DATA EXCLUSIVITY FOR PHARMACEUTICALS IN FREE TRADE AGREEMENTS: MODELS IN SELECTED UNITED STATES FREE TRADE AGREEMENTS

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I. INTRODUCTION

Although the United States did not succeed in its effort to see data exclusivity adopted as the official means of intellectual property protection in the final text of the Trade Related Intellectual Property Rights Agreement ("TRIPS"), it remained undeterred by this setback, choosing instead to pursue 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

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].

tenets of data exclusivity in almost all these bilateral free trade agreements.[2] Moreover, with the TRIPS Agreement disappointment perhaps still in mind, the United States was careful to insist upon the maximum constraints possible in these agreements, a result accomplished by incorporating various protective mechanisms not present in the TRIPS Agreement.

The first way in which the United States imposed these additional constraints was by expanding the reach of data exclusivity protection to include, 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

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.

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]

A final way in which the United States heightened intellectual property protection in these agreements was by defining the grounds for compulsory license issuance. Conversely, as to compulsory licenses, the TRIPS Agreement left it to each country to determine the grounds for compulsory license issuance.[10]

Given the above-mentioned strictures, those countries that signed FTAs with the United States are essentially deprived the benefits of the flexibilities found in the TRIPS Agreement.[11] Consequently, the impact will be critical on the 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.[12] Such impact will mainly affect developing countries who have signed an FTA with the United States namely, Bahrain, Chile, Columbia, Jordan, Korea, Oman, Morocco, Panama, Peru, Singapore, and the Central American parties to CAFTA (Costa Rica, Dominican Republic, El Salvador, Guatemala, Honduras and Nicaragua).[13]

This paper discusses different perspectives and various points of view to analyze the data exclusivity requirements in the signed

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8. Ruth Lopert & 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].

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. Lopert, *supra* note 8, at 199–200.

11. 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].

12. *Id.*

13. 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.

FTAs for selected countries at issue. This paper will tackle how earlier FTAs have fewer constraints than do later ones. From the Jordan 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. The paper will conclude with a comparison table illustrating the differences between how data exclusivity is incorporated into each selected country's FTA with the United States.

We will examine the FTAs for the following countries:

Jordan: Signed in October of 2000 and enforced in December of 2001, the Jordan–United States agreement was the first FTA with an Arab country.[14] This analysis is undertaken in order to clarify the data exclusivity obligations imposed on Jordan as a consequence of signing the FTA.

Chile: This FTA was signed in June of 2003.[15] Chile, in particular, was selected as a representative of a developing country from South America.

Australia: This agreement was signed in May 2004.[16] Australia was chosen as an example of an FTA with a developed country.

Morocco: This FTA was signed in June of 2004.[17] Morocco was chosen as an example of another Arab country from Africa, in addition to Jordan, that signed an FTA with the United States.

Central American Free Trade Agreement (DR–CAFTA):[18]

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14. El Said, *supra* note 11, at 76.

15. United States–Chile Free Trade Agreement, U.S.–Chile, June 6, 2003, 42 I.L.M. 1026 (2003), https://ustr.gov/trade-agreements/free-trade-agreements/chile-fta/final-text) [hereinafter U.S.–Chile FTA].

16. 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].

17. United States–Morocco Free Trade Agreement, U.S.–Morocco, June 15, 2004, 44 I.L.M. 544 (2005), https://ustr.gov/trade-agreements/free-trade-agreements/morocco-fta/final-text [hereinafter U.S.–Morocco FTA].

18. The United States–Central America–Dominican Republic Free Trade Agreement, U.S.–CAFTA–DR, Jan. 28, 2004, 43 I.L.M. 514 (2004) [hereinafter Dom. Rep.–CAFTA], https://ustr.gov/trade-agreements/free-trade-agreements/cafta-dr-dominican-republic-central-america-fta/final-text.

Signed on August 2005.[19] This FTA functions as an example of a multilateral regional agreement which includes five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras and Nicaragua) and the Dominican Republic.

Republic of Korea: This FTA entered into force in March of 2012.[20] Korea is considered as a major trading nation.[21]

II. EXTENDED DATA PROTECTION AND DATA EXCLUSIVITY

Article 39.3 of TRIPS states that the protection at issue applies to new chemical entities (NCEs);[22] the United States, however, used its post-TRIPS Agreement FTAs as an opportunity to expand the scope of the protection term.[23] 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.[24] The United States also extended the protection term to include new products instead of only new chemical entities; as a result, the protection in its FTAs will be extended to include both chemical entities and biological ones.[25] Additionally, the FTAs defined "new" as being new in the drug regulatory of the country, excluding the patent novelty definition.[26] In some FTAs, as with

19. Alberto R. Coll, *Wielding Human Rights and Constitutional Procedure to Temper the Harms of Globalization: Costa Rica's Battle Over the Central American Free Trade Agreement*, 33 U. PA. J. INT'L. L. 461, 462 (2011) [hereinafter Coll].

