

Test Data Protection: Different Approaches and Implementation in Pharmaceuticals

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TEST DATA PROTECTION: DIFFERENT APPROACHES AND IMPLEMENTATION IN PHARMACEUTICALS

WAEEL ARMOUTI* AND MOHAMMAD F. A. NSOUR**

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I. INTRODUCTION

Binding on all members of the World Trade Organization (“WTO”), the Agreement on Trade-Related Aspects of Intellectual Property Rights (“TRIPS”)¹ aimed to create a standard of international property protection.² In particular, Article 39.3 of TRIPS requires WTO members to protect the secret test data that originator pharmaceutical companies submit for regulatory approval of New Chemical Entities (NCE) against “disclosure” and “unfair commercial use.”³ Notably, however, Article 39.3 goes no further in defining these constitutive terms, a deliberate maneuver designed to give WTO members the freedom to interpret the parameters of the Article’s prohibition against disclosure and unfair commercial use. In effect, this latitude allows members to set their own rules and to implement the Article by adopting an approach that takes account of national individuality.

The importance of the interpretive freedom that Article 39.3 allows WTO members is reflected in the varied approaches to test data protection adopted by member countries: test data protection approaches differ along the lines of how the “unfair commercial use” obligation found in Article 39.3 is construed. Some of these approaches are considered public health-friendly more than data exclusivity.⁴ In practice, the permissive language of Article 39.3 permits a government to authorize a generic product based on an earlier grant of regulatory approval for the original product without running afoul of the Article’s prohibition on disclosing test data submitted by the original company.⁵

This article discusses different protection approaches. The first approach bans any policy that ultimately allows direct entry of generic products (*i.e.* misappropriation). The second approach is a cost-sharing mechanism that

1. Agreement on Trade-Related Aspects of Intellectual Property Rights, Apr. 15, 1994, Marrakesh Agreement Establishing the World Trade Organization, Annex 1C, Legal Instruments—Results of the Uruguay Round, 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994), [hereinafter TRIPS Agreement], available at http://www.wto.org/english/tratop_e/trips_e/t_agm0_e.htm. For a general outline of the TRIPS Agreement, see *Overview: The TRIPS Agreement*, WORLD TRADE ORGANIZATION, https://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Mar. 15, 2016).

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

3. TRIPS Agreement, *supra* note 1, art. 39.

4. Anthony Taubman, *Unfair Competition and the Financing of Public-Knowledge Goods: The Problem of Test Data Protection*, 3 OXFORD J. INTELL. PROP. L. & PRAC. 594, 595 (2008).

5. Valerie Junod, *Drug Marketing Exclusivity Under United States and European Union Law*, 59 FOOD & DRUG L.J. 479, 484–485 (2004).

ensures higher political acceptance and still meets the obligations of Article 39.3 of the TRIPS agreement to prevent unfair commercial use. The third approach is protecting clinical pharmaceutical test data submitted to regulatory agencies from generic drug manufacturing application (i.e. data exclusivity). Under the data exclusivity approach, a comparison to patents and their relation to compulsory license are discussed. The fourth approach allows releasing the data exclusively protected in certain public health variants, which mitigate the effect of data exclusivity.

After discussing these distinct approaches to test data protection, I will then consider the implementation of test data protection in the United States, Canada, and the European Union. I will conclude by comparing these approaches with the demonstrably less restrictive approaches to test data protection employed by both India and Egypt.

II. DIFFERENT PROTECTION APPROACHES

A. Bans on Misappropriation

Taking maximum advantage of the flexibilities afforded by the broad language of the TRIPS Agreement, this first approach is considered to facilitate the early entry of a generic product directly after the original product is approved.⁶ Operationally, the ban-on-misappropriation approach prohibits government officials from disclosing an originator's submitted test data to a third party, but it empowers them to rely on these data to grant marketing approval of a generic product.⁷ This approach finds legitimacy in several areas. Initially, the predicate interpretation of "unfair commercial use" utilized is consistent with the text of Article 39.3. Here, unfairness is limited to the means of access to the data by the competitor, not by the regulators.⁸ Furthermore, according to Article 39.3 of the TRIPS agreement, it is required to protect test data in accordance with domestic laws of unfair competition.⁹ Thus, the originator's test data will be protected against that which the relevant national law defines as unfair use of the data.¹⁰ Under this scenario, reliance on original test data when assessing the bioequivalence study of a generic company will not be considered to be an unfair use.

In general, the ban-on-misappropriation approach is considered to be a

6. Anthony Taubman, *supra* note 4.

7. *Id.*

8. *Id.*

9. TRIPS Agreement, *supra* note 1, art. 39.

10. Pamela Andanda, *Managing Intellectual Property Rights Over Clinical Trial Data to Promote Access and Benefit Sharing in Public Health*, 44 INT'L REV. INTEL. PROP. & COMPETITION L. 140, 147 (2013).

valuable alternative to the data exclusivity approach for developing countries;¹¹ some countries—Argentina, for example—recognized the advantages of test data protection and consequently went on to implement the approach.¹² Two such advantages include (1), the generic product will reach the market as quickly as possible, with no need to repeat the clinical test data; and (2), it is a simple approach to implement, because no regulatory burdens are imposed on the government.¹³

Conversely, numerous arguments have been leveled against this approach. First, the ban-on-misappropriation approach will undermine originator companies' investments in Research & Development (R&D). Second, this strategy will deny fair return to originator companies by allowing generic companies to unfairly free ride on their investment.¹⁴ However, both of these alleged failings of the ban-on-misappropriation approach may be of limited applicability in the milieu of a developing country.¹⁵ In such countries, the originator already has a large incentive to conduct R&D under a patent system. Also, developing countries have a small share of the global pharmaceutical market, so their policies will not affect the R&D investment decisions of the originator companies.¹⁶

Additionally, implementing a strong intellectual property system does not affect the decision of the originator companies to invest more in those countries.¹⁷ On the contrary, we can see that originator companies have made many investments in Egypt, which offers limited IP protection but have not made such investments in Jordan, which has adopted an expansive IP protection program.¹⁸

Model language for the misappropriation approach is “[g]overnment authorities shall prohibit misappropriation of test or other data submitted to obtain marketing approval for pharmaceutical or agricultural chemical products which utilize new chemical entities, except where necessary to protect the public; government authorities shall not disclose such data.”¹⁹

11. *Id.*

12. *See id.*

13. *Id.*

14. Robert Weissman, *Public Health-Friendly Options for Protecting Pharmaceutical Registration Data*, 1 INT'L J. INTELL. PROP. MGMT. 113, 115–17 (2006).

15. *Id.*

16. *Id.*

17. 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 (2007), <https://www.oxfam.org/sites/www.oxfam.org/files/all%20costs,%20no%20benefits.pdf>.

18. *Id.*

19. Weissman, *supra* note 14, at 118.

B. Compensatory regime or cost-sharing approach to registration data

1. Overview of Cost-Sharing Approach

According to this cost-sharing approach to data protection, a generic company may rely on the originator's submitted test data in its bid to attain regulatory approval if, and only if, the generic company offers fair compensation for the data to the originator company.²⁰ The key elements of this approach are: the cost of generating data must be documented;²¹ the generic company will pay a share of the costs apportioned to each national market;²² and avoiding overcompensation for originator data by taking into account the following criteria:²³ if the originator product is covered by a patent, then no compensation will be paid.²⁴

If the sales of the originator product earn multiple (20 times) its cost in generating test data, then no compensation from generic companies.²⁵

The right to compensation expires five years after the originator product obtained marketing approval.²⁶ The generic company will pay for the period they will be using the data during the course of the five years.²⁷

2. Compliance with Article 39.3

The cost-sharing approach meets Article 39.3 obligations to prevent unfair commercial use.

