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Data Exclusivity for Pharmaceuticals: Was It the Best Choice for Jordan Under the U.S.-Jordan Free Trade Agreement?

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INTRODUCTION

Article 39.3 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPs Agreement)[1] requires that all members of the World Trade Organization (WTO)[2] take measures to protect the confidential test data submitted by originator pharmaceutical companies as a part of their bid to attain regulatory approval for New Chemical Entities (NCEs).[3] Specifically, members must protect this data against "disclosure" and "unfair commercial use."[4] Essentially, this broad prescription in Article 39.3 gives WTO members the freedom to set their own rules by allowing them to interpret the Article's principal terminology and, further, by permitting WTO members to choose the proper approach with which to implement this article.

In practice, the permissive language of Article 39.3 permits a government to authorize a generic product on the basis of an earlier grant of regulatory approval for the originator product without running

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1 Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, LEGAL INSTRUMENTS−RESULTS OF THE URUGUAY ROUND, 1869 U.N.T.S. 299, 33 I.L.M. 1125, 1197 [hereinafter TRIPs Agreement].

2 The World Trade Organization is an organization that facilitates trade relationships between nations, as well as a forum in which governments can negotiate trade agreements. Operating under a system of global trade rules, the WTO functions as a place for governments to resolve trade problems and settle trade-related disputes. *See generally What is the WTO?*, WORLD TRADE ORGANIZATION, http://www.wto.org/index.htm (last visited Sept. 10, 2014).

3 The ICTSD defines the relevant test data as:

> The subject matter of the protection under this Article is undisclosed information contained in written material which details the results of scientific health and safety testing of drugs and agrochemicals, in relation to human, animal and plant health, impact on the environment and efficacy of use. This information is not "invented" or "created" but developed according to standard protocols. The protected data may also include manufacturing, conservation and packaging methods and conditions, to the extent that their submission is needed to obtain marketing approval.

Chapter 28: Undisclosed Information *in* RESOURCE BOOK ON TRIPS AND DEVELOPMENT at 530, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (ICTSD) (Nov. 30, 2004); *See also infra* note 37 and accompanying text.

4 TRIPs Agreement, *supra* note 1, art. 39.

afoul of the Article's prohibition on disclosing test data submitted by the originator company. However, this freedom enjoyed by some countries has been restricted for others, because of what are known as TRIPs-plus provisions. Found in bilateral and Free Trade Agreements (FTAs), TRIPs-plus provisions introduce greater intellectual property protection, a result accomplished by obliging the agreement's signatories to provide an exclusivity period for the test data submitted by the originator company.[5] This new protection regime is known as data exclusivity,[6] and its heightened intellectual property protections, those beyond the mandate of Article 39.3, have been justified by both an incentive rationale and considerations of fairness.[7]

Despite these purported benefits, however, the data exclusivity approach has had a negative effect on developing countries. For the reasons outlined herein, it is thus unfortunate that Jordan, as part of its accession to the WTO, has adopted both a five-year data exclusivity clause for NCEs in its "Unfair Competition and Trade Secrets Law,"[8] as well as a three-year data exclusivity clause for new uses of known NCEs as a part of the US-Jordan FTA.[9]

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5 Carsten Fink & Patrick Reichenmiller, *Tightening TRIPS: The Intellectual Property Provisions of Recent U.S. Free Trade Agreements* at 2, WORLD BANK TRADE NOTE (Feb. 7, 2005) (under these TRIPs-Plus agreements, "[o]nce a company has submitted original test data, no competing manufacturer is allowed to rely on these data for a period of five years to request marketing approval for its own drug."), http://siteresources.worldbank.org/INTRANETTRADE/Resources/WBI-Training/288464-1119888387789/trade_note_Feb7_05.pdf.

6 Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 65−68 (2009) [hereinafter Reichman, *Rethinking*].

7 *See* RESOURCE BOOK ON TRIPS AND DEVELOPMENT *supra* note 3, at 532 (noting that it would be unequitable to deny protection to the investment made by originator companies and that, beyond this, would discourage other companies from making similar investments), http://www.iprsonline.org/unctadictsd/docs /RB_2.28_update.pdf. However, some have questioned the validity of these rationales. *See* Hamed El-Said & Mohammed El-Said, *TRIPS, Bilateralism, Multilateralism & Implications for Developing Countries: Jordan's Drug Sector*, 2 MANCHESTER J. INT'L. ECON. L. 59 (2005) ("To start with, TRIPS will only benefit firms and countries that are at the frontline of technology."), http://www.bilaterals.org/?trips-bilateralism-multilateralism.

8 Law No. 15 of 2000 on Trade Secrets and Unfair Competition, OFFICIAL GAZETTE OF JORDAN, NO. 4423 (Apr. 2, 2000) [hereinafter Unfair Competition Law], http://www.wipo.int/edocs/lexdocs/laws/en/jo/jo013en.pdf.

9 Agreement Between the United States of America and the Hashemite Kingdom of Jordan on the Establishment of a Free Trade Area, U.S.-Jordan, Oct. 24, 2000, 41 I.L.M. 63 (2002), https://ustr.gov/sites/default/files/Jordan%20FTA.pdf [hereinafter U.S.-Jordan FTA].

First, this negative impact of the data exclusivity approach in developing countries means that the entry of cheap generic product has been delayed, even under compulsory license, which will have the injurious effect of limiting access to affordable medicines in developing countries.[10] Since the implementation of pharmaceutical data exclusivity in 2001, the prices of medicines have increased 20%, a direct result of data exclusivity's requirement that generic medicine cannot enter the market until the end of the prescribed five-year period following the approval of the originator's product. This price increase caused by delay of generic products' market entry has also increased the governmental bill for medicines.[11]

Furthermore, data exclusivity's constraints on the timely availability of generic medicines has adversely affected the pharmaceutical industry in Jordan in several ways, an outcome of particular importance since pharmaceuticals is the second largest export industry after garment manufacturing in Jordan.[12] First, delaying generic medicine registration in Jordan, which is considered the country of origin, will then delay its exportation worldwide.[13] Second, applying stricter intellectual property provisions has not resulted in local industry developing NCEs or new delivery systems, as the cost would exceed local industry financial resources.

Moreover, though the United States assured Jordan that the US-Jordan FTA would benefit Jordan in various ways, in particular by

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10 Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Geochemical Products Under Free Trade Agreements*, ICTSD-UNCTAD Dialogue on Moving the Pro-development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning, Bellagio, Nov. 29–Dec. 3, 2004, http://www.ictsd.org/sites/default/files/event/2008/12/report31.pdf [hereinafter Correa, *Protecting Test Data*].

11 *See generally* Chapter 17: Patents-Subject Matter and Patentability Requirements *in* RESOURCE BOOK ON TRIPS AND DEVELOPMENT at 364, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (ICTSD) (Nov. 29, 2004) (describing how "introduction of patents will normally lead to prices higher than those that would have prevailed in the absence of protection"), http://www.ictsd.org/sites/default/files/research/2008/06/rb_217-226_patents_update.pdf.

12 *Jordan Pharmaceutical Sector* at 1, GLOBAL INVESTMENT HOUSE (June 2007), http://www.globalinv.net/research/Jordan-Pharmaceutical-Sector-062007.pdf.

13 *See*, *e.g.*, Neil McAuslane et al., *A Cross-Regional Comparison of the Regulatory Environment in Emerging Markets* at 5, CENTER FOR INNOVATION IN REGULATORY SCIENCE (Feb. 2006) ("A major factor in the timely access of new medicines to patients is the time taken by national regulatory authorities for the review and approval of applications."), http://cirsci.org/sites/default/files/RD%2050%20Feb06%20EM%20Cross%20Regional%20Compar.pdf.gm.

increasing foreign direct investment within the country,[14] this prediction did not prove accurate. Since 2001, no originator companies have made the kind of foreign direct investments envisioned by the US.[15] Instead, the only case found was contract manufacturing with local industry, as secondary packaging without any transfer of product know-how. The reason for this was to obtain a higher public price for the originator product, based on considering Jordan as the country of origin, while in Egypt we can see that almost all originator companies have local manufacturing sites.[16]

I
DATA EXCLUSIVITY LEGAL FRAMEWORK

In this Part, we will discuss drug approval regulations for New Chemical Entities (NCEs), in particular the regulatory requirement that originator companies provide proof of a drug's safety, efficacy and quality. We will then discuss the incorporation of test data protection in regional and international agreements and elaborate on the interpretation of Article 39.3 in the context of TRIPs Agreement obligations and conditions. Finally, we will discuss the incorporation of data exclusivity in Jordan's Unfair Competition and Trade Secrets Law.

A. Drug Regulation and Approval

Before marketing, a drug should first be approved by the national or regional drug regulatory authority in order to prove its safety, efficacy and quality; this applies to both originator drug products and generic

14 CRS REPORT FOR CONGRESS: U.S.-JORDAN FREE TRADE AGREEMENT (May 1, 2001) (concluding that investigations undertaken by the U.S. government strongly support the possibility that "the FTA could substantially increase foreign direct investment in Jordan, both from the United States and from the rest of the world."), http://www.sice.oas.org/TPD/USA_JOR/Studies/CRS_E.pdf.

15 *See generally* Yusuf Mansur, *Overcoming Barriers to Foreign Direct Investment in Jordan*, INTERNATIONAL RESEARCH FOUNDATION OF OMAN AND THE FRASER INSTITUTE OF CANADA (June 2008), http://www.freetheworld.com/arab/Overcoming-Barriers_Foreign-Direct-Investment.pdf.

16 Rohit Malpani, *All Costs, No Benefits: How TRIPs-Plus Intellectual Property Rules in the U.S.-Jordan FTA Affect Access to Medicines*, 102 Oxfam Briefing Paper 5 (2007), [hereinafter Malpani], https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf.

drug products.[17] Though this review process may vary by country, they all share a common dependency on the drug regulatory authority in order to have a reliable health system.[18] For example, some countries require substantive review of the submitted data while others rely on the approval of a foreign drug regulatory authority.[19] Usually, when the originator company discovers a NCE, it applies for a patent and during the proceeding patent examination and granting stage, the originator company develops "test data."[20] These test data are important for health purposes, since they permit national authorities and users to evaluate the merits and risks of new drugs.[21] They are also important for commercial purposes, as the availability of the test data is a condition for obtaining marketing approval of new products, modifications or new uses of existing products.[22]

Preclinical research on new compounds is carried out in the company's laboratory, using a wide variety of techniques. In the first step of preclinical research, promising compounds are tested on animals in order to elucidate and investigate effects that cannot currently be predicted from the computer and test tube studies.[23] Animal testing will demonstrate the compound's safety and will prove it is not toxic at the effective dosing level.[24] During this time, the originator drug company files the related patents and decides whether to continue investigating this molecule, a decision based on its cost, potential profits and the likelihood of regulatory approval.[25] If the company decides to invest in the molecule, it should file it as an Investigational New Drug (IND) with the applicable drug regulatory authority in order to make sure that the molecule is safe, which will then allow the company to proceed to the next stage of the approval

17 Andy Gray, *Access to Medicines and Drug Regulation in Developing Countries: A Resource Guide for DFID*, DFID HEALTH SYSTEMS RESOURCE CENTRE 1 (Oct. 2004), http://apps.who.int/medicinedocs/documents/s18246en/s18246en.pdf.

