspects of Intellectual Property Rights (TRIPS) Agreement in 1994. The TRIPS Agreement sets forth minimum standards of intellectual property protection that WTO members must include in their domestic laws. TRIPS is recognized as having harmonized intellectual property rules at a very high standard worldwide.

The imposition of a higher level of intellectual property protection has created new burdens for developing countries.² Least-developed countries were permitted a longer time to implement the TRIPS Agreement, which has recently been extended until 2016. Studies have raised questions as to whether the protections required under TRIPS are appropriate for countries at lower levels of development, and whether the poorest countries will be ready by 2016 to institute such protections.

To balance the enhanced protection given to innovators, TRIPS contains carve-outs for protection of the public interest. For instance, it contains public health safeguards which countries can use to promote access to affordable medicines. In 2001, WTO members unanimously confirmed the right of all countries to use the TRIPS safeguards to promote public health, when they agreed to the “Doha Declaration on the TRIPS Agreement and Public Health.”

In addition to the new burdens already imposed by the TRIPS Agreement, the USA has pushed developing countries to introduce even higher levels of intellectual property (IP) protection – known as ‘TRIPS-plus rules’ - through a variety of mechanisms. The USA has negotiated TRIPS-plus rules as part of bilateral and regional free trade agreements (FTAs) with developing countries.³ The USA has pressured some developing countries to accept TRIPS-plus rules as part of the concessions required of countries newly acceding to the WTO. And the USA uses a variety of unilateral pressures to push for higher IP protection – including trade sanctions, reduction in foreign assistance, withdrawal of trade preferences, and the use of technical assistance programmes.

There is broad agreement that high levels of intellectual property protection can have damaging implications for public health, because the rules tend to increase prices for medicines by restricting generic production of medicines, and by preventing developing countries from using safeguards to provide affordable medicines to their population. TRIPS-plus rules exacerbate this problem by further restricting generic competition and government action. This is a view that has been articulated by developing-country trade negotiators

4 ***All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines***, Oxfam Briefing Paper, March 2007

and Ministers of Health,⁴ Members of the US Congress,⁵ inter-governmental organisations,⁶ and civil-society groups⁷ for many years.

Competition from generic drug producers is the main proven method to reduce the price of medicines in a sustainable manner. Generic competition is also crucial to models of price regulations for pharmaceuticals, and especially those that apply some form of reference pricing.⁸ Numerous studies forecast that TRIPS-plus rules will result in increases in medicine prices over time, putting a strain on health budgets and leaving poor people with catastrophic out-of-pocket expenses for medicines.⁹

Under the terms of its accession to the WTO in 2000, Jordan was required to introduce TRIPS-plus provisions in its national patent laws. Shortly thereafter, the US and Jordan negotiated an FTA. It was the first FTA to introduce a new framework of TRIPS-plus rules. Subsequent FTAs negotiated between the USA and other countries expanded the TRIPS-plus measures imposed on trading partners.

Since Jordan was effectively the first country to agree to TRIPS-plus rules, it makes a very useful case study to examine the costs and benefits, if any, of these measures. This paper attempts to examine the impact of TRIPS-plus rules on access to medicines in Jordan. In addition, this paper evaluates the claims of the benefits of TRIPS-plus rules for Jordan. Overall, Oxfam believes that TRIPS-plus rules have created significant new costs for Jordan that will threaten public health and access to medicines. At the same time, we find that the claimed benefits of TRIPS-plus measures have not emerged.¹⁰

1 Jordan's public health profile

Jordan is a lower middle-income country, with a population of about six million and a per-capita income of approximately \$2,450. Approximately one-third of the population lives below the poverty line.¹¹ In Jordan, health outcomes for poor people are much worse than in the overall population. According to a 2004 World Bank study, "the poor are exposed to greater health risks and have significantly lower access to health services than the rich - leading to higher infant and child mortality rates, greater childhood malnutrition, a higher incidence of disability, and higher fertility rates".¹² A recent National Poverty Alleviation strategy noted that "poverty is on the increase in Jordan", and "could be anywhere between 15 to 30 per cent".¹³ Health-care financing for the poorest 20 per cent is "highly regressive", with this group paying proportionately more out-of-pocket for out-patient care.¹⁴ Only 60 per cent of Jordanians have access to health insurance, resulting in out-of-

5 *All costs, no benefits: How TRIPS-plus intellectual property rules in the US-Jordan FTA affect access to medicines*, Oxfam Briefing Paper, March 2007

pocket payments among the uninsured that are double the payments of the insured.¹⁵

Although Jordan has a low prevalence of HIV and AIDS, non-communicable diseases (NCDs) have become a major cause of death and disability in Jordan. Cardiovascular diseases and cancer are the leading causes of death in the country.¹⁶ Recent estimates indicate that new diabetes cases will drastically outstrip population growth, growing from 195,000 cases (2000 estimate) to 680,000 by 2030.¹⁷

2 TRIPS-plus rules in Jordan's intellectual property law

Like most developing countries, Jordan relied heavily on generic medicines, until the country implemented the TRIPS Agreement in 2000. The new intellectual property protections introduced in the TRIPS Agreement tend to increase the price of new medicines, which keeps them out of reach for all but the elite in developing countries.¹⁸

Despite these issues, Jordan immediately entered into FTA negotiations with the USA that would introduce even higher levels of intellectual property protection. In December 2001, Jordan became the fourth country to implement an FTA with the USA, and was the first Arab country to sign an FTA. For the USA, the FTA is part of a wider US-Middle East Free Trade Initiative, which seeks to create a free-trade zone across the Middle East and North Africa. Since the US-Jordan FTA, the US has entered into FTAs with Morocco, Oman, and Bahrain¹⁹, each of which includes stricter levels of intellectual property protection.²⁰

TRIPS-plus rules incorporated into Jordan's IP law were a condition of Jordan's accession to the WTO, and were also imposed through the US FTA (See Box 1).

Box 1: Health-related TRIPS-plus rules and obligations in Jordan's IP code

Patent Law No. 32 (1999) and Patent Law No. 71 (2001)^{*}

- Forbids parallel importation without patent holder's prior consent.

Unfair Competition Law and Trade Secrets Law No. 15 (2000)^{**}

- Introduces five years of data exclusivity that commences on the medicine's date of registration in Jordan²¹

US-Jordan FTA (2001)

- Patent linkage (notification only)²²
- An additional three years of data exclusivity (beyond five years) for new uses of already known chemical entities
- Compulsory licensing permitted only to remedy an anti-competitive practice, in case of public non-commercial use, or in the case of national emergency or other situations of extreme urgency.
- Patent extension for unreasonable curtailment of patent term as a result of a delay in the marketing approval process
- *Best efforts* to accede to or ratify the Patent Cooperation Treaty (PCT)^{**}

* Patent Law No. 71 amends Patent Law No. 32 in accordance with the FTA, and should be read jointly with that law.

**Data exclusivity was a requirement of Jordan's accession to the WTO

***As of February 2007, Jordan had not yet acceded to the Patent Cooperation Treaty (PCT).

3 How TRIPS-plus rules have restricted generic competition in Jordan since 2001

Since the US-Jordan FTA was formally enacted on 17 December 2001,²³ 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

Many 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 firm, 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.²⁴

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;²⁵ (2) many medicines without a generic equivalent would have qualified for little or no patent protection in Jordan due to the original patent filing date;²⁶ and (3) pharmaceutical companies concluded that data exclusivity effectively prevents generic competitors from entering the market for five 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 five-year market monopoly for medicines that were launched onto the Jordanian market by mid-2006.²⁷

Box 2: What is data exclusivity?

Data exclusivity creates a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines for five 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. Studies indicate that enforcing data exclusivity results in significant price increases for medicines.²⁸

Data exclusivity prohibits generic competition for a specified period of time. The alternative would be for generic manufacturers to repeat clinical trials of drugs to prove their safety and efficacy. However, doing this would violate medical ethics because clinical trial methodologies would require some patients be given placebos. Giving placebos when the safety and clinical validity of the medicine being tested is already established is unethical.

