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Evolution of Data Exclusivity for Pharmaceuticals in Free Trade Agreements*

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Abstract

Free trade agreements (FTAs) introduce higher intellectual property (IP) protection than those established in the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS-plus provisions) that deprive the parties from benefits of the use of flexibilities found in the TRIPS Agreement to protect public health. One such TRIPS-plus requirement is that of data exclusivity. It establishes that the government should provide an exclusivity period for the test data developed by the originator company, on the grounds of an incentive rationale and considerations of fairness. The negative impact of the data exclusivity approach in developing countries means that the entry of cheap generic products is delayed, even under a compulsory license, which will affect access to affordable medicines. Countries that have already signed the FTAs can mitigate its effects on public health by limiting the scope of and providing exceptions to data exclusivity in national legislation.

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Les dispositions relatives à la propriété intellectuelle contenues dans les accords de libre-échange, imposent une protection de la propriété intellectuelle plus élevée que celles prévues dans l'Accord de l'OMC sur les aspects des droits de propriété intellectuelle qui touchent au commerce (ADPIC) qui privent les états parties à l'Accord des avantages liés à l'utilisation des flexibilités nécessaires à la protection de la santé publique. Parmi les dispositions qui introduisent un régime de protection plus strict est celles de l'exclusivité des données. Ces dispositions imposent aux gouvernements, dans le cadre d'une approche incitative ou sur la base de considérations liées à l'équité, d'octroyer une période d'exclusivité pour les données d'essai développées par l'entreprise de princeps. Cette approche a pour effet de retarder l'introduction sur les marchés des pays en développement de médicaments génériques, en dépit du mécanisme de licences obligatoires, et de rendre plus difficile l'accès à des médicaments bon marché. Les pays qui ont déjà signé ces accords de libre-échange peuvent en atténuer les effets sur la santé publique en limitant la portée des dispositions relatives à l'exclusivité des données et en prévoyant des exceptions dans leur législation nationale.

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Las disposiciones que figuran en los acuerdos de libre comercio prevén una mayor protección de la propiedad intelectual (PI) que las establecidas en el Acuerdo sobre los Aspectos de los Derechos de Propiedad Intelectual relacionados con el Comercio (ADPIC), las cuales privan a las partes de los beneficios del uso de las flexibilidades recogidas en el Acuerdo sobre los ADPIC para proteger la salud pública. Uno de esos requisitos más estrictos que los del ADPIC es el de la exclusividad de datos. En este se establece que el gobierno deberá otorgar un período de exclusividad para proteger los datos de pruebas elaborados por la empresa originaria, sobre la base de una lógica de incentivos y consideraciones de equidad. El efecto negativo del enfoque de la exclusividad de datos en los países en desarrollo se traduce en una demora en la entrada de productos genéricos a precios bajos, incluso de conformidad con una licencia obligatoria, lo cual afectará al acceso a medicamentos asequibles. Los países que ya han firmado los acuerdos de libre comercio pueden mitigar sus efectos en la salud pública si limitan el ámbito de aplicación de la exclusividad de datos en la legislación nacional y prevén excepciones al respecto en su legislación.

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I. Introduction

The United States did not succeed in its effort to see data exclusivity included as an obligation in the final text of the Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS"). Yet it remained undeterred by this setback, and pursued its data exclusivity agenda in subsequent bilateral agreements—free trade agreements or TRIPS-plus agreements—signed with other countries.[1] To this end, the United States included the principal tenets of data exclusivity in almost all of these bilateral free trade agreements.[2] Moreover, the United States insisted on setting the maximum constraints possible to the exercise of policy space of country parties in these agreements. This result was accomplished by incorporating various mechanisms not present in the TRIPS Agreement.