18 *Id.*

19 Correa, *Protecting Test Data*, *supra* note 10, at 2.

20 *Id.*

21 *Id.*

22 *Id.*

23 Meir Perez Pugatch, *Data Exclusivity: Implications for Developing Countries*, COMMENT, 9 BRIDGES 21 (2005), http://www.iprsonline.org/ictsd/docs/Data_Exclusivity_BRIDGES9-6-7-3.pdf [hereinafter Pugatch].

24 Brandon Powell, *Silence Is Not the Best Medicine: Requiring Disclosure of Clinical Trial Data for Abandoned Drugs*, 33 J. LEG. MED. 571, 575 (2012) [hereinafter Powell].

25 *Id.*

process—clinical testing on humans. Usually, the preclinical studies take around three to four years to complete.[26]

Subsequently, various clinical assessments in humans, funded by the originator company, are carried out following strict guidelines. Before carrying out these trials, the Institutional Review Boards (IRBs), which are independent committees, will review the trials and study their potential risk on humans. Additionally, the concerned drug regulatory authority will be responsible to supervise the trials.

Clinical trials are divided into four phases to prove the safety and efficacy of a molecule.[27] In phase I, a small group (between 20 and 100) of healthy volunteers receives dosages of the investigational drug for a short period of time. The primary purpose of this phase is to look for evidence of toxicity or unexpected undesirable reactions at certain dosages, and to study the bioavailability and pharmacokinetics of the NCE/drug applied to patients.[28] If the molecule is proved to be safe at the required dosage, it will then proceed to phase II.[29]

Phase II of clinical testing has a similar purpose to Phase I,[30] but takes into consideration the therapeutic context. Phase II's primary objective is to ascertain the effectiveness of the investigational drug.[31] The number of participants includes up to several hundred people who suffer from the disease under study.[32] The effectiveness of the molecule will be studied against placebos or other known molecules under controlled, randomized and double-blind studies.[33] If the molecule is found to be effective at this juncture, then Phase III testing will begin.[34]

Phase III clinical trials are conducted on a large member of patients, often involving several hundred human subjects and lasting for extensive periods of time. As with Phase I and II, Phase III tests are designed to determine the efficacy of the investigational drug and to uncover any unexpected side effects that the drug may have, taking into

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26 *Id.*
27 *Id.*
28 *Id.*
29 *Id.*
30 *Id.*
31 *Id.*
32 *Id.*
33 *Id.*
34 *Id.*

account age and gender considerations, drug interactions and specific dosage for different indications.[35]

While Phase III trials are underway, long-term animal toxicity studies are undertaken to determine the effects of prolonged exposure and the effects of the NCE on subsequent generations. The resulting test data is then compiled with all required regulatory data and is submitted to the drug regulatory authority. Following receipt of these materials, the drug regulatory authority will assess the New Drug Application (NDA) and will decide whether or not to grant the marketing authorization for the NCE. Generally, marketing approval is granted for a specific drug which is used for a specific therapy. Changing the composition of the drug, combining it with other drugs or administering it for a new therapeutic indication or group of patients (e.g., pediatric use) would require new trials and approval by a competent authority.[36] The results of all these studies constitute the "test data."[37]

Following the granting of marketing authorization, the newly authorized medicine is studied in large numbers of patients in hospitals and clinics to further assess its clinical effectiveness. This stage is called Phase IV, or post-marketing study.[38] Safety Assessment of Marketed Medicines (SAMM) studies are initiated after the medicine has been made available for doctors to prescribe and help to identify any unforeseen side effects. These studies may involve many thousands of patients.[39] Physicians' databases are also used to identify medicine safety issues and to explore the potential for new or better use of medicines, once the product is available for prescription.[40]

With regard to costs, according to Grabowski, the accumulation and compilation of the data included in a pharmaceutical registration file is estimated at $467 million, a figure which is more than 60% of the total cost of pharmaceutical R&D.[41] Dimasi, Hansen, and Grabowski estimate that the current average capitalized costs of developing a new drug are approximately $870 million.[42] Recent estimates by the Tufts

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35 *Id.*

36 Powell, *supra* note 24.

37 *Id.*

38 Pugatch, *supra* note 23, at 21−22.

39 *Id.*

40 *Id.*

41 *Id.*

42 Jerome H. Reichman, *Undisclosed Clinical Trial Data Under the TRIPs Agreement and Its Progeny: A Broader Perspective*, ICTSD-UNCTAD Dialogue on Moving Pro-

Center for the Study of Drug Development suggest that the fully capitalized cost to develop a new drug, including studies conducted after receiving regulatory approval, averages $897 million.[43] All told, the development of a new drug will take between ten to fifteen years to complete.[44]

It should be taken into consideration that the accuracy of this figure may be disputed at the margins. It necessarily includes the cumulatively high costs of clinical trials incurred for the many drugs that fail to be approved.[45] Following development, a drug will be reviewed by the drug's regulatory authority for marketing approval, during which time most of the drug's patent protection duration will elapse. In an effort to recoup the cost of the clinical studies, the originator companies lobbied for a system known in the United States as "marketing exclusivity" and in Europe as "data exclusivity."[46]

Data exclusivity establishes a period of time (generally five to ten years for NCEs) during which generic firms cannot win marketing approval based on the test data submitted by the originator.[47] This period of exclusivity may serve to keep generics off the market even in cases where there is no patent in place, or a compulsory license has been issued.[48]

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development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning, Bellagio, Nov. 29–Dec. 3, 2004, http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf [hereinafter, Reichman, *Undisclosed Clinical Trial Data*].

43 The Tufts Center for the Study of Drug Development is an independent, academic, nonprofit research group at Tufts University in Boston, Massachusetts. The Center develops strategic information to help drug developers, regulators, and policy makers to improve the quality and efficiency of pharmaceutical and biopharmaceutical development, review, and utilization. TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT, http://csdd.tufts.edu/about (last visited Sept. 1, 2014).

44 Pugatch, *supra* note 23, at 21−22. *See also* Henry Grabowski, *Patents and New Product Development in the Pharmaceutical and Biotechnology Industries*, 8 GEO. PUBLIC POL'Y REV 7, 10 (2003) (Figure 1 Data is adjusted to 2003 R&D expenditures); Joseph A. DiMasi et al., *The Price of Innovation: New Estimates of Drug Development Costs,* 22 J. HEALTH ECON. 151, 166 (2003).

45 Reichman, *Undisclosed Clinical Trial Data*, *supra* note 42, at 2−3.

46 Mike Palmedo, *Do Pharmaceutical Firms Invest More Heavily in Countries with Data Exclusivity?* 21 CURRENTS INT'L TRADE L.J. 38, 38−39 (2013). *See also* Mike Palmedo, *The TRADE Act of 2008's Provisions on Intellectual Property and Access to Medicines*, AMER. U. SCH. OF LAW, (Oct. 14, 2008), http://www.wcl.american.edu/pijip/go/palmedo10142008.

47 *Id.*

48 *Id.*

In this system, the drug regulatory authority gives the originator a period of protection after its approval and does not rely on its clinical studies to approve other generics.[49] This system does not depend on the patent status of the originator; instead, the drug regulatory authority automatically provides protection for the originator company's test data after it has granted approval for that drug.[50] The protection period differs from country to country. In Jordan, it is five years for NCEs, as is the case in the United States, while in Europe it is "8 years data exclusivity and 2 years marketing exclusivity + 1 year new use data exclusivity."[51] Applying this system in a country whose drug regulatory authority requires substantive review of the submitted data[52] will prevent the generic product from relying on the originator's data.[53] In this case, the generic producer has two options: either to wait for the data exclusivity period to end, or generate its own clinical data. Neither option available to a generic producer is a good one. Waiting for the protection period to end will delay the entry of the generic product to the market,[54] which will affect access to medicine with affordable prices, and repeating studies is considered unethical and lengthy.

Furthermore, conducting its own trials is not a viable option for generic producers since doing so would exceed their financial capacity.[55] The rising economic significance of data exclusivity is a combination of three factors: (1) the lengthy and costly process of clinical trials; (2) the ongoing innovative productivity challenges the pharmaceutical industry; and (3) the fierce legal patent disputes between research-based and generics-based pharmaceutical companies.[56] In fact, data exclusivity is becoming increasingly dominant as an additional intellectual property layer of protection, which affects both research-based and generic-based companies.[57]

B. Regional and International Agreements

In 1992, the North American Free Trade Agreement (NAFTA), Article 1711, first introduced the protection of undisclosed

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49 Pugatch, *supra* note 23, at 21−22.

50 *Id.*

51 *Id.*

52 *Id.*

53 *Id.*

54 *Id.*

55 Pugatch, *supra* note 23, at 21−22.

56 *Id.*

57 *Id.*

information. This inclusion was based on the pharmaceutical product originators' desire to protect clinical data that they could not protect under patent law because there is no inventive step. This measure advanced the interests of these companies since it would benefit them to keep the data secret in order to prevent competitors from capitalizing on the data derived from costly clinical studies. Therefore, it was included in TRIPs Article 39.3 to provide a separate type of protection of test data.

1. NAFTA[58]

The first agreement including "Data Exclusivity Protection" was the North American Free Trade Agreement (NAFTA). This regional free trade agreement concluded by the United States, Canada, and Mexico granted a minimum of five-years data exclusivity for the originator drug company for submitting undisclosed test data.[59]

Data exclusivity is incorporated in Article 1711.[60] Section (5) of this article considers this test data as a "trade secret," while section (6) determines the minimum protection period as five years, and section (7) discusses the case of the reliance of marketing approval on other authorities.[61]

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58 North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993), https://www.nafta-sec-alena.org/Home/Legal-Texts/North-American-Free-Trad-Agreement/ctl/SectionView/mid/1588/sid/b6e715c1-ec07-4c96-b18e-d762b2ebe511 [hereinafter NAFTA]. On January 1, 1994, the North American Free Trade Agreement between the United States, Canada, and Mexico (NAFTA) entered into force. All remaining duties and quantitative restrictions were eliminated, as scheduled, on January 1, 2008. *North American Free Trade Agreement (NAFTA)*, U.S. TRADE REP., http://www.ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta (last visited Sept. 3, 2014).

59 NAFTA, *supra* note 58.

60 NAFTA, *supra* note 58, art. 1711, alena.org/Default.aspx?tabid=97&ctl=SectionView&mid=1588&sid=b6e715c1-ec07-4c96-b18e-d762b2ebe511&language=en-US#A1711.