Recently, 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 eight and ten years to get a medicine to the market from the time the patent application is filed. Data exclusivity will ensure that even if a patent application is rejected, the pharmaceutical company can secure at least five years of monopoly protection.²⁹

B. 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 five-year market monopoly.³⁰

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 (see Appendix 1 for methodology). Jordanian generic manufacturers interviewed by Oxfam expressed frustration at the data exclusivity law because multinational pharmaceutical companies can rely upon data exclusivity to preclude generic competition.³¹ 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 intellectual property 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.³²

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 five 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 due to generic competition are unrestricted). (See Table 1.)

Table 1: Relative prices between medicines with no generic competition in Jordan (due to enforcement of data exclusivity) and the price of the lowest-priced generic equivalent in Egypt

Country (company)	Active Pharmaceutical Ingredient (dosage)	Medical use	Price per Unit (in Jordanian dinars at prevailing exchange rate)	Jordan price compared to Egyptian price
Egypt (local generics manufacturer)	Metformin (850 mg)	Anti-diabetic	.02	800%
Jordan (Merck)	Metformin (500 mg)		.16	
Egypt (local generics manufacturer)	Atenolol (100 mg)	Anti-hypertensive	.03	367%
Jordan (Kleva)	Atenolol (100 mg)		.11	
Egypt (local generics manufacturer)	Rosiglitazone maleate (4 mg)	Anti-diabetic	.40	167%
Jordan (Glaxo SmithKline)	Rosiglitazone maleate (2 mg)		.67	
Egypt (local generics manufacturer)	Simvastatin (20 mg)	Anti-hyperlipidemic	.452	498%
Jordan (Merck)	Simvastatin (20 mg)		2.25	
Egypt (local generics)	Ramipril	Anti-hypertensive	.14	557%

manufacturer)		hypertensive		
Jordan (Sanofi- Aventis)	Ramipril		.78	

Source: Jordan and Egypt Ministries of Health (2006)

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 prices for these medicines through generic competition, and the prices for these medicines would have been much higher. The result would have been increased health-care costs and less medical treatment, especially for poor people.

C. 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.³³ 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'.³⁴ On the contrary, the government argued that a 'new use' only extends, at a maximum, to new indications for old medicines.³⁵ Despite this narrow definition, at least 25 medicines have received an additional three years of monopoly protection for new indications. A list of 18 medicines with additional monopoly protection is provided in Appendix 2.³⁶

D. Consequences of other TRIPS-plus rules upon generic competition

Oxfam did not analyse how other TRIPS-plus rules restricted generic competition in Jordan since implementation of its WTO accession package and the FTA. These additional TRIPS-plus rules severely restrict the use of important public-health safeguards, including parallel importation and compulsory licensing. Both safeguards play an important role in preventing abuses of market monopolies by multinational pharmaceutical companies. In Kenya, for example, parallel importation reduced the price of first-line anti-retroviral medicines to one-third of the price of the patented version.³⁷ An

inability to use either safeguard effectively will increase medicine prices significantly. (See Appendix 5 for an explanation of how these additional TRIPS-plus rules restrict access to affordable medicines.)

4 Medicine prices and TRIPS-plus rules

Medicine prices in Jordan increased by 20 per cent since the country entered into an FTA in 2001.³⁸ These price increases have been distributed across a wide range of therapeutic classes of medicines³⁹. Since 2001, 91 therapeutic classes have undergone a price increase exceeding 20 per cent, while an additional 88 therapeutic classes experienced a price increase of between 0 per cent and 20 per cent.⁴⁰

A. Why medicine prices have increased

There are many factors that can contribute to changes in medicine prices, including: new economies of scale, procurement negotiations, inflation, and currency shifts. Alongside these factors, one reason for higher medicine prices has been the introduction of new medicines with no generic equivalent on the market, mostly due to data exclusivity and, in a few instances, patent protection. The high cost of new medicines means many are unsold on the Jordanian market. However, some medicines have captured a large share of the local market despite their high costs, due to the public health benefits the new medicines bestow.

In 2002, medicines with no generic equivalent comprised only three per cent of the Jordanian market by value. Since then, medicines with no generic equivalent have progressively captured a larger share of the domestic market and, by the second quarter of 2006, these medicines comprised 9.4 per cent⁴¹ (See Table 2).

Table 2: Market share of medicines with no generic equivalent (2002-2006)

	2002	2003	2004	2005	2006 (first two quarters)
Market Share (%)	3.0	5.3	7.2	9.1	9.4
Sales (US\$) in thousands	2964	6192	9217	13,699	14,296

Some new medicines provide significant therapeutic benefits compared to the older medicines that they replace. Physicians interviewed for this study identified numerous expensive blood and tumour medicines that are increasingly used to address a rapidly escalating burden of NCDs, but for which no inexpensive alternative

is currently available. Technology barriers and patents prevent generic competition for some new medicines, especially biotechnology medicines. However, other medicines launched in Jordan since 2001, are not available in a generic form as a result of TRIPS-plus rules.

Box 3: How TRIPS-plus rules increased the price of Plavix

In the therapeutic class of anti-thrombotic agents, the launch of Sanofi-Aventis' Plavix in 2001 increased average unit prices for this class of medicines from 12 Jordanian Dinars (JD) to JD 50 by 2006 (416 per cent). Increased market share for Plavix coincided with a decline in market share for a generic anti-thrombotic registered in 1999 and priced at JD 10.4. Yet Plavix is not available in a generic form in Jordan solely because of the imposition of data exclusivity; Sanofi-Aventis does not have a patent for Plavix in Jordan. A generic version of Plavix has been available in India, where there is no patent protection for Plavix, and no data exclusivity, for only JD 0.12 per unit.

B. The role of scientific offices

However, other new medicines increasingly used over older generic versions offer little or no therapeutic advantage but lead to higher medicine prices. Multinational drug companies have invested heavily in scientific offices in Jordan. These offices are staffed with sales representatives employing aggressive marketing strategies that encourage doctors to prescribe expensive, new medicines, even though existing generic treatments are equally effective and far more affordable.

In field interviews conducted in Jordan, physicians, hospital administrators, and public health officials described aggressive sales tactics, bonuses, and incentives employed by sales representatives to improve market share for their medicines, even when generic equivalents were already available and being used.

This problem is not confined to Jordan. Indeed, a recent study in Canada demonstrates that expenditure for prescription medicines doubled between 1996 and 2003, and of this increase, 80 per cent was due to the use of new, patented medicines that did not offer an improved treatment outcome over less expensive alternatives.⁴²

C. How much has the price of medicine increased because of TRIPS-plus rules?

Between 2002 and mid-2006, cumulative expenditure for new medicines with no generic competition was approximately \$46m, representing 10 per cent of total sales. A portion of the \$46m only occurred as the result of enforcing TRIPS-plus rules in Jordan.

Oxfam estimated how much TRIPS-plus rules influenced these costs by looking at medicines protected from generic competition exclusively by TRIPS-plus measures, rather than by traditional patent protection. Oxfam identified 81 medicines out of 108 that do not have a generic equivalent because the companies use data exclusivity (total sales for these 81 medicines was \$31.49 million from 2002-mid 2006, or 68 per cent of the total sales of all new medicines without a generic equivalent).⁴³

After implementing the FTA, Jordan instituted a price ceiling that prevents a generic version of a medicine from exceeding 80 per cent of the originator's price. Yet generic competition can reduce medicine prices far more than 20 per cent. Previous studies have found that generic competition causes the prices of medicines to fall between 30 and 70 per cent.⁴⁴ For present purposes, Oxfam assumes medicine prices fall between 30 and 80 per cent due to generic competition in Jordan.

Applying this range, the Jordanian government and consumers could have saved between \$6.3m and \$22.04m (see Appendix 1) on the 81 medicines that have no generic equivalent due to data exclusivity. This represents between 13.7 per cent and 47.9 per cent of the cumulative cost of new medicines with no generic equivalent on the Jordanian market, or between 1.2 per cent and 4.4 per cent of total pharmaceuticals spending.