The first way in which the United States imposed these additional constraints was by expanding the TRIPS obligation on test data protection to require data exclusivity protection that includes, in addition to new chemical entities ("NCEs"), new uses of old chemical entities and new dosage forms.[3] In addition to increasing the subject matter falling under the data exclusivity umbrella, these agreements also include a linkage requirement.[4] Under the concept of linkage, a decision by regulatory authorities to grant marketing approval for drugs that enjoy patent protection is ultimately dependent on the will of the patent holder.[5] Ensuring there were no loopholes to exploit, these agreements added an additional point which prevented an applicant from receiving registration recognition from other drug regulatory authorities. In case there was recognition from another drug regulatory authority ("DRA"), the agreement provided that this country should employ the same data exclusivity term as would have been implemented domestically.[6] These agreements lack time periods within which the product must be submitted to the DRA.[7] The linkage requirement is problematic because it requires the DRA to determine the validity of patents, which may be beyond its capabilities.

A further constraining mechanism added in almost all the signed free trade agreements ("FTAs") was the extension of the patent term for pharmaceutical companies—a measure intended to compensate these companies for the portion of the product's patent term that elapsed while awaiting a regulatory decision regarding marketing approval.[8] This extension in the FTAs goes beyond the requirements of the TRIPS Agreement, which does not include any such compensation period, only specifying that the protection period of a patent is twenty years.[9]

Given the above-mentioned strictures, those countries that signed FTAs with the United States are essentially deprived of the benefits of the flexibilities found in the TRIPS Agreement.[10] Consequently, the impact will be critical on public health and access to affordable medicines by increasing the monopoly period of the originator drug companies and delaying the entry of the cheap generic products.[11] Such impact will mainly affect developing countries that have signed an FTA with the United States, namely Bahrain, Chile, Colombia, Jordan, South Korea, Oman, Morocco, Panama, Peru, Singapore, and the Central American parties to CAFTA (Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua.[12]

This paper discusses different perspectives and various points of view to analyze the data exclusivity requirements in the signed FTAs with Jordan and Korea. This paper will tackle how earlier FTAs have fewer constraints than do later ones. From the Jordanian to the Korean FTA, the United States added many additional constraints with respect to data exclusivity and intellectual property rights related to the pharmaceutical and drug industry.[13]

Jordan: Signed in October of 2000 and enforced in December of 2001, the United States–Jordan agreement was the first FTA with an Arab country.[14]

Republic of Korea: This FTA entered into force in March of 2012.[15] Korea is considered to be a major trading nation.[16]

II. Extended Data Protection and Data Exclusivity

Article 39.3 of TRIPS states that the protection at issue applies to NCEs;[17] the United States, however, used its post-TRIPS Agreement FTAs as an opportunity to expand the scope of the protection term.[18] New applications for new indications, new formulations, and new combinations are ordinarily entitled to three years of exclusivity if at least one new clinical investigation is essential for regulatory approval.[19] The United States also extended the protection term to include new products instead of only NCEs; as a result, the protection in its FTAs will be extended to include both chemical entities and biological ones.[20] Additionally, the FTAs defined "new" as being new in the drug regulatory authority of the country, excluding the patent novelty definition.[21] In some FTAs, as with Morocco's and the Republic of Korea's, the condition of "undisclosed test data" is no longer prerequisite for a company to receive the protective benefits of data exclusivity, in effect disallowing generic producers from utilizing said data without any inquiry into whether the originator company had intended to keep its assumedly valuable information confidential.[22]

Another new constraint related to drug regulatory approval that was added in almost all the signed FTAs is patent term extension.[23] In this new restriction, the patent term will be extended to compensate the patent holder for unreasonable curtailment of the patent term due to regulatory delay during the marketing approval of the product.[24] In most FTAs, this was related to the product patent, but in the Korean FTA, this was extended to method of use and method of making patents.[25] This is an example of the United States' FTA becoming stricter over time.