3. Advantages of Cost-Sharing Approach

The cost-sharing approaches has numerous advantages.²⁸

It will avoid the free-rider problem,²⁹ as it requires the generic companies to share the cost of the clinical trials done by the originator company.³⁰

It will encourage the originator to invest more in developing new

20. *Id.*

21. Weissman, *supra* note 14, at 112–124.

22. *Id.*

23. *Id.*

24. *Id.*

25. *Id.*

26. *Id.*

27. *Id.*

28. Brandon Powell, *Silence Is Not the Best Medicine: Requiring Disclosure of Clinical Trial Data for Abandoned Drugs*, 33 J. LEGAL MED. 571, 591 (2012). See also *FDA 101: Clinical Trials and Institutional Review Boards*, FDA (Apr. 14, 2009), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm134723.htm>.

29. See *id.*

30. *Id.*

products.³¹

It adds value to abandoned drugs; an originator company can benefit from its abandoned products because it will receive a percentage of the gross sales from the competitor who wishes to proceed in this drug.³²

It will reduce the costs of drug development, since the cost-sharing system compensates a company for research that otherwise would have generated zero income for it. As a result of this compensation, the company will in turn charge a lower price for the drug,³³ with the aggregate effect of this causal relationship being industry-wide cost reductions.

It will benefit the scientific community because this approach mandates the disclosure of the test data; consequently, knowledge will be increased, resources are conserved and more drugs will be produced.³⁴

4. Problems with Cost-Sharing Approach

The principal problem with this regime is that this fair compensation requirement may exceed generic companies' financial capacity. There are disadvantages of the cost sharing approach.³⁵

The system is complicated or difficult to administer.³⁶ However, any such administrative difficulties are lessened when the cost-sharing system at issue allows a generic producer to establish an automatic right to rely on originators' data; in this scenario, the only dispute or administrative difficulty will concern the amount of compensation. Even on this potential administrative morass, the U.S.'s approach to handling the amount of compensation points to ways to simplify the process of compensation.³⁷ Moreover, there is a suggestion that the Drug Regulatory Authority should substitute a royalty payment.³⁸

Other disadvantages include over-compensating of originator companies for test data, which consequently increases the cost charged to consumers.³⁹ The response to this objection is that the actual cost for the generic companies will be modest, especially in smaller market.⁴⁰

31. *Id.*

32. *Id.*

33. *Id.*

34. *Id.*

35. Weissman, *supra* note 14, at 120–24.

36. *Id.*

37. *Id.*

38. *Id.*

39. *Id.*

40. *Id.*

5. Issues with Calculating Costs Under this Approach

Most disputes under the cost-sharing system concern how to calculate the actual costs of generating test data incurred by the originator company. In practice, dispute arbitrators will usually reduce the estimates submitted by the originator company.⁴¹ To resolve disputes over the validity of a particular company's estimates, two predicate questions must be addressed. First, what is the appropriate methodology with which to calculate the originator company's expenditure? Second, does this estimate include the cost of failed molecules?

As to the second inquiry regarding the financial value of an originator company's failed attempts, it is important to determine the extent to which the failed efforts ultimately contributed to the successful molecule's market entry.⁴² The Pharmaceutical Research and Manufacturers of America (PhRMA) and the European Federation of Pharmaceutical Industries and Associations (EFPIA) report that for every 5,000 drugs tested, an average of only five make it to clinical trials, and only one of these is ultimately approved for patient use.⁴³ This data confirms that such failed efforts are a common occurrence. Thus, the data lends validity to the originator company's attempt to pass some portion of the costs associated therewith onto a generic producer. Though a generic producer may seek to utilize the originator's final test data, this sought-after information may owe its existence to the lessons learned from earlier failed attempts.

Another question involving how to calculate the originator's costs considers what is the appropriate percentage of said costs to be allotted to each company. Specifically, should the apportionment be similar for all companies in all countries,⁴⁴ regardless of both the country's market share? Should this determination consider how many generic competitors are requesting marketing approval, or how long the originator product has been in the market?⁴⁵

Mr. Robert Weissman drafted a model for the cost-sharing approach, in which a generic company will pay a percentage of the originator's documented cost that is based on the market share in which the generic product will be

41. Aaron Xavier Fellmeth, *Article: Secrecy, Monopoly, and Access to Pharmaceuticals in International Trade Law: Protection of Marketing Approval Data Under the TRIPS Agreement*, 45 HARV. INT'L L.J. 443, 479 (2004).

42. *Id.*

43. *Id.*

44. Jerome H. Reichman, *Undisclosed Clinical Trial Data Under the TRIPS Agreement and Its Progeny: A Broader Perspective*, ICTSD-UNCTAD Dialogue on Moving Pro-development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning, Bellagio, Nov. 29–Dec. 3, 2004, available at http://www.iprsonline.org/unctadictsd/bellagio/docs/Reichman_Bellagio4.pdf.

45. *Id.*

sold.⁴⁶ Under the Weissman cost-sharing model, compensation will be divided according to the number of generic companies seeking marketing approval.⁴⁷ The amount of compensation will be subject to case-by-case negotiation, and will not stand in the way of a generic use or of reliance on the data to obtain marketing approval.⁴⁸

A simple model was proposed to avoid litigation, in which the generic companies pay reasonable royalty from their gross sales for a specified period, not to exceed five years.⁴⁹ In this model, compensation correlated to its value to each generic company, a valuation based upon its sales. Until 1992, Canada used to impose a four percent royalty on the right to use patented pharmaceuticals.⁵⁰ The royalty percentage can vary according to each country, from one to four percent. In other words, the disadvantage of this model is the overcompensation of the originator company.⁵¹

Additionally, there are two other notable models of cost calculation: the Simple Divisions Royalties Model and the more-sophisticated Readjustable Royalties Model. The following discussion of these two models utilizes an analysis by Professor Fellmeth.

a. The Simple Division Royalties Model

In this model, all drug registrants will pay fixed cost-sharing. Here, the originator company has the burden to prove the cost of submitted trials required to gain the drug marketing approval.⁵² Once validated, this cost will then be divided by the number of the registrants in any given year,⁵³ and all registrants will share an equal percentage of the total cost.⁵⁴

The difference between the Simple Division Royalties Model and the North American Free Trade Agreement (“NAFTA”) is that no exclusivity period will be provided for the originator company, which allows a generic company to request registration immediately after proving that its product is bioequivalent to the originator’s.⁵⁵ Also, this model differs from the FIFRA model by having

46. *Id.*

47. *Id.*

48. *Id.*

49. Jerome H. Reichman, *Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach*, 13 MARQ. INTELL. PROP. L. REV. 1, 31–32 (2009).

