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Sudan's Access to Medicine: To TRIPS or Not to TRIPS

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Sudan's Access to Medicine Puzzle

Introduction

Firstly it is important to mention that Sudan is split into Sudan and South of Sudan and that this article focuses primarily on Sudan. Sudan is a Least Developing Country (LDC) which has not yet had the opportunity of accession to the World Trade Organisation (WTO) and the Trade Related Aspect of Intellectual Property Rights (TRIPS) Agreement. Sudan has recently re-opened negotiations into acceding into WTO and has been commended, for its efforts to continue negotiations after 13 years of 'impasse'.¹ Sudan is going through legal changes and gearing up to be a part of the TRIPS family. Studies carried out by Oxfam, have raised questions as to whether the protections required under TRIPS are appropriate for countries at lower levels of development. This article recommends steps that Sudan can take to improve its access to medicines before acceding into WTO, TRIPS and signing Free Trade Agreements (FTA) .

Health and Economic factors affecting Sudan's access to medicine

It is essential to consider health and economic factors when discussing access to medicine in Least Developing Countries (LDCs) because it sheds lights on the capabilities that a country has to implement and police change. Barriers for access to medicine, in poorer countries, have been from 'on the ground' which means that it is not due to inflated patent prices or delayed entry of generics or the prohibition of using compulsory licenses in times of emergency, as is the case with developing and many developed countries, but issues such as 'market failure, corruption, non-existent health human resources and infrastructure and the lack of both local and international political will' which were present in the last 20 years in LDCs² and continue to affect access to health.

HIV/AIDS remains an issue today, for many developing countries and LDCs including Sudan, which affects 56,000 adults and children.³ This is not a new issue and has been on the rise since 1990s in Sudan.⁴ Sudan also suffers from Malaria, which is a major public health problem and a deadly

¹ WTO, 'Positive momentum for Sudan's WTO membership negotiations' , 14 July 2017, available on https://www.wto.org/english/news_e/news17_e/acc_sdn_17jul17_e.htm , last accessed on 27 August 2018

² D. W. Taylor, Pharmaceutical Access in Least Developed Countries: on-the-ground barriers and industry successes", Cameron Institute, 2010 available on <http://apps.who.int/medicinedocs/documents/s17815en/s17815en.pdf> (Hereafter Taylor 2010) Also see P. Farmer, AIDS and Accusations: Haiti and the Geography of Blame, Berkeley CA: University of California Press, 1990; World Health Organization. The Rational Use of Drugs: Report of a conference of experts, Nairobi, 25-29 November 1985.

³ UNAIDS Fact Sheet, Sudan 2016, <http://www.unaids.org/en/regionscountries/countries/sudan>

⁴ Ibid

disease⁵ and has the highest rate of visceral leishmaniasis or ‘kala azar’ ,where Sudan’s Al Gedaref accounts for 70% of the world’s patient population. ⁶

Over 20% of ‘medicines supplied to government-run facilities in LDCs are stolen and resold by staff thus explaining, in part, the chronic stock shortages in public health system dispensaries.’⁷ Other factors that limit the individuals access to medicine are the supply chain mark ups from manufacturers which ‘found in private pharmacies and other retailers are typically 300-500% for generics and 1000-1500% leading brand name medicines’. ⁸ Moreover, patients are often ‘ill-advised and inadequately supported in medicine purchasing’⁹ and lack medical human resources¹⁰ as Africa for example needs 800,000 doctors and nurses. ¹¹

Sudan’s productive capacity is limited and has severe infrastructure deficits.¹²Sudan struggles with improving human development and social development and lacks adequate governance capacities and suffers from extreme poverty.¹³ It is of no surprise, therefore, that ‘the healthcare infrastructure has totally collapsed in sub-Saharan Africa.’¹⁴ Further issues such as ‘the stigma of HIV/AIDS, the low status of women, and the absence of potable water’ renders access to medication ‘problematic’. ¹⁵ Statements by the International Development Research Centre (IDRC) of CIDA (the Canadian International Development Agency) calls into ‘serious question’ the possibility of achieving any ‘health related goals’ when taking into consideration ‘the disparity between the financial commitments that are needed even for a minimal package of essential healthcare interventions and current levels of development assistance.’¹⁶

The issues that LDCS have struggled with health and economy have not gone unnoticed. There are many forums where LDCs have been recognised as needing particular attention and well targeted support measures to eradicate poverty, sustainable development and overcome its vulnerabilities; these forums include the ‘United Nations Conferences on the Least Developed Countries’, the

⁵ Regional Health System Observatory World Health Organization, ‘ Health System Profile: Sudan’ , 2006, available on <http://apps.who.int/medicinedocs/documents/s17310e/s17310e.pdf>

⁶ MSF, International Activity Report 2017, Sudan, available on <https://www.doctorswithoutborders.org/what-we-do/countries/sudan> , last accessed on 20 December 2018

⁷ Taylor 2010

⁸ Ibid

⁹ Ibid

¹⁰ Ibid

¹¹ Ibid

¹² UN, ‘Programme of Action for the Least Developed Countries for the Decade 2011-2020’,Fourth United Nations Conference on the Least Developed Countries, District General 11 May 2011, Istanbul, Turkey 9-13 May 2011, <http://ldc4istanbul.org/uploads/IPoA.pdf>, Health and Human Rights Resource Guide, available https://www.hhrguide.org/2017/06/09/access-to-medicines-and-human-rights/#_ftnref10

¹³ Ibid

¹⁴ Taylor 2010

¹⁵ Ibid

¹⁶ Ibid

‘Millennium Declaration’, the ‘Monterrey Consensus of the International Conference on Financing for Development’, the ‘Plan of Implementation of the World Summit on Sustainable Development’ (Johannesburg Plan of Implementation), the ‘2005 World Summit Outcome’, the ‘Doha Declaration on Financing for Development’ and the outcome document of the ‘High-level Plenary Meeting of the General Assembly on the Millennium Development Goals’.¹⁷

IP reform

In order to accede into WTO Sudan will need to implement and develop ‘effective’ laws.¹⁸ Sudan has joined several organisations, conventions and agreements which are relevant to IP these include:¹⁹

- the African Regional Intellectual Property Organization (ARIPO) in 1978;
- WIPO (1967) in 1974;
- the Paris Convention (1883) in 1974;
- the Berne Convention (1886) in 2002;
- the Madrid Agreement on International Registration of Marks (1891) in 1984; and
- the Patent Cooperation Treaty (PCT) (1970) in 1984.²⁰

¹⁷ UN, ‘Programme of Action for the Least Developed Countries for the Decade 2011-2020’, Fourth United Nations Conference on the Least Developed Countries, District General 11 May 2011, Istanbul, Turkey 9-13 May 2011, <http://lde4istanbul.org/uploads/IPoA.pdf>

¹⁸ Effective legislation has been debated in the ‘context ‘of Article 27.3(b) of the TRIPS Agreement in relation to plant varieties. Mosoti, Victor. “The Legal Implications of Sudan’s Accession to the World Trade Organization.” African Affairs, vol. 103, no. 411, 2004, pp. 269–282. JSTOR, www.jstor.org/stable/3518612.

¹⁹ Samia Satti Osman Mohamed Nour (2015) The economic importance and impacts of intellectual property rights (IPRs) in Sudan, African Journal of Science, Technology, Innovation and Development, 7:2, 126-143, DOI: 10.1080/20421338.2014.903014

²⁰ Sudan’s legal framework is encapsulated in the following laws:

- The Trademarks Law (1931, 1969);
- Patent Law (1971);
- Copyright Law (1974);
- Industrial Designs Law (1974);
- Civil Procedures Law (1983);
- Civil Transactions Law (1984);
- Copyright and Related Rights Law (1996);
- Criminal Law (1991);
- Criminal Procedure Law (1991); and
- Literary and Artistic Works Law (2000).