The difference between patent term extension and data

exclusivity is that the former will be granted after the expiration of the patent and will compensate for the duration needed to obtain the regulatory approval for the originator product.[26] While the latter will be effective immediately after the originator product's marketing approval, the generic company will be prevented from relying on the originator's submitted data, but can generate its own data and submit it during the data exclusivity period.[27]

III. Linkage Between Patent Status and Regulatory Approval

The Patent Linkage term was introduced by the United States in the FTAs, in which the generic approval is linked to the expiration of the originator's patent.[28] Consequently, a generic product will not be approved until the expiration or invalidation of the related patent.[29] To ensure the patent linkage requirements were met, the United States devised a system wherein the originator submits a list of patents that cover its product to the United States FDA. This information about the available patents for each product is published on the FDA's website or Orange Book.[30] Generic drug applicants can then review the published data and decide either to wait until the expiration of the patent or to apply for Paragraph IV Certification. In this latter situation, those filing an Abbreviated New Drug Application ("ANDA") must notify the originator drug company of its filing, and explain that the applicant is not infringing the originator's patent or, in the alternative, assert that the patent at issue is invalid.[31] In response, the originator drug company has the right to file an infringement lawsuit.[32] Accordingly, the generic drug registration will be suspended for thirty months, after which time the FDA will issue a tentative approval.[33] In practice, most generic drug applicants wait until the litigation is resolved before marketing their products in order to avoid damages liability.[34]

Proponents of patent linkage requirements say that they provide a transparent system for both originator and generic companies.[35] In this view, generic companies are allowed the opportunity to review the published patent information and determine if it overlaps the scope of their product or not.[36] As a result, a better investment decision can be made by not investing in products covered by a patent.[37] Furthermore, it is believed that the patent linkage system will reduce patent infringement litigation, since generic companies will be able to assess in advance if they are infringing upon the originator's product, which serves the dual purpose of safeguarding the patent holder by preventing patent violation.[38]

However, the patent linkage system has its detractors as well. One objection to these requirements finds it problematic that this new intellectual property regime assigns DRA the role of the patent enforcing authority,[39] given that such a role is beyond the capabilities of the DRA in most of the countries.[40]

Another criticism is that this new system will result in the delay of generic drug approval and, consequently, limit the availability of medicines at affordable prices; this is so because, in most cases, the patent will be weak or will not cover the generic product.[41] Moreover, many generic companies will not take the risk of submitting their products for approval because of the possibility of litigation, which will be a very costly and lengthy process.[42]

A linkage regime of some type can be found in almost all the signed FTAs, with differences in the scope it covers and the mechanism of application.[43] The Jordanian FTA, for example, includes a simple notification system, while the Korean FTA includes a more advanced linkage system.[44] Under the more advanced linkage system in the Korean FTA, the Korean DRA should not grant marketing approval for a generic product if there is a related patent for the product, for the method of use or for the method of doing patents.[45] In addition, the Korean DRA should notify the patent holder company of such an application.[46]

IV. Comparison Between FTAs in Terms of Data Exclusivity and Other Related Measures of Drug Regulatory Approval

A. United States–Jordan Free Trade Agreement[47]

Signed in October of 2000, the United States–Jordan FTA was the first one of its kind concluded between the United States and an Arab country.[48] The impact of this agreement was significant for Jordanian public health.[49] In particular, the additional constraints relating to intellectual property rights found in this agreement directly affected the Jordanian generic drug industry and ultimately resulted in the delay of cheap product entering the market.[50] However, being one of the first countries to sign the FTAs gave Jordan an advantage in terms of the constraints added, since later-signed FTAs included even more strictures on intellectual property rights.[51]

The following measures related to drug regulatory approval were added:

1. Data Exclusivity:

As part of its accession to the World Trade Organization ("WTO"), Jordan implemented a data exclusivity regime, which provided for a five-year exclusivity period for NCEs for pharmaceutical products.[52] This was included in Article 8 of Unfair Competition and Trade Secrets Law 2000.[53] One year later, the FTA Jordan signed with the United States emphasized additional features of the data exclusivity regime by adding the following new constraints, those that were not imposed by Article 39.3 of the TRIPS Agreement.[54]

New added constraints as compared to Article 39.3 of the TRIPS Agreement are:

New use for old chemical entity data exclusivity for three years. As stated in footnote 10 of Article 4.22, "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."[55] A new use was not

defined in this agreement. The Jordan Food and Drug Administration ("JFDA") has defined "new use" as "new indication."[56]