61 Article 1711 of NAFTA states:

> (5) If a Party requires, as a condition for approving the marketing of pharmaceutical or agricultural chemical products that utilize new chemical entities, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data is protected against unfair commercial use.
>
> (6) Each Party shall provide that for data subject to paragraph (5) that are submitted to the Party after the date of entry into force of this Agreement, no person other than

These provisions outlined the scheme of data exclusivity as follows:

1. Scope of coverage: Though this agreement did not define NCE clearly, it did determine that NCE was applicable in both pharmaceutical and agrochemical contexts. It was argued whether a drug should be considered an NCE in regards to any other product in any country or only in the same country. The commonly accepted definition was "a product previously approved in a foreign country will continue to be 'new' for that Party until it is registered there, even if this happens many years after its first marketing approval."[62] Also, this agreement did not require protection for new uses or new dosage forms.[63]

2. Subject Matter and Conditions of Protection: The protection is only for "undisclosed information" that has not been published or disclosed in the public domain.[64] Published test data will not be protected. Also, another condition is that the production of the test data at issue involved "considerable effort."[65]

3. Terms of Protection: A reasonable period of five years as a minimum should be provided from the date of marketing approval. This period can be extended by taking into consideration the nature of test data and the efforts involved for producing such data. In case of reliance on another country's approval, the protection period will be

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> the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean not less than five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and the person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence and bioavailability studies.
>
> (7) Where a Party relies on a marketing approval granted by another Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

NAFTA, *supra* note 58, art. 1711.

62 G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPs Agreement*, 24 NW. J. INT'L L. & BUS. 1, 2−6 (2003) [hereinafter Skillington & Solovy].

63 *Id.*

64 Pei-kan Yang, *Current Development of Canada's Data Exclusivity Regime: How Does Canada React to NAFTA, TRIPs and Dangle Between Pharmaceutical Innovation and Public Health?*, 4 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 65, 67−69 (2009) [hereinafter Yang].

65 *Id.*

the same as in the relied-upon country. This point was included to prevent the delay of originator product registration.[66]

4. Nonreliance and Nondisclosure Obligations: The drug regulatory authority shall not rely on such test data until the end of the protection period. At that time, authorities may then register a generic product on the basis of it submitting a bioequivalence study.[67] Moreover, the authority should protect the test data from disclosure to a third person except where it is necessary to protect the public, or unless steps are taken to protect these test data against unfair commercial use.[68]

5. Article 39.3 of the TRIPs Agreement and Article 1711 of NAFTA: The two are similar in terms of their scope of coverage, subject matter, and conditions of protections. An important difference between the two agreements is that TRIPs did not specify an exclusive protection period for the submitted data,[69] so each country is free to introduce the suitable approach for the protection of these undisclosed test data against "unfair commercial use," except countries that signed bilateral agreements with the United States.[70] Another difference is that the TRIPs Article 39.3 lacks a clear definition of "unfair commercial use," and does not cement the link between "nonreliance" and data exclusivity. In other words, TRIPs does not determine whether reliance on such test data is to be considered as an "unfair commercial use."[71]

2. TRIPs Provisions on Data Exclusivity

TRIPs provisions have extended the prohibition of unfair competition within the meaning of Article 10 *bis* of the Paris Convention to all WTO members. Nevertheless, the inclusion of Article 10 *bis* in Article 39.1 of the TRIPs Agreement did not widen the boundaries of the obligation.[72]

The intellectual property protection Article 39.3 provides is considered to be a reward for the investment pharmaceutical companies make in the generation of test data and aims to encourage such

66 *Id.*
67 *Id.*
68 *Id.*
69 *Id.*
70 *Id.*
71 Yang, *supra* note 64.
72 Reichman, *Undisclosed Clinical Trial Data*, *supra* note 42, at 21−23.

companies to invest more in generating test data.[73] The test data is developed through standard protocols and procedures, which explains why they cannot be protected through the patent system, as these processes lack the novelty condition requisite for protection under patent law.[74] According to this article, test data protection is classified as a category of intellectual property but this inclusion in the TRIPs Agreement does not mean the granting of exclusive rights.[75]

Article 39 of TRIPs[76] outlines WTO members' obligations against test data protection.[77] Article 39.1 identifies undisclosed information to be submitted to regulatory authority to be protected from unfair competition as stated in Article 10bis of Paris Convention (1967).[78]

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73 *See* Reichman *supra* note 6.

74 Carlos Maria Correa, *Unfair Competition Under the TRIPs Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals*, 3 CHI. J. INT'L L. 69, 72-73 (2002) [hereinafter Correa, *Unfair Competition*].

75 *Id.*

76 Article 39 of TRIPs states:

> 1. In the course of ensuring effective protection against unfair competition as provided in Article 10 *bis* of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.
>
> 2. Natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to acquire by, or used by others without their consent in a manner contrary to honest commercial practices so long as such information:
>
> (a) Is secret in the sense that it is not, as a body or in the precise configuration and assembly
>
> of its components, generally known or readily accessible to persons within the circles
>
> that normally deal with the kind of information in question;
>
> (b) Has commercial value because it is secret; and
>
> (c) Has been subject to reasonable steps under circumstances, by the person lawfully in
>
> control of the information, to keep it secret.
>
> 3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.

TRIPs Agreement, *supra* note 1, art. 39.

77 Skillington & Solovy, *supra* note 62, at 2−6.

78 *Id.*

Article 39.2 clarifies the standards for this protection.[79] Meanwhile, Article 39.3 specifies that undisclosed information regarding pharmaceutical and agricultural NCEs which is submitted to regulatory authorities must receive governmental protection against unfair commercial use under certain conditions.[80]

Article 39.2 clarifies that certain conditions have to be met in order for the data to receive protected status. A party seeking protection for its product must submit "undisclosed test or other data" for a drug containing a "new chemical entity" of a pharmaceutical or agricultural product[81] to a national drug regulatory authority. Additionally, generating the test data must have required "considerable effort" which was put forth in a bid to obtain marketing approval for the drug. If these conditions are met, then WTO members are obliged to protect the test data against unfair commercial use and, further, to avoid disclosing such data unless they have put in place a system designed to protect the data against unfair commercial use.[82] Disclosure, however, is allowed in the case of the protection of public.[83] After the TRIPs implementation, this article was subjected to different interpretation, as many of the terms used are not clearly defined. These terms are "unfair commercial use," "new chemical entities," "considerable effort," and "necessary to protect the public."[84] The difference in interpreting these terms created different implementation approaches between developing and developed countries.[85]

C. Interpretation and Controversies on Interpretation

As noted earlier, the pliant language of Article 39.3 makes it susceptible to various interpretations. Essentially, the Article's definitional silence concerning its key terminology allows WTO members the latitude to determine what "unfair commercial," "new chemical entities," "considerable effort," and "necessary to protect the public" mean. Indeed, the TRIPs Agreement deliberately avoids

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79 *Id.*

80 *Id.*

81 Shreya Matilal, *Do Developing Countries Need a Pharmaceutical Data-exclusivity Regime?* 32 EUR. INTELL. PROP. REV. 268, 272−75 (2010) [hereinafter Matilal].

82 *Id.*

83 *Id.*

84 *Id.*

85 *Id.*

defining the terms found in Article 39.3 in order to give member countries the freedom to implement the protection approach that they believe would be the most beneficial within their individual countries.[86] However, this interpretive freedom is not meant to be *carte blanche*, and any individual WTO member's interpretation of Article 39.3 must still cohere with the general aim the drafters of the article sought to achieve with its passage. The most important element in interpreting Article 39.3 is to refer to the history of negotiation of this article and to employ Article 31(2) of the Vienna Convention on the Law of the Treaties,[87] which instructs that the object and purpose of the treaty must be carefully considered where necessary[88] to determine the ordinary meaning of a particular word.[89]

Recourse to these traditional methods of construction, however, has not fully resolved conflicting interpretations of the article's provisions. In particular, there has been a debate between developed countries, who insist that the proper interpretation of the article includes data exclusivity requirements, and developing countries, who insist that Article 39.3 requirement that members cannot disclose the originator company's test data to third parties does not prohibit a regulatory authority from relying on this test data when granting a generic product market approval.[90]

Ultimately, Article 39.3 perhaps anticipated this debate, and its language reflects a compromise between the conflicting policy of access to affordable medicines and considerations of strong intellectual-property protection policy, and gave the boundaries for the protection of test data, and left its implementation for each member country to choose what benefits it best.[91]

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86 *Id.*

87 Vienna Convention on the Law of Treaties (VCLT) is a treaty concerning the international law on treaties between states. It was adopted on 22 May 1969, opened for signature on 23 May 1969. The Convention entered into force on 27 January1980. It applies only to treaties concluded between states, so it does not cover agreements between states and international organizations or between international organizations themselves. Vienna Convention on the Law of Treaties, May 23, 1969, 1155 U.N.T.S. 331; 8 I.L.M. 679 (1969) [hereinafter VCLT], https://treaties.un.org/doc/Publication/UNTS/Volume%201155/volume-1155-I-18232-English.pdf.

88 Correa, *Unfair Competition*, *supra* note 74, at 84.

89 *Id.*

90 Matilal, *supra* note 81, at 271.

91 *Id.*

1. Conditions of Protection

a. Data Necessary for Marketing Approval

"Members, when requiring, as a condition of approving the marketing of . . ."[92]

The first condition of this article is territorial: If the drug regulatory authority of the member country requires test data submission in order to get the approval of marketing of the pharmaceutical product, then it should protect this test data.[93]

Generally, there are two competing interpretations of this sentence. On one side, Correa has concluded that if the drug regulatory authority does not require the submission of test data for approving a pharmaceutical product, then this article will not apply.[94] Following from this, any test data voluntarily submitted or in excess of what is required to approve a pharmaceutical product in that country, would not be subjected to the provisions of Article 39.3.[95]

On the other side, Skillington and Solovy have a different interpretation concerning what data falls under the provisions of Article 39.3, namely that TRIPs Article 39.3 does not expressly limit protection to data submitted directly to the drug authority of the WTO member to acquire the protection.[96] In this scheme, the drug authority may rely on the assessment and approval of the drug product in other countries, or if it requires the submission of test data to a nongovernmental research facility for its evaluation.[97] Thus, contrary to Correa, Skillington and Solovy assert that Article 39.3 requires the protection of the data regardless of to which authority the data was submitted or who did the evaluation. This interpretation is predicated on the idea that, without their evaluation, they would not approve the marketing of this product in the country; therefore, protection is deemed necessary.[98]

I have the same opinion of Correa, namely that where the submission of test data is not required, any submitted data should not receive

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92 TRIPs Agreement, *supra* note 1, art. 336.

93 Correa, *Unfair Competition*, *supra* note 74, at 72−73.

94 *Id.*

95 *Id.*

96 Skillington & Solovy, *supra* note 62, at 47−52.

97 *Id.*

98 *Id.*

protection under Article 39.3. This logic extends to situations where there has been reliance on other reference countries' approval, particularly since this condition was omitted from the draft Article 39.3.