20. 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).

21. 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].

22. Correa, *supra* note 1, at 8.

23. 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).

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

25. Correa, *supra* note 1, at 8

26. *Id.*

Morocco's and the Republic of Korea's, the condition of "undisclosed test data," is no longer a 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.[27]

Another new constraint related to drug regulatory approval that was added in almost all the signed FTAs is patent term extension.[28] 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.[29] In most FTAs, this was related to the product patent, but in the Korean FTA, this was extended to the method of use and method of making patents.[30] 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.[31] 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.[32]

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.[33] Consequently, a generic

27. *Id.*
28. Lopert, *supra* note 8, at 201.
29. Correa, *supra* note 1, at 5 n. 15.
30. U.S.–S. Kor. FTA, *supra* note 20.
31. Acquah, *supra* note 23, at 259.
32. *Id.*
33. Karin L. Ferriter, Linkages Between Generic Approval and the Patent System

product will not be approved until the expiration or invalidation of the related patent.[34] 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.[35] 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 his patent or, in the alternative, assert that the patent at issue is invalid.[36] In response, the originator drug company has the right to file an infringement lawsuit.[37] Accordingly, the generic drug registration will be suspended for thirty months, after which time the FDA will issue a tentative approval.[38] In practice, most generic drug applicants wait until the litigation is resolved before marketing their products in order to avoid damages liability.[39]

Proponents of patent linkage requirements say that they provide a transparent system for both originator and generic companies.[40] In this view, generic companies are allowed the opportunity to review the published patent information and determine if it overlaps the scope of its product or not.[41] As a result, a better investment decision can be taken by not investing in products covered by a patent.[42] Furthermore, it is believed that the patent linkage system will reduce patent infringement litigation, since generic companies will be able to assess in

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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.

34. *Id.*
35. *Id.* at 35, 44–47.
36. *Id.* at 49–50.
37. *Id.*
38. *Id.* at 51.
39. Ferriter, *supra* note 33, at 51.
40. *Id.* at 54.
41. *Id.* at 52.
42. *Id.* at 54.

advance if it is infringing upon the originator's product, which serves the dual purpose of safeguarding the patent holder by preventing patent violation.[43]

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,[44] given that such a role is beyond the capabilities of the DRA in most of the countries.[45]

Another criticism is that this new system will result in the delay of generic drug approval, and consequently, will 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.[46] 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.[47]

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.[48] The Jordanian FTA, for example, includes a simple notification system, while the Korean FTA includes a more advanced linkage system.[49] Under the more

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43. *Id.* at 53.

44. Baker, *supra* note 13, at 12.

45. *See* Ellen 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).

46. Baker, *supra* note 13, at 12.

47. Ferriter, *supra* note 33, at 52–53.

48. 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).

49. *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 & Joel Lexchin, *'Linkage' Pharmaceutical Evergreening in Canada and Australia,* 4 AUSTL. AND N.Z. HEALTH POL. 6 (2007) (noting that in the Korean FTA the notification process to commence the patent

advanced linkage system in the Korean FTA, the Korean drug regulatory authority should not grant marketing approval for a generic product if there is related patent for the product, for the method of use or for the method of doing patents.[50] In addition, the Korean drug regulatory authority should notify the patent holder company of such an application.[51]

IV. COMPARISON BETWEEN FTAS IN TERMS OF DATA EXCLUSIVITY AND OTHER RELATED MEASURES OF DRUG REGULATORY APPROVAL

A. Jordan-United States Free Trade Agreement[52]

Signed in October of 2000, the Jordan-United States FTA was the first one of its kind concluded between the United States and an Arab country.[53] The impact of this agreement was significant for Jordanian public health.[54] 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.[55] 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.[56]

The following measures related to drug regulatory approval were added:

1. Data Exclusivity

As part of Jordan's accession to the World Trade Organization

holder must first notify the safety and efficacy regulator).

50. U.S.–S. Kor. FTA, *supra* note 210.

51. *Id.*

52. 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.

53. El Said, *supra* note 11, at 76.

54. *Id.* at 89.

55. *Id.* at 84.

56. *Id.* at 95.

("WTO"), Jordan implemented a data exclusivity regime, which provided for a five-year exclusivity period for new chemical entities for pharmaceutical products.[57] This was included in Article 8 of Unfair Competition and Trade Secrets Law 2000.[58] 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.[59]

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."[60] A new use was not defined in this agreement. The Jordan Food and Drug Administration ("JFDA") has defined "new use" as "new indication."[61]

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.[62] 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."[63]

2. Linkage

Instead of the more draconian patent linkage requirement wherein marketing approval for a generic drug is made

57. *Id.* at 86.