See also Samia Satti Osman Mohamed Nour (2015) The economic importance and impacts of intellectual property rights (IPRs) in Sudan, African Journal of Science, Technology, Innovation and Development, 7:2, 126-143, DOI: 10.1080/20421338.2014.903014

Sudan is also a member of the African Regional Intellectual Property Organization²¹ (ARIPO).²² This organisation includes a Harare Protocol;²³ which is relevant to patents. ARIPO aims to harmonise patent laws with the members national laws.²⁴

Sudan has Patent Regulations of 1981 which are linked to its Patent Law No.58 of 1971.²⁵ A closer look at Sudan's Patent Law No.58 of 1971 reveals the following:

- Sudan's patentability criteria includes: any invention which is new, involves an inventive step and is capable of industrial application.²⁶ However Sudan's patent law also stipulates that '**any invention constituting an improvement**' on the patented invention is also patentable 'if it is new, involves an inventive step and is capable of industrial application'²⁷. This definition is too wide and could result in an ever greening loophole that pharmaceutical companies may exploit.
- Section 18 on granting a patent 'as to without Examination as to the Substance of the Application' is confusing because it states that the tests for patentability, listed in the previous sections of the 1971 Act, will not apply if: the terms of application in section 12 are observed²⁸, there is a unity of the invention as per section 14²⁹, fees are paid as per section

²¹ South Sudan, however is not part of ARIPO, but it may create its own set of laws, Will south Sudan get its IP right? 2012. Managing Intellectual Property (03), <https://search.proquest.com/docview/994905624?accountid=17233> , last accessed August 6, 2018.

²² This organisation has four protocols to which Sudan is a party to two; the Lusaka Agreement which Sudan signed on 2 May 1978, and the Harare Protocol which Sudan signed on 25 April 1984. ARIPO Annual Report 2016, ARIPO Harare, Zimbabwe 2017, available on <http://www.aripo.org/publications/annual-reports/item/199-aripo-annual-report-2016> , last accessed on 6 August 2018. (Hereafter ARIPO Report 2016)

²³ ARIPO Report 2016

²⁴ ARIPO Report 2016.

²⁵ Patent Regulation 1981 available at WIPO, <https://wipolex.wipo.int/en/legislation/details/15035>

²⁶ Section 3.1 Chapter two, Sudan Patent Law No.58 1971

²⁷ Section 3.2 Chapter two, Sudan Patent Law No.58 1971

²⁸ Section 12 states: Terms of Applications:

(1) An application for a patent shall be made to the Patent Application Office and shall contain:

(a) the complete name and address of the applicant and, if the applicant's address is outside the Democratic Republic of the Sudan, the indication of an address for service within the Democratic Republic of the Sudan;

(b) a description of the invention with the drawings, if any, referred to therein;

(c) one or more claims.

(2) Where appropriate, the application for the patent shall be accompanied by a declaration, signed by the true inventor, requesting that he be mentioned as such in the patent and giving his name and address.

(3) Where the application is made by an agent, it shall be accompanied by a signed power of attorney; authentication or certification of the signature shall not be necessary.

(4) The details of the formal requirements with which an application for a patent must comply shall be prescribed in the Regulations.

²⁹ Section 14 states: Unity of the Invention:

(1) An application for a patent shall relate to one invention only.

(2) Subject to the preceding subsection, an application for a patent may include, in particular:

(a) apart from claims for one or more products, claims for one or more manufacturing processes for the product or products, and claims for one or more applications of the product or products;

16³⁰, and examination that these have been complied with as per section 17.³¹ This is confusing because these sections outline the filing process which will always mean that the patentability criteria could be side-stepped.

- Furthermore an inventive step has been defined as a process which ‘does not obviously follow...either as to the method or as to the industrial results it produces’³² which means patenting, technically, should not include new uses for old chemical entities. However section 14.2(a) and (b) contradict this by stating that ‘claims for one or more manufacturing processes for the product or products, and claims for one or more applications of the product or products’ and ‘claims for means of working the process or processes, claims for the product or products which result from that working, and claims for the application of such products’ are patentable.
- It is not clear what the scope of protection includes under section 22 of the Act.³³
- It is interesting to note the prior manufacturing section which states that if a products has been manufactured or made preparations to manufacture or use, in good faith, it should continue to be manufactured even when a patent has been granted.³⁴

(b) apart from claims for one or more manufacturing processes, claims for means of working the process or processes, claims for the product or products which result from that working, and claims for the application of such products.

³⁰ Section 16 states: Payment of Fees: An application for a patent shall not be accepted unless the fee prescribed for this effect has been paid.

³¹ Section 17 states: Examination of Application as to Form:

(1) The Patent Office shall examine the application as to its conformity with Sections 12, 14, 15 and 16.

(2) Where the provisions of Sections 12 or 16 have not been complied with, a patent shall not be granted; where the provisions of Section 15 have not been complied with, the Patent Office shall not mention in the patent the priority claimed.

(3) Where the application does not fulfill the requirements of Section 14, the applicant shall be invited by the Patent Office to restrict the application so that it relates to only one invention. At the same time, the Patent Office shall notify the applicant that, within a period of three months, he may file, for the rest of the application, one or more divisional applications, which shall benefit from the date of the filing of the original application, and, if relevant, from the priority date claimed under Section 15. Where the applicant does not comply with this invitation to restrict the original application to one invention, no patent shall be granted.

³² Section 5 Chapter two, Sudan Patent Law No.58 1971

³³ Section 22 states: Scope of Protection:

(1) The scope of the protection conferred by the patent shall be determined by the terms of the claims.

(2) The description and the drawings included in the patent shall be used to interpret the claims.

³⁴ Section 24 states: Rights Derived from Prior Manufacture Use:

Any person who, at the date of the filing of the patent application by another person, or at the date of priority claimed in respect of such validly application, was, in good faith, manufacturing the product or applying the process, which is the subject of the invention, or had made serious preparations with a view to such manufacture or use, shall, despite the

- Section 25.1 states that a duration of a patent is 20 years from the date of filing.³⁵
- Chapter 9 is concerned with compulsory licensing and lists ‘non-working and similar conditions’ where importation, interestingly, is not considered as working a patent³⁶. A compulsory license is granted ‘for Products and Processes Declared to be of Vital Importance for the Defense or Economy of the Country or for Public Health’³⁷ and on the basis of ‘inter-dependence of patents’.³⁸

Reading Sudan’s Patent Law No.58 of 1971 has been difficult because of the many typographical errors and redundancies that exist within the text.³⁹ A thorough examination of the language is necessary to ensure clarity in this legislation so that the government and interested parties could utilise it efficiently and without any ambiguity.

Assistance

There is a suggestion that Sudan should make allies of countries that have acceded into the WTO as this will mean less pressure in the Working Party bilateral and multilateral negotiations.⁴⁰ However bilateral negotiations are inevitable before such accessions for example Cambodia’s accession was delayed because it was based on its bilateral negotiations with the EU.⁴¹

Sudan should also adopt a similar approach to the Tokyo Round’s ‘a la carte pluri-lateral approach’ where members were at liberty to choose which ‘codes’ to apply.⁴² The single undertaking approach is preferred by multilaterals as it encourages the ‘unconditional most favoured nation obligation’ which the ‘a la carte’ approach threatens.⁴³ A ‘pick and mix’ approach for Sudan means that it will be able to benefit from the tools provided by the WTO to improve its economy and access to medicine.

patent, have the right to continue such acts
and, with respect to products obtained thereby, to perform the other acts
referred to in section 21. This right is only transferable with the
undertaking which is the
beneficiary of the right.