These estimates may tend to understate the impact of TRIPS-plus rules on prices and costs because:

1. Oxfam was not able to ascertain patent status of many medicines, thus excluding these medicines from the analysis,
2. higher prices for medicines with no generic equivalent depressed demand – if there were no sales, then there were no costs, and
3. it was difficult to estimate how far medicine prices can fall in Jordan as a result of generic competition.

At the same time, these estimates could also overestimate the impact of TRIPS-plus rules because of the difficulty in determining the contribution of inflation to higher medicine prices.

Clearly, TRIPS-plus rules have required the government's public health system and patients to pay higher prices for many important, new medicines that are needed to achieve better health outcomes. These medicines are needed to treat a variety of serious non-communicable illnesses, including cardiovascular disease, hypertension, asthma, diabetes, and mental illness. (See Appendix 4)

5 US government statements extolling the benefits of the US-Jordan FTA are false or misleading

Above, we have described the increased costs of TRIPS-plus rules in Jordan, but are there any benefits? Since signing the US-Jordan FTA, US officials have repeatedly claimed that TRIPS-plus rules have a positive influence on access to medicines in Jordan, and stated that the FTA has encouraged foreign direct investment (FDI), stimulated local research and development (R&D), and encouraged drug companies to launch at least 65 innovative products.⁴⁵ Our analysis shows that these statements are either incorrect or misleading.

A. The US-Jordan FTA has not encouraged FDI into Jordan's local drug industry

US government officials lauded the US-Jordan FTA for having encouraged FDI into the local pharmaceutical industry, which the US government asserts can improve access to medicines.⁴⁶ In particular, US officials cite increased licensing, clinical trial outsourcing, and staffing of scientific offices as examples of how a FTA with TRIPS-plus rules improves access to medicines.

However, since the FTA was signed, FDI, in the words of most generics manufacturers and government officials, has been a 'disappointment'.⁴⁷ From 1995 to 2000, there was hardly any investment in Jordanian pharmaceutical manufacturing, and following the passage of the FTA, despite claims by USTR that FDI would flow to Jordan, it never materialised.⁴⁸

Furthermore, local generics companies complain that multinational pharmaceutical companies neither signed more licensing agreements nor transferred technology to local manufacturers. Thus, most new medicines are imported rather than produced locally. According to the Jordanian Association of Pharmaceutical Manufacturers (JAPM), most licensing agreements that are in effect today were signed before 1999.⁴⁹ Furthermore, existing licensing agreements transfer little know-how to local manufacturers, and often are only distribution agreements. In interviews, many producers noted that licensing agreements are merely for the packaging of life-style drugs, including Cialis, an erectile-dysfunction medicine.⁵⁰ Licensing agreements for synthesis or manufacturing are nearly non-existent.

Instead, foreign drug companies have invested in establishing or expanding scientific offices in Jordan, whose sole purpose is to market new medicines through the use of aggressive sales tactics.

By comparison, FDI into Egypt, which implemented minimum obligations under TRIPS, and introduced patent protection in 2005,

has been substantial over the last decade. This is in spite of implementing an insufficient level of intellectual property protection, according to the multinational pharmaceutical industry. PhRMA (Pharmaceutical Research and Manufacturers of America) requested that Egypt be placed on the US Special 301 Priority Watch List, and reported that Egypt's inadequate enforcement of intellectual property rights cost PhRMA members nearly \$200m in 2006.⁵¹

Even though Egypt offers less IP protection than Jordan, the multinational industry invests heavily there. From 1995 to date, while Jordan received no investment in pharmaceutical manufacturing, Egypt has received \$223m, 39 per cent of which came from foreign multinationals.⁵² This has also included numerous licensing agreements to local generics companies and the establishment of wholly owned subsidiaries of foreign drug companies. According to PhRMA, 30 per cent of all output in Egypt is via locally based subsidiaries of multinational drug companies, and 35 per cent of all output in Egypt is through licensing agreements between foreign drug companies and local generics companies.⁵³ There are obvious reasons why greater FDI has flowed into Egypt, compared with Jordan, namely Egypt's larger market, which presents commercially attractive opportunities for the pharmaceutical industry.

By contrast, no more than five per cent of medicines produced in Jordan by generic companies are through licensing agreements with multinational drug companies. Further, no multinational company has a local subsidiary to produce affordable versions of branded medicines.⁵⁴

A lack of FDI can have serious implications for the affordability of medicines. A comparison of medicine prices (see Appendix 3) shows that medicines produced through locally based subsidiaries or sub-license agreements in Egypt are significantly less expensive than the same medicines imported into Jordan. While Egypt only imports 10 per cent of its medicines, Jordan imports an estimated 70 per cent.⁵⁵

Implementing an intellectual property framework exceeding TRIPS obligations does not guarantee that FDI will flow into a country to help improve the capacity of the domestic industry. A variety of studies and experts have noted that stronger IP rules in a developing country do not necessarily encourage FDI for pharmaceutical R&D or manufacturing, and Jordan's lack of FDI since the FTA was implemented supports this assertion.⁵⁶

B. Jordanian companies engage in minimal R&D and are not inventing new medicines

US trade officials have also projected that, since enacting the FTA, the Jordanian drug industry started to develop its own innovative medicines.⁵⁷ However, recent studies show that local Jordanian

companies are only investing approximately 0.1 per cent of sales into R&D.⁵⁸ These investments were designed with the aim of introducing new techniques to administer medicines, which is a standard area of research for generics manufacturers, and to introduce trivial modifications to existing medicines, but not to develop new medicines.

In fact, since 2000, no Jordanian manufacturer has filed a patent application for a new medicine.⁵⁹ The inability of Jordanian manufacturers to engage in new drug development is the result of: (1) the lack of available capital, and (2) little if any FDI over the last decade. Considering that Jordanian generics manufacturers have: (1) insufficient capital to conduct clinical trials to override data exclusivity, and (2) weak infrastructure and insufficient expertise to conduct original research and development, it is hardly surprising that these companies cannot engage in new research and development.

C. Statistics on innovative product launches in Jordan are misleading

Finally, US government officials declared that TRIPS-plus rules benefit developing countries because they encourage drug companies to introduce medicines locally. A US official recently noted that Jordan benefited from 65 new product launches since passage of the FTA.⁶⁰ However, Jordan appears to be getting only a fraction of the most popular new medicines. Of the top 26 medicines by sales currently sold in the USA, only nine are sold in Jordan.⁶¹ Similarly, an analysis of the complete product portfolio of six major multinational companies, namely Pfizer, BMS, Merck, Genzyme, Roche, and Genentech, indicate that only 33 of their 82 products are currently registered on Jordan's market.⁶² In reality, the majority of developed country medicines have not been introduced to the Jordanian market.

Furthermore, many of the medicines that have actually been launched on the Jordanian market are virtually unaffordable for all patients. Table 3, below, shows that ordinary Jordanians cannot afford these medicines, particularly those paying out-of-pocket. For example, for an ordinary civil servant to purchase one unit of Fludara, which is used to treat chronic myeloid leukaemia, she would have to work for 244 days.⁶³ The relatively few units of these medicines sold between 2002 and 2006 are a testament to their excessive cost, since these medicines otherwise provide important medical benefits to suffering patients.⁶⁴

Table 3: Affordability of new product launches in Jordan**

Manufacturer (Trade name of medicine)	Price (Jordanian Dinars)	Medical use	Affordability*	Number of units sold (2002– 2006) ⁶⁵
Ipsen (Somatuline Autogel)	1885.29	Treat acromegaly	628 days	0
Genzyme (Cerezyme)	1781.16	Enzyme replacement therapy for Type I Gauchers disease	337 days	0
Schering AF (Fludara Tab)	727.84	Treatment of chronic myeloid leukaemia	244 days	0
Genentech (Xolair)	513.53	Treatment of asthma	171 days	0
Roche-Nutley (Xeloda Tablet)	478.78	Oral chemotherapy for breast and colorectal cancer	159 days	35
Novartis (Exjade Disperable cab)	423.72	Treatment of chronic iron overload	141 days	0
Hoffman-La Roche (Bondronat Tab)	347.34	Treatment of metastatic bone disease	116 days	0
Novartis (myfortic tab)	342.07	Prevention of organ rejection after kidney transplantatio n	114 days	0
Serono (Follitropin alpha)	337.04	Fertility treatment	112 days	900

*Affordability is measured by the number of days a least-paid civil servant in Jordan would work to afford one unit of the medicine.