58. Malpani, *supra* note 49, at 7.

59. TRIPS Agreement, *supra* note 1, at art. 39.3.

60. U.S.–Jordan FTA, *supra* note 52, at art. 4.22 n. 10.

61. 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.

62. U.S.–Jordan FTA, *supra* note 52, at 7.

63. *Id.* at art. 4.22 n. 11.

contingent upon the decision of the patent holder, the Jordan–United States. FTA instead utilized a notification system.[64] 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."[65] The JFDA has implemented this point by publishing all the drug files submitted for registration on its website.[66]

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."[67]

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

A definition of new chemical entity or new product.[68]

Linkage system, which was replaced with a notification system.[69]

In the case of reliance on other countries' approval, Jordan has to implement, at a minimum, the protection period provided by that country from their date of approval, whichever is later.[70]

Protection period of the new chemical entity; this was specified in Article 8 of Unfair Competition and Trade Secrets Law 2000.[71]

Scope of protection expanded only by adding new uses were to be granted data exclusivity; later FTAs state new clinical

64. *Id.* at art. 4.23(b).

65. *Id.*

66. The notification list is available on the JFDA's website, www.jfda.jo (last visited Aug. 15, 2014).

67. U.S.–Jordan FTA, *supra* note 52, at art. 4.23(b).

68. *See, e.g.,* U.S.–Austl. FTA, *supra* note 16, at art. 17.10(1)(d).

69. Malpani, *supra* note 49, at 31.

70. U.S.–Austl. FTA, *supra* note 16, at art. 4.22 n. 11.

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

information, which may include new dosage form or new combinations.[72]

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.[73]

B. Chile–U.S. Free Trade Agreement

This agreement entered into force on January 1, 2004.[74] As with other FTAs, this agreement contains new constraints imposed by the United States in the pharmaceutical field.[75] These constraints are data exclusivity, linkage, and patent extension predicated on regulatory approval delay.[76] As with Jordan, when compared to other FTAs, the Chilean FTA contains fewer constraints than those later in time.[77]

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

1. Data Exclusivity

As mentioned above, data exclusivity for five years was granted for new chemical entities of pharmaceutical products before this agreement; this point was stated in Article 17.10.1 of the agreement.[78] In this FTA, neither new use nor reliance point were added.[79]

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

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72. U.S.–Jordan FTA, *supra* note 52, at art. 4.22 n. 10.

73. *Id.* at art. 4.22–4.23.

74. *The U.S.–Chile Free Trade Agreement: An Early Record of Success*, OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE (Sept. 15, 2017, 12:24 AM), https://ustr.gov/about-us/policy-offices/press-office/fact-sheets/archives/2004/june/-us-chile-free-trade-agreement-early-record-suc; U.S.–Chile FTA, *supra* note 15.

75. U.S.–Chile FTA, *supra* note 15.

76. *Id.*

77. *Compare* U.S.–Chile FTA, *supra* note 15, *with* U.S.–Australia FTA, *supra* note 16 (noting that, for instance, Australia's FTA includes definitions of a new chemical entity or new product).

78. U.S.–Chile FTA, *supra* note 15, at art. 17.10.1.

79. *See* U.S.–Chile FTA, *supra* note 15 (omitting new use and reliance sections from the agreement).

Definition of new product: Defined in Article 17.10.1. as, "which product has not been previously approved to grant a marketing approval or sanitary permit for such product."[80] This excludes the definition of new as patent novelty and does not specify the time limit to be considered new.[81]

2. Linkage

Linkage is an important requirement that was added to the Chilean regulatory system. This system prevents the marketing approval of a generic product during the protection period of the originator's patent and imposes a requirement to notify the originator's company of the application.[82] This was stated in Article 17.10.2.b: "make available to the patent owner the identity of any third party requesting marketing approval effective during the term of the patent; and not grant marketing approval to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner."[83]

3. Patent Term Extension

In Article 17.10.2.a, the patent term is extended in order to compensate for the regulatory delay in the marketing approval to "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."[84]

C. Australia–U.S. Free Trade Agreement[85]

In 1948, Australia established the Pharmaceutical Benefits Scheme ("PBS"). This impressive system has made effective medicines more affordable for the Australian people[86] and has

80. *Id.* at art. 17.10.1

81. *Id.*

82. *Id.* at art. 17.10.2(b).

83. *Id.*

84. *Id.* at art. 17.10.2(a).