³⁵ Patent Law No. 58 of 1971

³⁶ S.34.2 states : ‘...importation shall not constitute a legitimate reason’

³⁷ S.35 Patent Law No. 58 of 1971

³⁸ S. 36 Patent Law No. 58 of 1971

³⁹ For example s.35 states: ‘The Minister may, by order, provide that, for certain patented products or processes, or for certain categories of such products **and** processes, which are declared by that order of vital importance for the defense or the economy of the Democratic Republic of the Sudan or for public health, compulsory licenses may be granted, in the conditions provided for in Section 34, **even** before the expiration of the period mentioned in subsection (1) of that Section and even for importation into the Democratic Republic of the Sudan.’

⁴⁰ Mosoti, Victor. “The Legal Implications of Sudan's Accession to the World Trade Organization.” *African Affairs*, vol. 103, no. 411, 2004, pp. 269–282. JSTOR, JSTOR, www.jstor.org/stable/3518612.

⁴¹ *Ibid*

⁴² Kennedy 2006

⁴³ Kennedy 2006

However, an approach that will review the existing laws and establish which ones are beneficial to Sudan through the expertise of an international organization such as the WTO will be expensive for Sudan,⁴⁴ especially that an implementation structure is necessary to follow such recommendations.⁴⁵

Technical assistance by developing countries is required by Article 67 of TRIPS and reiterated in 2005 TRIPS Council decision⁴⁶. To assess the effectiveness of technical assistance the TRIPS Council has requested that developed countries produce annual activity reports of their assistance to LDCs.⁴⁷ Communication from the Delegation of Zambia shows that although some assistance has been provided it has not been the right or adequate amount of assistance⁴⁸. The Sudanese Minister of Trade re-affirmed this by stating that they have received some assistance, in the form of donations in \$100,000 to support Sudan's accession and a re-affirmation of support from China under its 'WTO's Least-Developed Countries and Accessions Programme'⁴⁹ from WTO members, however, they require more technical assistance to help them with their accession.⁵⁰ It is not only the case of affordable medicine but the availability of medicine which is the issue in Sudan.⁵¹ This means that Sudan has not been receiving enough technical assistance to help access to medicine.

Attracting Foreign Direct Investment (FDI) before acceding into TRIPS

As well as making allies of WTO members Sudan should attempt to re-build its relationship with the outside world and attract FDIs, especially that the US sanctions have been lifted, and because Sudan

⁴⁴ Walden Bello, *Multilateral Punishment: The Philippines in the WTO*, 199, Mosoti, Victor. "The Legal Implications of Sudan's Accession to the World Trade Organization." *African Affairs*, vol. 103, no. 411, 2004, pp. 269–282. JSTOR, JSTOR, www.jstor.org/stable/3518612.

⁴⁵ Walden Bello, *Multilateral Punishment: The Philippines in the WTO*, 199, Mosoti, Victor. "The Legal Implications of Sudan's Accession to the World Trade Organization." *African Affairs*, vol. 103, no. 411, 2004, pp. 269–282. JSTOR, www.jstor.org/stable/3518612.

⁴⁶ K. Kennedy, *e2005 TRIPS Extension for the Least-Developed Countries: A Failure of the Single Undertaking Approach?*, 40 *Int'l Law*. 683 (2006). (Hereafter Kennedy 2006)

⁴⁷ Council for Trade-Related Aspects of Intellectual Property Rights, *Decision of the Council for TRIPS of 19 February 2003, Implementation of Article 66.2 of the TRIPS Agreement*, IP/c/28 (Feb. 20, 2003). Kennedy 2006

⁴⁸ Kennedy 2006, *Communication from the Delegation of Zambia on behalf of the Least-Developed Country Members, Request for an Extension of the Transitional Period under Article 66.1 of the TRIPS Agreement*, IP/c/w/457 (Oct. 21, 2005)

⁴⁹ WTO, 'Sudan resumes WTO membership negotiations', 31 January 2017, available on https://www.wto.org/english/news_e/news17_e/acc_sdn_31jan17_e.htm

⁵⁰ WTO, 'Positive momentum for Sudan's WTO membership negotiations', 14 July 2017 available on https://www.wto.org/english/news_e/news17_e/acc_sdn_17jul17_e.htm

⁵¹ World Health Organization EMRO, 'Access to key medicine for nearly 2 million Sudanese due to USAID contribution', available on <http://www.emro.who.int/sdn/sudan-infocus/access-to-key-medicine.html>, accessed on 28 November 2017

and South Sudan have signed a peace agreement in September 2018 ending their civil war which started in 2013.⁵² Building relationships, however, may be difficult, especially that Sudan has the ‘the fifth-worst ranking in Transparency International’s global Corruption Perceptions Index.’⁵³ Therefore ‘attracting investors, analysts say, needs changes in everything from business regulations to education, as well as investment in roads, rail and ports.’⁵⁴ However, Uganda, Rwanda and Cambodia were able to benefit from their ties with the developing world.⁵⁵ Sudan could attempt to benefit from its relationship with China as one of its biggest investors⁵⁶.

There has been a lot of debate on whether strong IP attracts FDI and the correlation between increased IPRS and increased flow FDI is a contested issue. Increased IPRS means that imitation is reduced by national companies and supports multinational companies which arguably also hinder FDI flows as they form market monopolies that discourages investments.⁵⁷ The benefits of trade between the Jordan and the US are yet to be realised. Indeed, Jordan’s production still lags behind developed countries⁵⁸. This could be because Jordan has small industries hence penetrating the US market is hard. Critics of globalisation, however, have disapproved of FTAs as a myth circulated by developed countries to pre-emptively gain access to developing country markets and retort that FTAs should result in fair trade instead.⁵⁹

An International Intellectual Property Institute Report (IPI) of 2004 claims that Jordan’s economy has benefitted from increased IPR protection between 1998 and 2001 in that health-service

⁵² Jason Burke and Benjamin Takpiny, ‘South Sudan celebrates new peace accord amid joy – and scepticism’, The guardian, 31 October 2018, available on <https://www.theguardian.com/global-development/2018/oct/31/south-sudan-celebrates-new-peace-accord-amid-joy-and-scepticism>, last accessed on 20 December 2018

⁵³ S. Gebre and O. Francis, ‘Revival Beckons for Sudan as U.S. Lifts Economic Sanctions’, January 30, 2017. (Hereafter Gebre and Francis)

⁵⁴ Gebre and Francis

⁵⁵ E. Bonadio, ‘Should the world’s poorest countries be allowed to continue copying patent-protected drugs?’, 24th November, 2015, CITY University of London, <https://www.city.ac.uk/news/2015/november/should-the-worlds-poorest-countries-be-allowed-to-continue-copying-patent-protected-drugs> (Hereafter Bonadio 2015)

⁵⁶ See Statement by H.E. Mr Badr Eldin Suleiman

Advisor, Presidency of the Republic and National Chief Negotiator for the Accession of Sudan to the WTO congratulating China in 2001 on its WTO accession and calling it a ‘historic accession not merely because of China's size or weight in global trade but essentially for greater symbolic and actual status of the People's Republic of China in the midst of the developing nations and its unique contributions to the world's civilization’ see also Joseph Hammond, Sudan: China's Original Foothold in Africa, June 14, 2017 <https://thediplomat.com/2017/06/sudan-chinas-original-foothold-in-africa/>