Nevertheless, some WTO members have resolved this debate by clarifying the issue in their Free Trade Agreements (FTAs), ultimately deciding this interpretive option is no longer available. For example, the U.S.-Jordan FTA specifies in article 4 footnote 11, "[i]t is understood that, in situations where there is reliance on evidence of approval in another country, Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use."[99] Thus, the provisions of this FTA mean that Jordan cannot use this flexibility found in TRIPs.

b. New Chemical Entity

"*[P]harmaceutical or of agricultural chemical products which utilize new chemical entities . . .*"[100]

−New Definition, Local or Universal

The second condition stated in Article 39.3 provides that in order to receive protection, test data should be related to a "new chemical entity" of pharmaceutical and agricultural chemical products. In this condition, there is some ambiguity as to the parameters of the word "new," and TRIPs did not provide a definition. The ordinary meaning of the word "new" is not existing before, of a kind now first invented or introduced; novel; or now known, experienced, used, etc. for the first time. According to Vienna Convention Article 31, the word should be interpreted according to its use within the context.[101] There has been a schism here, with some considering that "new" should be interpreted as novel, as in the patent articles of the TRIPs Agreements, while others have interpreted it as used for the first time, because contextually the word refers to the status of a chemical entity within the drug regulatory authority.[102] Also, issues have arisen as to whether the newness of a

99 U.S.-Jordan FTA, *supra* note 9, at 7.

100 TRIPs Agreement, *supra* note 1, art. 336.

101 Skillington & Solovy, *supra* note 62, at 26−27.

102 *Id.*

drug is to be determined universally or locally, if it is the first application in the world or in the member country.[103]

Ultimately, the best course of action is for each member country to define a period after which the chemical entity will not be considered new. This action will encourage the originator drug company to register new chemical entities directly without any delay, and consequently the generic product will be in the market faster.

−*Known chemical entity*

Another issue is whether a chemical entity should be considered new if it was already known within another field, but a new therapeutic indication was found for this old chemical entity.[104] On this account, one view, which is in line with TRIPs Article 39.3, states that if the chemical entity was previously received by the same drug regulatory authority[105] it should be excluded and not acquire a protection period, even if the relevant authority required the submission of test data, such as new dosage forms, new combinations, new uses, crystalline forms, isomers, etc., of the old chemical entity.[106] This view was supported by the European Court of Justice's decision in *Regina v. The Licensing Authority, ex parte Generics* (1968) (UK).[107] Here, the Court decided not to provide a new period of marketing exclusivity for a new indication, a new dosage form or a new dosage schedule.[108] The European Court of Justice held that

> [A] (second) product is essentially similar to an earlier approved product if the second product has the same qualitative and quantitative composition in terms of active principles, the same pharmaceutical form and is bio-equivalent to the first product, unless it is apparent in the light of scientific knowledge that it differs significantly from the original product as regards safety or efficacy.[109]

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103 Susan Scafidi, J.D., Case Study Question, *How Do International Trade Agreements Influence the Promotion of Public Health?*, 4 YALE J. HEALTH POL'Y L. & ETHICS 341, 343 (2004) [hereinafter Scafidi].

104 *Id.* at 345.

105 *Id. See also* Correa, *Unfair Competition*, *supra* note 74, at 74−79.

106 Scafidi, *supra* note 103.

107 *See* Case C-368/96, The Queen v. Licensing Auth. *ex parte* Generics Ltd., Case C-368/96 [1992] E.C.R. I-7967.

108 Correa, *Unfair Competition*, *supra* note 74, at 75.

109 *Id.*

In contrast to the European Court of Justice, the United States has elaborated this condition within its FTAs to include "new uses of old chemical entity," i.e., "second indication," new dosage forms and combinations. Article 4, footnote 10 of the U.S.-Jordan FTA adds the protection of new uses of old chemical entities for three years: "It is understood that protection for "new chemical entities" shall also include protection for new uses for old chemical entities for a period of three years."[110]

−Naturally and Biological products

As with the words "known" and "new," Article 39.3's use of the word "chemical" has also prompted conflicting views as to what this entails. One view holds that the word "chemical" means biological products, and, thus, naturally occurring products are not protected.[111] Opposing this view, Skillington and Solovy hypothesized that this interpretation would discourage drug companies from investing in safe and effective, naturally occurring substances, such as biological substances which are not patentable and important in cancer therapies.[112] These biotech products, like monoclonal antibodies, are very difficult for generic companies to develop and the absence of data exclusivity in a country would discourage the originator company from entering this market, which would have the deleterious effect of depriving people of the benefits of these drugs.[113]

On the official front, The Jordan Food and Drug Administration (JFDA)[114] provided a definition of "new chemical entity" in a circular from June 2009. In this circular, the JFDA holds that, in order to be considered new, a chemical entity should be submitted for registration to the JFDA within eighteen months of its first approval in any other countries.[115] Additionally, the JFDA stated that isomers and new

110 U.S.-Jordan FTA, *supra* note 9, at 7.

111 Skillington & Solovy, *supra* note 62, at 25−28.

112 *Id.*

113 Matilal, *supra* note 81, at 275.

114 JORDAN FOOD AND DRUG ADMINISTRATION, http://www.jfda.jo/Default.aspx (last visited Aug. 15, 2014).

115 In an official circulation dated June 16, 2009, JFDA Director General of JFDA, Dr. M. Rawashdeh states:

> New Chemical Entity is the pharmaceutical product that contains active moiety or moieties that is responsible for physiological or pharmacological effect whereby no more than eighteen months have elapsed from the date of first registration of any of its ingredients (components) singly or collectively in any country in the world irrespective of any difference in, including but not limited to, type of salt, ester, isomer, complex or other derivative. A pharmaceutical product shall be considered

crystalline forms are not considered as new chemical entities.[116] This point will be discussed in the second part of this paper.

c. Undisclosed Data

"[T]he submission of undisclosed test or other data . . ."[117]

The third condition for gaining protection is that the test data should be undisclosed. This means disclosed information in the public domain will not granted any protection,[118] and a generic company can rely on this published data to register its products. Also, if the relevant drug regulatory authority requires the submission of published data, then no protection will be granted.[119] Skillington and Solovy commented on this point, namely that the test data should be undisclosed at the time of submission and the disclosure afterward does not end the protection period.[120] Also, test data disclosure by a third party still requires protection against unfair commercial practices.[121]

This condition necessitates that drug regulatory authorities ascertain whether the submitted data is disclosed or not before granting the protection period. Furthermore, the authority's assessment as to whether the submitted data has been disclosed should not depend on the applicant's declaration.[122] The JFDA, among other drug regulatory authorities, does not investigate this point, although they do assess only the published data of Phase III.[123] Nevertheless, they grant five years data exclusivity, as I will explain in the second part of this paper.

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to have the same chemical entity even if there is a difference in polymorph, metabolite, enantiomer, solvate, size of particles, formulation, combination, or method of use, pharmaceutical dosage form or concentration.

This translation was adopted by the JFDA. Circulation No. 2/9/1/17645, June 16, 2009, *in* Official Gazette of Jordan [hereinafter JFDA Circulation].

116 *Id.*

117 TRIPs Agreement, *supra* note 1, art. 39.

118 Correa, *Unfair Competition*, *supra* note 74, at 74.

119 *Id.* at 73.

120 Skillington & Solovy, *supra* note 62, at 32.

121 *Id.*

122 Correa, *Unfair Competition*, *supra* note 74, at 74.

123 Ryan B. Abbott et al., *The Price of Medicines in Jordan: The Cost of Trade-based Intellectual Property*, 9 J. GENERIC MED. 75, 77 (2012) ("The JFDA does not check to see whether data submitted for regulatory approval has been previously disclosed.").

d. Considerable Effort

"*[T]he submission of undisclosed test or other data, the origination of which involves a considerable effort . . .*"[124]

Article 39.3 provides that the origination of test data should involve considerable effort, and drug regulatory authorities should ask the applicant to prove that the test data submitted is the result of considerable effort. The problem in applying this article is that the type of effort required and its magnitude are left vague.[125] As per Skillington and Solovy, the ordinary meaning of "considerable" is "worthy of consideration or regard," "of consequence or worthy of consideration by reason of magnitude," or "somewhat large in amount, extent, duration."[126] The ordinary meaning of "effort" is "exertion or striving, physical or mental; a vigorous attempt" or "the result of any concentrated or special activity."[127] Therefore, it is likely that the term "considerable effort" would be interpreted to mean concentrated or special activities, physical or mental, that are extensive in scope or duration.[128] The conduct of the tests needed to produce data required by health authorities would normally fall within this interpretation of the phrase "considerable efforts."[129]

Skillington and Solovy concluded that the origination of test data required by most drug regulatory authorities complies with the Article 39.3's requirement of considerable efforts.[130]

2. TRIPs Obligations

If the test data fulfills the above conditions, WTO members are obliged to protect it against disclosure and unfair commercial use.[131] Based on TRIPs Article 39.3, this protection is not absolute, because disclosure is permitted in a case where it is necessary to protect public health, and if steps are taken to ensure that the data is protected against unfair commercial use.[132] Under the language of Article 39.3, granting marketing approval for a generic product based on its similarity to the

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124 TRIPs Agreement, *supra* note 1, at 336.

125 Skillington & Solovy, *supra* note 62, at 28−29.

126 *Id.*

127 *Id.*

128 *Id.*

129 *Id.*

130 *Id.*

131 Correa, *Unfair Competition*, *supra* note 74, at 75−76.

132 *Id.*

originator product may not be considered dishonest use.[133] The definition of dishonest or unfair commercial practice is dependent on social perceptions in each country.[134]

a. Nondisclosure

Article 39.3 requires members to protect the submitted undisclosed data from disclosure without defining of the maximum period of preventing the disclosure, which is apparently until the submitted materials become known.[135] However, there are two cases in which disclosure is permitted, according to this article.

The first case is when the disclosure is important to protect the public; this exception is limited to the necessity degree which is according to General Agreement on Tariffs and Trade GATT/WTO rules, each country should determine when the necessity is found.[136] Nevertheless, Skillington and Solovy noticed that the cases that the disclosure would benefit the public are few,[137] because the volume of these test data is huge, and it would be difficult to the public to read it unless they are experienced in this topic, and only competitors would benefit from this disclosure by using these data to submit their product.[138]

The second case is when steps are taken to prevent unfair commercial use, how the protection is guaranteed and what is unfair commercial use is unclear.[139] Skillington and Solovy concluded that the emphasis of this point for the second time in Article 39.3 requires members to provide additional regulations, like providing a much longer period of exclusivity in the case of disclosure.[140]

b. Acts of Unfair Commercial Use

"[S]hall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except

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133 *Id.*
134 *Id.*
135 *Id.*
136 *Id.*
137 Skillington & Solovy, *supra* note 62, at 48.
138 *Id.*
139 *Id.*
140 *Id.*

where necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use."[141]

Of all the competing views concerning the ambiguous language of Article 39.3, the interpretation of the above-referenced obligation has been the most controversial. This controversy has centered on the issue of whether it is an "unfair commercial use" where a drug regulatory authority relies on test data submitted by an originator drug company in its evaluation of a secondary applicant.[142]

As discussed earlier, according to Vienna Convention, the interpretation should refer to the ordinary meaning of words in their relevant context, taking into account the agreement's object and purpose, and should also look to the negotiation history of the legal instrument at issue.[143]

In this case, the ordinary meaning of "unfair commercial use," as stated by Skillington and Solovy, breaks down the term into its component parts: "The ordinary meaning of 'unfair' is 'not equitable, unjust; not according to the rules, partial,'"[144] and "[c]ommercial" means "engaged in the commerce of pertaining to, or bearing on commerce" or "interested in financial return rather than artistry; likely to make a profit; regarded as a mere matter of business."[145] Finally, "use" means an "action of using or state of being used; application or conversion to some purpose and 'ability to be used, especially for a particular purpose; usefulness; advantage.'"[146]

Heeding the analytical devices outlined in the Vienna Convention, going back to the negotiation history of this article reveals that, according to the United States' proposal, a protection period of a minimum five years was included in the article draft. The text below is the draft presented to the Ministerial Conference in Brussels in December 1990:

> 4A PARTIES, when requiring, as a condition of approving the marketing of new pharmaceutical products or of a new agricultural chemical product, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall [protect such data against unfair commercial use. Unless the person submitting the information agrees, the data may not be relied upon

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141 TRIPs Agreement, *supra* note 1, art. 39.