50. *Id.*

51. *Id.*

52. Fellmeth, *supra* note 41, at 481–82.

53. *Id.*

54. *Id.*

55. *Id.*

a fixed cost-sharing, and it will not involve any arbitral procedure that will delay the entrance of the generic product.⁵⁶

A significant disadvantage of this model is that the generic company will have to pay a large percentage of the clinical trials cost, a cost which generic companies in developing countries cannot afford.⁵⁷ Moreover, this model does not account for all the generic producers requesting marketing approval. Predictably, not all generic producers will enter the market at exactly the same time; the Simple Divisions Royalties Model, however, does not address the staggered market entry of generic producers and the calculation protocol this model does provide would create a messy procedure in the calculation of the right percentage.⁵⁸

This model's insufficiency is further demonstrated by the point that some generic companies may not enter the market after gaining the marketing approval, so it is not fair to correlate it to marketing approval if no real marketing has happened.⁵⁹

b. The Readjustable Royalties Model

This model links the market access benefits with the costs obtaining this access.⁶⁰ The subsequent generic companies will pay a royalty for predetermined years after gaining marketing approval. Many mathematical formulae were proposed to apply this model. One of these formulae proposes a higher royalty on the first generic companies, as they will gain the greatest benefits. Under this calculus, companies will eventually be paid a lower royalty as the benefit they will gain will be less from the initial ones.⁶¹ In this proposed formula, the originator will not recover more than the 80% of its cost, and the higher the number of generic competitors, the more of its cost will be recovered.⁶²

The flexibility of this model is one of its key strengths, as formulae can be changed to allow negotiation on critical issues, such as how many generic companies should pay the royalty, and for how long the royalty should be paid. Moreover, this model ensures that the originator will not recover more than 100% of its real cost.⁶³ If applied properly, this model will foster competition in the market and will disperse the cost of the clinical trials among all available

56. *Id.*

57. *Id.*

58. *Id.*

59. *Id.*

60. *Id.* at 482–99.

61. *Id.*

62. *Id.*

63. *Id.*

competitors.⁶⁴

6. How U.S. Utilizes Cost-Sharing Approach

This approach is consistent with the U.S.'s position and ensures higher political acceptance.⁶⁵ U.S. law has already established a version of the cost-sharing approach for agricultural chemical registration under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA).⁶⁶ The difference is that in this model, there is an exclusive period, which is followed by an automatic right to use the registration data after paying compensation royalties.

It may be noted that cost-sharing approach did not appear in any FTA signed with the United States, as they were able to include the harsher approach that is data exclusivity.⁶⁷

7. Cost-Sharing approach & Developing Countries

However, developing countries can be in a good position to negotiate a cost sharing approach—more than the bans on misappropriation approach—to challenge the demand of the United States for data exclusivity approach.⁶⁸

Recently, this approach was successfully negotiated by the Korean government in its FTA with the European Free Trade Association (EFTA).⁶⁹ Moreover, the Indian government has considered the cost sharing approach as one of several options, while resisting data exclusivity in its negotiation with the USTR.⁷⁰

C. Data Exclusivity Approach

Under the data exclusivity approach, the interests of the originator company are paramount; in effect, this approach creates a new monopoly for originator companies, even when there is no patent registered.⁷¹ Moreover, the data exclusivity regime also seeks to accommodate, to the greatest extent, the interests of the originator companies; a feat this approach accomplishes by

64. *Id.* at 481–82.

65. Reichman, *supra* note 44, at 15–16.

66. *Id.*; *see also* Weissman, *supra* note 14, at 10.

67. *Id.*

68. Reichman, *supra* note 44, at 15–16.

69. Reichman, *supra* note 49, at 34.

70. *Id.*

71. *See, e.g.,* Meir Perez Pugatch, *Intellectual property and pharmaceutical data exclusivity in the context of innovation and market access*, (2004), available at https://www.iprsonline.org/unctadic/tsd/bellagio/docs/Pugatch_Bellagio3.pdf (discussing how the European Commission, a High Level Group, was tasked with “propos[ing] a new agenda to improve the framework for competitiveness in the pharmaceutical industry to improve the framework for competitiveness in the pharmaceutical industry.”).

delaying the entry of generic products for a fixed time period.⁷²

Developed countries have implemented this approach in their drug regulatory system.⁷³ The two existing prototypes are the U.S. and the European Union.⁷⁴ The U.S. includes this in section 355 of the Federal Food, Drug, and Cosmetic Act of 1997.⁷⁵ The period of data exclusivity in the U.S. is five years for NCEs, and three years for new uses of old drugs.⁷⁶ Endorsing an even more expansive data protection period than the U.S., in December of 2003, the European Parliament harmonized the level of data exclusivity to “8 years data exclusivity plus 2 years as marketing exclusivity and one additional year for new use of old entity.”⁷⁷

The supporters of data exclusivity have justified it as the only means available to encourage research and development in new pharmaceutical products and to guarantee fair compensation for the efforts made by the originator companies.⁷⁸ It should be noted that the years between the late 1990s and early 2000s saw a decline in the number of new drugs approved: in 1996, fifty-three NCEs were approved and by 2000, that number had fallen to only twenty NCEs approved as most research-based companies focus development of new delivery systems and new uses.⁷⁹

The disadvantages of data exclusivity include the following: it will delay the entry of generic products in the market, thus impeding consumer access to affordable medicine;⁸⁰ it is unethical to ask the generic company to duplicate clinical trials;⁸¹ it is considered a form of double protection if there is a patent, as both are justified by the cost of investment;⁸² it can make compulsory licenses of patents ineffective;⁸³ and the concept of data exclusivity is inconsistent with the legislative intent of the TRIPs Agreement: There is no uniform interpretation of Article 39.3, and data exclusivity was rejected by WTO members.⁸⁴

72. *Id.*

73. *Id.*

74. *Id.*

75. *Id.*

76. *Id.*

77. *Id.*

78. *Id.*

79. *Id.*

80. *Id.*

81. *Id.*

82. *Id.* at 22.

83. *Id.*

84. INT'L FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASS'NS, ENCOURAGEMENT OF NEW CLINICAL DRUG DEVELOPMENT: THE ROLE OF DATA EXCLUSIVITY 3 (2007) [hereinafter IFPMA].

1. Data Exclusivity versus Patent

Data exclusivity and patents are the most important intellectual property rights related to the pharmaceutical industry.⁸⁵ These two forms of IPR differ in terms of the scope, rights conferred, obligations, duration, and related authority.⁸⁶ Legally, data exclusivity and patents are discrete forms of protection, mutually exclusive in their operation and effect.

In addition, data exclusivity is the expression of a trade secret, which is in itself a distinct form of intellectual property. The originator companies request such protection in exchange for submitting studies for approval in the Drug Regulatory Authority to recoup their cost in conducting such trials.⁸⁷ On average these trials cost \$800 U.S. dollars and take ten to fifteen year to complete. The fruits of these labors see one in every 5,000 molecules investigated obtain the FDA's approval for marketing.⁸⁸

A patent system was developed to encourage inventions in order to disseminate this knowledge for the public in order to benefit from it. As concerns pharmaceuticals, patents are granted to the inventions, embodied in a new drug.⁸⁹

The rights conferred by the patent are to exclude others from making, using, selling, offering for sale, importing, or circulating the patented product.⁹⁰ Data exclusivity prevents reliance on the originator test data, and thus limits the possibility of using these data to evaluate the generic product.⁹¹ Therefore, data exclusivity is considered to provide less expansive protection than patents, because it does not prevent other generic companies from generating their own data and then seeking marketing approval for their product.⁹²

A National Drug Regulatory Authority grants exclusivity automatically after the originator product has been approved for marketing, done without any request from the originator product company and irrespective of its patent

85. *Id.*

86. *Id.*

87. Andy Gray, *Access to Medicines and Drug Regulation in Developing Countries: A Resource Guide for DFID*, DFID HEALTH SYSTEMS RESOURCE CENTRE 1, 1–4 (Oct. 2004), available at <http://apps.who.int/medicinedocs/documents/s18246en/s18246en.pdf>.