⁵⁷ Zhang H & Yang, X ‘Trade-related aspects of intellectual property rights agreements and the upsurge in foreign direct investment in developing countries’, Economic Analysis and Policy, Volume 50, June 01, 2016, Pages 91-99

⁵⁸ Sara Elizabeth William, ‘ANALYSIS: Jordan struggles to keep economic fires burning’, Middle East Eye 28 September 2016, available on <http://www.middleeasteye.net/news/analysis-lights-are-about-go-out-jordan-s-long-suffering-economy-2060454736>

⁵⁹ Joseph Stiglitz, Globalization and Its Discontents, (New York: W.W. Norton, 2002); Ha-Joon Chang, Bad Samaritans: Rich Nations, Poor Policies and the Threat to the Developing World, (London: Random House, 2007) and —Rigged Rules and Double Standards: Trade, Globalization, and the Fight Against Poverty, Oxfam International, 2002. <http://www.maketrade-fair.com/en/>

contributions to the Jordanian gross domestic product grew from 2.8% in 1997 to 3.5% in 2001, and health-services employment grew 52% since 1997.⁶⁰ The report further stated that pharmaceutical exports from Jordan expanded 30 percent from 1999 to 2002.⁶¹ This economic growth was attributed to Jordan's increased patent protection.⁶² This report however, was found to be 'exaggerated and the costs under-estimated'⁶³.

There is no evidence to support claims that the FTAs in Jordan have 'enhanced availability and accessibility of medicines in Jordan, attracted foreign investment, improved R&D capacity of local manufacturers or led to more collaboration between national and multinational pharmaceutical companies.'⁶⁴ Another study of the FTA in 2007 by Oxfam⁶⁵ reported that medicines prices 'have increased significantly' and predicts that medicine prices will continue to rise and that the TRIPS flexibilities will not be used to reduce the costs of medicines.⁶⁶ The most recent study on the effect of TRIPS plus on Jordan's medicine reaffirms that there is undoubtedly a significant increase in prices of medication.⁶⁷

⁶⁰ Ryan MP and Shanebrook J. Establishing globally competitive pharmaceutical and bio-medical technology industries in Jordan: assessment of business strategies and the enabling environment. Online, http://pdf.usaid.gov/pdf_docs/PNADA539.pdf, Ryan B Abbott, Rania Bader, Lina Bajjali, Taher Abu ElSamen, Thamer Obeidat, Hanan Sboul, Mustafa Shwayat and Ibrahim Alabbadi 'The price of medicines in Jordan: the cost of trade-based intellectual property', Journal of Generic Medicines Vol 9, Issue 2, pp. 75 – 85, May-24-2012, 10.1177/1741134312447499, can be accessed on <http://journals.sagepub.com/doi/pdf/10.1177/1741134312447499>

⁶¹ R. Abbott, 'Inside Views: Access to Medicines And Intellectual Property in Jordan', Intellectual Property Watch, 23/07/2012 can be accessed on <https://www.ip-watch.org/2012/07/23/access-to-medicines-and-intellectual-property-in-jordan/>, See Michael P. Ryan and Jillian Shanebrook, Establishing Globally Competitive Pharmaceutical and Bio-medical Technology Industries in Jordan: Assessment of Business Strategies and the Enabling Environment, International Intellectual Property Institute, Washington DC and Achievement of Market-Friendly Initiatives and Results Programme (AMIR), Jordan, August 2004

⁶² Ryan MP and Shanebrook J. Establishing globally competitive pharmaceutical and bio-medical technology industries in Jordan: assessment of business strategies and the enabling environment. Online, http://pdf.usaid.gov/pdf_docs/PNADA539.pdf, Ryan B Abbott, Rania Bader, Lina Bajjali, Taher Abu ElSamen, Thamer Obeidat, Hanan Sboul, Mustafa Shwayat and Ibrahim Alabbadi 'The price of medicines in Jordan: the cost of trade-based intellectual property', Journal of Generic Medicines Vol 9, Issue 2, pp. 75 – 85, May-24-2012, 10.1177/1741134312447499, can be accessed on <http://journals.sagepub.com/doi/pdf/10.1177/1741134312447499>

⁶³ El-Said H and El-Said M. TRIPS-plus implications for access to medicines in developing countries: lessons from Jordan– United States free trade agreement. J World Intellectual Property 2007; 10(6): 438–475.

⁶⁴ R. Abbott, 'Inside Views: Access to Medicines And Intellectual Property in Jordan', Intellectual Property Watch, 23/07/2012 can be accessed on <https://www.ip-watch.org/2012/07/23/access-to-medicines-and-intellectual-property-in-jordan/>

⁶⁵ Malpani 2007

⁶⁶ Malpani 2007

⁶⁷ Ryan B Abbott, Rania Bader, Lina Bajjali, Taher Abu ElSamen, Thamer Obeidat, Hanan Sboul, Mustafa Shwayat and Ibrahim Alabbadi 'The price of medicines in Jordan: the cost of trade-based intellectual property', Journal of Generic Medicines, Vol 9, Issue 2, pp. 75 – 85, May-24-2012, 10.1177/1741134312447499, can be accessed on <http://journals.sagepub.com/doi/pdf/10.1177/1741134312447499>

Jordan's FDIs pre-TRIPS, pre Jordan US FTA (JUSFTA) and pre Jordan EU Associate Agreement (JEUAA) were stronger and were on the rise in 1997 due to privatisation.⁶⁸ The fact that stronger IPRS have not attracted any significant FDIs in Jordan not only affects Jordan's access to medicine nor does it help Jordan's economy. An explanation for this could be the increased unrest in the region as mentioned above due to the Persian War of 1991. This is an important factor to consider Jordan's continuous political unrest undoubtedly has affected its trade profile and economy. This is reaffirmed by a WTO report which stated that FDI inflows have decreased between 2008 to 2012 due to the global financial crisis, however despite the fact that inflows have improved since then they continue to 'mainly due to concerns about the due to political instability and conflict in the region.'⁶⁹ More specifically according to Santander's Trade Portal Jordan's FDI 'skyrocketed' until 2006⁷⁰ but then has arguable declined because of economic crisis,

The above means that FTAs in Jordan have reaped little or no benefit with respect to attracting FDI because of increased IPRS. This disproves the US's prediction that the JUSFTA will result in great trade expansion for Jordan.⁷¹ This prediction, along with special 301 report discussed previously, could be another form of pressure on Jordan to agree to the terms set out by the US in the FTA and agree to sign other FTAs. 'Predictions' or promises by the US have not been the only pressure exerted on Jordan to agree the terms of the JUSFTA. Threat of trade sanctions may have been another form of pressure used by the US. For example, The Department of Commerce's Market Access and Compliance offices monitor JUSFTA to ensure that Jordan fully complies with its trade obligations.⁷²

It could be argued that there has not been an increase in FDIs due to Jordan's unstable economy in dealing with crisis and especially the Syrian crisis.⁷³

⁶⁸ Council for Trade-Related Aspects of Intellectual Property Rights, TRIPS and Public Health: Submission by the African Group et al., at 3-4, IP/C/W/296 (June 29, 2001) (describing Resolution 200/33 adopted by the 57th Session of the U.N. Commission on Human Rights, which called upon its members to take measures to safeguard access to preventative, curative, or palliative pharmaceuticals); Council for Trade-Related Aspects of Intellectual Property Rights, Ministerial Declaration on the TRIPS Agreement and Public Health: Submission by the African Group et al., IP/C/W/312 (Oct. 4, 2001)