142 Correa, *Unfair Competition*, *supra* note 74, at 76−77.

143 *Id.*

144 Skillington & Solovy, *supra* note 62, at 29−30.

145 *Id.*

146 *Id.*

> for the approval of competing products for a reasonable time, generally no less than five years, commensurate with the efforts involved in the origination of the data, their nature, and the expenditure involved in their preparation. In addition, PARTIES shall protect such data against disclosure, except where necessary to protect the public.[147]

The draft text[148] included two points that were omitted in the final text. First, a prohibition on authorities' reliance on previously submitted test data as a basis for the approval of competing products;[149] and, second, a statement requiring a minimum protection period of five years.[150]

The omission of these points in the final text has been interpreted differently.[151]

For one, Correa argued that the U.S. draft proposal of Article 39.3 did not have the support of WTO members. Therefore, Correa's view holds that because these provisions were purposely removed due to a lack of consensus, Article 39.3 should not be interpreted on the basis of this draft which the supporters of data exclusivity regime are referring.[152] Moreover, despite the opportunity to do so, the final text knowingly does not include a prohibition relating to an authority's reliance on submitted data when evaluating subsequent applications, nor does the final text contain any language suggesting such a practice is an "unfair commercial use." Correa, interpreting this article according to the ordinary meaning of the words in light of their context, found that the plain language of Article 39.3, in addition to its negotiation history, does not require exclusive rights.[153] Instead, the obligations of this article can be fulfilled by other approaches, the particular approach being left to each individual country's judgment.[154]

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147 *Id. See also* TRADE NEGOTIATIONS COMMITTEE, Draft Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations, GATT. Doc. MTN.TNC/W/35 (Dec. 3, 1990) [hereinafter Draft Final Act].

148 Draft Final Act, *supra* note 147; *see also* Chapter 28: Undisclosed Information *in* RESOURCE BOOK ON TRIPS AND DEVELOPMENT at 526, INTERNATIONAL CENTRE FOR TRADE AND SUSTAINABLE DEVELOPMENT (ICTSD) (Nov. 30, 2004) (discussing the import of the various omissions in the final text of the TRIPs Agreement).

149 Correa, *Unfair Competition*, *supra* note 74, at 83−84.

150 *Id.*

151 *Id.*

152 *Id.*

153 *Id.*

154 *Id.*

Correa acknowledges that Article 39.3 does impose an unequivocal duty on WTO members that obliges them to protect any applicable test data.[155] Ultimately, though, Correa concludes that a government authority's reliance on earlier-submitted test data does not constitute unfair commercial use.[156] Correa referred to the "UNCTAD" conference in relation to this article in supporting his interpretation [157]

Correa arrived at the above-discussed conclusion by parsing out the operative terms of Article 39.3 on a linguistic level. The word "unfair," for example, should be interpreted in accordance with Article 39.1's reference to Article 10 *bis* of the Paris Convention,[158] which allows differences between countries in defining "unfair commercial use."[159] In defining "commercial," Correa posits that commercial use should be in reference to an entity that is already on the market. Regarding word use,[160] he explained that there are different approaches followed by drug regulatory authorities when approving a generic product (1) Some authorities require the generic product producer to submit its own test data; (2) Others rely on originator test data after payment has been made to compensate the originator for the expense of generating the test data; (3) Certain regulatory authorities rely on the originator test data in order to approve the generic product; (4) And, finally, a fourth approach to approving a generic product sees numerous regulatory authorities approve the generic product without examining the originator test data.[161] According to Correa, none of the above approaches could be considered unfair commercial uses, as the generic company is not accessing the originator test data by himself.[162]

According to Correa, this interpretation has judicial support in two cases: in *Ruckelshaus v. Monsanto*,[163] a U.S. case, and in *Bayer v. Canada*, a Canadian case.[164] Though their analytical postures differed,

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155 *Id.*

156 *Id.*

157 U.N. Conference on Trade and Development, *The TRIPs Agreement and Developing Countries* (1996), U.N. Doc. UNCTAD/ITE/1, http://unctad.org/en/docs/ite1_en.pdf.

158 Correa, *Unfair Competition*, *supra* note 74, at 77−80.

159 *Id.*

160 *Id.*

161 *Id.*

162 *Id.*

163 *Id.*

164 *See Ruckelshaus v. Monsanto*, 467 U.S. 986, 1005 (1984) (holding that any inquiry into whether a governmental agency runs afoul of the U.S. Constitution where it discloses a company's submitted test data requires a court to assess "the character of the governmental action, its economic impact, and its interference with reasonable investment-backed

both courts held that the government's approval of a subsequent application on the basis of an originator's prior registration was proper. As to these outcomes, some countries may consider a health authority's reliance on test data to approve a second entrant to be an "unfair commercial use," while others may not. As with the U.S. and Canada, however, each country is free to give effect to its own interpretation, done according to each country's values and competitive advantages.[165]

In 2001, developing countries submitted a group paper to the TRIPs council confirming their position against data exclusivity.[166] In this paper, these countries clarified that it is their collective interpretation that there is no data exclusivity requirement within the text of TRIPs Article 39.3. Following from this premise, the developing countries asserted their position that a drug regulatory authority's reliance on originator test data as a basis for granting approval to a generic product, did not constitute an "unfair commercial use." Thus, any such reliance does not necessitate the wait period established under the data exclusivity regime.[167] Instead, the developing countries saw that an "unfair commercial use" occurred where generic companies directly accessed the originator's submitted test data. As such, Article 39.3 required drug regulatory authorities to protect an originator's undisclosed test data against subsequent improper disclosure, and should put in place a legal framework to prevent generic companies from accessing the undisclosed data. The position of the developing countries can be summarized as follows:[168] the protection is to be granted against 'unfair commercial use' of confidential data. This means that a third party could be prevented from using the results of test undertaken by another company as background for an independent

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expectations") (quoting *PruneYard Shopping Center v. Robins*, 447 U.S. 74, 83 (1980); *see also Bayer* v. *Canada* (Attorney General), [1999], 243 N.R. 170 (Fed. Ct.) (Can.), *appeal denied* [2000] 259 N.R. 200 (Can.). In this case, the court held that a generic product may be approved by a regulatory authority "by showing that the[ir] product is the pharmaceutical and bioequivalent of the [originator's] product." However, if the generic product's approval is predicated on the basis of data submitted by the originator company, then the five-year data exclusivity period will be applicable. The Bayer Court justified this holding on the rationale that in the aforementioned scenario, "the safety and effectiveness of the generic product will only be established by reference to confidential information provided to the Minister by the [originator].").

165 Correa, *Unfair Competition*, *supra* note 74, at 77.

166 *Id.*

167 *Id.*

168 *Id.*

submission for marketing approval,[169] if the data had been acquired through dishonest commercial practices.[170] However, Article 39.3 does permit a national competent authority to rely on data in its possession to assess further applications, relating to the same drug, since this would not imply unfair commercial use.[171]

A second interpretation of what Article 39.3 mandates in terms of data protection is presented in the work of Skillington and Solovy, which supports the data exclusivity approach, contingent on the negotiation history of the relevant legal instrument.[172] Skillington and Solovy point to an interpretation of "unfair commercial use" provided by the United States Trade Representative (USTR) as evidence of support for their position. The USTR provided the following interpretation of "unfair commercial use" in light of the negotiating history in 1995, after the implementation of the TRIPs Agreement:[173]

> TRIPs negotiators understood it [the term "unfair commercial use"] to mean that the data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data.[174] Any other definition of this term would be inconsistent with the logic and the negotiating history of the provision.[175]

In addition to this statement by the USTR, Skillington and Solovy present a statement made by the New Zealand government, a statement they see as espousing the data exclusivity approach:[176]

> Defining 'unfair commercial use' can only properly be done by reference to the context of the complete provision, i.e., the purpose behind the provision. In the light of this, we interpreted Article 39.3 as meaning that there is a restriction on the use which regulatory authorities can make of original data they hold in order to approve subsequent applications for approval of generic medicines, animal remedies or pesticides. In other words, where undisclosed information is provided to a regulatory authority by an applicant so that the authority can approve the applicant's product, if this

169 Matilal, *supra* note 81, at 271−72.

170 *Id.*

171 *Id.*

172 Skillington & Solovy, *supra* note 62, at 33.

173 *Id.*

174 *Id.*

175 *Id.*

176 *Id. See also* INT'L FED'N OF PHARMACEUTICAL MANUFACTURERS ASSOC., ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 2 (2000), http://www.who.int/intellectualproperty/topics/ip/en/DataExclusivity_2000.pdf [hereinafter IFPMA].

> information is then used by the authority to approve the product of a second applicant this is, in New Zealand's view, 'unfair commercial use.'[177] In effect, the regulatory authority is giving a commercial advantage to the second applicant in that the applicant does not have to generate the data which was required of the first applicant. This can be a significant economic saving.[178]

Skillington and Solovy arsenal of support for data exclusivity goes on to include a statement from the European Commission:[179]

> Both the logic and the negotiating history of Article 39.3 of TRIPs leave no doubt that providing data exclusivity for a certain period of time was the envisaged way to protect data against unfair commercial use as prescribed by Article 39.3. Whether any system other than data exclusivity over a reasonable period of time would meet the requirements of Article 39.3 of the TRIPs Agreement is to be assessed on a case-by-case basis, but examples of actual application by WTO Members of alternative—and TRIPs compliant—systems to nonreliance over a reasonable period do not appear to exist.[180]

In addition Skillington and Solovy have referred to one of the views that the members who are approving the reliance on test data are protecting test data against disclosure and not protecting the data from unfair commercial use. This practice violates TRIPs Article 39.3.[181]

Because the TRIPs Agreement does not specify any particular protection period, those endorsing the data exclusivity approach must account for this. Here, Skillington and Solovy advance the idea that the appropriate waiting period reaches its conclusion when the originator company recovers the cost invested in originating the test data. Functionally, the usual period under this rubric is five to ten years, depending on both the effort expended and the country at issue.[182] Overall, Skillington and Solovy's work confirms their joint position that data exclusivity is the best approach to satisfy the purpose of data protection, which in their view, is to encourage originator companies

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177 Skillington & Solovy, *supra* note 62, at 31.