85. U.S.–Austl. FTA, *supra* note 16.

86. Peter Sainsbury, *Australia–United States Free Trade Agreement and the Australian Pharmaceutical Benefits Scheme*, 4 YALE J. HEALTH POL'Y, L. & ETHICS 387, 387–89 (2004).

resulted in Australia having the cheapest drug bills of the developed countries.[87]

Data exclusivity was already found in Australia before the signing of the Australia–United States FTA.[88] Prior to the FTA, a generic drug company waited five years before applying for marketing approval in the Therapeutic Goods Administration.[89] The new condition found in this agreement was the obligation imposed on the Therapeutic Goods Administration as the linkage system.[90] Before this agreement, the administration did not check the patent status of the originator drug product when having a generic drug application.[91] The generic company was allowed to complete the registration process, but was not allowed to market the product before the end of the related patent.[92] The agreed-upon principles in the Australia–United States FTA reflect a compromise between Australia's competitive access philosophy and the United States' universal access philosophy.[93]

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

1. Data Exclusivity

As mentioned above, data exclusivity for five years was granted for new chemical entities before this agreement, as reiterated in Article 17.10 of the agreement.[94]

The new added constraints compared to Article 39.3 of the TRIPS Agreement are:

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87. *Id.*

88. Teresa Schafer, *Operation of the Data Exclusivity Regime in Australia*, LEGAL RX 11 (2011), http://www.davies.com.au/ip-news/data-exclusivity-provisions-under-the-therapeutic-goods-act-1989.

89. Katherine M. Van Maren, *Bartering with a Nation's Health or Improving Access to Pharmaceuticals? The United States–Australia Free Trade Agreement*, 14 PAC. RIM L. & POL'Y J. 801, 820 (2005) [hereinafter Van Maren]; Nicholas Tyacke, *The Impact of the US Free Trade Agreement on the Generic Pharmaceutical Industry and the PBS: Much Ado About Nothing?* (2004), http://www.mondaq.com/article.asp?article_id=28427&signup=true (last updated Sept. 23, 2004).

90. Van Maren, *supra* note 89 at 820.

91. *Id.*

92. *Id.*

93. *Id.* at 802–03.

94. U.S.–Austl. FTA, *supra* note 16.

Definition of new product: this was defined in Article 17.10.1(d) "a new product is one that does not contain a chemical entity that has been previously approved for marketing in the Party."[95] This excludes the definition of new as a patent novelty, and, further, did not define the time limit to be considered new.

In the 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 Australia or that country whichever is later.[96] This is stated in Article 17.10.1(c).[97] Furthermore, new clinical information is granted data exclusivity for three years as per Article 17.10.2.;[98] this may include new uses and new combinations. Finally, data exclusivity protection continues even if the patent protection period terminates earlier than the data exclusivity period. This is stated in Article 17.10.3.[99]

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95. *Id.* at art. 17.10.1(d).

96. *Id.* at art. 17.10.1(c).

97. The U.S.–Austl. FTA reads as follows:

If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously submitted information concerning safety or efficacy to market the same or a similar product on the basis of evidence of prior marketing approval in another territory, or information concerning safety or efficacy that was previously submitted to obtain marketing approval in another territory, for at least five years, from the date of marketing approval by the Party, or the other territory, whichever is late.

U.S.–Austl. FTA, *supra* note 16, at art. 17.10.1(c).

98. The U.S.–Austl. FTA reads as follows:

With respect to pharmaceutical products, if a Party requires the submission of: (a) new clinical information (other than information related to bioequivalence) or (b) evidence of prior approval of the product in another territory that requires such new information, which is essential to the approval of a pharmaceutical product, the Party shall not permit third persons not having the consent of the person providing the information to market the same or a similar pharmaceutical product on the basis of the marketing approval granted to a person submitting the information for a period of at least three years from the date of the marketing approval by the Party or the other territory, whichever is later.

U.S.–Austl. FTA, *supra* note 16, at art. 17.10.2.

99. The U.S.–Austl. FTA reads as follows:

When a product is subject to a system of marketing approval in accordance with paragraph 1 or 2, as applicable, and is also subject to a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to paragraph 1 or 2 in the event that the patent protection terminates on a date earlier than the end of the term of

2. Linkage

This is an important requirement to be added to the Australian regulatory system.[100] This system will prevent the marketing approval of a generic product during the protection period of the originator patent.[101] In this system, the generic company during the final approval stage of its product will provide a certificate to the drug regulatory authority stating either that it will not market their product in a way that infringes a valid patent claim,[102] or that it has notified the originator company that it will market its product before the end of the protection term of their patent.[103]

The linkage system is mentioned in Article 17.10.4.[104] This new certification system may lead to litigation between the originator and the generic company. This could lead to a delay in the market entrance of generic products, with the ensuing result being an increase in the cost of medicines that the PBS will bear.[105] In this case, the estimated delay for a generic product's entrance into the market is twenty-four months.[106]

3. Patent Term Extension

In Article 17.9.8.b,[107] the patent term extension compensates for the regulatory delay in the marketing approval. *Even though Australia is considered to be one of the developed countries, the*

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protection specified in paragraph 1 or 2, as applicable.