⁶⁹ WTO, Trade Policy Review report by the Secretariat, WT/TPR/S/325, 13 October 2015, available on [https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=\(%20@Symbol=%20wt/tpr*%20or%20press/tprb/*%20\)%20and%20\(%20@Title=%20bahrain%20\)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=(%20@Symbol=%20wt/tpr*%20or%20press/tprb/*%20)%20and%20(%20@Title=%20bahrain%20)&Language=ENGLISH&Context=FomerScriptedSearch&languageUIChanged=true#)

⁷⁰ JORDAN: FOREIGN INVESTMENT: FDI in Figures, Santander Trade Portal, available on <https://en.portal.santandertrade.com/establish-overseas/jordan/investing>

⁷¹ Charles T. Collins-Chase, Comment, The Case Against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics, 29 U. PA. J. INT'L L. 763, 766-69 (2008) .793 available at [https://www.law.upenn.edu/journals/jil/articles/volume29/issue3/CollinsChase29U.Pa.J.Int'IL.763\(2008\).pdf](https://www.law.upenn.edu/journals/jil/articles/volume29/issue3/CollinsChase29U.Pa.J.Int'IL.763(2008).pdf) accessed on 30 March 2016

⁷² <http://www.export.gov/fta/jordan/>

⁷³ European Commission, Report on Implementation of EU Free Trade Agreements 1 January 2017 - 31 December 2017, 2018, available on http://trade.ec.europa.eu/doclib/docs/2018/october/tradoc_157468.pdf, last accessed on 3 December 2018

The reported FDIs into Jordan, since the signing of JUSFTA, has been by foreign drug companies which expanded their scientific offices, and used aggressive sales tactics to ensure that expensive patented medicines are used in lieu of inexpensive generics.⁷⁴ This strengthening of the drug companies position has not been favourable and it was foreseen by the Jordanian Industrial Development Bank (“IDB”), which published a study in 1995 that found strengthened IPRS would harm local production, in terms of both investment and output; decrease local production, and thus employment levels; increase drug imports and decrease exports; and increase pharmaceutical prices.⁷⁵

Jordan has not reaped any real benefits since signing the FTA with US as domestic innovation was not encouraged and there has not been an increase in additional FDI in pharmaceutical manufacturing or R&D.⁷⁶ Signing FTAs, however, has not stopped Jordan from taking international initiatives to endorse generic competition which includes ‘restricting data protection to a narrow definition of ‘new’ uses and limiting applications for data protection to a short period following market approval in the originator country.’⁷⁷

In comparison with Jordan Bahrain, an essentially crisis free country, pre-TRIPS attracted ‘very little’ FDIs from outside the GCC region.⁷⁸ Bahrain still has FDI restrictions in which a number of businesses are reserved for Bahraini nationals and GCC nationals⁷⁹; however, they are ‘healthy and growing’⁸⁰. Bahrain has been increasing its efforts to diversify from its oil and gas, however it still

⁷⁴Charles T. Collins-Chase, Comment, The Case Against TRIPS-Plus Protection in Developing Countries Facing AIDS Epidemics, 29 U. PA. J. INT’L L. 763, 766–69 (2008) P.793 available at [https://www.law.upenn.edu/journals/jil/articles/volume29/issue3/CollinsChase29U.Pa.J.Int'lL.763\(2008\).pdf](https://www.law.upenn.edu/journals/jil/articles/volume29/issue3/CollinsChase29U.Pa.J.Int'lL.763(2008).pdf) accessed on 30 March 2016

⁷⁵ Council for Trade-Related Aspects of Intellectual Property Rights, TRIPS and Public Health: Submission by the African Group et al., at 3–4, IP/C/W/296 (June 29, 2001) (describing Resolution 200/33 adopted by the 57th Session of the U.N. Commission on Human Rights, which called upon its members to take measures to safeguard access to preventative, curative, or palliative pharmaceuticals); Council for Trade Related Aspects of Intellectual Property Rights, Ministerial Declaration on the TRIPS Agreement and Public Health: Submission by the African Group et al., IP/C/W/312 (Oct. 4, 2001)

⁷⁶ Malpani 2007

⁷⁷ Ryan B Abbott, Rania Bader, Lina Bajjali, Taher Abu ElSamen, Thamer Obeidat, Hanan Sbouh, Mustafa Shwayat and Ibrahim Alabbadi ‘The price of medicines in Jordan: the cost of trade-based intellectual property’, Journal of Generic Medicines, Vol 9, Issue 2, pp. 75 – 85, May-24-2012, 10.1177/1741134312447499, can be accessed on <http://journals.sagepub.com/doi/pdf/10.1177/1741134312447499>

⁷⁸ WTO, Bahrain’s Trade Policy Review Body, Report by the Secretariat, WT/TPR/S/74, 11 September 2000 available on [https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=\(\(+%40Title%3d+bahrain\)+or+\(+%40CountryConcerned%3d+bahrain\)\)+and+\(+\(+%40Symbol%3d+wt%2ftpr%2fs%2f*+\)+or+\(+%40Symbol%3d+wt%2ftpr%2fg%2f*+\)+or+\(+%40Symbol%3d+wt%2ftpr%2fm%2f*+not+add*\)\)+or+\(+%40Symbol%3d+wt%2ftpr%2fm%2f*+and+add*\)\)+or+\(+%40Symbol%3d+press%2ftprb%2f*+\)\)&Language=ENGLISH&Context=FormerScriptedSearch&languageUIChanged=true](https://docs.wto.org/dol2fe/Pages/FE_Search/FE_S_S006.aspx?Query=((+%40Title%3d+bahrain)+or+(+%40CountryConcerned%3d+bahrain))+and+(+(+%40Symbol%3d+wt%2ftpr%2fs%2f*+)+or+(+%40Symbol%3d+wt%2ftpr%2fg%2f*+)+or+(+%40Symbol%3d+wt%2ftpr%2fm%2f*+not+add*))+or+(+%40Symbol%3d+wt%2ftpr%2fm%2f*+and+add*))+or+(+%40Symbol%3d+press%2ftprb%2f*+))&Language=ENGLISH&Context=FormerScriptedSearch&languageUIChanged=true) Page 12

⁷⁹ WTO, 22 and 24 April 2014, Trade Policy Review of Qatar, The Kingdom of Bahrain and Oman, Minutes of the Meeting, 19 June 2014 , WT/TPR/M/294 WT/TPR/M/295 WT/TPR/M/296 , available on https://www.wto.org/english/tratop_e/tpr_e/tp_rep_e.htm#bycountry

⁸⁰ WTO, 22 and 24 April 2014, Trade Policy Review of Qatar, The Kingdom of Bahrain and Oman, Minutes of the Meeting, 19 June 2014 , WT/TPR/M/294 WT/TPR/M/295 WT/TPR/M/296 , available on https://www.wto.org/english/tratop_e/tpr_e/tp_rep_e.htm#bycountry

needs to attract more FDI to ‘accelerate Bahrain’s economic diversification efforts’.⁸¹ Further attempts to implement steps to attract FDI in Bahrain were futile as Bahrain’s FDI rate dropped sharply in 2015 (-4.5%) after reaching stable growth rates between 2.7% and 3% since 2011.⁸²

Egypt, for example, used compulsory licensing as a tool before fully implementing TRIPS and the Doha Declaration to issue a compulsory license for a generic form of Viagra two months after Pfizer’s patented Viagra entered into the market which resulted in a decrease of FDI from \$948 million in 1987⁸³ to \$509.4 million in 2001- 02.⁸⁴ FDIs have increased since, however, these increases have been predominantly petroleum based investments⁸⁵. Moreover Pharmaceutical companies ‘have deliberately avoided’⁸⁶ investing in Egypt, a country ‘which relies heavily on FDI’ as a result.⁸⁷ Egypt’s issuance of a compulsory license, for the generic form of Viagra, would have been allowed under the Doha Declaration⁸⁸. If Egypt was subject to stricter IPRS then the use of a compulsory license would have been limited to a national emergency which does not seem to be the case. If Egypt was subject to stricter IPRS then, arguably, it would not have missed out on an increase of FDIs. Unsurprisingly extensive compulsory licensing in Egypt has reportedly led to a decrease of FDI from \$948 million in 1987 to \$509.4 million in 2001–02.⁸⁹