178 *Id.*

179 *Id.*

180 *Id. See also* EUROPEAN COMMISSION, PUBLICATION ON QUESTIONS ON TRIPS AND DATA EXCLUSIVITY: AN EU CONTRIBUTION 18−22 (2001), http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf.

181 Skillington & Solovy, *supra* note 62, at 33−34.

182 *Id.*

to invest more in the invention of new drugs and, correspondingly, to provide the incentives to accomplish greater investment.[183]

Concerning the economic implications of the data exclusivity approach, Sheryia, like Skillington and Solovy, espouses the view that a failure to implement the data exclusivity regime serves narrow self-interests, a condition that will ultimately lead to serious economic problems by destabilizing the incentive balance that intellectual property provides to originator companies to invest more in developing drugs.[184] Moreover, an economic landscape without data exclusivity protections will produce originator companies that are reluctant to enter developing countries' markets, the consequence of which will be a lack of the supply to those countries.[185]

To summarize the preceding section, the controversy surrounding the interpretation of Article 39.3 of the TRIPs Agreement allows for the conclusion that the open-ended language of Article 39.3 was intentional, left on purpose for each member country to apply the protection approach that conforms best to its need for better health and economic situations, areas in which there is chasm of difference between developed and developing countries.[186] If the data exclusivity regime, which is supported by developed countries like the United States and the European Union, fulfills their economic and health needs, this does not mean it will be the appropriate approach for developing countries.[187]

Up until now, there has been no WTO ruling regarding members that have not implemented exclusive rights.[188] In one case, the U.S. initiated a case against Argentina for its failure to properly implement protections for test data.[189] This dispute was resolved after two years of discussion, and in the end, Argentina did not change its law nor did it

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183 *Id.*

184 Matilal, *supra* note 81, at 269.

185 *Id.*

186 CARLOS MARÍA CORREA, SOUTH CENTRE, PROTECTION OF DATA SUBMITTED FOR THE REGISTRATION OF PHARMACEUTICALS: IMPLEMENTING THE STANDARDS OF THE TRIPS AGREEMENT 6–7 (2002) [hereinafter CORREA, SOUTH CENTRE], http://www.who.int/medicines/areas/policy/protection_of_data.pdf.

187 *Id.*

188 *Id.*

189 Argentina—Patent Protection for Pharmaceuticals and Test Data Protection for Agricultural Chemicals—Notification of Mutually Agreed Solution According to the Conditions Set Forth in the Agreement, WT/DS171/3, WT/DS196/4 (June 20, 2002); *see also* CORREA, SOUTH CENTRE, *supra* note 186.

apply exclusive rights.[190] In addition, the United States Trade Representative (USTR) has listed, under the special section of 301 of the Trade Act, many countries that it does not see as applying adequate protection for test data.[191]

Bilateral agreements were the solution for some countries like the U.S. in which they elaborated on the standards of regulatory data protection and were able to secure greater intellectual property than that which was provided in Article 39.3.[192] These bilateral agreements, known as TRIPs-plus or Free Trade Agreements (FTAs), have defined the protection period and extended the protection term to include not only NCEs but, among others, new uses of old chemical entities and new dosage forms.[193]

D. Jordan Unfair Competition and Trade Secrets Law

In Article 8 of its Unfair Competition and Trade Secrets Law of 2000, Jordan adopted a five-year data exclusivity period for NCEs.[194] As discussed above, though the TRIPs Agreement did not require a member state to implement any particular exclusivity period, Jordan forewent this freedom for political reasons, and its adoption of a five-

190 Correa, SOUTH CENTRE, *supra* note 186, at 6–7.

191 *Id.*

192 Anthony Taubman, *Unfair Competition and the Financing of Public-Knowledge Goods: The Problem of Test Data Protection*, 3 OXFORD J. INTELL. PROP. L. & PRAC. 594 (2008).

193 Malpani, *supra* note 16, at 11.

194 Article 8 states:

> If an official party stipulated, for approving for the marketing of pharmaceuticals, or agrochemical products in which new chemical materials are used, the submission of secret formulae or any data attained through considerable efforts such party should observe the following:
>
> A. The protection of such data from the unclassified commercial use, through preventing any other person who did not obtain the applicant approval from depending thereon for marketing his pharmaceuticals and products except after 5 years as of the date of the applicant obtaining any approval for marketing his products.
>
> B. Protecting such data from disclosure, unless:
>
> 1. The disclosure is necessary for protecting the public.
>
> 2. The official party has taken the necessary steps for the protection from unclassified commercial use of such data. The translation of the word "unclassified" is not correct, the right translation is (unfair).

Unfair Competition Law, *supra* note 8 art. 8.

year data exclusivity period was done as part of its accession to the WTO.

In the same year, Jordan signed a bilateral agreement, an FTA, with the United States.[195] This FTA includes more intellectual property constraints. These new obligations are:

− To accede to or ratify the Patent Cooperation Treaty (PCT); until now Jordan did not accede to the PCT.[196]

− Notification System; the JFDA has effectuated this obligation by publishing all submitted registration application on its website.[197]

− Grounds for the issuance of compulsory licenses are limited to a situation where such a license is a necessary to remedy an anti-competitive practice, in case of public noncommercial use, or in the case of national emergency or other situations of extreme urgency.[198] And, on the ground of failure to meet working requirements, it is provided that importation shall constitute working.[199]

− Patent extension to compensate for the delay in marketing approval process.[200]

− Data exclusivity period of three years for new uses of old chemical entities.[201]

− In case of reliance on another drug regulatory authority's approval, Jordan shall at a minimum protect such information against unfair commercial use for the same period of time the other country is protecting such information against unfair commercial use.

Therefore, the U.S-Jordan FTA added two additional constraints regarding protection of test data, one constraint through the addition of a data exclusivity period of three years for new uses of old chemical entities, and the other by the FTA's consideration that reliance on the other reference drug regulatory authority should be granted a data exclusivity period similar to that country. Ultimately, these constraints in the U.S-Jordan FTA have the effect of denying Jordan the freedom to apply other data protection approaches and thus benefiting from the flexibilities found in the TRIPs Agreement.[202]

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195 U.S.-Jordan FTA, *supra* note 9.

196 Malpani, *supra* note 16, at 11.

197 *Id.*

198 *Id.*

199 *Id.*

200 *Id.*

201 *Id.*

202 *Id.*

II
NATIONAL EXPERIENCE

The Jordan Administration of Food and Drugs (JFDA) is the authority responsible for enforcing data exclusivity in Jordan. To this effect, the JFDA implemented data exclusivity protections for NCEs after the adoption of the Unfair Competition and Trade Secrets Law in 2000. Furthermore, the JFDA have allowed for the newly adopted data exclusivity provisions to be applied retroactively, meaning that NCEs approved prior to Jordan's adoption of the Unfair Competition and Trade Secrets law would now be granted the protections of the data exclusivity regime.[203] The effect of the JFDA's retroactive implementation of data exclusivity was to block the registration of many generic products, which affected the local industry extensively.[204] Meanwhile, the JFDA began enforcing data exclusivity protection for new uses of existing chemical entities in December of 2004, at the end of the three-year grace period after signing the US-Jordan FTA.[205]

In this Part, I will discuss the procedure followed by the JFDA to implement data exclusivity protection, and I will assess the impact of data exclusivity in Jordan with regard to access to affordable medicine, foreign investments in Jordan and its cumulative effect on the local pharmaceutical industry.

A. JFDA Data Exclusivity Implementation Procedure

In the period after Jordan's acceptance of the data exclusivity regime, it restricted the submission of the registration file of a generic product until the final year of the data exclusivity period for the originator product. In turn, the marketing approval for a generic product will become effective at the end of this data exclusivity period as per the drug registration criteria.[206]

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203 Ryan B. Abbot et al., *The Price of Medicines in Jordan: The Cost of Trade-Based Intellectual Property*, 9 J. GENERIC MED. 75 (2012), [hereinafter Abbot], http://academic.ju.edu.jo/i.abbadi/Lists/PublishedResearches/DispForm.aspx?ID=4&ContentTypeId=0x010028AB12C9A1820347BFF3C806BD2A70BB.

204 E-mail from Hiba Zarour, Hikma Pharmaceuticals to Wael Armouti (Aug. 31, 2014).

205 *Id.*

206 The Criteria of Registration of Drugs (Regulation of Drug Registration and Its Amendments), OFFICIAL GAZETTE OF JORDAN NO. 4639 (2014), [hereinafter Registration of Drugs], http://www.jfda.jo/Default.aspx (last visited Oct. 10, 2014).

However, the criteria used by the JFDA for granting data exclusivity for NCEs and for new uses of existing chemical entities are, unfortunately, not well defined.[207] In fact, the JFDA does not investigate whether the test data at issue, that which was submitted with the originator product, even fulfills all the conditions of Article 39.3 of the TRIPs Agreement prerequisite to data exclusivity protection.[208]

As discussed above, the four conditions to be fulfilled are:

1. Data necessary for marketing approval: The JFDA requests the submission of preclinical and clinical data as a condition of approval of a new product, and does not rely on other countries approval.[209] The JFDA in its registration criteria requests the marketing of a new product for at least one year for safety purposes. The submitted test data are assessed by the technical committee for new products which contain clinicians and academic experts.[210]

2. NCE definition: The JFDA, along with the collaboration of Jordan's Ministry of Industry and Trade, issued a circular defining NCE in June of 2009. This definition was the result of the efforts undertaken by the Jordanian Association of Pharmaceutical Manufacturers (JAPM)[211] to define both the NCE and the period after which the active ingredient will no longer be considered as a NCE.[212] The JAPM supported its request through a legal consultation with an American law firm and through World Intellectual Property Organization (WIPO) consultation, in which both confirmed that nothing prevented Jordan from legislatively adopting its own definition for NCE. Jordan would still meet the obligations found in both the TRIPs Agreement and the U.S.-Jordan FTA. Also, the American counsel and WIPO both confirmed that the practice of adopting its own definition of an Article 39.3 term had already implemented by some countries such as Israel.[213] Additionally, the JAPM supported its

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207 *Id.*

208 Saad Abughanm, The Protection of Pharmaceutical Patents and Data under TRIPs and the U.S.-Jordan FTA: Exploring the Limits of Obligations and Flexibilities: A Study of the Impacts on the Pharmaceutical Sector in Jordan (Apr. 29, 2009) (unpublished Ph.D. dissertation, University of Toronto) at 327 [hereinafter Abughanm], https://tspace.library.utoronto.ca/bitstream/1807/32296/1/Abughanm_Saad_A_201203_SJD_thesis.pdf.