In the case of reliance on other countries' marketing approval, Jordan will protect this molecule for the same protection period as would be required in that country granting the approval.[57] As included in footnote 11 of Article 4.22, "[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 unfairness."[58]

2. Linkage:

Instead of the more draconian patent linkage requirement wherein marketing approval for a generic drug is made contingent upon the decision of the patent holder, the United States–Jordan FTA instead utilized a notification system.[59] Under this system, the JFDA should notify the originator drug company in the case of a generic company submitting its registration file; as stated in Article 4.23(b), "the patent owner shall be notified of the identity of any third party requesting marketing approval effective during the term of the patent."[60] The JFDA has implemented this point by publishing all the drug files submitted for registration on its website.[61]

3. Patent Term Extension:

A compensation period for the pharmaceutical product's regulatory approval period was added in Article 4.23(b): "each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process."[62]

The United States–Jordan agreement did not include the following points, which were included in later FTAs:

- A definition of NCE or new product.[63]

- Linkage system; in contrast, the Jordanian FTA included a notification system.[64] In the case of reliance on other countries' approval, Jordan has to implement, at a minimum, the protection period provided by that country from the date of approval, whichever is later.[65]

- Protection period of the NCE; this was specified in Article 8 of Unfair Competition and Trade Secrets Law 2000.[66] Scope of protection expanded only by adding new uses to be granted data exclusivity; later FTAs state new clinical information, which may include new dosage forms or new combinations.[67]

Another point included in this agreement that was related to pharmaceutical products was restrictions on compulsory licenses, which the agreement accomplished by specifying the grounds upon which a compulsory license could be issued.[68]

B. United States–Korea Free Trade Agreement[69]

This FTA is the first FTA between the United States and a major trading nation in Asia. It was signed in June of 2007 and ratified in March of 2012.[70] This FTA faced some objections from representatives of non-governmental organizations ("NGOs"), academics and former high-level government officials on the basis of the FTA's terms, which are more constraining than the TRIPS Agreement, and the potential impact of these terms on the Republic of Korea's economy and society.[71] Despite these objections, the United States was able to include many restrictions in this FTA, especially concerning intellectual property rights (IPR) related to pharmaceuticals.[72]

Regarding the pharmaceutical intellectual property rights, the terms were extended beyond those found in earlier FTAs.[73] An example here is the linkage system, which requires the marketing of a generic product covered by a patent for the product and its method of use to be prevented.[74] Likewise, the patent term extension is for patents not only covering the products per se, but also for patents covering its method of making and method of use.[75]

The following measures which are related to drug regulatory approval were added:

1. Data Exclusivity

Data exclusivity for five years was granted for an NCE before this agreement.[76] This point was stated in Article 18.9.1(a) of the agreement.[77] It is noted that "undisclosed" was removed.[78] Moreover, the agreement contained additional constraints as compared to Article 39.3 of the TRIPS Agreement, which include the following: first, the required "undisclosed" condition of data was removed, so disclosure in case it was necessary to protect the public was removed;[79] second, the protection against "unfair commercial use" was removed and replaced by granting a period of exclusivity for five years.[80] Most importantly, Article 18.9.1(c) introduced a definition of new products.[81] This excludes the definition of new as patent novelty and if the product was known in other regulatory authority in the same territory, it will still be considered as new for pharmaceutical. In case of reliance on other countries' marketing approval, the authority should provide an exclusivity period of five years' protection from the date of marketing in Korea pursuant to Article 18.9.1(b).[82]

- With respect to new clinical information, new clinical information is granted data exclusivity for three years in Article 18.9.2(a) and (b).[83] This may include not only new use, but also a new combination and a new dosage form.