U.S.–Austl. FTA, *supra* note 16, at art. 17.10.3

100. Ruth Lopert & Deborah Gleeson, *Globalization, Pharmaceuticals, Patents and Free Trade, The High Price of "Free" Trade: United States Trade Agreements and Access to Medicines*, 41 J. L. MED. & ETHICS 199, 203 (2013) [hereinafter Lopert & Gleeson]; *see also* THERAPEUTIC GOODS ACT 1989 (Cth) s 26b (Austl.), http://www.comlaw.gov.au/Details/C2012C00355 (last visited Oct. 5, 2014).

101. Lopert & Gleeson, *supra* note 100.

102. *Id.*

103. *Id.* at 203.

104. U.S.–Austl. FTA, *supra* note 16, at art. 17.10.4.

105. Van Maren, *supra* note 89, at 822.

106. Charles T. Collins-Chase, *The Case against TRIPS-PLUS Protection in Developing Countries Facing AIDS Epidemics*, 29 U. PA. J. INT'L L. 763, 795 (2008).

107. U.S.–Austl. FTA, *supra,* note 16, at art. 17.9.8.b ("With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.").

terms included in its FTA are very similar to those included in the proposed Thailand–U.S. FTA.[108] Indeed, the presence of the PBS as a distinguished system in Australia will ensure that drug prices remain low for the Australians.[109]

D. Morocco–U.S. Free Trade Agreement[110]

This FTA was signed in June of 2004, and entered into force in January of 2006.[111] The following measures related to drug regulatory approval are specified in Article 15.10.[112]

1. Data Exclusivity

As with Chile, Singapore, CAFTA and Australia, Morocco had already granted a five-year data exclusivity protection term for NCEs or new products before signing an agreement with the United States. This point was stated in Article 15.10.1 of the agreement.[113] New added constraints compared to Article 39.3 of the TRIPS Agreement is the definition of a new product specified in Article 15.10.1.[114] This excludes the definition of new as patent

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108. *Compare* U.S.–Austl. FTA, *supra,* note 16, at art. 17.9.8.b *with* Duangrat Laohapakakul, *United States - Thailand Free Trade Agreement Negotiations: Potential Effects on Pharmaceutical Patent Protection in Thailand*, Working Paper: LEDA at Harvard Law School (April 2006), https://dash.harvard.edu/bitstream/handle/1/8889472/Laohapakakul06.html?sequence=2 .

109. Van Maren, *supra* note 89, at 802.

110. U.S.–Morocco FTA, *supra* note 17.

111. *Id.* at art. 15.10

112. *Id.*

113. The U.S.–Morocco FTA reads as follows:

If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of:

(a) safety and efficacy data, or

(b) evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party's territory. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party's territory.

U.S.–Morocco FTA, *supra* note 17, at art. 15.10.1.

114. *Id.* ("For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party's Territory.")

novelty and did not define a time limit to be considered new.[115] Furthermore, in the case of reliance on other countries' marketing approval, the authority should provide an exclusivity period for five years' protection from the date of marketing in Morocco. This is stated in Article 15.10.1.[116]

Another added constraint is the new clinical information data exclusivity for at least three years in Article 15.10.2.[117] This may include new uses and new combinations. Data exclusivity protection continues even if the patent protection period terminates earlier than the data exclusivity period. This is stated in footnote 12 of Article 15.10.1.[118]

2. Linkage

This system will prevent the marketing approval of a generic product during the protection period of the originator patent.[119]

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115. *Id.*

116. The U.S.–Morocco FTA reads as follows:

(b) evidence of prior approval of the product in another territory requires such information, the Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party's territory.

U.S.–Morocco FTA, *supra* note 17, at art. 15.10.1

117. The U.S.–Morocco FTA reads as follows:

If a Party requires the submission of

(a) new clinical information that is essential to the approval of a pharmaceutical product (other than information related to bioequivalence), or

(b) evidence of prior approval of the product in another territory that requires such new information, the Party shall not permit third persons not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. A Party may limit such protection to new clinical information the origination of which involves considerable effort.

Id. at art. 15.10.2.

118. The U.S.–Morocco FTA reads as follows:

. . . In addition, when a product is subject to a system of marketing approval pursuant to this paragraph and is also subject to a patent in the territory of a Party, that Party may not alter the term of protection that it provides in accordance with this paragraph in the event that the patent protection terminates before the end of the term of protection specified in Article 10.1.

Id. at art. 15.10.2 n.12.

119. *Id.* at art. 15.10.4(a).