Thailand is another country which suffered a decrease of FDI as a result of its lax approach towards compulsory licensing as permitted by the Doha Declaration.⁹⁰ For example announcing using a

⁸¹ WTO, 22 and 24 April 2014, Trade Policy Review of Qatar, The Kingdom of Bahrain and Oman, Minutes of the Meeting, 19 June 2014 , WT/TPR/M/294 WT/TPR/M/295 WT/TPR/M/296 , available on https://www.wto.org/english/tratop_e/tpr_e/tp_rep_e.htm#bycountry

⁸² http://www.bti-project.org/fileadmin/files/BTI/Downloads/Reports/2018/pdf/BTI_2018_Bahrain.pdf

⁸³ Keith E. Maskus, *The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer*, in *INTELLECTUAL PROPERTY AND DEVELOPMENT: LESSONS FROM RECENT ECONOMIC RESEARCH* 44 (Carsten Fink and Keith E. Maskus eds., 2005), McGill 2009

⁸⁴ Egyptian Ministry of Investment, Foreign Direct Investment, <http://www.investment.gov.eg/en/Investment/pages/foreigninvestment.aspx>, McGill 2009 Also see Abeer Allam, *Seeking Investment, Egypt Tries Patent Laws*, N.Y. Times, Oct. 4, 2002, available on <https://www.nytimes.com/2002/10/04/business/seeking-investment-egypt-tries-patent-laws.html> , last accessed on 2 October 2018, See also Robert Bird & Daniel R. Cahoy, *The Impact of Compulsory Licensing on Foreign Direct Investment: A Collective Bargaining Approach*, 45 Am. Bus. L.J. 283, 306 (2008);

⁸⁵ Egyptian Ministry of Investment, Foreign Direct Investment,

<http://www.investment.gov.eg/en/Investment/pages/foreigninvestment.aspx>, McGill 2009

⁸⁶ S. Aziz, ‘Linking Intellectual Property Rights in Developing Countries with Research and Development, Technology Transfer, and Foreign Direct Investment Policy: A Case Study of Egypt’s Pharmaceutical Industry’, 10 ILSA J. INT’L & COMP. L. 1, 22 (2003). (Hereafter Aziz 2003)

⁸⁷ Aziz 2003

⁸⁸ A. M. McGill, Note, *Compulsory Licensing of Patented Pharmaceuticals: Why a WTO Administrative Body Should Determine What Constitutes a Public Health Crisis Under the Doha Declaration*, 10 Wake Forest Intell. Prop. L. J. 69, 72 (2009). (Hereafter McGill 2009)

⁸⁹ McGill 2009); Baird 2013

⁹⁰ Kirida Bhaopichitr et al., World Bank, *Thailand Economic Monitor* 25 (Apr. 2007) as quoted in McGill 2009 http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_report.pdf,

compulsory license for ARV efvarinez in 2006⁹¹ and considering breaking patents in non-life threatening conditions⁹² resulted in private investment falling ‘dramatically between 2005 and 2007’⁹³ and ‘gross private investment growth fell from 10.6% to .5% in 2007, its lowest since 2000.’⁹⁴ Furthermore as a result of using compulsory licenses FDI in Thailand has ‘transferred amazingly little tacit knowledge and technology, as only a handful of companies have set up research establishments in Thailand.’⁹⁵ This failure, undoubtedly, has been because the US has downgraded Thailand in its special 301 report from being on the ‘Watch List’ to being on the ‘Priority Watch List’.⁹⁶

FDI is about attracting the right type of investment⁹⁷ to diversify the economy.⁹⁸ There is an argument which suggests that ‘countries with weaker protection can become more attractive as they strengthen their IPRs, and the relative attractiveness of those with strong IPRs already in existence can fall’⁹⁹.

⁹¹ Stephanie Skees, Thai-ing Up the TRIPS Agreement: Are Compulsory Licenses the Answer to Thailand’s AIDS Epidemic?, 19 PACE INT’L L. R. 233, 235 (2007).
as quoted in McGill 2009

http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_report.pdf,

⁹² James Hookway & Nicholas Zamiska, Thai Showdown Spotlights Threat to Drug Patents, WALL ST. J., Apr. 24, 2007, at A1; Kaiser Network, Kaiser Daily HIV/AIDS Report, Thai Government to Issue Compulsory Licenses for Two More Drugs (May 30, 2007), http://www.kaisernetwork.org/daily_reports/rep_index.cfm?hint=1&DR_ID=45220.
as quoted in McGill 2009

http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_report.pdf,

⁹³ Kirida Bhaopichitr et al., World Bank, Thailand Economic Monitor 25 (Apr. 2007) as quoted in McGill 2009
http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_report.pdf,

⁹⁴ Kirida Bhaopichitr et al., World Bank, Thailand Economic Monitor 25 (Apr. 2007),
http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_report.pdf,
McGill 2009

⁹⁵ Kirida Bhaopichitr et al., World Bank, Thailand Economic Monitor 25 (Apr. 2007) as quoted in McGill 2009
http://siteresources.worldbank.org/INTTHAILAND/Resources/Economic-Monitor/2007april_tem_report.pdf,

⁹⁶ and See ‘The campaign for use of compulsory licensing in Thailand’, 18 February 2015, available on <http://makemedicinesaffordable.org/en/the-campaign-for-use-of-compulsory-licensing-in-thailand/> last accessed on 2 October 2018

⁹⁷ Kenney 2006

⁹⁸ Kennedy 2006

⁹⁹ Maskus, K.E. (2004) ‘The Role of Intellectual Property Rights in Encouraging Foreign Direct Investment and Technology Transfer’. In C. Fink and K.E. Maskus (eds) Intellectual Property and Development: Lessons from Recent Economic Research, pp. 41–74. New York: World Bank/Oxford University Press.

Hassan, Emmanuel, Ohid Yaqub and Stephanie Diepeveen. Intellectual Property and Developing Countries: A review of the literature. Santa Monica, CA: RAND Corporation, 2010.
https://www.rand.org/pubs/technical_reports/TR804.html.

In addition, FDI in stricter IP countries are more relevant to high technology industries¹⁰⁰. Licensing is encouraged when there is a strong IPRS.¹⁰¹ This means that firms choose FDI ‘over licensing when protection is weak, as firms are more able to maintain direct control over their proprietary assets through internalised foreign production or in-house foreign R&D.’¹⁰² This means that stronger IPRS ‘diminishes the incentive for FDI at the margin for R&D-intensive industries’.¹⁰³

As a result Sudan should attempt to attract as much FDI as possible before acceding into WTO. It may be difficult, for Sudan, however, to attract FDI unless Sudan teams up with a capital holder. It is difficult for Sudan to attract FDI because it operates outside the scope of the WTO with a lack of IP rights. Uganda for example has teamed up with CIPLA to manufacture and produce triple – combination antiretroviral drugs.¹⁰⁴ Uganda’s FDI flow has been on the increase and it is ‘one of the countries that attracts the most FDI in East Africa’.¹⁰⁵ Being a manufacturer of generics, however, does not guarantee FDI flow; for example Rwanda has not been able to attract a constant flow of FDI due to various factors such as ‘low human resource capacity, poor infrastructure, landlocked position, high operating costs, limited natural resources and the political instability’.¹⁰⁶ Sudan could start by approaching capital holders such as CIPLA to follow in Uganda’s approach in attracting FDI.