2. Linkage

The linkage system is tackled in Article 18.9.5.[84] The Article 18.9.5 approval process depends for the larger part on product and method of use patents notifying the patent holder of the submission of a generic product.[85]

3. Patent Term Extension

In Article 18.8.6,[86] the patent term is extended to com-

pensate for the regulatory delay in the marketing approval procedures; the extension of the patent is not only for the product patent, but also for method of making and method of use.[87]

Finally, the United States–Korea FTA differs from earlier FTAs in several aspects: first, the agreement does not contain any condition relating to "unfair commercial use" and the five-year exclusivity period must be granted without a reason;[88] second, the definition of new product is specific to the pharmaceutical regulatory authority in Korea, even if the issue could fall under the jurisdiction of another agency;[89] finally, patent extension in case of marketing approval procedure delays covers not only the product patent, but also the method of making and method of use patents.[90]

V. Conclusion

Unlike the WTO rules, TRIPS-plus provisions in FTAs introduce higher intellectual property protection, in which the government should provide an exclusivity period for the test data done by the originator company, on the grounds of an incentive rationale and considerations of fairness. This new protection regime is known as data exclusivity.

The negative impact of the data exclusivity approach in developing countries means that the entry of cheap generic product is delayed, even under compulsory license, which will affect access to affordable medicines. Countries that have already signed the FTA can mitigate its effects on public health by limiting the scope of and providing exceptions to data exclusivity in national legislation. There are various remedies that may work to decrease the harmful effects of data exclusivity. Such corrective measures include waiving data-exclusivity protection in cases of compulsory licensing, limiting data exclusivity for NCEs, limiting data exclusivity for unpublished data, establishing a compulsory licensing system for registration data, and shortening the term of data exclusivity.

Other developing countries should not enter into a bilateral agreements before taking into consideration their potential effects on public health and, further, should take the opportunity learn from other countries' experiences. Additionally, developing countries should use all the flexibilities found in the TRIPS Agreement to ensure access to medicine in their countries and in other developing countries.

Endnotes:

[1] Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Geochemical Products Under Free Trade Agreements* 5–6, ICTSD-UNCTAD Dialogue on Moving the Pro-development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning (Nov. 29–Dec. 3, 2004), http://www.ictsd.org/sites/default/files/event/2008/12/report31.pdf [hereinafter Correa, *Protecting Test Data*]; 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] Correa, *Protecting Test Data, supra* note 1, at 5–6.

[3] *Id.* at 8.

[4] *Id.* at 5 n. 15.

[5] *Id.* at 5.

[6] *Id.* at 6–7.

[7] *Id.* at 6.

[8] Ruth Lopert and Deborah Gleeson, *The High Price of Free Trade: U.S. Trade Agreements and Access to Medicines*, 41 J. L. MED. & ETHICS, 199, 201 (2013) [hereinafter Lopert & Gleeson].

[9] The United States currently has FTAs in place with twenty countries. *See* U.S. Trade Representative, *Free Trade Agreements*, USTR.GOV, https://ustr.gov/trade-agreements/free-trade-agreements (last visited Aug. 5, 2014) (providing background information and final text for each of the twenty FTAs).

[10] Mohammed El Said, *The Morning After: TRIPS-Plus, FTAs and Wikileaks – Fresh Insights on the Implementation and Enforcement of IP Protection in Developing Countries*, 28 AM. U. INT'L REV. 71, 84 (2012) [hereinafter El Said].

[11] *Id.*

[12] Brook K. Baker, Overview of Data Protection, Data Exclusivity and Patent/Registration Linkage, Presentation at Health GAP, Northeastern University School of Law, Program on Human Rights and the Global Economy (Sept. 2, 2010), http://ipatm.ukzn.ac.za/Libraries/Notes_and_Slides/ukzn_data_exclusivity_linkage_2010.sflb.

[13] This paper was written before the final approval of the United States-Mexico-Canada Agreement (USMCA) which also contains provisions on data exclusivity. See in this regard, Maria Fabiana Jorge, "The US-Mexico-Canada Agreement: Putting Profits Before Patients", South Centre Policy Brief 61 (May 2019) available at https://www.southcentre.int/policy-brief-61-may-2019/ .

[14] El Said, *supra* note 10, at 76.