209 Interview with Wesal Haqaish, Lina Bajjali, Maha Jaghbeer, Department Officials, JFDA (Sept. 19, 2014) [hereinafter Haqaish Interview].

210 *Id.*

211 JORDANIAN ASSOCIATION OF PHARMACEUTICAL MANUFACTURERS, http://www.japm.com (last visited May 3, 2015).

212 Letter from JAPM to Ministry of Health, No. 163/2007 (June 3, 2007).

213 *Id.*

request that Jordan adopt its own definition of NCE by referencing the current position of the United States, a position made clear in a letter authored by various members of the U.S. Congress which was addressed to the USTR, Ambassador Susan Schwab The letter emphasized the right of nations to use the flexibilities found in the TRIPs Agreement so as to promote better access to affordable medicine.[214] The letter stated that the provisions found in current FTAs have extended the monopolies of the originator companies without taking into consideration public health and the right of access to affordable medicine, and they should revise the provisions of intellectual property rights related to pharmaceuticals found in the FTAs under consideration.[215]

This circular provides a definition of NCE which excludes many products that used to be considered NCEs, such as isomers and different salts. In addition, it limits the period, to eighteen months, during which the originator can submit the NCE registration file to the JFDA in order to get the data exclusivity of five years,[216] an inclusion designed to prevent the delay in introducing an NCE, which would consequently the generic version of the NCE at issue.[217]

After issuing this circular, the JFDA's stated practice was to investigate whether the originator product fulfills the conditions stated therein. In several cases, the originator product came after the allotted eighteen-month period and, as a result, was not granted a five-year data exclusivity period.[218] Additionally, the JFDA's practice is to grant five years of data exclusivity protection for biological products which are not considered to be chemical entities; many countries do not grant data exclusivity for those products under these circumstances.[219] In 2006, the Minister of Trade and Industry issued a letter to the JFDA instructing it to define new uses as new therapeutic indications only and to exclude new dosage forms, new routes of administration as well

214 Letter from Rep. Henry A. Waxman et al., (Mar. 12, 2007), [hereinafter Letter to Ambassador Schwab], http://www.cptech.org/ip/health/c/thailand/congressional-schwab letter-thailand-10 jan06.pdf (Members of U.S. Cong., to Ambassador Susan C. Schwab, U.S. Trade Representative).

215 *Id.*

216 Circulation, *supra* note 115.

217 *Id.*

218 Haqaish Interview, *supra* note 209.

219 *Id.*

as new strengths from this definition.[220] Furthermore, the eighteen-month period afforded to a drug in order to be considered new is not applicable to new uses.[221] Despite these constraints, the effect of new uses is less harmful than for NCEs, because the generic product can register its product with the old use. The only condition to which a generic producer is subjected is the requirement that it not mention the new use on the leaflet. In practice, however, the generic product is marketed with the new use as an "off-label" use.[222] Together, these two circulars are considered to be one of the major steps the JFDA has taken to mitigate the negative effects of data exclusivity within the country.[223]

3. Undisclosed Data: The JFDA does not examine whether the submitted data are confidential and not published. On the contrary, they request Phase III of the clinical trials to be published.[224] This practice of the JFDA does not fulfill the requirements Article 39.3 of the TRIPs Agreement as to data confidentiality.

4. Considerable efforts: The JFDA does not examine if the generation of the submitted data involves considerable efforts nor has a definition of considerable efforts, a practice that also fails to meet the standards set forth in the TRIPs Agreement.[225]

The JFDA does not examine whether the submitted test data are confidential or whether its generation involves considerable efforts. The JFDA should define these two conditions and require the originator company to submit a declaration or certificate stating how these conditions are fulfilled.[226]

B. Data Exclusivity Statistics

Each February, the United States Embassy in Amman submits a letter to the Ministry of Industry and Trade addressing the efforts made by the different Jordanian agencies that are responsible for protecting and enforcing intellectual property rights (IPR).[227] This letter announces the start of the annual procedure of "Special 301" to

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220 *Id.*

221 Letter from Ministry and Trade to JFDA, No 18/1/15331 (June 6, 2006).

222 Abbott, *supra* note 203.

223 Abughanm, *supra* note 208, at 331.

224 Haqaish Interview, *supra* note 209.

225 *Id*.

226 Abughanm, *supra* note 208, at 284−87.

227 *See, e.g.*, SPECIAL 301 REPORT, OFFICE OF U.S. TRADE REP. (2004), https://ustr.gov/archive/assets/Document_Library/Reports_Publications/2004/2004_Special_301/asset_upload_file963_5996.pdf.

examine countries' protection and enforcement of IPR. The following agencies are requested to submit their position: Ministry of Industry and Trade; the National Library Department of Culture; the Audiovisual Commission; the Jordan Institution of Standards and Metrology (JISM); the Jordan Food and Drug Administration (JFDA); the Jordan Customs Department, the Public Security Department; and the Ministry of Justice."[228]

In the JFDA's annual position paper, it emphasized its efforts to enforce data exclusivity as found in Article 8 of the Jordanian Unfair Competition and Trade Secrets Law and in the U.S.-Jordan FTA.[229] As evidence of enforcement, the JFDA states the number of seized counterfeit drugs during the preceding year.[230] In the last report issued by the JFDA, issued in February of 2014, regarding the enforcement of the data exclusivity until 2013, the JFDA announced that it is committed to implementing five-year data exclusivity for any NCE, calculated from the date of marketing approval of the product.[231] Since 2000, 357 NCEs have been granted this five years of data exclusivity,[232] and the number of new uses granted three years of protection period comes in at 61, as recorded from December of 2004.[233] Furthermore, the JFDA report emphasizes that it is complying with the U.S.-Jordan FTA notification obligation for the originator companies concerning the submitted applications of generic products. The JFDA has accomplished this by publishing all the submitted registration applications on its website.[234]

After applying the NCE definition adopted in 2009, the number of NCEs granted five years' data exclusivity was drastically reduced:[235] From 2000–2009, 335 NCEs were granted five years data exclusivity products,[236] as compared to the period 2010–2013, in which only 22 NCEs received this same protection.[237]

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228 *Id.*

229 JFDA position paper submitted to the U.S. embassy regarding enforcing data exclusivity (JFDA Data 2000-2014) [hereinafter Jordan Position Paper].

230 *Id.*

231 JFDA letter to Ministry of Industry and Trade, No. 1/1/14/4442 (Feb. 9, 2014).

232 *Id*.

233 *Id*.

234 Jordan Position Paper, *supra* note 229.

235 *Id*.

236 *Id*.

237 *Id*.

C. Judicial Opinion (Merck Sharp & Dohme (MSD) vs. JFDA)

To date, only one case related to data exclusivity has been filed against the JFDA, the 2003 case *Merck Sharp & Dohme v. JFDA*.[238] The case was filed against the director of the JFDA, the JFDA board and against the High Committee of Drug at the JFDA. The plaintiff, MSD, had objected to the 2013 registration of a local generic product Alendomax (70 mg) by the Jordan Sweden Medical and Sterilization (JOSWE), claiming that the JFDA violated Article 8 of the Unfair Competition and Trade Secrets Law and Article 39.3 of TRIPs by not implementing the five years' data exclusivity for its originating product, Fosamax (70 mg). MSD asserted that this product merited data exclusivity protection period due to its new strength considered that its new strength 70 mg deserves the five years data exclusivity. MSD has previously registered Fosamax at a dosage of 10 mg. in 2008.

However, the case was dismissed for jurisdictional infirmities, claiming MSG had not brought suit against the appropriate committee (Technical Committee for Generic Drugs),[239] and consequently the court did not discuss the fact that a new strength for an old chemical entity does not require data exclusivity, nor did it discuss other technical issues material to the case.

D. Potential Impacts of Data Exclusivity in Jordan

Data exclusivity has influenced Jordan from many points of view, notably including price increases and a decrease in access to affordable medicines. Moreover, the promise of the data exclusivity approach bringing more foreign investments to Jordan did not come to fruition, nor did greater IPR protection promote local industry research in the manner prognosticated by proponents of the data exclusivity regime.

1. Access to Affordable Medicine

In order to control diseases, people must be able to access affordable medicines. International human rights have stated that access to affordable medicine, health facilities and services should be accessible to all without discrimination.[240] Instead of enabling this internationally mandated access to affordable medicines, the data exclusivity approach

238 Merck Sharp & Dohme et al. v. Jordanian Food & Drug Adminstration, Decision of the Jordanian High Court of Justice No. 512/2003, (Jan. 1, 2013).

239 *Id*.

240 Chuan-feng Wu, *Raising the Right to Health Concerns Within the Framework of International Property Law*, 5 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 141 (2010).

operates by delaying the entrance of generic (affordable) medicines into the market, which has the consequence of increasing the monopoly duration of the originator companies.[241] Under this regime, prices of medicine will increase by 20%, according to the pricing regulations which give the generic product a maximum of 80% of the originator product's price. Also, after the entrance of the generic product, some originators decrease their prices.[242] According to an Oxfam report, data exclusivity has contributed to the problem by comparing the prices of selective medicines between Jordan and Egypt. This comparison illustrates the fact that prices in Jordan are much higher than Egypt, which is not currently implementing data exclusivity protection.[243] Dr. Michael P. Ryan has responded to this Oxfam report, indicating that Jordanian prices are similar to prices in Saudi Arabia, and the pricing is according to the pricing regulation at the JFDA.[244] Dr. Ryan did not take into account, however, the fact that for more than five years only the originator product will be present on the market.

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

Jordanians obtain medicine through either the public or private system. The public insurances cover 55% of the Jordanian population,[246] and this system buys the medicines through tenders announced by the Joint Procurement Department (JPD). Data exclusivity's effect on the prices is very obvious when one looks at the assigned prices for the tenders. The government is obliged to buy the

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241 Bashar H. Malkawi, *Patent Protection and the Pharmaceutical Industry in Jordan*, 4 ASIAN J. WTO & INT'L HEALTH L. & POL'Y 93 (2009) [hereinafter Malkawi].

242 *Id*.

243 Malpani, *supra* note 16.

244 Michael Ryan, *Intellectual Property Reforms, Pharmaceuticals, and Health Competitiveness in Jordan: Misunderstanding and Misinformation from* 102 OXFAM INTERNATIONAL 2, CREATIVE & INNOVATIVE ECONOMY CENTER, GEORGE WASHINGTON UNIVERSITY LAW CENTER (2007) [hereinafter Ryan]; *see generally* Roy Zwhalen, *Data Protection, the Trans Pacific Partnership, and the U.S.-Jordan FTA*, BIOTECHNOW.COM, http://www.biotech-now.org/public-policy/patently-biotech/2011/09/data-protection-the-trans-pacific-partnership-and-the-us-jordan-fta-post (last visited Sept. 15, 2014).