Arguably Sudan will attract more FDI once it has acceded into WTO. In theory, if TRIPS is implemented then FDI will allegedly be attracted which will improve the economy of Sudan. However, there are three issues with this, firstly that the economies of LDCs, such as Sudan, are lacking in any event and ‘without the fundamentals firmly in place-political stability, desirable geographic location, adequate infrastructure, human capacity, functioning legal institutions,

¹⁰⁰ Smarzynska Javorcik, B. (2004) ‘The Composition of Foreign Direct Investment and Protection of Intellectual Property Rights: Evidence from Transition Economies’. *European Economic Review* 48(1): 39–62. Hassan, Emmanuel, Ohid Yaqub and Stephanie Diepeveen. *Intellectual Property and Developing Countries: A review of the literature*. Santa Monica, CA: RAND Corporation, 2010.

https://www.rand.org/pubs/technical_reports/TR804.html.

¹⁰¹ MJ Ferrantino (1993) ‘The Effect of Intellectual Property Rights on International Trade and Investment’. *Weltwirtschaftliches Archiv* 129: 300–31. Hassan, Emmanuel, Ohid Yaqub and Stephanie Diepeveen. *Intellectual Property and Developing Countries: A review of the literature*. Santa Monica, CA: RAND Corporation, 2010. https://www.rand.org/pubs/technical_reports/TR804.html.

¹⁰² MJ Ferrantino, (1993) ‘The Effect of Intellectual Property Rights on International Trade and Investment’. *Weltwirtschaftliches Archiv* 129: 300–31. Hassan, Emmanuel, Ohid Yaqub and Stephanie Diepeveen. *Intellectual Property and Developing Countries: A review of the literature*. Santa Monica, CA: RAND Corporation, 2010. https://www.rand.org/pubs/technical_reports/TR804.html.

¹⁰³ C.A. Primo Braga, and C. Fink (1997) ‘Economic Justification for the Grant of Intellectual Property Rights: Patterns of Convergence and Conflict’. *Chicago–Kent Law Review* 439(72): 439–62. Hassan, Emmanuel, Ohid Yaqub and Stephanie Diepeveen. *Intellectual Property and Developing Countries: A review of the literature*. Santa Monica, CA: RAND Corporation, 2010. https://www.rand.org/pubs/technical_reports/TR804.html.

¹⁰⁴ Bonadio 2015

¹⁰⁵UGANDA: FOREIGN INVESTMENT: FDI in figures, Santander Trade Portal

<https://en.portal.santandertrade.com/establish-overseas/uganda/investing-3>

¹⁰⁶ RWANDA: FOREIGN INVESTMENT: FDI in Figures, available at <https://en.portal.santandertrade.com/establish-overseas/rwanda/investing-3>

enforceable contract rights, open trade policies, and intellectual property protection—a country will not be an attractive host site for FDI’¹⁰⁷ and subsequently implementing TRIPS is not possible at this stage. Secondly lessons from Jordan and Bahrain show that implementing TRIPS does not necessarily attract FDIs and thirdly even if FDI is attracted there is no menu to choose from the right amount of FDI that Sudan will attract.

It is argued that there are many benefits to Sudan from acceding into WTO such as: trade facilitation, development of pro-growth trade policies and profiting from a dispute settlement mechanism¹⁰⁸. Disadvantages to Sudan could be a draining of resources in the lengthy and costly process of accession, political opposition to accession.

Additionally, Sudan is not likely to attract much FDI especially when the US has previously placed economic sanctions against Sudan declaring it as a state sponsor for terrorism.¹⁰⁹ Attracting investment could also be difficult because of Sudan’s ‘negative picture’¹¹⁰ which has led to its ‘international isolation’.¹¹¹ Likewise, acceding into TRIPS is not an end-all game for Sudan but could be the beginning of a chain of bilateral agreements and TRIPS plus conditions as evidenced by Jordan and Bahrain which will restrict Sudan’s access to medicine.

Further negatives to Sudan will include increased commitments that other recently acceded LDCs have undergone ‘For example, while original LDC members have undertaken commitments on 20 services subsectors, on average - out of the 160 subsectors identified by the WTO classification list - Cambodia, Nepal, and Cape Verde undertook commitments in 94, 99 and 77 of their service subsectors, respectively.’¹¹² A newly acceded LDC does not necessarily have the capacity to deal with the bureaucracy and commitments imposed by the WTO.

Manufacturing generics

¹⁰⁷ Kennedy 2006

¹⁰⁸ Charles Data Alemi, Jaime de Melo and Astrid R.N. Haas, Pursuing WTO accession: Advantages and disadvantages for South Sudan, Policy Brief, International Growth Centre, July 2016 available on https://www.theigc.org/wp-content/uploads/2016/07/201607PolicyBriefSouthSudanWTO_SLEdits.pdf

¹⁰⁹ Nizar Manek, ‘Sudan Says U.S. Backs Its WTO Bid as Sanctions Decision Due’, July 10, 2017, <https://www.bloomberg.com/news/articles/2017-07-10/sudan-says-u-s-backs-bid-to-join-wto-as-sanctions-decision-due>

¹¹⁰ Gebre and Francis

¹¹¹ Gebre and Francis

¹¹² ST/ESA/2011/DWP/109, p. 13 and WT/COMTD/LDC/W/44, International Centre for Trade and Sustainable Development, ‘An Analysis of the WTO Accession Guidelines for Least Developed Countries’, INFORMATION NOTE. November 2012

As mentioned above Sudan is an LDC and LDCs have until 2033 to comply with TRIPS. This is one area of strength which Sudan could benefit from. Sudan could become a manufacturer of generics. The LDC's market is a huge market comprising of 900m and is a market which suffers a much higher 'disease burden'¹¹³. This means that the demand for medication is constant.¹¹⁴ It will be interesting to note the effect of the India-EU on India's access to medicine.¹¹⁵ Countries such as Uganda, Cambodia and Rwanda have also taken advantage of the WTO's 2033 extension by developing their own pharmaceutical industries.

Sudan should learn from Rwanda's difficulties in being a manufacturer. Rwanda's struggles to become a robust manufacturer of generics because of various issues such as: 'underdeveloped regulatory framework coupled with inadequate regulatory capacity, a lack of harmonization between industrial and health policies, a cumbersome and unclear procurement process for key inputs, the necessity of importing raw materials or active pharmaceutical ingredients (APIs), and high water and energy costs, that increase the overall cost of production.'¹¹⁶

A private sector brief by USAID has identified that the majority of African countries have a 'pharmaceutical manufacturing capability'¹¹⁷ and identified that an LDC could develop a 'homegrown pharmaceutical sector' through various means such as:

-Phased development: this means that Sudan should start slowly by basic production before progressing into more complex drugs.¹¹⁸ Sudan has twenty four registered pharmaceutical manufacturers¹¹⁹ which produce 'generic medicines in oral and topical pharmaceutical dosage form'¹²⁰, however local production only presents 5% of the Sudanese population's needs of essential medicines¹²¹. This means that Sudan should perhaps increase or diversify its pharmaceutical

¹¹³ Bonadio 2015

¹¹⁴ Bonadio 2015

¹¹⁵ European Commission, 'Countries and regions: India', Last updated 16 April 2018, available on http://ec.europa.eu/trade/policy/countries-and-regions/countries/india/index_en.htm, last accessed on 4 October 2018