[15] United States–Korea Free Trade Agreement, art. 18, U.S.–Korea, Jun. 30, 2007, 46 I.L.M. 642 (2007), https://ustr.gov/sites/default/files/uploads/agreements/fta/korus/asset_upload_file273_12717.pdf [hereinafter U.S.–S.Kor. FTA]; *see also* Carolyn B. Gleason, David J. Levine, Raymond Paretzky, *Landmark U.S.–Korea Free Trade Agreement Enters Into Force*, NAT'L L. REV. (March 19, 2012).

[16] Yong-Shik Lee et al., *The United States–Korea Free Trade Agreement: Path to Common Economic Prosperity or False Promise?* 6 E. ASIA L. REV 111, 113 (2011) [hereinafter Lee et al.].

[17] Correa, *supra* note 1, at 8.

[18] Daniel Acquah, *Extending the Limits of Protection of Pharmaceutical Patents and Data Outside the EU – Is There a Need to Rebalance?* 45 INT'L REV. INTELL. PROP. & COMP. L. 256, 257 (2014).

[19] *Id.* at 8, 261 (discussing the Hatch-Waxman Act's three-year data exclusivity provisions).

[20] Correa, *supra* note 1, at 8.

[21] *Id.*

[22] *Id.*

[23] Lopert & Gleeson, *supra* note 8, at 201.

[24] Correa, *supra* note 1, at 5 n. 15.

[25] U.S.–S. Kor. FTA, *supra* note 15.

[26] Acquah, *supra* note 18, at 259.

[27] *Id.*

[28] Karin L. Ferriter, Linkages Between Generic Approval and the Patent System in the United States (Nov. 6, 2007), http://www.wipo.int/export/sites/www/meetings/en/2007/lifesciences/sym_regulation/lss3_ge_07_ferriter.pdf.

[29] *Id.*

[30] *Id.* at 35, 44–47.

[31] *Id.* at 49–50.

[32] *Id.*

[33] *Id.* at 51.

[34] *Id.*,

[35] *Id.* at 54.

[36] *Id.* at 52.

[37] *Id.* at 54.

[38] *Id.* at 53.

[39] Baker, *supra* note 12, at 12.

[40] *See* Ellen 't Hoen, *TRIPS, Pharmaceutical Patents, and Access to Essential Medicines: A Long Way from Seattle to Doha*, 3 CHI. J. INT'L L. 27, 42–43 (2003) (noting that developing countries are under pressure from industrialized countries and the pharmaceutical industry to implement patent legislation that goes beyond the obligations of TRIPS and fails to take into account the health needs of the population).

[41] Baker, *supra* note 12, at 12.

[42] Ferriter, *supra* note 28, at 52–53.

[43] Burcu Kilic, *Defending the Spirit of the DOHA Declaration in Free Trade Agreements: Trans-Pacific Partnership and Access to Affordable Medicines*, 12 LOY. U. CHI. INT'L L. REV. 23, 52–54 (2014) (highlighting the United States' proposal that would require countries to agree to patent linkage when entering into FTAs, and specifically analyzing the differences between the US–Australia FTA and the US–Chile FTA).

[44] *Compare* Rohit Malpani, *All Costs, No Benefits: How TRIPs-Plus Intellectual Property Rules in the US–Jordan FTA Affect Access to Medicines*, 102 OXFAM BRIEFING PAPER 5, 31 (2007), https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf, [hereinafter Malpani], *with* Thomas A. Faunce and Joel Lexchin, *'Linkage' Pharmaceutical Evergreening in Canada and Australia,* 4 AUSTRALIA AND NEW ZEALAND HEALTH POL. 6 (2007) (noting that in the Korean FTA for the notification process to commence the patent holder must first notify the safety and efficacy regulator).

[45] U.S.–S. Kor. FTA, *supra* note 15.

[46] *Id.*

[47] 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) [hereinafter U.S.–Jordan FTA], https://ustr.gov/trade-agreements/free-trade-agreements/jordan-fta/final-text.

[48] El Said, *supra* note 10, at 76.

[49] *Id.* at 89.

[50] *Id.* at 84.

[51] *Id.* at 95.

[52] *Id.* at 86.