88. Carlos M. Correa, *Protecting Test Data for Pharmaceutical and Geochemical Products Under Free Trade Agreements 2*, ICTSD-UNCTAD Dialogue on Moving the Pro-development IP Agenda Forward: Preserving Public Goods in Health, Education and Learning, Bellagio (Nov. 29–Dec. 3, 2004), available at <http://www.ictsd.org/sites/default/files/event/2008/12/report31.pdf>.

89. Pugatch, *supra* note 71, at 22.

90. INT'L FEDERATION OF PHARMACEUTICAL MANUFACTURERS & ASS'NS, DATA EXCLUSIVITY: ENCOURAGING DEVELOPMENT OF NEW MEDICINES 16–17 (2011), available at http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity_En_Web.pdf

91. Junod, *supra* note 5, at 484.

92. Pugatch, *supra* note 71, at 6–7.

situation. In contrast, a patent is only granted if the patent owners take the affirmative effort of applying for one at the country's patent office.⁹³ Additionally, applying for a patent is considered to be a complex and costly administrative procedure;⁹⁴ a patent attorney and agent are needed to prepare the application and to pay the application fees and annual fees or otherwise it will be invalid.⁹⁵ As opposed to the patent protection procedure, data exclusivity does not stand on such formalities in order to receive protection, as accomplished mainly by its automatically grant of protection following marketing approval. Moreover, data exclusivity is considered to be a cheaper alternative to patent, since no administrative procedure or fees are required to obtain or maintain data exclusivity.⁹⁶

To grant a patent, the invention should fulfill the patentability conditions, namely novelty, non-obviousness and industrial applicability. The protection period is twenty years from the day of the patent application.⁹⁷

Under data exclusivity, there are several conditions that must be met in order for data to be granted protection: first, the product at issue must be a new chemical entity (NCE) of pharmaceutical or agricultural products; second, the data must be unpublished; third, the generation of the data must have involved considerable efforts; and, finally, those data are requested, not submitted voluntarily, to get marketing approval.⁹⁸

The duration and scope of data exclusivity varies between countries.⁹⁹ Jordan, for example, grants five years of protection for NCEs and three years for new use of an old chemical entity.¹⁰⁰ Europe grants eight years data exclusivity plus two years as marketing exclusivity and one year for new use.¹⁰¹ Other countries may not provide any data exclusivity and may apply other data protection approaches that are compliant with the mandates found in TRIPS Article 39.3.¹⁰²

The unique importance of data exclusivity for originator companies appears in many situations. An example is seen when there is no patent registered in that country.¹⁰³

93. *Id.*

94. Junod, *supra* note 5, at 484.

95. *Id.*

96. *Id.*

97. *Id.*

98. *Id.*

99. Pugatch, *supra* note 71, at 6–7.

100. *Id.*

101. *Id.*

102. *Id.*

103. Junod, *supra* note 5, at 484–485.

This is the case in Jordan, in which data exclusivity was recognized as an alternative source of protection in a situation where most originator products not being protected through patents and data exclusivity was the alternative for this protection.¹⁰⁴

Moreover, data exclusivity is important when the product cannot be patented, as happens with biological products and also where the new development of an old product lacks the novelty criteria.¹⁰⁵

Data exclusivity can also provide protection where other forms of IPR cannot in a situation where the development period for the product was too long and took most of the patent duration.¹⁰⁶ To this point, between 1998 and 2004, the U.S. FDA has approved 137 new drugs.¹⁰⁷ Of these 137 products, 27 were developed without patent protection, and it is for these 27 products that data exclusivity provided some measure of protection where patent protection was no longer viable.¹⁰⁸

The table below is taken from *Intellectual Property and Pharmaceutical Data Exclusivity*, as presented in the context of innovation and market access;¹⁰⁹ the calculations are based on the U.S. FDA Orange Book.¹¹⁰ This table gives examples for products where the protection granted by data exclusivity extended beyond the product's patent term duration.¹¹¹

Table 1: Patent and data exclusivity expiration periods in the US for selected drugs.¹¹²

PRODUCT	Taxol(Paclitaxel)	Eprex (Epeotin Alpah)	Arava (Leflunomide)
Purpose	Breast Cancer/ Ovarian Cancer and others	Severe Anemia	Rheumatoid Arthritis

104. Malpani, *supra* note 17, at 1.

105. Junod, *supra* note 5, at 485–86.

106. *Id.* at 487.

107. *Id.*

108. *Id.*

109. Pugatch, *supra* note 71, at 6–7.

110. *Id.*; see also FDA, ORANGE BOOK: APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS, 35TH ED. (2015), available at <http://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/UCM071436.pdf> (last visited Mar. 15, 2014).

111. *Id.*

112. *Id.*

U.S. Market Approval	Discovered in 1962. Approved in 1994/1998.	2000	1998
U.S. Patent Expiration	—————	2004	2001
U.S. DE Expiration	2004(Orphan Drug)	2005	2003

The following table illustrates the differences between patents and data exclusivity.

Table 2: Differences between patents and data exclusivity.

Parameter	Patent	Data exclusivity
Rationale	Encourage inventions by giving protection for 20 years in order to disseminate this knowledge for the public in order to benefit from it. Patents are granted to the inventions embodied in a new drug.	Recoup originator companies cost in conducting clinical studies for approval in the Drug Regulatory Authority.
Duration	20 years	Differ from country to country. United States: 5 years protection for new chemical entity and years for new use of old chemical entity. Europe: “8 years data exclusivity plus 2 years as marketing exclusivity and 1 year for new use”, Some countries do not provide data

		exclusivity.
Competent authority	Patent Office/ Ministry of Industry.	Drug Regulatory Authority
Costs and administrative procedure	Application fees and it should be paid annually to maintain the patent or otherwise it will be invalid	No fees or follow-up needed
Granting Procedure	Applicant should apply for patent in the competent authority and then this application will be studied to check if the patent application fulfills the criteria then it can be granted or not.	Automatic right is conferred from the date of marketing approval without any request or application.
Preventing Generic Product Approval	Generic company can submit its registration application to the DRA and the DRA can grant him marketing approval. Patent holder can stop the registration process, only by placing a law suit	The DRA will prevent the marketing approval of any generic product till the end of the data exclusivity period
Conditions	Protects an invention, which must be novel, non-obvious and capable of industrial applications.	New chemical entity. Undisclosed information. Considerable efforts. Condition of marketing approval.
Public health/ compulsory license	Compulsory license can be issued to protect public health so a generic product can be produced.	Compulsory license will not stop data exclusivity.