The drug regulatory authority should take measures to prevent the generic product's marketing approval during the patent term of the product or patents covering approved indications, as stated in footnote 14, and should also notify the originator of such an application.[120] This new system is stated in Article 15.10.4.[121]

3. Patent Term Extension

Article 15.10.3 states the patent term extension to compensate for the regulatory delay in marketing approval.[122] The Moroccan FTA added more constraints when compared to earlier FTAs; for example, the condition found in Article 39.3 of the TRIPS Agreement regarding "undisclosed data" is not mentioned in this agreement.[123] Additionally, the obligation to protect against "unfair commercial use" found in Article 39.3 of TRIPS also is not mentioned in this agreement.[124] Linkage is for both product patents and new indication patents.[125] Finally, new clinical information is granted a three-year protection period,

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120. *Id.* at art. 15.10.4(a)(b) n. 14.

121. The U.S.–Morocco FTA reads as follows:

With respect to any pharmaceutical product that is subject to a patent, and where a Party permits authorizations to be granted or applications to be made to market a pharmaceutical product based on information previously submitted concerning the safety and efficacy of a product, including evidence of prior marketing approval by persons other than the person that previously submitted such information, that Party:

(a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent during the term of that patent, unless by consent or with the acquiescence of the patent owner, and

(b) if it allows applications to be made to market a product during the term of a patent covering that product, shall provide that the patent owner shall be notified of the identity of any such other person who requests marketing approval to enter the market during the term of a patent notified to or identified by the approving authority as covering that product.

U.S.–Morocco FTA, *supra* note 17, at art. 15.10.4

122. The U.S.–Morocco FTA reads as follows:

With respect to patents covering pharmaceutical products, each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.

Id. at art. 15.10.3.

123. *Compare* TRIPS Agreement, *supra* note 1, at art. 39.3, *with* U.S.–Morocco FTA, *supra* note 17.

124. *Id.*

125. U.S.–Morocco FTA, *supra* note 17, at art. 15.10.4(a) n. 14.

which is not only for new indications, but may include new dosage forms and new combinations, amongst others.[126]

E. CAFTA–DR–U.S. Free Trade Agreement[127]

CAFTA–DR FTA is a regional agreement between the United States and a group of smaller developing countries, signed in August of 2004. This agreement includes the following five Central American countries (Costa Rica, El Salvador, Guatemala, Honduras, and Nicaragua) and the Dominican Republic.[128] This agreement is in force for all signed countries.[129] The last country where this agreement entered into force was Costa Rica, in January of 2009.[130]

The supporters of this agreement gave reasons similar to those advanced for all FTAs;[131] that is, the originator company should be rewarded for its innovation and development of new products, and stronger intellectual property rights are necessary to recoup the high cost of such investments.[132] From this rationale follows the corollary that, if generic companies were allowed to obtain a free ride on the originator's test data in developing their own products, there will be a decline the ability of the originator companies to discover new products, and consequently public health will be threatened.[133] This is

126. *Id*. at art. 15.10.2(a).

127. Dom. Rep.–CAFTA, *supra* note 18.

128. *CAFTA–DR – An Overview*, EXPORT, https://www.export.gov/article?id=7-1-CAFTA-DR-Overview ("[E]ntered into force for the United States, El Salvador, Guatemala, Honduras, and Nicaragua in 2006, for the Dominican Republic in 2007, and for Costa Rica in 2009.") (last updated Oct. 18, 2016).

129. *Id*.

130. *Id*.

131. The United States Bilateral Investment Treaties (BIT) program embodies this position in its basic aims, which include "protect[ing] investment abroad in countries where investor rights are not already protected through existing agreements" and "encourag[ing] the adoption of market-oriented domestic policies that treat private investment in an open, transparent, and non-discriminatory way." Office of the United States Trade Representative, *Bilateral Investment Treaties*, USTR, https://ustr.gov/trade-agreements/bilateral-investment-treaties (last visited April 6, 2017).

132. Christine A. Chung, *A Cry for Cheap Drugs: CAFTA's Inflexible Intellectual Property Protections Create an Ominous Impact on Life-Saving Medicines*, 13 SW. J. L. & TRADE AM. 171, 177–80 (2006) [hereinafter Chung].

133. Mark B. McClellan, Commissioner, Food and Drug Administration,

important for Central American countries, especially in the case of HIV/AIDS patients.[134] Moreover, the supporters of this agreement state that countries with poor intellectual property rights will have fewer new products, poor local industry and consequently a poor health system.[135] Additionally, they question the quality of the generic drugs as compared to the originator's product, emphasizing the fact that having stronger intellectual property rights will ensure the availability of effective drugs.[136]

The opponents of this agreement argued that this FTA would increase the monopoly of the originator companies, that data exclusivity is a double protection to the existing patent system, and that the DR–CAFTA would kill the generic industries in Central America.[137] Pointing to its dubious efficacy, opponents also argued that poor people will not be able to buy expensive medicine, so there will be no returns for the originator companies.[138]