** Source: IMS Health and JFDA, 2006.

6 Public health under threat

Over time, the USA will continue seeking higher levels of intellectual property protection across the Middle East and the developing world. The growing burden of non-communicable diseases makes developing countries across Asia, the Middle East, and Latin America a commercially attractive market for the pharmaceutical industry. According to recent figures, the Middle East is one of the world's fastest growing markets, and is expected to grow from \$8bn in 2005 to \$12bn by 2010.⁶⁶

But the case of Jordan shows that countries should be careful about signing up to TRIPS-plus rules. In Jordan, a national health insurance plan that already does not provide coverage to approximately 40 per cent of the population will be further undermined by higher medicine prices. For those Jordanians without health insurance, higher medicine prices would require significant out-of-pocket expenditures and will disproportionately harm the poorest.

The steep increase in medicine prices since 2002 has affected the budget of the Ministry of Health (MOH) and individual hospitals. MOH figures indicate that over 25 per cent of its budget is now devoted to buying medicines.⁶⁷ The rising cost of medicines is now seen as a serious threat to the country's public health programmes.⁶⁸

At the same time, hospitals have witnessed an alarming surge in costs for medicines since 2002. The Royal Jordanian Hospital estimates that from 2002 to 2006, spending on medicines increased six-fold, or from two million Jordanian Dinars (JD) to 12 million JD per annum.⁶⁹

Higher medicine prices will place a strain upon the public health system. If current trends are any indication, new medicines, regardless of their additional therapeutic benefit, will represent an increased share of the overall market, and their price will have a significant impact on overall health-care costs. To address the looming challenge of higher medicine prices and spiralling costs, Jordan has fewer options now that TRIPS-plus rules are in place. With strict levels of intellectual property protection, Jordan's government will be unable to mitigate higher medicine prices through use of public health safeguards that encourage generic competition.⁷⁰

Other Middle Eastern countries, and particularly Egypt, should consider the consequences of TRIPS-plus rules in Jordan as a warning to not enter an FTA with the USA that includes stricter levels of intellectual property protection. While Jordan has received nearly no FDI, it must endure higher medicine prices. On the contrary, Egypt continues to attract robust FDI without introducing TRIPS-plus rules, and also has lower medicine prices.

7 Conclusion

TRIPS-plus rules introduced into Jordan's IP framework have had a negative impact on access to medicines:

- TRIPS-plus rules, particularly data exclusivity, independently prevent generic competition for 79 per cent of medicines launched by 21 multinational pharmaceutical companies since 2001.
- Additional expenditures for medicines with no generic competitor, as a result of enforcement of data exclusivity, were between \$6.3m and \$22.04m.
- There has been nearly no FDI by foreign drug companies into Jordan since 2001 to synthesise or manufacture medicines in partnership with local generics companies, and this has harmed public health. The only FDI into Jordan by foreign drug companies has been to expand scientific offices, which use aggressive sales tactics to ensure that expensive patented medicines are used in lieu of inexpensive generics.
- Stricter intellectual property rules have not encouraged companies in Jordan to engage in R&D for medicines since the passage of the FTA, and these companies have not developed any new medicines.
- New product launches in Jordan are only a fraction of total product launches in the USA and the EU. Many new medicines launched in Jordan are exorbitantly priced and unaffordable for ordinary people. Few or no units of these recently launched medicines have actually been purchased on the local market.

8 Recommendations

Access to medicines is a core element of the basic human right to health. However, TRIPS-plus rules in the US-Jordan FTA, and in subsequent FTAs between the USA and developing countries, threaten to undermine poor people's rights to medicines.

To reduce the burden of the US TRIPS-plus agenda and its effects upon access to medicines, Oxfam recommends the following:

Jordan

- Do not ratify the Patent Co-operation Treaty (PCT): Jordan should not ratify the PCT; it is not required by TRIPS, and the 'best efforts' requirement in the FTA may not force ratification. If Jordan ratifies the PCT, then it is likely that the Jordan Patent Authority would be burdened by significantly more patent applications, which would reduce generic competition.⁷¹
- Restrict scope of patentability: The US-Jordan FTA replicates TRIPS requirements for defining patentability. Jordan should amend its IP code and severely restrict which medicines can be patented in accordance with TRIPS obligations. In particular, Jordan should consider a narrow definition of scope of patentability.⁷²
- Mitigate data exclusivity: There are exceptions that Jordan can introduce to mitigate the impact of data exclusivity, including obligating an originator drug company to forfeit data exclusivity if the company fails to submit an application for marketing authorisation in Jordan within one year of marketing authorisation worldwide. Jordan could also clarify that data exclusivity is waived in the case of a compulsory license or government use order.
- Allow parallel importation: Jordan could significantly reduce its financial burdens for medicines by repealing its restrictions on parallel imports, which were not restricted by the FTA. Parallel importation is allowed under the TRIPS Agreement.

USA

- Stop coercing developing countries into adopting TRIPS-plus IP protections through bilateral and regional trade agreements and through other forms of pressure and inducement.

Other developing countries

- Prevent introduction of TRIPS-plus rules in national legislation, and fully implement TRIPS safeguards to ensure production of generic medicines for domestic consumption and for export to other developing countries.

Appendix 1: Procedures for data calculations

Identifying medicines which have no generic competitors solely because of data exclusivity

We analysed current IMS (Intercontinental Marketing Services) Health data for Jordan and identified 260 medicines available with no generic equivalent. We used a review of patent applications filed at the Jordan Patent Office to analyse 108 medicines, which were launched in Jordan by 21 foreign pharmaceutical companies since 2001, to determine whether any product patents had or have obstructed generic competition. Our analysis indicated that only five medicines had product patent protection.

However, this study estimates that some medicines would not be available in a generic form in Jordan regardless of patent protection or data exclusivity. This is because certain medicines are unavailable because of technology barriers (primarily, certain biotechnology medicines cannot be produced in a generic form, and in fact, even many developed countries do not have legislation enabling marketing approval of biosimilars). India, which possesses one of the largest and most advanced generics industries, and whose IP framework is only starting to issue patents as a result of a TRIPS-mandated transition period lasting until 2005, has not yet introduced generic versions for 29 medicines that currently do not have a generic equivalent in Jordan. Of those 29 medicines, Internet searching found that generic versions of seven medicines were available elsewhere at far lower prices. In total, this study estimates that 79 per cent of medicines, or 81 of the 103 medicines without a patent, are not available in a generic form in Jordan solely as a result of data exclusivity.

Calculating monetary costs of TRIPS-plus rules in Jordan from 2002–2006

Sales figures for all medicines were obtained using IMS Health data from 2002 to 2006. In total, overall sales for medicines with no generic equivalent were \$46m (according to IMS Health, total market sales for all medicines from January 2002 through to mid-2006 was \$496m). Only market sales for the 81 medicines with no generic competitor because of data exclusivity were analysed to tabulate total sales. This study was unable to analyse the patent status of 157 medicines that

had no generic equivalent since 2002; thus total sales for medicines with no generic equivalent solely because of data exclusivity could not be determined.

For the 81 medicines identified by Oxfam, total sales were \$31.49m (68.5 per cent of total sales for new medicines with no generic equivalent)⁷³. This cumulative figure was reduced by 30 to 80 per cent, because, according to Jordan's national pricing policy, generic medicines are to be priced up to 80 per cent of the originator's price. Earlier studies of generic competition indicate that, on average, generic competition can reduce medicine prices from 30 to 70 per cent. For present purposes, Oxfam assumed medicine prices fall between 30 and 80 per cent due to generic competition in Jordan.