2. Effect of Data Exclusivity on Compulsory License

Data exclusivity represents a barrier for generic product approval, even if a compulsory license is issued for this product.¹¹³ Compulsory licenses were conceived by the Council of TRIPs in August of 2003 in order to solve the problem raised by the Doha Declaration.¹¹⁴ The Doha Declaration emphasized members' right to access to medicine to all, in this declaration it reconfirms member's ability to issue compulsory licenses and to permit parallel importation. Additionally, it proposed the extension of the transition period to implement and enforce patents in the least developed countries and their obligation to comply with data protection and mailbox-market-exclusivity rules.¹¹⁵ The gap in the Doha Declaration was that it did not limit the rights conferred by Article 39.3 of the TRIPs Agreement in case of issuance of compulsory license.¹¹⁶

In past years, Canada issued compulsory licenses as a means to promote the generic pharmaceutical industry. Therefore, the United States targeted this system in 1987, with Canada ultimately acquiescing to U.S. pressure by passing Bill C-22, legislation that had the effect of weakening the compulsory license system as a whole.¹¹⁷ Nevertheless, Canada has established the PMPRB.¹¹⁸ This independent body monitors the potential increase in drug prices. If excessive prices were to be found, then they can remove the protection against compulsory license.¹¹⁹

In a country providing protection under data exclusivity regime, it will be difficult to implement the compulsory licensing system unless there is a clear provision to waive data exclusivity in the case of a compulsory license.¹²⁰ Chile has implemented this in article 91(b) through (e) of Decree 153 (2005).¹²¹ This article listed four grounds under which data protection could be revoked, one of which is in the case of compulsory license issuance. Regarding this

113. Brook K. Baker, *Ending Drug Registration Apartheid: Taming Data Exclusivity and Patent/Registration Linkage*, 34 AM. J.L. & MED. 303, 320–21 (2008).

114. *Id.*

115. *Id.*

116. *Id.*

117. See Canada. Parliament. House of Commons. 41st Parliament, 2nd Session, 2013–2014, Bill C-22.

118. PMPRB, PATENTED MEDICINES PRICES REVIEW BOARD: ANNUAL REPORT 2013, available at http://www.pmprb-cepmb.gc.ca/CMFiles/Publications/Annual%20Reports/2013/2013-Annual-Report_2013-09-15_EN.pdf.

119. 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, 812 (2004).

120. Weissman, *supra* note 14, at 201.

121. See Chile's Decree 153

exception to data exclusivity's reach, the U.S. Trade Representative (USTR) included Chile on the priority watch list. The USTR and big Pharma use the watch list and bilateral agreements as their weapon to impose data exclusivity and a linkage system.¹²² In 2006, the USTR placed forty-eight countries on the priority watch list, twenty-five of which were criticized for data exclusivity and patent-registration linkage.¹²³

Avoiding the ire of the U.S., and in contrast to Chile's position on scope of data exclusivity protection, the European Commissioner confirmed that a data exclusivity regime would disallow, or at least delay, European member states from using compulsory licenses to permit the market entry of a generic alternative to Tamiflu in case of a Bird Flu pandemic.¹²⁴

Developing countries have requested assurances that data exclusivity and patent/registration linkage will not prevent the use of TRIPS flexibilities as a compulsory license.¹²⁵ Therefore, the USTR issued side letters that reassure that the IPR provisions of the FTAs will not prevent access to medicines for all.¹²⁶

Developing countries should resist efforts by the United States to implement registration-related IPRs.¹²⁷ If countries have already incorporated these provisions, as with Jordan, they should instead revise their national laws in order to mitigate the effects of these clauses based on the new trade policy of the United States for data exclusivity to allow exceptions to promote public health and access to medicines conforming to TRIPS and Doha Declaration.¹²⁸

D. Public Health Variants of the Data-Exclusivity Approach

Despite the data exclusivity's privileging of originator companies, there are seven variants that may decrease the harmful effects of data exclusivity.¹²⁹ Unfortunately, some of these variants cannot be applied by some countries because of obligations found within their bilateral agreements.¹³⁰ These variants are:

122. Baker, *supra* note 113, at 300.

123. *Id.*; IFPMA, *supra* note 84.

124. Judit Sanjuan et al., *Protection of Pharmaceutical Test Data: A Policy Proposal*, KEI RESEARCH PAPER 1 (Nov. 21, 2006), available at <http://www.cptech.org/ip/health/data/CPTech-Test-Data.pdf>.

125. *Id.*

126. *Id.* at 331.

127. *Id.*

128. *Id.* at 342.

129. Correa, *Protecting Test Data*, *supra* note 88, at 11–12.

130. *Id.*

1. **New Chemical Entities (NCEs):** Restrict data exclusivity to New Chemical Entities (NCEs), this variant is in compliance with Article 39.3 of the TRIPS Agreement. This excludes new uses of old chemical entities, new dosage forms or new methods of administering drugs.¹³¹
2. **Unpublished Information:** Data exclusivity will be restricted to unpublished information.¹³² If the test data was published, then the generic companies can rely on this published data to prove the safety and efficacy in order to obtain the marketing approval by conducting the bioequivalence study only.¹³³ Weissman said “tying data exclusivity to lack of disclosure gives pharmaceutical companies an incentive not to publish their clinical testing data.”¹³⁴ Unictetra is a Swiss technology transfer organization that supports scientists from Basel;¹³⁵ Bern and Zurich Universities to commercialize their research results.¹³⁶ This organization ensures that researchers’ rights to publish research results and the university will reserve the full publication rights, which will be delayed for a period of three months to enable the collaborating company to apply for patents.¹³⁷ If the commercial company did not publish the research within one year, then the collaborating university has the right to do so to facilitate data sharing.¹³⁸
3. **Waiving data-exclusivity protection in cases of compulsory licensing:** In case of the issuance of a compulsory license, the generic company is still required to submit clinical trials.¹³⁹ Therefore, data exclusivity should be waived in such cases.¹⁴⁰
4. **Waive data exclusivity protection in cases of having patent:**¹⁴¹ The basis of this waiver is that the originator will recoup his investment through the product patent, with no need for data exclusivity.¹⁴²
5. **Compulsory licensing system for registration data:** The proposal in this case is that countries should be free to determine conditions under which compulsory licenses should be granted over

131. *Id.*

132. Adanda, *supra* note 10, at 168–70.

133. *Id.*

134. *Id.*

135. *Id.*

136. *Id.*

137. *Id.*

138. Adanda, *supra* note 10, at 168–70.

139. *Id.*

140. *Id.*

141. *Id.*

142. *Id.*

registration data.¹⁴³ Jordan cannot apply this variant, as the grounds for issuing compulsory license is specified in the JOR-US FTA.¹⁴⁴

6. **Shortening the term of data exclusivity:** Weissman stated that any country can decide to shorten the exclusivity years as the five or ten years were not based on any criteria.¹⁴⁵
7. **Start date of data exclusivity:** a country can consider the start date for granting data exclusivity is the first registration of the product worldwide.¹⁴⁶

These seven variants will ensure fair access to clinical data and it will reserve the intellectual right properties.¹⁴⁷

III. TEST DATA PROTECTION IMPLEMENTATION IN DIFFERENT COUNTRIES

Members of the WTO have applied the obligation of TRIPS Article 39.3 in different ways that suited their needs and interests.¹⁴⁸ The United States and the European Union have applied the data exclusivity approach even prior to the TRIPS agreement. According to the International Federation of Pharmaceutical Manufacturers Association (IFPMA), many countries have entered into bilateral or regional agreements, or adopted into their legislation data exclusivity regime to protect test data against unfair commercial use and disclosure.¹⁴⁹ It should be noted that some countries, such as India, did not apply the data exclusivity approach through relying into the marketing approval of other countries.¹⁵⁰

I will discuss the practical implementation of different approaches of test data protection in the following countries:

United States: The first country implemented data exclusivity system in 1984. Many originator companies are based in the United States. Also, the United States has signed many bilateral agreements with the intent of encouraging other countries to follow suit by implementing their own data exclusivity approach.