[53] Malpani, *supra* note 44, at 7.

[54] TRIPS Agreement, *supra* note 1, at art. 39.3.

[55] U.S.–Jordan FTA, *supra* note 47, at art. 4.22 n. 10.

[56] James Love, *Implementing the Jordan FTA rules on exclusive rights in regulatory test data*, KNOWLEDGE ECOLOGY INT'L BLOG (Sept. 2, 2011 23:24 PM), https://www.keionline.org/node/1224.

[57] U.S.–Jordan FTA, *supra* note 47, at 7.

[58] *Id.* at art. 4.22 n. 11.

[59] *Id.* at art. 4.23(b).

[60] *Id.*

[61] The notification list is available on the JFDA's website, www.jfda.jo (last visited June 24, 2019).

[62] U.S.–Jordan FTA, *supra* note 47, at art. 4.23(b).

[63] *See, e.g.,* United States–Australia Free Trade Agreement, U.S.–Austl., May 18, 2004, 43 I.L.M. 1248 (2004), https://ustr.gov/trade-agreements/free-trade-agreements/australian-fta/final-text [hereinafter U.S.–Austl. FTA], at art. 17.10(1)(d).

[64] Malpani, *supra* note 44, at 31.

[65] U.S.–Austl. FTA, *supra* note 63, at art. 4.22 n. 11.

[66] TRADE SECRETS AND UNFAIR COMPETITION LAW NO. 15 FOR THE YEAR 2000, 4423 Official Gazette Art. 8 (Feb. 4, 2000).

[67] U.S.–Jordan FTA, *supra* note 47, at art. 4.22 n. 10.

[68] *Id.* at art. 4.22–4.23.

[69] U.S.–S. Kor. FTA, *supra* note 15.

[70] Lee et al., *supra* note 16, at 113; *see also* Lopert & Gleeson, *supra* note 8, at 203.

[71] Lee et al., *supra* note 16, at 114.

[72] *Id.* at 114–15.

[73] *Compare* U.S.–S. Kor. FTA, *supra* note 15, at art. 18, *and* U.S.–Jordan FTA, *supra* note 47, at art. 4; *see also* Lee et al., *supra* note 16, at 140 (noting "the level of protection demanded under the U.S.–S. Kor. FTA exceeds that of the TRIPS agreement" and described as "state of the art").

[74] Lopert & Gleeson, *supra* note 8, at 201.

[75] *Id.*

[76] Article 18.9.1(a) of the U.S.–S. Kor. FTA reads:

If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the origination of which involves a considerable effort, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the territory of the

Party, authorize another to market a same or a similar product based on:

(i) the safety or efficacy information submitted in support of the marketing approval; or

(ii) evidence of the marketing approval, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the territory of the Party.

U.S.–S. Kor. FTA, *supra* note 15, at art. 18.9.1(a).

[77] *Id.*

[78] *Id.*

[79] *Compare* TRIPS supra note 1, at art. 39.3, *with* U.S.–S. Kor. FTA, *supra* note 15.

[80] *Id.*

[81] U.S.–S. Kor. FTA, *supra* note 15, at art. 18.9.1(c) (defining a new pharmaceutical product as "one that does not contain a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product").

[82] Article 18.9.1(b) of the U.S.–S. Kor. FTA reads:

If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person that previously submitted the safety or efficacy information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on:

(i) the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or

(ii) evidence of prior marketing approval in the other territory,

for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval of the new product in the territory of the Party.

U.S.–S. Kor. FTA, *supra* note 15, at art. 18.9.1(b).

The Parties acknowledge that, as of the date of signature of this Agreement, neither Party permits a person, not having the consent of the person that previously submitted safety or efficacy information to obtain marketing approval in another territory, to market a same or similar product in the territory of the Party on the basis of such information or evidence of prior marketing approval in such other territory.

U.S.–S. Kor. FTA, *supra* note 15, at art.18.9.1(b) n. 24.