According to calculations, TRIPS-plus rules increased expenditures from \$6.3m to \$22.04m for the 81 medicines analysed by Oxfam. This accounts for 13.7 per cent to 47.9 per cent of total expenditures for all 261 new medicines with no generic equivalent from 2002 through mid-2006.

Further research must be performed on the remaining 157 medicines, whose patent status was undetermined, to ascertain the full consequences of TRIPS-plus rules on expenditures for medicines in Jordan.

Appendix 2: Medicines receiving additional monopoly protection of three years for new uses of already known chemical entities

Brand name	Company name	New Indication
Forlax	Ipsen	Extension of indication to Children from eight years
Cancidas	Merck (MSD)	Fungal infection
Enbrel	Wyeth	Ankylosing spondylitis
Topamax	Janssen	Migraine
Gonal F	Serono	Severe hormone deficiency
Xyzal tab	UCB	Extension of age indication 12-6
Humira	Abbott	Psoriatic A
Risperida	Janssen	Manic episodes associated with bipolar depression
Diovan	Novartis	Post myocardial infarction
Singulair	Merck (MSD)	Symptomatic relief of seasonal allergic rhinitis
Novoseven	Novo nordisk	Glanzmann thrombasthenia
Atacandtab	Astra zeneca	Heart failure
Celebrex cap	Pfizer USA	Ankylosing spondylitis
Remicade vial	Schering Plough	Plaque psoriasis
Exlon cap	Novartis	Treatment of dementia of alzheimer
Vfend tab	Pfizer	Plaque psoriasis
Exelon cap	Novartis	Dementia associated with Parkinson
Nasonex nasal spray	Schering Plough	Polyposis

Appendix 3: Comparative prices of products manufactured under license in Egypt by drug company subsidiaries against import prices in Jordan

Country (Company)	Trade Name (concentration)	Filling	Price (Jordanian Dinar)	Percentage increase in Jordan due to lack of licensing agreement
Jordan (Merck) Egypt (Biochimie)	Baneocin Ointment (250 IU/g) Baneocin Ointment (250 IU/g)	20 g 20 g	1.68 .63	267%
Jordan (Merck) Egypt (Merck Egypt)	Concor (10 mg) Concor (10 mg)	30 capsules 10 capsules	12.55 1.18	1064%
Jordan (Merck) Egypt (Merck Egypt)	Singulair Pediatric Granules (4 mg) Singulair Pediatric Granules (5 mg)	28 capsules 28 capsules	41.81 19.0	220%
Jordan (Bristol Myers Squibb) Egypt (Bristol Myers Squibb)	Capotel Tablets (50 mg) Capoten tablets (50 mg)	30 capsules 10 capsules	11.01 1.14	966%
Jordan (Bristol Myers Squibb) Egypt (BMS Egypt)	Megace Oral Suspension (40 mg/ml) Megace (40 mg)	240 mg/ml 100 tablets	118.91 19.72	959%
Jordan (Pfizer) Egypt (Pfizer Egypt)	Difulcan (150 mg) Difulcan (150 mg)	1 tablet 1 tablet	8.6 3.0	287%
Jordan (Pfizer) Egypt (Pfizer Egypt)	Lipitor (10 mg) Lipitor (10 mg)	30 tablets 7 tablets	31.9 5.1	625%

Jordan (Pfizer)	Zithromax (250 mg)	6 tablets	15.46	255%
Egypt (Pfizer Egypt)	Zithromax (250 mg)	6 tablets	6.07	

Appendix 4: Additional financial expenditures for new medicines without a generic equivalent due solely to TRIPS-plus rules (2002–mid-2006)

Active pharmaceutical ingredient (manufacturer)	Medical use	Sales (2002–mid 2006) in US Dollars	Additional financial expenditure assuming generic competition could reduce price between 30% and 80% (range provided)
Gabapentin (Pfizer)	Epilepsy and Herpes	\$1,400,000	\$280,000 – \$980,000
Clopidogrel Hydrogen sulphate (Pfizer)	Cardiovascular disease	\$1,951,000	\$390,000 - \$1,365,700
Montelukast (Merck)	Asthma	\$1,532,000	\$304,000 - \$1,066,100
Glibenclamide (Merck)	Diabetes	\$286,300	\$57,260 - \$200,410
Hydrochlorothiazide (Novartis)	Hypertension	\$2,810,000	\$562,000 - \$1,967,000
Tiotropium bromide (Boehringer-Ingelheim)	Chronic obstructive pulmonary disease	\$281,000	\$56,200 - \$196,7000
Rosiglitazone (Smithline Beecham)	Diabetes	\$742,100	\$148,420 - \$519,470
Insulin aspart (Novo Nordisk)	Diabetes	\$481,780	\$96,296 - \$337,246
Risedronic Acid (Aventis Pharma)	Osteoporosis	\$961,000	\$192,000 - \$672,700
Budesonide – Symbicourt (Astra Zeneca)	Asthma	\$656,000	\$131,200 - \$459,200
Metoprolol (Astra Zeneca)	Cardiovascular disease	\$270,900	\$54,180 - \$186,630
Levocetirizine (Merck)	Hypercholesterolaemia	\$854,379	\$170,875 - \$598,065

Desloratadine - Aerius Tab (Schering Plough)	Anti-histamine	\$1,280,000	\$256,000 - \$896,000
Ramipril (Aventis Pharma)	Cardiovascular disease	\$853,000	\$170,000 - \$597,000
Amisulpride (Sanofi Winthrop)	Schizophrenia	\$671,000	\$134,200 - \$469,700

Appendix 5: How TRIPS-plus rules in the US-Jordan FTA and Jordanian IP law hinder or obstruct access to affordable medicines

Patent extensions caused by delays in marketing approval:

TRIPS Agreement: There is no provision in the TRIPS Agreement requiring compensation for delays in marketing approval (or for delays in issuing patents).

US-Jordan FTA: Provisions extend patent protection beyond the 20 years established in the TRIPS Agreement to compensate for delays in granting marketing approval. These measures even exceed US law, which includes limitations to ensure that the product is a truly novel medicine and which put a ceiling on the extension period. In many developing countries, there is a bottleneck of new patent and new drug applications that will overwhelm under-staffed patent and drug regulatory staffs. Thus, if regulatory approval exceeds an administrative time limit, patent extensions will be granted for many medicines.

Restricted use of compulsory licensing:

TRIPS Agreement: Each country is permitted to determine the grounds upon which it grants compulsory licenses, subject to those limitations included in Article 31.

US-Jordan FTA: The US-Jordan FTA limits the grounds under which a compulsory license can be issued far beyond those in Article 31 of the TRIPS Agreement. It only permits compulsory licenses to: remedy anti-competitive practices, for public non-commercial use, for a 'national emergency', or in case of 'extreme urgency'. Furthermore, compulsory licenses can only be granted to government entities or legal entities operating under the government. These limits can undermine the government's ability to bargain for cheaper patented drugs or to promote competition by generic products that can reduce prices and increase access to medicines.

Five years of data exclusivity:

TRIPS Agreement: The TRIPS Agreement protects only 'undisclosed data' to prevent 'unfair commercial use'; it does not confer either exclusive rights or an automatic period of marketing monopoly.

Jordan's WTO accession package: Provisions implemented as part of its accession create a new system of monopoly power, separate from patents, by blocking the registration and marketing approval of generic medicines for five years, even when no patent exists. Drug regulatory authorities are prevented from using the clinical trial data of the patented medicine to approve the marketing of a generic drug that has already been shown to be equivalent to the original one, thereby delaying or preventing generic competition. Furthermore, the FTA also requires an additional three years of data exclusivity for new uses of already known chemical entities.