Canada: A developed country famous for its generic industry,

143. *Id.*

144. *Id.*

145. *Id.*

146. *Id.*

147. *Id.*

148. SATWANT REDDY & GURDIAL SINGH SANDHU, REPORT OF STEPS TO BE TAKEN BY GOVERNMENT OF INDIA IN THE CONTEXT OF DATA PROTECTION PROVISIONS OF ARTICLE 39.3 OF TRIPS AGREEMENT 13–15 (2007), available at <http://chemicals.nic.in/DPBooklet.pdf>.

149. G. Lee Skillington & Eric M. Solovy, *The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement*, 24 NW. J. INT'L L. & BUS. 1, 49 (2003).

150. REDDY & SANDHU, *supra* note 148, at 13–15.

which adopted the data exclusivity approach in 1995 as a means to fulfill obligations required by NAFTA.

The European Union: Many originator companies are based in the European Union; therefore, they have implemented data exclusivity approach in 1987.

India: Famous for its generic industry and has been listed on the special 301 Priority Watch List since 1989. The practice in India is to rely on other countries approval without requesting test data.

Egypt: A developing Arab country, considers the reliance on the originator submitted data of the originator product to approve a generic product is not an act of unfair commercial use.

A. United States

Grounded in the Hatch-Waxman Act,¹⁵¹ data exclusivity became the chosen system in the United States beginning in 1984.¹⁵² The Hatch-Waxman Act aimed to balance the rights of the originator company, so as to encourage them to invest more in discovering new products, with the need for access to medicine through the approval of generic companies.¹⁵³ This act provides data exclusivity for five years for NCEs, calculated from the date of marketing approval of the originator's product, and three years for new clinical information.¹⁵⁴ Moreover, this act lengthened the patent duration from seventeen to twenty and granted a five-year patent term extension in order to compensate originators for administrative delays in patent registration.¹⁵⁵

In addition to the Hatch-Waxman Act there are two further types of marketing exclusivity: orphan drug exclusivity and pediatric exclusivity.¹⁵⁶

In the U.S., a five-year data exclusivity period is codified by federal statute,¹⁵⁷ and provides that, during this five year exclusivity, the generic company cannot apply for registration of its generic.¹⁵⁸ In practice, the generic product's market entry will usually be delayed by approximately six-and-a-half

151. Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 101, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355 (2012) and 35 U.S.C. § 156) [hereinafter Wax-Hatchman Act].

152. Shreya Matilal, *Do Developing Countries Need a Pharmaceutical Data-exclusivity Regime?* 32 EUR. INTELL. PROP. REV. 268, 269 (2010).

153. 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, 260–61 (2014).

154. *Id.*

155. *Id.*

156. Junod, *supra* note 5, at 488–89.

157. 21 U.S.C. § 355(c)(3)(D)(ii); 21 U.S.C. § 355(j)(5)(D)(ii) (2012).

158. Junod, *supra* note 5, at 493.

years. This additional delay results because the FDA typically takes eighteen months to consider a generic candidate's application,¹⁵⁹ though the only condition that a generic producer must satisfy is to have a new chemical entity that had not previously been approved by the FDA.¹⁶⁰ This marketing exclusivity is considered to be a very strong form of protection because it cannot be challenged, unlike a granted patent.¹⁶¹ The only case where the exclusivity period is reduced to four years is in the event a generic company challenges the validity of the patent and applies for certificate IV.

As noted in the foregoing paragraph, the sole condition to be met predicate to the five-year exclusivity grant is that the product must be a new chemical entity that has never been approved in the FDA;¹⁶² thus, an applicant need not provide any evidence of significant therapeutic advance or innovation. This application is usually submitted through a 505(b)(1) NDA application. Ester and salt forms of a compound are not considered to be new chemical entities.¹⁶³ An enantiomer version of the racemate drug is also not considered to be as new chemical entity, but at best it may receive three years of exclusivity.¹⁶⁴

As with the five-year data exclusivity period, the corresponding three-year period of marketing exclusivity for new clinical information is incorporated by federal statute.¹⁶⁵ Unlike the five-year exclusivity period, however, a generic company can apply for its ANDA file during the three-year exclusivity period, and get tentative approval. This perk of the three-year period is available to both originator and generic companies.¹⁶⁶ The new changes that can benefit from the three-year exclusivity period are new indication, new strength, and new dosage form, new routes of administration, new dosage schedule and new studied population.¹⁶⁷

A generic company can benefit from this marketing regime if it submits its own data. Other conditions must be met to receive the three years of data exclusivity, including the requirement that the applicant should sponsor or conduct clinical trials that are germane to the data the producer must provide the regulatory authority in order to get approval of this new change.¹⁶⁸

This marketing exclusivity only protects the new change and not the already

159. *Id.*

160. *Id.*

161. *Id.* at 492.

162. *Id.* at 494.

163. *Id.*

164. Junod, *supra* note 5, at 495.

165. 21 U.S.C. § 355(c)(3)(D)(ii), (j)(5)(D)(ii) (2012).

166. Junod, *supra* note 5, at 494.

167. *Id.*

168. *Id.*

approved drug; so a generic company can market its product without the new addition.¹⁶⁹

The originator companies based in the United States are requesting a longer exclusivity period, like the one available in the European Union: that is, to extend the exclusivity period to ten years.¹⁷⁰

The marketing exclusivity information is available in the Orange Book website.¹⁷¹

B. Canada

In 1995, Canada implemented data exclusivity system into section C.08.004.1 of its Food and Drug Regulations. This incorporation was a result of the obligations required by NAFTA.¹⁷² Specifically, Article 1711 of NAFTA requires the protection of confidential information submitted for governmental authorities for the purpose of approving a pharmaceutical product for five years.¹⁷³ This was weakened by the judicial ruling of the Federal Court of Appeal in 1998 in the case of *Bayer Inc. v. Canada*. The court held that the approval of a generic product on the basis of proving equivalency with the originator product with the bioequivalence study is not considered as reliance.¹⁷⁴ In this case, Bayer had filed a new drug submission (Drug X) for a new product that had no patent and which had as its active ingredient one used previously in Drug Z, used for the treatment of certain animal disease.¹⁷⁵ Furthermore, the same active ingredient was used in Drug Y outside Canada to treat another human disease other than the one applied by Bayer.¹⁷⁶ The issue in this case was whether to grant Bayer the five-year exclusivity period as per Canadian law, or whether to deny protection in this instance, since the active ingredient was already approved in Drug Z for animal disease. The court held that the relevant law was applicable to Drug X.

The aforementioned judicial interpretation broadens the application of data exclusivity to those drugs approved in Canada but not for human diseases. Subsequently, the Federal Court of Appeal held that Section C.08.004.1 does

169. *Id.* at 496.

170. *Id.*

171. *Id.*

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

173. Food and Drug Law Group, Blake, Cassels & Graydon, *Developments in Canadian Law Relating to Food, Drugs, Devices, and Cosmetics as of December 1992*, 49 *FOOD & DRUG L.J.* 323, 335 (1994).