¹¹⁶ J. Bumpas and E. Betsch (2009). Exploratory Study on Active Pharmaceutical Ingredient Manufacturing for Essential Medicines, USAID, 'local manufacturing: a case for generics Production in Rwanda', August 2016 | No. 1, Private Sector Brief, available on <https://banyanglobal.com/wp-content/uploads/2017/06/3.pdf> (Hereafter USAID local manufacturing 2016)

¹¹⁷ P. Mackmillan (2016). Making Medicines in Africa, USAID, 'local manufacturing: a case for generics Production in Rwanda', August 2016 | No. 1, Private Sector Brief, available on <https://banyanglobal.com/wp-content/uploads/2017/06/3.pdf>

¹¹⁸ USAID local manufacturing 2016

¹¹⁹ Sudan & South Sudan Pharmaceuticals & Healthcare Report. Q3 2018, . Business Monitor International, ISSN: 2049-0135, available on <http://web.a.ebscohost.com/ehost/pdfviewer/pdfviewer?vid=3&sid=d2ad6bb4-d746-4697-b275-00042a082a03%40sessionmgr4007>

¹²⁰ E. I. Elamin et al, 'Availability of Essential Medicines in Sudan', Sudanese Journal of Public Health, January 2010 Vol5 No.1- This study excluded Darfur and Southern States of Sudan (Hereafter Elamin et al)

¹²¹ Elamin et al

manufacturer capacities especially with Malaria identified as the number one cause of being admitted into hospital.

- Multinationals involvement: Sudan could team up with a multinational and many multinational pharmaceuticals have seized the opportunity to partner up with local entities in an LDC to spur production in countries as diverse as South Africa, Nigeria, Kenya, Zimbabwe, Tanzania, Botswana, Uganda, Ethiopia and Ghana.^{122 123}

- Specialisation: South Africa and Ghana to produce Active Pharmaceutical Ingredients which require high quality standards. Most African countries have also specialised in 'producing generic medicines and importing APIs and excipients, primarily from India and China.'¹²⁴ Sudan could utilise its speciality acquired across its fourteen pharmaceutical manufacturers to

-Supportive policies: alignment of various policies such as investment policies will have an impact on strengthening Sudan's pharmaceutical capability¹²⁵

- Joint ventures: A joint venture could be beneficial to Sudan as it will mean that skills and technology could be learned and transferred. Many countries such as Kenya, Tanzania and Ethiopia has reaped benefits from joint partnerships which have become wholly locally owned private firms.¹²⁶

Improving Standards

It has been recommended by a recent study that the availability of medicine in Sudan may be improved with by a 'Central Medicines Supplies (CMS) which is a governmental corporation; among its responsibilities is to ensure quality medicines and other medical supplies are available with affordable prices.'¹²⁷ CMS will be able to enhance access to medicine through an 'implementation of good procurement practice, good storage practice and good distribution and transportation practices'.¹²⁸ This could be achieved through creating a government assisted RDF (Revolving Drug Fund) which will 'be responsible for drug supply management system at the state level.'¹²⁹

Safeguarding public health by guaranteeing that pharmaceuticals and medicines meet appropriate 'standards of safety, quality and efficacy' is a the primary objective of state and federal departments

¹²² USAID local manufacturing 2016

¹²³ USAID local manufacturing 2016

¹²⁴ USAID local manufacturing 2016

¹²⁵ USAID local manufacturing 2016

¹²⁶ USAID local manufacturing 2016

¹²⁷ Elamin et al

¹²⁸ Elamin et al

¹²⁹ Elamin et al

of pharmacy.¹³⁰ The Pharmacy and Poisons Act and the Federal General Directorate of Pharmacy (FGDOP) are the tools which Sudan uses to ensure that these objectives are achieved.¹³¹ This is important because there have been issues over the quality of medicine in Sudan.¹³²

Training pharmacists in Sudan is also recommended because ‘there are many pharmacies working without qualified pharmacists.’¹³³ Furthermore an effort, by FDGOP, into ensuring that medicines ‘are registered and they came from legal sources’¹³⁴; is crucial to Sudan’s public’s access to medicine.

The CMSPO should also stop encourage and importing manufacturing and registering unregistered medicines¹³⁵ and selling tender’s products to private pharmacies because it ‘

it makes inspectors task too difficult (that is, cannot identify the source of medicine whether it is CMSPO or not).’¹³⁶

Form an advisory committee

Sudan needs to form an advisory committee to advise on negotiating and acceding to agreements which may impact public health. This is a very important lesson because both Bahrain and Jordan have not had the benefit of an advisory committee before entering into FTAs. The benefit an advisory committee will provide is negotiating favourable terms for Sudan when entering into any agreement which will impact its access to health.

It is inevitable that the Sudanese government will sign more international agreements to appease to the international arena. Sudan has already signed a trade agreement with the US Trade and Investment Framework Agreement (TIFA) in 2001¹³⁷. Sudan has also entered into thirty three Bilateral Investment Agreements (BITs) with various countries;¹³⁸. An advisory committee would have been able to advise on the signing of such agreements.

¹³⁰ GKM Ali and AM Omer, ‘Pharmaceuticals in Sudan: Development in regulations, governance and implementation of national drug policies. Afr J Pharm Pharmacol, 2012; 6(1): 1-12, African Journal of Pharmacy and Pharmacology Vol. 6(1), pp. 1-12, 8 January, 2012 Available online at <http://www.academicjournals.org/AJPP>, DOI: 10.5897/AJPP11.023, ISSN 1996-0816 ©2012 Academic Journals, last accessed on 8 August 2018 (Hereafter Ali and Omer 2012)

¹³¹ Ali and Omer 2012

¹³² Ali and Omer 2012

¹³³ Ministry of Health, MOH (2003). 25 years Pharmacy Strategy Khartoum: Sudan. Unpublished Report, Ali and Omer 2012

¹³⁴ Ali and Omer 2012

¹³⁵ Ali and Omer 2012

¹³⁶ Ali and Omer 2012

¹³⁷ USTR, <https://ustr.gov/countries-regions/africa/east-africa/sudan>

¹³⁸ Only 14 of these BITs are in force which are with the following countries:

- 1) China
- 2) Egypt

Furthermore Sudan should also benefit from a the Regional Dialogue platform created in 2017 which was established for countries to discuss issues that they have struggled with when acceding into WTO. This platform, whilst only annual, will be invaluable for Sudan on its accession journey into WTO membership.¹³⁹ The experience that other countries

Conclusion

Sudan should focus on the most limiting factor which constrains its access to medicine. Sudan has the benefit of learning from developing countries as well least developing countries to develop its manufacturing capabilities and further assist the country's healthcare needs. Sudan is unlikely to attract FDIs once it acceded into the WTO/TRIPS with its history and especially that it has been singled out by the US as a terrorist state. Furthermore, it has not been proven that strengthened IPRS attracts FDI. Sudan is struggling with poverty could it afford to a) implement TRIPS b) pay for high price medications c) go through the bureaucracy of applying compulsory licenses. The issue is not that TRIPS will make access to medicine expensive but that it will also hinder Sudan from progressing economically as it will attract more bilateral agreements from other countries and especially the US with its new approach.

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- 3) Ethiopia
 - 4) France
 - 5) <http://investmentpolicyhub.unctad.org/IIA/CountryBits/199>

¹³⁹ WTO, Djibouti hosts Second Regional Dialogue on WTO Accessions for the Greater Horn of Africa, 4 December 2018, available on https://www.wto.org/english/news_e/news18_e/acc_04dec18_e.htm , last accessed on 20 December 2018