No parallel importation:

TRIPS Agreement: Article 6 of the TRIPS Agreement recognises parallel importation by explicitly stating that intellectual property restrictions do not curtail its use. The Doha Declaration on TRIPS and Public Health reaffirms the right of developing countries to use this safeguard by permitting each country to set its own parallel importation regime.

Jordanian IP law: Jordan amended its law to require prior consent of a patent holder. Jordan has effectively negated use of this safeguard to import less expensive versions of patented medicines since prior consent prevents parallel importation.

Notes

¹ According to the 2005 National Health Strategy, the “rise in the pharmaceuticals bill” represents one of the main “challenges that face...continuation of health programmes... and sustainability of funding for those programmes.”

² For example, the World Bank estimates that the legal and administrative costs of providing the protections that the TRIPS Agreement requires will itself amount to between \$1.5m and \$2m per year per country. World Bank (2002).

³ After signing an FTA with Jordan, and the trade promotion authority (TPA) was passed in 2002, the USA has concluded negotiations for FTAs with Australia, Bahrain, Chile, Central American countries, the Dominican Republic, Colombia, Panama, Peru, Morocco, Oman, and Singapore. It is currently negotiating bilateral FTAs with South Korea, Thailand, Malaysia, the United Arab Emirates, and Ecuador, and attempted to pursue regional negotiations in Southern Africa and the entire Western hemisphere (FTAA).

⁴ See Declaration of Ministers of South America over Intellectual Property, Access to Medicines and Public Health, Geneva, 23 May 2006. The Ministers of Health were from Argentina, Bolivia, Brazil, Chile, Colombia, Ecuador, Paraguay, Peru, Uruguay, and Venezuela at lists.essential.org/pipermail/ip-health/2006-May/009594.html. See also Gabarone Declaration, 2nd Ordinary Session of the Conference of African Ministers of Health, Gabarone, Botswana, 10-14 October 2005, CAMH/Decl.1(II), lists.essential.org/pipermail/ip-health/2005-October/008440.html.

⁵ See letter from 12 Members of US Congress to US Trade Representative Susan Schwab on March 12, 2007 <http://oversight.house.gov/Documents/20070312150354-57129.pdf>, and Representative Henry A. Waxman, ‘Trade Agreements and Access to Medicines under the Bush Administration’, United States House of Representatives, Committee on Government Reform – Minority Staff, Special Investigations Division, June 2005 at <http://oversight.house.gov/Documents/20050609094902-11945.pdf>. See also Statement by Senator Edward Kennedy to US Senate on the Doha Declaration and the Trade Promotion Authority Act of 2002, Made on 16 February 2005.

⁶ See WHA 56.27, May 2003, www.who.int/gb/ebwha/pdf_files/WHA56/ea56r27.pdf and also see ‘Public Health, Innovation and Intellectual Property Rights’, World Health Organisation, April 2006 – for example, see recommendation 4.21 at www.who.int/intellectualproperty/report/en

⁷ See also ‘Access to Medicines at Risk across the globe’, Briefing Note, MSF Campaign for Access to Essential Medicines, May 2004, www.accessmed-msf.org/documents/ftabriefingenglish.pdf

⁸ Reference pricing refers to the process by which insurers cover only the low-cost, benchmark drugs in a therapeutic class and patients pay the difference in price if they want higher-cost alternatives. It is being used in Canada, Germany, and elsewhere in an attempt to control spending on prescription drugs. Generic competition drives down the benchmark price and helps lower overall health care expenses.

⁹ According to a Colombian study using a model developed by the Pan American Health Organisation, a FTA between the USA and Colombia would require the Colombian health system to pay an additional \$919 million per year to cover the cost of medicines, and approximately 5.2 million users would have no access to medicines through the health system. See Mision Salud and IFARMA, ‘Intellectual Property in the FTA: Impacts on Pharmaceutical Spending and Access to Medicines in Colombia’, October 2006. According to the Peruvian Ministry of Health, a FTA between the USA and Peru would cause prices for medicines to rise by 9.6 per cent

on average in the first year, 100 per cent in 10 years and 162 per cent in 18 years. In 10 years, Peru would incur additional medicine expenses of \$199.3 million – of which \$110 million would have to be met by Peruvian households. See G. Valladares Alcalde et al., 'Evaluacion de los potenciales efectos sobre acceso a medicamentos del Tratado de Libre Comercio que se negocia con los Estados Unidos de America', Lima, Ministry of Health, April 2005. According to the World Bank, if the USA and Thailand had signed a free trade agreement, compulsory licensing that could have reduced the cost of second line ARVs by 90 per cent, would have been severely restricted. Issuing compulsory licenses for second line ARVs would represent a saving of \$3.2 billion for the Thai national health budget over 20 years. See A. Revenga et al., *The Economics of Effective AIDS Treatment: Evaluating Policy Options for Thailand*, World Bank, 2006.

¹⁰ Three researchers were commissioned to conduct field research in Jordan during August–September 2006, and subsequently in Egypt and Jordan in January 2007. Pricing data for medicines were primarily obtained from the Ministry of Health and IMS Health, intellectual property materials and patent information was obtained from the Jordan National Patent Office, and extensive interviews were conducted with Jordanian government officials in the Ministry of Health, in the Jordanian Food and Drug Administration, among local government officials in hospitals and pharmacies, and directly with medicinal providers, generics company manufacturers, industry trade groups, and multinational pharmaceutical companies. Further data were obtained from the author of MIMS India and the World Health Organisation.

¹¹ CIA factbook.

¹² World Bank. Jordan Poverty Assessment: Executive Summary. Volume 1, December 2004, p.27.

¹³ Ministry of Social Development (MoSD) (2002). *Poverty Alleviation for a Stronger Jordan: A Comprehensive National Survey*, Amman, JPAP, MoSD, pp. 14 and 15.

¹⁴ World Bank. Jordan Poverty Assessment: Executive Summary. Volume 1, December 2004, p.27.

¹⁵ Ministry of Health (2006). National Health Strategy 2006-2010, Amman p. 52-53.

¹⁶ Cardiovascular diseases, according to WHO figures, cause 35 per cent of all deaths in Jordan. See www.emro.who.int/ncd-Regionalsituation-jor-Back.htm

¹⁷ See who.int/diabetes/facts/world_figures/en/print.html

¹⁸ In 1993, under the North American Free Trade Agreement (NAFTA), Mexico implemented intellectual property rules nearly identical to those rules subsequently introduced under the TRIPS Agreement (although some elements of the FTA may be considered TRIPS plus). Despite having implemented most public health safeguards available to developing countries to control the price of medicines, the price of medicines has drastically increased. By 1999, the prices for medicines in Mexico were nearly the same as those in European countries, and actually exceeded the average price for medicines in France and Canada. Thus, there was dramatically lower per capita consumption of medicines in Mexico, which confirms that these medicines are unaffordable to most people. See P.M. Danzon and M.F. Furukawa, 'Prices and availability of pharmaceuticals: Evidence from Nine Countries', Health Affairs, October 2003,

<http://content.healthaffairs.org/cgi/content/abstract/hlthaff.w3.521v1>

¹⁹ Previously, the USA concluded an FTA with Israel, and entered negotiations (now stalled) with the United Arab Emirates in 2005. The USA has also entered into trade and investment framework agreements with Algeria, Egypt, Kuwait, Qatar, Saudi Arabia, Tunisia, and Yemen, and is working on accession to the World Trade Organisation with Lebanon, Algeria, and Yemen.

²⁰ In particular, subsequent FTAs include patent linkage (see footnote 22), explicitly broaden the scope of patentability, extend data exclusivity for up to 10 years, include patent extensions for delays in granting a patent, and mandate accession to the PCT (instead of best efforts).

²¹ Jordan's Unfair Competition Law and Trade Secrets Law No. 15 does incorporate a public health protection in its data exclusivity rule. Pursuant to Article 8, data exclusivity shall not apply "where it is necessary to protect the public interest". However, our study does not indicate that this exception has ever been used in Jordan, and it would probably be difficult because of pressures exerted by USTR to impose ever-higher levels of intellectual property protection in developing countries.