[83] Articles 18.9.2(a) and 18.9.2(b) of the U.S.–S. Kor. FTA read:

(a) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person that previously submitted such new clinical information to obtain marketing approval in the territory of the Party, authorize another to market a same or a similar product based on:

(i) the new clinical information submitted in support of the marketing approval; or

(ii) evidence of the marketing approval based on the new clinical information,

for at least three years from the date of the Party.

(b) If a Party requires or permits, in connection with granting marketing approval for a pharmaceutical product of the type specified in subparagraph (a), the submission of evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory, other than evidence of information related to bioequivalency, such as evidence of prior marketing approval based on the new clinical information, the Party shall not, without the consent of the person that previously submitted such new clinical information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on:

(i) The new clinical information submitted in support of the prior marketing approval in the other territory; or

(ii) Evidence of prior marketing approval based on the new clinical information in the other territory, for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.

Data exclusivity protection continues even if the patent protection period terminates earlier than the data exclusivity period. Article 18.9.4 states, "[s]ubject to paragraph 3, when a product is subject to a system of marketing approval in the territory of a Party in accordance with paragraph 1 or 2 and is also covered by a patent in that territory, the Party may not alter the term of protection that it provides in accordance with those paragraphs in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in those paragraphs.

U.S.–S. Kor. FTA, *supra* note 15, at art.18.9.2(a)-(b), 18.9.4.

[84] Article 18.9.5 of the U.S.–S. Kor. FTA reads:

Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on that information or on evidence of safety or efficacy information of a product that was previously approved, such as evidence of prior marketing approval in the territory of the Party or in another territory, that Party shall:

(a) Provide that the patent owner shall be notified of the identity of any such other person that requests marketing approval to enter the market during the term of a patent notified to the approving authority as covering that product or its approved method of use; and

(b) Implement measures in its marketing approval process to prevent such other persons from marketing a product without the consent or acquiescence of the patent owner during the term of a patent notified to the approving authority as covering that product or its approved method of use.

U.S.–S. Kor. FTA, *supra* note 15, at art.18.9.5.

[85] *Id.*

[86] Article 18.8.6(b) of the U.S.–S. Kor. FTA reads:

With respect to patents covering a new pharmaceutical product

that is approved for marketing in the territory of the Party and methods of making or using a new pharmaceutical product that is approved for marketing in the territory of the Party, each Party, at the request of the patent owner, shall make available an adjustment of the patent term or the term of the patent rights of a patent covering a new pharmaceutical product, its approved method of use, or a method of making the product to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that pharmaceutical product in the territory of that Party. Any adjustment under this subparagraph shall confer all of the exclusive rights, subject to the same limitations and exceptions, of the patent claims of the product, its method of use, or its method of manufacture in the originally issued patent as applicable to the product and the approved method of use of the product.

U.S.–S. Kor. FTA, *supra* note 15, at art. 18.8.6(b).

For greater certainty, new pharmaceutical product in subparagraph (b) means a product that at least contains a new chemical entity that has not been previously approved as a pharmaceutical product in the territory of the Party.

Id. at art. 18.8.6(b) n.21.

[87] U.S.–S. Kor. FTA, *supra* note 15 (noting that the terms of the article apply to a product's method of use or method of making).

[88] *See* U.S.–S. Kor. FTA, *supra* note 15 (making no mention of "unfair commercial use" and stating that a party shall not "authorize another to market a same or a similar product for at least five years" without giving any reasons for the exclusivity); *see also* Lopert & Gleeson, *supra* note 8, at 212–17 (noting that "at least five years of protection" is required but does not list any reasons for such protection and noting further that the TRIPS agreement "requires protection of undisclosed data from unfair commercial use" while the FTA omits the "unfair commercial use" language).

[89] U.S.–S. Kor. FTA, *supra* note 15.

[90] U.S.–S. Kor. FTA, *supra* note 15, at art. 18.8.6(b).

The South Centre is the intergovernmental organization of developing countries that helps developing countries to combine their efforts and expertise to promote their common interests in the international arena. The South Centre was established by an Intergovernmental Agreement which came into force on 31 July 1995. Its headquarters is in Geneva, Switzerland.

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