174. Yang *supra* note 172, at 65.

175. *Id.*

176. *Id.*

not apply if the Minister did not physically examine the originator test data when approving a generic product.¹⁷⁷ Therefore, the Minister can approve a generic product based on the bioequivalence study before the five-year period has elapsed.¹⁷⁸ This rule was criticized by the Pharmaceutical Research and Manufacturers of America (PhRMA), which declared that this rule was not consistent with Canada's NAFTA obligations; consequently, the United States included Canada on its Special 301 Watch List in 2003.¹⁷⁹

As a result of this pressure, the Canadian government amended its regulation in 2006.¹⁸⁰ The new amendments extended the data exclusivity to eight years for a new chemical entity and six months for pediatric studies. Also, it has extended the concept of reliance to cover the governmental examination of test data when approving a generic product. Additionally, the generic company cannot file its product for six of the eight years in the exclusivity period, to then be followed by a two-year no-marketing period. These amendments have been criticized for their negative impact on access to affordable medicines.¹⁸¹

Despite such criticisms, however, the new amendments do contain some provisions that mitigate the negative impact of data exclusivity, such as narrowing the scope of protection to innovative drugs, meaning that new indications or dosage forms are not entitled to data exclusivity.¹⁸² An innovative drug is defined as "a drug that contains a medicinal ingredient not previously approved in a drug by the Minister and that is not a variation of a previously approved medicinal ingredient such as a salt, ester, enantiomer, solvate or polymorph."¹⁸³ The new data exclusivity regime is only applicable for innovative drugs that are marketed in Canada; if it was withdrawn from the market no data exclusivity will be offered.¹⁸⁴ It should be noted in this context that an active ingredient that has been previously approved will not be granted the data exclusivity period

Additionally, the new amendments encourage pediatric research by including a six-month exclusivity protection period if the generic producer's application was filed within the first five years of the eight-year period.¹⁸⁵ The new amendments allow the generic company to file under Canada's Access to

177. *Id.*

178. *Id.*

179. *Id.*

180. Yang *supra* note 172, at 65.

181. *Id.*

182. *Id.*

183. *Id.*

184. *Id.*

185. *Id.*

Medicines Regime (CAMR), during the new filing period of the six years. CAMR is only applicable to generic medicines imported to treat HIV/AIDS and malaria and other medicines to developing and least developed countries. This is grounded in C.07.003, Division 7 of Food and Drug Regulation entitled “Sale of Drugs for the Purposes of Implementing the General Council Decision”.¹⁸⁶

C. The European Union

Prior to adopting the data exclusivity approach, the European Union protected pharmaceutical test data through established trade secrets law, with Union members employing different approaches to implementation.¹⁸⁷ In 1987, the E.U. introduced the data exclusivity period, in which a generic product that is “essentially similar”¹⁸⁸ may rely on the test data of the originator product after the expiration of the data exclusivity period. The stated reason for this exclusivity period was in order to give the originator protection in countries that did not grant patents for medicinal products,¹⁸⁹ such as in countries like Spain and Portugal that did not grant patents until 1992. However, this rationale for mandating an exclusivity period is no longer applicable, as all the European countries grant strong patent protection to medicinal products.¹⁹⁰ The directive of the data exclusivity was consolidated in 2001 in a single Code Directive 2001/83/EC.¹⁹¹ Data exclusivity is included in Article 10.1(a)(iii) of this Code. Within the E.U.’s approach, the data exclusivity starts from the time of the first marketing approval of a medicinal product in any country maintaining membership in the E.U. There are four durations of data exclusivity provided by this article:¹⁹²

Ten-year mandatory period: for medicinal products that are approved through the centralized procedure at EMEA which is “high-tech” products. High-tech products are biotechnology and products that represent a significant innovation or therapeutic advance.¹⁹³

186. *Id.*

187. Matital, *supra* note 152, at 270. *See also* Sanjuan, *supra* note 124.

188. *See* Sanjuan, *supra* note 124.

189. Junod, *supra* note 5, at 205.

190. *Id.* at 502.

191. Directive 2001/83, of the European Parliament and of the Council of 6 November 2001 on the Community Code Relating to Medicinal Products for Human Use, 2001 O.J. (L 311), 67 (EC), replacing Council Directive 87/21, 1987 O.J. (L 015) 36 (EC), available at <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2001:311:0067:0128:en:PDF>.

192. Junod, *supra* note 5, at 503–04.

193. *Id.*

Six-year minimum period: for all medicinal products approved through either national or mutual recognition procedures.¹⁹⁴

Six-year minimum period capped by the patent duration: Greece, Spain and Portugal have chosen this option of data exclusivity period. If a supplementary protection certificate is issued to cap for this period at the instant the patent protecting the medicinal product expires.¹⁹⁵

Ten-year optional period: members can either apply six or ten year data exclusivity period's. Extension of the period to ten years should be based on the necessity of public health and applied for all medicinal products without any discrimination.¹⁹⁶ Members applied this duration are Belgium, Germany, France, Italy, the Netherlands, Sweden, the United Kingdom, and Luxembourg. The notion of "reliance" refers to reliance of the agency in the originator test data when approving the generic product which is similar to the United States interpretation.¹⁹⁷

The only requirement needed to grant data exclusivity in the European Union is that it must be a new medicinal product. This directive does not require that NCEs under consideration receive prior .¹⁹⁸

Unlike the United States, the European Union did not grant data exclusivity periods for the modification of the same medicinal product, such as with new indications. Additionally, in the European Union, a generic product can be marketed with the new modification after the expiration of the data exclusivity period granted to the original originator product.¹⁹⁹ That approach was confirmed by the decision of the European Court of Justice in 1998.²⁰⁰

In July 2001 the European Union initiated a revision of its legislation related to pharmaceuticals, including data exclusivity.²⁰¹ The originator companies requested the harmonization of the data exclusivity period to be ten years,²⁰² as the different durations created confusion.²⁰³ They also requested three years of data exclusivity for the modifications done on original medicinal products such as new indications, an approach similar to that of the United

194. *Id.*

195. *Id.*

196. *Id.*

197. *Id.* at 506.

198. Junod, *supra* note 5, at 506.

199. *Id.*

200. *Id.* at 508.

201. *Id.* at 511–14.