²² The US-Jordan FTA requires notification only. However, it should be noted in subsequent agreements that patent linkage is far more stringent – instead of only requiring notification, subsequent FTAs state that drug regulatory authorities are prohibited from registering generic versions of medicines until after the patent has expired, with no exceptions. Thus, these public agencies charged with verifying a drug's safety and efficacy would have to become a sort of "patent police", with the burden of enforcing private property rights, instead of leaving the patent owner with the responsibility of using the judicial system to that end. Unlike US law, the FTAs do not include any measures to ensure timely resolution of patent disputes when generics producers challenge such patents, resulting in *de facto* patent extension.

²³ The presidential announcement concerning enactment of the US-Jordan FTA can be found at www.whitehouse.gov/news/releases/2001/12/20011207-5.html

²⁴ The study aimed to examine the patent status of all medicines introduced since 2001, however, due to the difficulty of identifying patent applications and interpreting patent data, patent applications were isolated for the largest 21 multinational pharmaceutical companies, whose 108 medicines represent about 70 per cent of the market of new medicines with no generic equivalent (by sales) between 2002 and mid-2006.

²⁵ As of February 2007, Jordan has not become a member of the PCT. See www.wipo.int/pct/en/. Under the US-Jordan FTA, Jordan is required to give best efforts to accede to or ratify the PCT. It is not clear what 'best efforts' entails, but under Article 17.1(a)(iii), also known as the 'non-violation' clause, if Jordan does not join the PCT, it could result in the USA arguing that Jordan, pursuant to Article 17, has 'severely distorted the balance of trade benefits accorded by [the] Agreement.'

²⁶ Developing countries that had not introduced product patent protection were not required, under the terms of the TRIPS Agreement, to issue patents for new medicines that had already been patented in another country which recognized product patents prior to 1995. Furthermore, patent holders, pursuant to the Paris Convention, must file all patent applications on a new invention within one year of the first patent filing date. Jordan did not accede to the WTO until 2000, and thus was not required to patent older medicines; furthermore, many medicines launched on the Jordanian market after 2000 had been patented at least 12 months before in a different jurisdiction. Nevertheless, in Jordan's Patent Law No. 32 (as amended by Patent Law No. 71), the country did allow companies to apply for patent protection in Jordan, with terms of protection running from the original filing date. However, most companies did not file for patent protection, particularly since they could enforce data exclusivity and receive the same or a longer term of monopoly protection.

²⁷ The pharmaceutical companies which do not have any recorded patents for medicines that have been launched in Jordan (up until mid-2006) are: Astra Zeneca, Novartis, Pfizer, Kleva, Wyeth, SmithKline Beecham (now Glaxo SmithKline), Aventis (now Sanofi-Aventis), Abbott, Bayer, Boehringer Ingelheim, Bristol Myers Squibb, Hoffman-La Roche, Genentech, Genzyme, Novo Nordisk, Eli Lilly, Ipsen, and Serono. For medicines that are still under drug development, the Jordan Patent Office indicated that drug companies are now filing patent applications for the drug precursors in Jordan also. These medicines, due to the drug discovery cycle, will be eventually marketed in Jordan once clinical trials are concluded and the medicine is approved.

²⁸ In Canada, the generics medicine industry, for instance, has estimated that a new data exclusivity law introduced into Canada will have a significant impact on access

to medicines. According to their figures, if data exclusivity had been introduced in Canada from 2001 until 2006, the additional cost to the Canadian government and consumers would have equalled \$600 million US. Canada recently introduced eight years of data exclusivity due to pressure exerted by the USTR and the pharmaceutical industry. The Canadian generics industry has now asked a Canadian court to overturn this decision. See 'Generic drug makers launch legal challenge to new federal data exclusivity rules', Canadian Generic Pharmaceutical Association, November 14, 2006.

²⁹ Data exclusivity, besides restricting generic competition even when a pharmaceutical company does not obtain a patent, also prevents generic competition during and after a period of monopoly protection conferred by a patent. When data exclusivity is enforced by a multinational pharmaceutical company, a government cannot issue a compulsory license or a government use license to either import or produce generic versions of medicines during the period of exclusivity (unless the government specifically legislates that data exclusivity does not prevent use of a compulsory license or a government use license). Secondly, even if a generic producer develops and manufactures a new form of a patented medicine that is not covered by the patents for that medicine, the generic manufacturer will be unable to market the medicine during all or part of the patent term because the generic manufacturer will be unable to rely upon the clinical trial data of the originator medicine due to enforcement of data exclusivity. Finally, even when a patent term expires, data exclusivity could still prevent generic competition if the medicine is registered late in the patent term (the medicine is registered with less than five years remaining on the patent term).

³⁰ Furthermore, a pharmaceutical company can extend data exclusivity for an additional three years if the company discovers a new use of an already known chemical entity (See Section 3C below).

³¹ Interview conducted with Dr Adnan Bedawee, August 30th, 2006. Dr Bedawee is the head of a local generics manufacturer, JPM.

³² There is considerable dispute over whether all pharmaceutical companies benefit from TRIPS-plus rules introduced through an FTA because of the 'most favored nation' clause of the TRIPS Agreement.

³³ Correspondence with Hanan Sboul, Chairwoman, Jordanian Association of Pharmaceutical Manufacturers.

³⁴ Merck, upon receiving data exclusivity for a 10 mg capsule of *Fosamax*, an osteoporosis medicine, attempted to introduce a new 70 mg version of the medicine, which itself would have received additional monopoly protection based upon a trivial change to its dosage. To prevent a local manufacturer from introducing a generic version of the 70 mg version, Merck unsuccessfully filed a lawsuit in a Jordanian court. PhRMA has also requested the US Trade Representative to pressure Jordan to change its definition of 'new use' through its annual submission to the Special 301 report. See PhRMA Special 301 Report (2006) and PhRMA Special 301 Report (2007).

³⁵ A new indication refers to a new medical use for an existing medicine.

³⁶ Researchers were unable to identify the other seven medicines that received an additional three years of data exclusivity for a new indication.

³⁷ ARV price comparison chart for Kenya, provided by Health Action International via e-mail on 15 September 2006.

³⁸ See IMS Health (2002-2006). The increase in medicine prices in Jordan is similar to the increase in medicine prices in the USA. According to the Government Accountability Office, medicine prices for Medicare recipients rose 21.8 per cent, and the average price for medicines used by others rose 22.8 per cent. See www.gao.gov/new.items/d05104r.pdf

³⁹ Drug regulatory agencies group medicines into various therapeutic classes that are defined by the physiological effect or therapeutic benefit the medicine bestows. For a sample listing of therapeutic classes, please see:

http://support.dialog.com/searchaids/dialog/f128_therapycodes-6.shtml

⁴⁰ See IMS Health (2006)

⁴¹ IMS Health (2006)

⁴² Using data produced by Canada's Patented Medicines Pricing Review Board (PMPRB), the study indicates that of 1,147 medicines introduced into British Columbia, Canada between 1990 and 2003, only 68 products (5.9 per cent) were considered to be 'breakthrough' medicines, or 12.1 per cent if one includes all formulations and new drugs in each sub-class. For the remaining medicines, the PMPRB judged that there was no evidence of any substantial therapeutic advantage over existing medicines. The launching and adoption of new medicines resulted in a doubling of per capita expenditure on prescription medicines between 1996 and 2003 in Canada, and of this increase, most (80 per cent) was explained by the use of new, patented medicines that did not offer a therapeutic improvement over less expensive alternatives. See Therapeutics Initiative, "Increasing Drug Costs: Are we getting Good Value", April-July 2006. See also "Breakthrough drugs and growth in expenditure on prescription drugs in Canada", *British Journal of Medicine*, 2005; 331:815-816.