245 Interview with Nafez Sutari, Pharma chairman (2010−2011), (Oct. 21, 2014) [hereinafter Sutari Interview].

246 JORDAN DEPT. OF STATISTICS, REPORT OF HEALTH INSURANCE IN JORDAN (2010), http://www.dos.gov.jo/sdb/dos_home/dos_home_a/health_ins.pdf.

originator product for almost six years with no competition from the generic product.[247] After the approval of a generic product, the originator product price will come down. The JAPM has conducted an analysis study of the official tender (JPD) prices in 2009, 2010 and 2011.[248] This study showed the cost savings for the government after the availability of the local generic products.[249] The prices of the local generic products in 2009 and 2010 JPD tenders for ten therapeutic groups were less than the second bidders, at $25 million JPD. Table 1 illustrates the savings that resulted from buying local generic products, as compared to the originator prices for these two years.[250]

System	2009	2010
Antiobiotics	1,956,498.1100	1,173,401.8240
GI	1,912,968.1250	34,404.5800
Respiratory	275,010.2800	206,476.0000
Neuromuscular	3,891,611.7092	926,471.3680
Neutritions	43,365.9250	1,803,268.1000
Cardiovascular	8,418,327.8305	1,694,837.1760
Cutaneous	759,014.7740	527,354.8200
Anesthesia	188,055.4210	120,173.7600
Ophthalmics	319,820.1000	87,579.6000
Endo-Gyne	24,774.7200	1,298,258.4500
Total JDs	17,789,446.9947	7,872,225.6780

Table 1. The savings from buying Jordanian pharmaceutical products compared to prices bid by multinational pharmaceutical companies in 2009 and 2010.[251]

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

247 Abbot, *supra* note 203.

248 Interview with Hanan Sboul, Secretary General, JAPM, (Aug. 20, 2014) [hereinafter Sboul Interview].

249 *Id*.

250 *Id*.

251 *Id*.

compared to their prices for the year before local generic products were introduced.

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

System	2010	2011
Antibiotics	2,320,042.4356	350,852.5855
GI tract	28,365.8800	11,425.4896
Respiratory	62,043.8480	139,480.4303
Neuromuscular	9,459,931.1424	341,010.6933
Nutrition	436.5150	2.8000
Vaccines	1,400,792.0000	29,248.8400
Cardiovascular	461,551.6651	12,693.8667
Cancer	525,459.2660	115,349.9840
Cutaneous	8,658.6700	71,520.8000
Anesthesia	38,089.6320	26,229.3907
Ophthalmic	8,471.1800	169,423.8700
Endo-Gyne	281,067.2287	492,235.0950
Total	14,594,909.4627 JDs	1,761,484.8451 JDs

Table 2. The difference in prices bid by multinational pharmaceutical companies before and after participation of Jordanian pharmaceutical companies in tenders of the same products.[253]

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

Also, the JAPM has conducted an analysis of the price of a cancer product in public tenders. The 2009 tender price of this drug was 170.960 JD, while in the same year the generic product was registered

252 *Id.*
253 *Id.*
254 *Id.*
255 *Id.*

with a public price of 86.700 JD. Thus, the price of the generic product was half the tender price. In 2010 tender, the originator product's tender price was 56.000 JD, nearly 33% of the previous year's tender price.[256]

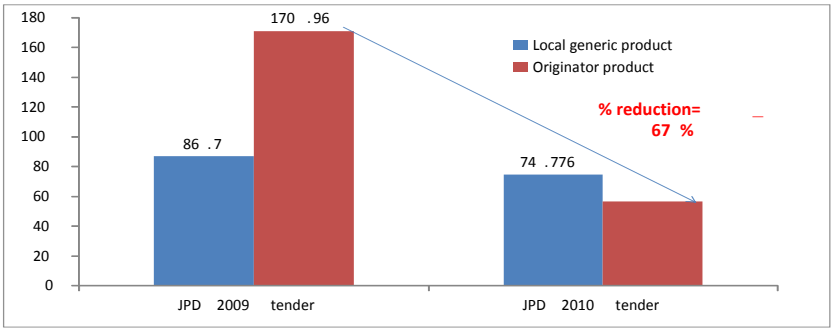

Chart 1. The price difference between JPD tender of 2009 and 2010 of an originator cancer product after the introduction of the local generic product.[257]

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

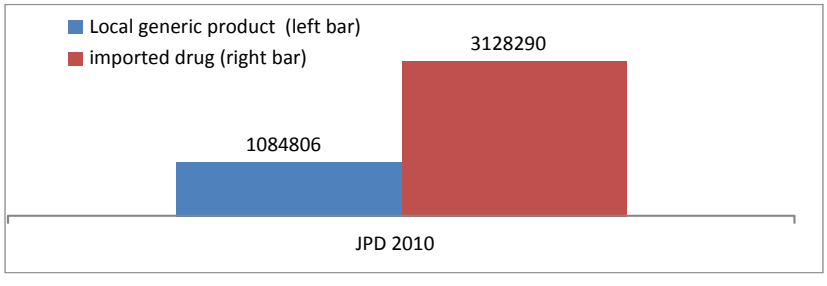

Chart 2. The price difference of six products from the same therapeutic category between the local generic products and originator products in tender JPD 2010 for one therapeutic category.

Uninsured people buy through the second system, the private system. Here, the pricing of the originator product depends on the

256 *Id.*
257 *Id.*
258 *Id.*

JFDA's pricing regulations which assign a fixed public price. The JFDA will assign the lowest price after analyzing the following criteria: country of origin price; export price based on cost; insurance and freight; and Saudi Arabia cost or the median price of at least three countries out of seven specified European countries. The same principle is applied for pricing the generic product with a ceiling of a maximum 80% of the originator product price from the current price, registration price or re-registration price, whichever is lowest.[259] The pharmacy profit margin is fixed at 26%, so the pharmacist will derive more benefit by selling the originator product.[260]

2. Investments

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

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

259 *The Criteria of Pricing Drugs (Regulation of Pricing Drugs, 2012)*, *in* JORDANIAN OFFICIAL GAZETTE No. 5164 /2012, http://jfda-apps01:3334/ (last visited Oct. 10, 2014).

260 Letter from Prime Minister of Jordan, to Jordan Ministry of Health, No. 10/48/4845 (July 26, 1979); Letter from Prime Minister of Jordan, to Jordan Ministry of Health, No. 12 (June 30, 2002).

261 Malpani, *supra* note 18.

262 Ryan, *supra* note 244.

insisted that hospitals, doctors and pharmacies have benefited from health tourism due to drug availability.[263]

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

3. Promotion of Pharmaceutical Local Industry

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

Eighty-one percent of local production is exported to 60 countries because of the high quality reputation of the local pharmaceutical industry, and it is considered number one between the Arab countries.[269] Chart 3 represents the export of the local industry between 2004-2013.[270]

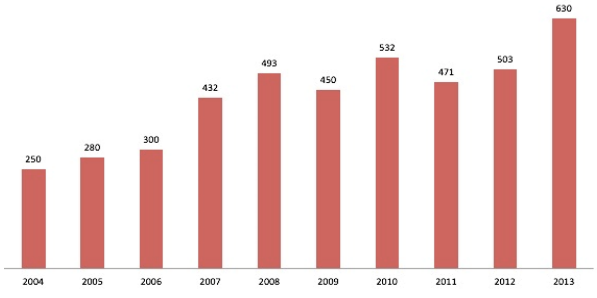

Chart 3. The export of the local industry between 2004-2013 (U.S. Million Dollars)

263 Sutari Interview, *supra* note 245.
264 Ryan, *supra* note 244.
265 Sboul Interview, *supra* note 248.
266 *Id*.
267 Malkawi, *supra* note 241.
268 Sboul Interview, *supra* note 248.
269 JAPM, http://www.japm.com (last visited Sept. 15, 2014).
270 Sboul Interview, *supra* note248.

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

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

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

Contrary to the situation in Jordan, the generic pharmaceutical industries of other countries like Israel and India have evolved to counter the effects of data exclusivity. These countries have set

271 Ryan, *supra* note 244.

272 Sutari Interview, *supra* note 245.

273 Sboul Interview, *supra* note 248.

274 Malpani, *supra* note 16.

275 Malkawi, *supra* note 241.

legislation in such a way as to promote their generic industry.[276] For example, Israel registers a generic product during the exclusivity period of the originator product for the purposes of export.[277]

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

Some local pharmaceutical companies have found in merger and acquisitions the solution to withstand the competition and expand markets.[279]

CONCLUSION

Ultimately, data exclusivity provisions introduced in Jordan were not the best option for the country, as they have undermined people's accessibility to affordable medicine and have had a negative impact on the local pharmaceutical industry. As we have discussed throughout this paper, data exclusivity for NCEs is not mandatory under Article 39.3 of the TRIPs Agreement and Article 4.22 of our FTA with the United States. The following measures are recommended to mitigate the negative impact of data exclusivity while still maintaining compliance with the obligations set in both Article 4.22 of the U.S.-Jordan FTA and Article 39.3 of the TRIPs Agreement. Many of these measures are already adopted in some countries without any adverse WTO ruling. To apply these measures, there must be amendments to the Unfair Competition and Trade Secrets Law and to the JFDA's registration criteria. To establish a special regulation for granting data exclusivity, the following is needed:

1. Shortening the term of data exclusivity for new chemical entities; neither TRIPs nor the U.S.-Jordan FTA mandates a five-year period.

2. Start Date of Data Exclusivity: A country can consider that the start date for granting data exclusivity is the first registration of the product worldwide.

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276 Sboul Interview, *supra* note 248.

277 Abughanm, *supra* note 208, at 339.

278 Sboul Interview, *supra* note 248.

279 Malkawi, *supra* note 241.

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

4. NCE and new uses definitions to be included in the registration criteria. Also, the eighteen-month period for which an applicant can register an NCE should also be applicable to new uses.

5. Undisclosed test data: This term should be defined in the registration criteria and the JFDA should investigate this condition by requesting a certificate from the originator company declaring that the submitted test data have not been published in any capacity. If the data should later become nonconfidential, then the JFDA has the right to end the data's exclusivity period.

6. Considerable efforts: This term should be defined in the registration criteria and the JFDA should investigate this condition by requesting evidence from the originator company showing that the generation of the submitted test data involved considerable efforts, as demonstrated by the reported costs and by the duration of the period in which the the submitted test data was generated.

7. Data exclusivity term should not extend beyond the patent term.

8. Allow registration of the generic product for the purposes of export.

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

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

11. Waive data exclusivity in cases of emergency and public interest.

12. Waive data exclusivity for products intended for the treatment of life threatening diseases.

Applying all these measures to mitigate the negative effects of the data exclusivity approach in Jordan may raise many challenges and take time, but in our experience, some of these measures can be implemented with relative ease, especially those that do not require amending existing laws. The JFDA has the authority to apply some of

these measures, which may need only regulations amendments or create a new regulation to control data exclusivity granting.

If these measures were to be applied or at least part of these measures, Jordan would minimize the effect of data exclusivity and promote access to medicine by providing a cheap generic product which is an equivalent product for the expensive originator product.

In future negotiations of bilateral agreements, the governments should involve all concerned stakeholders to prevent any negative consequences.