202. *Id.*

203. *Id.*

States.²⁰⁴ While the European generic industry requested the harmonization of the data exclusivity period between all the European Union members to be five years similar to the United States²⁰⁵ and rejected the line extension exclusivity period based on the decision held by the European Court of Justice in 1998.²⁰⁶ In April 2004 the revised directive was published, and the implementation date was in October 30 2005.²⁰⁷

The new revised directive is applicable to all new drugs approved through either centralized or mutual recognition procedure.²⁰⁸ The new formula is $8+2+I$;²⁰⁹ the data exclusivity will last for eight years from the time of marketing approval of the originator product, followed by two years of marketing exclusivity in which the generic product can be filed but cannot be marketed until the end of the ten-year period.²¹⁰ The generic company can market its product even if the originator product was withdrawn from the market.²¹¹ A *Bolar* provision was added allowing the generic companies to do their tests before the expiration of the related patent.²¹² New use was granted an additional year of data exclusivity for one time only, provided two conditions are met: first, the product must have been submitted for approval during the first eight years of the data exclusivity period; and, second, the new use must have significant clinical benefit as compared to the existing usage.²¹³ Other modifications such as new dosage form or new strengths were not eligible for this period.²¹⁴ During the additional one-year new use exclusivity period, the generic product cannot be marketed even for the old use.²¹⁵

Additionally, switching from *Rx* (prescription) to *OTC* (over-the counter) will be granted one-year protection period if the switch was based on significant clinical or preclinical testing.²¹⁶ The generic company can market its product as a prescription product.²¹⁷

204. Junod, *supra* note 5, at 511–14.

205. *Id.*

206. *Id.*

207. *Id.*

208. *Id.*

209. *Id.*

210. Junod, *supra* note 5, at 511–14.

211. *Id.*

212. *Id.*

213. *Id.*

214. *Id.*

215. *Id.*

216. Junod, *supra* note 5, at 511–14.

217. *Id.*

D. India

There is no distinct law to protect the disclosure of confidential information in India;²¹⁸ existing provisions regarding the undisclosed information of pharmaceuticals can be found in India's Drugs and Cosmetics Rules, 1945 (as corrected up to November 30, 2004) rule 53²¹⁹ provides that the drug regulator should not disclose any confidential information to a third party without prior written approval from relevant superior officials.²²⁰ In addition, India has implemented many rules related to patents that aim to increase access to medicines while still complying with TRIPS obligations; such obligations include restricting the scope of patentability, increasing the grounds for compulsory license issuance.²²¹ Since 2007, the European Union and India have been in negotiations to reach consensus on the terms of a bilateral agreement between the two countries; however, as of now, these negotiations have failed to produce any such agreement.²²²

In 2005, India's Ministry of Health and Family Welfare amended Schedule Y of the Drugs and Cosmetics Rules (2005).²²³ These new amendments waive the requirements of the toxicological and clinical of new drugs for life threatening diseases, as deemed appropriate by the drug regulator.²²⁴ In 2004, an Inter-ministerial committee was established as a consultative group on this matter, and in 2007, this committee released the Reddy Report.²²⁵ The Reddy Report concluded that existing legal provisions were inadequate to meet the obligations imposed by Article 39.3 of the TRIPS Agreement. Consequently, the Reddy Report recommended existing law be amended in order to be in compliance with Article 39.3.²²⁶

The report proposed numerous scenarios, one of which envisioned a data protection period of five years for a pharmaceutical product that contains a new chemical entity from the date of first marketing authorization anywhere in world.²²⁷ This report recommends some conditions for applying data protections, such as the recommendation that protection should be granted only

218. REDDY & SANDHU, *supra* note 148, at 30–33.

219. Noti. ***[No. F. 28-10/45-H (1)], Drugs and Cosmetics Rules, 1945, Ministry of Health and Family Welfare [Department of Health].

220. *Id.*

221. Acquah, *supra* note 153, at 273.

222. *Id.* at 272.

223. REDDY & SANDHU, *supra* note 148, at 30–33.

224. *Id.*

225. *Id.*

226. *Id.*

227. *Id.*

for new chemical entity and not for new uses or other modifications.²²⁸ Also, this protection term for a patented drug would be limited to the patent term in India. Further, the report suggests a maximum period of twenty-four months, from the time of an originator's first marketing approval anywhere in the world, in which the originator company should apply for marketing approval in India. It should be launched within six months of the approval date in India.²²⁹ Another condition was to start the data protection period from the first marketing approval date anywhere in the world. The Reddy Report justified its recommendations regarding the implementation of a more expansive data protection system and other related intellectual property rights,²³⁰ by hypothesizing that India's current protection legislation, that which the Report found to be inadequate, could lead to the international perception of India as a country that did not fully protect innovation.²³¹

Consequently, this negative image of India in the international community could limit India's ability to enter many conventions, such as the Pharmaceuticals Inspection Convention/Pharmaceuticals Inspection Cooperation Scheme (PIC/S).²³² This in turn could negatively impact a generic producer's ability to export to other countries, because the United States will increase the number of bilateral agreements with other countries. These bilateral agreements have stricter intellectual property rights that prohibit parallel importation than those encompassed in TRIPS.²³³

India has been listed on the Special 301 Priority Watch List from the first report on 1989 until now.²³⁴ On its submission for the Special 301 of 2014, the Pharmaceutical Research and Manufacturers of America (PhRMA) requested to include India on the priority watch list,²³⁵ based on India's current insufficient intellectual property legislation and the market access barriers. Lack of data protection was one point mentioned on this report.²³⁶ For example, India's current practice when granting regulatory approval is to rely on the approval of another country when approving an originator product, and there is no need to submit the test data.²³⁷ According to (PhRMA), this practice is

228. *Id.*

229. *Id.*

230. *Id.*

231. *Id.*

232. *Id.*

233. *Id.*

234. PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA, SPECIAL 301 SUBMISSION 24–29 (2014), available at <http://www.phrma.org/sites/default/files/pdf/2014-special-301-submission.pdf> [hereinafter PhRMA].

235. *Id.*

236. *Id.*

237. *Id.*

inconsistent with Article 39.3 of the TRIPS Agreement and ultimately leads to unfair commercial use.²³⁸

E. Egypt

As with India, Egypt does not provide data protection for test data submitted by the originator companies. Article 56 paragraph 2 of the Egyptian IP law states “The competent authorities who receive such information shall protect it against disclosure and unfair commercial use from the date of its submission to the competent authorities until it is no longer confidential, or for a period not exceeding five years, whichever comes first.”²³⁹ According to Article 56, the Egyptian health authority does not consider reliance on an originator’s submitted data to approve a generic product as an act of unfair commercial use, a determination based on the rationale that this reliance does not involve the disclosure of the test data to the generic company.²⁴⁰

Like India, PhRMA requested to list Egypt on the Priority Watch list of 2014 because of its deteriorating intellectual property environment and because of barriers to market access.²⁴¹ The above practices in implementing test data protection is proof that members of the WTO can apply the obligations of Article 39.3 in different ways that suited their needs and interest.

IV. CONCLUSION

Each WTO member should choose the right approach that best suits its country, taking public welfare issues into consideration. To ensure that public welfare issues have received due consideration, WTO members should re-evaluate the approach they have implemented/employed, to evaluate its effect on the public health and access to medicines relative to other approaches and benefit from other members experiences.

Data exclusivity provisions were not the best option for developing countries, as they have undermined people’s accessibility to affordable medicine and have had a negative impact on the local pharmaceutical industry.

We argue that the bans-on-misappropriation approach facilitates the early entry of a generic product directly after the originator product is approved, and takes maximum advantage of TRIPS flexibilities. According to Article 39.3 of TRIPS, test data must be protected in accordance with relevant domestic

238. *Id.*

239. Law No. 82 of 2002 (Law on the Protection of Intellectual Property Rights), *Al Jarida Al-Rasmiyya*, 3 June 2002, (Egypt), available at http://www.wipo.int/wipolex/en/text.jsp?file_id=126540.

240. *Id.*

241. PhRMA, *supra* note 234.

laws on unfair competition. Unfairness is limited to the means of access to the data by the competitor, not by the regulators.

The test data of the originator will be protected against what national law defines as unfair use of the data, so reliance on original test data when assessing the bioequivalence study of a generic company will not be considered to be unfair. This approach is considered to be a very good alternative to the data exclusivity approach for developing countries.