⁴³ In Jordan, there were 260 medicines with no generic equivalent between 2002 and 2006. Given the constraints of the Jordanian patent office and a local law firm that was engaged for this research, Oxfam only analyzed patent applications and patent data for medicines developed by 21 pharmaceutical companies. Additional medicines should be studied in a follow-up examination of the patent applications, but based upon the available data, it is expected that nearly all medicines do not have a generic equivalent.

⁴⁴ Frank, Richard.G. and Salkever, David S. (1997) 'Generic Entry and the Pricing of Pharmaceuticals', *Journal of Economics & Management Strategy*, pages 75–90. Also available at: <http://papers.nber.org/papers/w5306.v5.pdf>

⁴⁵ See "CAFTA and Access to Medicines", CAFTA Facts at www.ustr.gov. See also Aziz, Fauwaz Abdul, "US official: Our FTA aims misperceived" at malaysiakini.com on 1/22/2007.

⁴⁶ See, for example http://uae.usembassy.gov/pr_10mar2005.html Assistant USTR Novelli stated, concerning intellectual property rules in the US – Jordan FTA: "Also in the intellectual property area, where very high standards were agreed to, this has spurred investment by research pharmaceutical companies, and has created a lot of jobs. Jordan exported thirty per cent more pharmaceuticals produced by local firms last year than it had before, so its exports are increasing. It has also opened a whole new sector of clinical trials for its scientists where they can take part in things regionally that they had not before, as well as created incentives for medical tourism, so there are a number of specific and concrete benefits there." See also http://kuwait.usembassy.gov/june_4_2005.html. The US Ambassador to Kuwait speech claims: "Protecting IPR is vital to U.S. industry, so much of which is knowledge-driven. But IPR protection is also essential if our trade partners want to attract high technology investments and jobs. Under an FTA, a partner government must protect copyrights, patents and trademarks, and must criminalize end-user piracy to deter IPR violations that hurt both U.S. and domestic businesses and discourage investors."

⁴⁷ Multiple field interviews conducted by Dr Hamid El-Said in August 2006.

⁴⁸ See General Authority for Investment and Free Zones, GAFI Egypt (2006)

⁴⁹ Interview between Dr El-Said and Ms Hanan Sboul, Chairwoman, Jordanian Association of Generics Manufacturers, August 2006.

⁵⁰ Interview with Lua'I Al-Khuzai, Country Manager, Informational Medical System.

⁵¹ PhRMA Special 301 Submission (2006).

⁵² See General Authority for Investment and Free Zones, GAFI Egypt (2006)

⁵³ PhRMA Special 301 Submission (2006).

⁵⁴ Ryan and Shanebrook, p.19.

⁵⁵ See 'Major pharmaceutical markets in the Middle East', Urch Publishing, 2006. It should be noted that the non-discrimination of Article 27.1 of the TRIPS Agreement prevents countries from discriminating against medicine imports. This has, according to some sources, encouraged disinvestment in local manufacturing capacity in countries such as Peru and South Africa.

⁵⁶ For example, numerous economists have found that stronger IP protection does not stimulate innovation. See Deardorff A, "Welfare effects of global patent protection", *Economica* 1992; 59:35-51 and Branstetter LG 'Do Stronger Patents Induce More Local Innovation' in KE Maskus and JH Reichman (eds), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime*, Cambridge University Press. Cambridge 2005; 309-320. Country-specific examples also demonstrate the tenuous nature of this relationship. Italy, for example, strengthened its pharmaceutical patent protection in 1978 and this was found to have little or no impact on R&D spending or on the rate of invention. See Commission on Intellectual Property Rights, Study paper 1b, *Intellectual Property Rights Technology and Economic Development: Experiences of Asian Countries*, Nagesh Kumar. In fact, other factors, cited in numerous other studies, have been found to be more relevant to encouraging FDI. For instance, a UN study on intellectual property rights and FDI found that there is insufficient linkage between patents and foreign direct investment, but instead found that cost, market size, levels of human capital and infrastructure development, and broad macro-economic conditions were more important. See 'Intellectual Property Rights and Foreign Direct Investment', United Nations, New York, 1993. For example, China and India had large amounts of FDI when they had low levels of intellectual property protection, while in contrast, African countries have had the highest levels of intellectual property protection and very low levels of FDI. See Bhagwati, Jagdish, 'Testimony before the US House of Representatives Committee on Financial Services', at www.columbia.edu/~jb38/testimony.pdf and www.oup.com/isbn/0-19-567482-0?view=in

⁵⁷ http://www.ustr.gov/Document_Library/Fact_Sheets/2004/US-Bahrain_FTA_Fact_Sheet_on_Access_to_Medicines.html. The document claims that: "Since enactment of the FTA, the Jordanian drug industry has begun to develop its own innovative medicines. This is an example of how strong intellectual property protection can bring substantial benefits to developing countries." See also http://www.ustr.gov/Document_Library/Fact_Sheets/2004/US-Morocco_Free_Trade_Agreement_Access_to_Medicines.html.

⁵⁸ Ryan and Shanebrook, p.7. The Jordanian Association of Pharmaceutical Manufacturers states that R&D expenditures in 2000 were 2.8 per cent of sales, increasing to five per cent in 2005. Under either figure, it is insufficient to encourage R&D for new medicines. Source: Hanan Sboul, Jordanian Association of Pharmaceutical Manufacturers.

⁵⁹ Jordanian Food and Drug Agency (JFDA), Annual Statistic Reports (2006).

⁶⁰ Op. cit. 57.

⁶¹ See IMS Health (2006) and JFDA, 2006

⁶² Company information and US Food and Drug Administration (2006)

⁶³ Jordan Food and Drug Administration (2006). Treatment of chronic myeloid leukemia (CML) requires approximately three to five units of Fludara; thus an average patient in Jordan requiring Fludara to treat CML, without health insurance, would have to devote anywhere from 632 days to 1,220 days of work to pay for the medicine. Source: Correspondence with Dr Datta Nori, chief of oncology at Weill Cornell, New York, on February 20th, 2007.

⁶⁴ It should be noted that these are the prices of the medicines on the private market, according to IMS Health. It is possible that prices charged to public hospitals, clinics,

and non-governmental organisations may be higher or lower. This could not be determined through Oxfam's research in Jordan.

⁶⁵ Number of units sold from 2002-2006 are based upon calculations from IMS Health data for Jordan during that period. For those medicines for which some units were sold (and for most medicines listed, no units are sold), the number of units sold is an approximation based upon the total sales and the average sales price per unit. Thus, the actual number of units sold may be slightly higher or lower.

⁶⁶ See Bailey, Edwin, 'Freedom of Change' Scrip supplement on Arab Health 2007, 19 January, 2007, number 3226.

⁶⁷ Interview Dr Salah Mawajdeh, Head of the Jordan Food and Drug Department, 29 August, 2006.

⁶⁸ Op. cit. 1.

⁶⁹ Interview with Mr Gheith Hadidi, Vice President of the Pharmaceutical Department at UJH, 23 August, 2006.

⁷⁰ Op. cit. 29.

⁷¹ According to an unpublished study provided to Oxfam that was based upon the World Intellectual Property Organisation's (WIPO) own data, for all countries except one, since joining the PCT, there has been a significant increase in patent applications. This includes Canada, China, Croatia, Israel, Mexico, New Zealand, Serbia and Montenegro, and Turkey. In China, for example, patent applications increased five-fold, Iceland increased 12-fold, and Vietnam increased 15-fold.

⁷² India became TRIPS compliant in 2005, but civil-society pressure ensured inclusion of crucial safeguards. In particular, Section 3(d) of the Patents Act excludes patent protection for introduction of trivial changes or minor modifications to already known substances, unless there is a significant increase in therapeutic efficacy. By narrowing the scope of patentability, the Indian government prevents the pharmaceutical industry from abusing the patent system via 'evergreening', or by seeking patents for minor modifications of older medicines, which thereby delays introduction of generic equivalents upon expiration of the original patent.

⁷³ Sales for nine medicines (of the 81 medicines) were not available from IMS Health data because the medicines were introduced recently and thus have not been sold on the Jordanian market.

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