HIV/AIDS is the second biggest cause of death in Latin America.[139] In 2000, the originator product price of antiretroviral drugs was more than $10,000 per patient per year.[140] Meanwhile, today, the generic drug cost of the same originator is $168 per patient per year.[141]

The major points in the CAFTA agreement designed to strengthen intellectual property rights were the extension of patent terms as a result of regulatory delays, and the exclusivity period of five years for the originator product, during which a

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Colloquium on Generic Medicine at the First International Colloquium on Generic Medicine (Sept. 25, 2003), http://www.fda.gov/NewsEvents/Speeches/ucm053614.htm (last updated Dec. 31, 2008) (stating that "without an assurance of payment for success that reflects the value of these new treatments to the world, the developers of new medical products will not do it. They will not risk the high cost and the years of effort in collaboration across an increasingly broad range of scientific disciplines.").

134. Chung, *supra* note 132, at 178.

135. *Id.*

136. *Id.* at 178–79.

137. *Id.* at 180.

138. *Id.* at 174, 181.

139. *Id.* at 172.

140. Chung, *supra* note 132, at 177-80.

141. *Id.* at 173.

generic product cannot be marketed.[142]

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

1. Data Exclusivity

Five year data exclusivity was stated in Article 15.10.1.a.[143] New added constraints compared to Article 39.3 of the TRIPS Agreement are:

Definition of a new product: this was defined in Article 15.10.1. C.[144] This excludes the definition of new as patent novelty, and does not specify a time limit to consider it new.

In the case of reliance on other countries' marketing approval, the authority should provide an exclusivity period for five years' protection from the date of marketing approval in the other country. This is stated in Article 15.10.1.b.[145]

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142. Coll, *supra* note 19, at 498.

143. Article 15.10.1(a) and footnote 15 of the Dom. Rep.–CAFTA read:

If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.

Dom. Rep.–CAFTA, *supra* note 18, at art. 15.10.1(a).

Where a Party, on the date it implemented the TRIPS Agreement, had in place a system for protecting pharmaceutical or agricultural chemical products not involving new chemical entities from unfair commercial use that conferred a period of protection shorter than that specified in paragraph 1, that Party may retain such system notwithstanding the obligations of paragraph 1.

Dom. Rep.–CAFTA, *supra* note 18, at art. 15.10.1(a) n.15.

144. *Id.* at art. 15.10.1(c) (defining a new product as "one that does not contain a chemical entity that has been previously approved in the territory of the Party").

145. Article 15.10.1(b) of the Dom. Rep.–CAFTA reads:

If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from

2. Linkage

In this system, there was a requirement to prevent the marketing approval based on product and method of use patents and to notify the patent holder of the submission of a generic product. The linkage system is mentioned in Article 15.10.2.[146]

3. Patent Term Extension

CAFTA requires an extension of the pharmaceutical patent term to compensate for the delays in granting marketing approval, as stated in Article 15.9: "Each Party . . . shall adjust the term of a patent to compensate for unreasonable delays that occur in granting the patent . . . [or] resulting from the marketing approval process."[147]

The primary differences from earlier FTAs include the following: first, no new use or new clinical information is found in the CAFTA;[148] second, nothing indicates in the agreement that data exclusivity extends after patent duration ends;[149] third, the protection against disclosure or "unfair commercial use" in not

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the date approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory.

Id. at art. 15.10.1(b)

146. Article 15.10.2 of the Dom. Rep.–CAFTA 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 evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party:

(a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and

(b) Shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.

Id. at art. 15.10.2.

147. *Id.* at art. 15.9.6(a)(b)

148. Dom. Rep.–CAFTA, *supra* note 18.

149. *Id.*

mentioned.[150]

F. Korea–U.S. Free Trade Agreement[151]

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.[152] 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 Korea's economy and society.[153] Despite these objections, the United States was able to include many restrictions in this FTA, especially concerning intellectual property rights (IPR) related to pharmaceuticals.[154]

Regarding the pharmaceutical intellectual property rights, the terms were extended beyond those found in earlier FTAs.[155] 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.[156] 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.[157]

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

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150. *Id.*

151. U.S.–S. Kor. FTA, *supra* note 20.

152. Lee et al., *supra* note 21, at 113; *see also* Lopert & Gleeson, *supra* note 100, at 203.

153. Lee et al., *supra* note 21, at 114.

154. *Id.* at 114–15.

155. *Compare* U.S.–S. Kor. FTA, *supra* note 20, at art. 18, *with* U.S.–Chile FTA, *supra* note 15, at art. 17, U.S.–Austl. FTA, *supra* note 16, at art. 17, U.S.–Morocco, *supra* note 17, at art. 15, Dom. Rep.–CAFTA, *supra* note 18, at art. 15, *and* U.S.–Jordan FTA, *supra* note 52, at art. 4; *see also* Lee, *supra* note 21, 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").

156. Lopert & Gleeson, *supra* note 100, at 201.

157. *Id.*

1. Data Exclusivity

Data exclusivity for five years was granted for a new chemical entity before this agreement.[158] This point was stated in Article 18.9.1(a) of the agreement.[159] It is noted that "undisclosed" was removed.[160] 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;[161] second, the protection against "unfair commercial use" was removed and replaced by granting a period of exclusivity for five years.[162] Most importantly, Article 18.9.1.C introduced a definition of new products.[163] 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.[164]

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[158] 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 20, at art. 18.9.1(a).

159. *Id.*

160. *Id.*

161. *Compare* TRIPS *supra* note 1, at art. 39.3, *with* U.S.–S. Kor. FTA, *supra* note 20.

162. U.S.–S. Kor. FTA, *supra* note 20.

163. U.S.–S. Kor. FTA, *supra* note 20, 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").

164. 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

With respect to new clinical information, new clinical information is granted data exclusivity for three years in Article 18.9.2.a and b.[165] This may include not only new use, but also a

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 20, 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 20, at art.18.9.1(b) n. 24.

165. 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

new combination and a new dosage form.

2. Linkage

The linkage system is tackled in Article 18.9.5.[166] 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.[167]

3. Patent Term Extension

In Article 18.8.6,[168] the patent term is extended to compensate

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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, at art.18.9.2(a)–(b), 18.9.4.

166. 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, at art.18.9.5.

167. *Id.*

168. 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

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.[169]

Finally, the Korea-United States 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;[170] second, the definition of new product was specific to the pharmaceutical regulatory authority in Korea, even if the issue could fall under the jurisdiction of another agency.[171] 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.[172]

V. FTAS COMPARISON TABLE

The table below summarizes and emphasizes the differences between the aforementioned FTAs and TRIPS.

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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.

Id. 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.

169. U.S.–S. Kor. FTA, *supra* note 20 (noting that the terms of the article apply to a product's method of use or method of making).

170. *See id*. (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 100, 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).

171. U.S.–S. Kor. FTA, *supra* note 20.

172. *Id*. at art. 18.8.6(b).

Term	**TRIPS (Article 39.3)** [173]	Jordan (Article 4.22 and 4.23)[174]	Chile (Article 17.10)[175]	**Australia (Article 17.9.8.b and 17.10**	**Morocco (Article 15.10)**[176]	**CAFTA (15.9.6.b and 15.10)**[177]	**Korea (18.8.6.b and 18.9)** [178]
Data Exclusivity	X	√	√	√	√	√	√
New Chemical Entity	√	√ (unfair law)	√	New product	New product	New product	New product
Condition "Undisclosed data"	√	√	√	√	X	√	X
Duration of protection of new product	X	X (unfair law)	√	√	√	√	√
Reliance on other country approval	X	√	X	√	√	√	√
New definition	X	X	√	√	√	√	√

173. Correa, *Protecting Test Data, supra* note 1, at 14.
174. U.S.–Jordan FTA, *supra* note 52, at art. 4.22–4.23.
175. U.S.–Chile FTA, *supra* note 15, at art. 17.10.
176. U.S.–Morocco FTA, *supra* note 17, at art. 15.10.
177. Dom. Rep.–CAFTA, *supra* note 18, at art. 15.9.6(b), 15.10.
178. U.S.–S. Kor. FTA, *supra* note 20, at art. 18.8.6(b), 18.9.

New clinical information	X	√ (only new use)	X	√	√	X	√
Duration of protection	X	√ (three years)	X	√	√	X	√
Reliance on other country approval	X	√	X	√	√	X	√
Considerable efforts	√	√	X	X	X	X	X
Protection against "unfair commercial use"	√	√	X	X	X	X	X
Exclusivity extends after patent duration end	X	X	X	√	√	X	√
Linkage:	X	Notification system only	√	√	√	√	√
1. Obligation ("each Party shall")	X	X	√	√	√	√	√
2. Provide a system	X	X	X	√	√	√	√
To identify	X	X	√	√	√	√	√
To notify patent holder	X	√	√	√	√	√	√
Product	X	√	√	√	√	√	√

patent							
Method of Use patent	X	X	√	√	√	X	√
Automatic delay of marketing approval	X	X	√	√	√	√	√
C. Pharmaceutical Patent extension	X	√	√	√	√	√	√

Table 1: FTAs Comparison Table:
√: included
X: not included

VI. 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 which have already signed the FTA can mitigate its effects on public health by limiting the scope of and provide 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 new chemical entities; 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 in bilateral agreements before taking into consideration its potential effects on public health and, further, should take the opportunity to 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.