Test Data Exclusivity

6.1 Introduction

As explained in previous chapters, the originator of a drug must first apply for regulatory approval with a national drug regulatory authority to ensure that the drug is safe, effective and of sufficient quality before distributing a drug on the market. The regulatory authority acts on the information submitted by the applicant, which includes clinical trial and other relevant data and information, but does not undertake clinical trials or otherwise test the drugs. When a generic manufacturer later applies for marketing approval for the same drug, the regulatory authority does not require it to submit data of its own tests, but rather allows the applicant to prove that the drug it seeks to distribute is of the same quality and therapeutically equivalent to the previously approved drug. Thus, while the originator must demonstrate safety and efficacy through the production of costly and time-consuming test data, the generic applicant essentially “free rides” on the R&D. Generic applications are usually approved on the basis of comparative studies known as bioequivalence information, which simply demonstrate that the applicant can meet the same safety and efficacy standards as the originator pharmaceutical.\(^1\) Referred by some as springboarding, this process not only facilitates the entry of generic competition into the marketplace, but allows those companies to save millions of dollars in tests, and thus the final product is made available on the market at a fraction of the originator’s price.\(^2\)

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Test data exclusivity is a sui generis right that protects data generated by the holder from being referred to or used by another person or company for a specific period of time. Test data exclusivity precludes the regulatory authority from even accepting applications from generic applicants, which rely on the test data until the exclusivity period ends. By contrast, in what is referred to as “market exclusivity,” the regulatory authority is prevented from granting marketing approval until the exclusivity period ends. Test data exclusivity is the stronger form of protection, as it provides an additional period of de facto exclusivity equal to the time it takes the regulatory authority to consider the application and grant the marketing approval.

Test data exclusivity is not traditionally a recognized IPR and can be categorized more as a quasi-IPR that attaches irrespective of whether the product is subject to patent protection. Test data exclusivity provides the holder with limited term protection against others using or referencing its preclinical, clinical trial or other data in an application for marketing approval or from the drug regulatory authority relying in its own right on the originator’s test data for approval of a generic pharmaceutical product. In this regard, test data exclusivity is an automatic right and a negative right – it essentially acts as a right to exclude others from using as opposed to a right to use.3

The objective of test data exclusivity is to compensate the manufacturer of a new product (and hence allow them to protect their investment) for time and money invested in inventing, testing and bringing the product to market. The costs involved in this process are hugely expensive, and therefore it makes sense to ensure that the fruits of the investment are not simply handed over to generic competitors. This need to incentivize clinical trials and the generation of test data is of course balanced by other interests, such as the right to health and information. The question is whether patent rights alone are sufficient compensation and protection or if an additional layer of rights is warranted. Proponents of test data exclusivity argue that patent rights do not always apply and may not ensure an effective term of protection for the generation of test data such

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*Intellectual Property Law Review* 1, 9 (“the costs of clinical trials are high, growing higher, and have lately become potentially unsustainable”).

3 But see International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), “Encouragement of New Clinical Drug Development: The Role of Data Exclusivity” (2000) 5, www.eldis.org/go/home&id=29224&type=Document#.WLpaTxKGNCaA, accessed 4 March 2017 (stating that test data exclusivity “provides a limited duration of time during which only the owner or generator of...preclinical and clinical trial data can use it for purposes of marketing authorization”).
that innovators are rewarded and encouraged to continue creating new products. Thus, additional sui generis rights must apply in tandem with patent rights. In this regard, test data exclusivity prevents generic manufacturers from making “unfair commercial use” of such data (i.e., free riding on the research of the innovator company) for a set period of time that effectively ensures a minimum period of marketing exclusivity for the originator/innovator company. On the other hand, critics view test data exclusivity as merely another method utilized by the branded industry to prolong the period of marketing exclusivity and maximize profits to the detriment of public health.

Section 6.2 of this chapter reviews the international framework regulating test data exclusivity. It begins with a review of the TRIPS Agreement before analyzing the evolution of test data exclusivity in domestic legislation and through the proliferation of FTAs. Section 6.3 critically reviews Hong Kong’s commitment to apply test data exclusivity and offers recommendations for how the jurisdiction can limit the negative effects of such protection through targeted legislative drafting and interpretation. Part IV concludes.

6.2 The International Framework

6.2.1 The TRIPS Agreement

Test data is recognized as a category of intellectual property in Article 1.2 of the TRIPS Agreement. To many commentators, referring to test data protection as an IPR is misplaced. Prior to the TRIPS Agreement, very few countries provided for any form of test data or market exclusivity and even fewer would have recognized it as an IPR. Regardless, after much discussion and debate, test data protection was included in the TRIPS Agreement and thus now forms part of the international framework. More specifically, Article 39(3) of the TRIPS Agreement states:

4 Test data exclusivity does not prevent generic manufacturers from conducting their own tests, submitting the results to the regulatory authorities and obtaining marketing approval on the basis of these tests. However, requiring generic manufacturers to redo toxicological and clinical tests is unnecessary, wasteful, financially prohibitive and arguably unethical as such tests would be of limited value to society, as safety and efficacy have already been determined, and would at the same time expose animal and/or human lives to unnecessary dangers. For more on human rights aspects of such tests, see Xavier Seuba, “Pharmaceutical Test Data Protection and Human Rights,” in Peter K. Yu and Molly Land (eds.), Reshaping Intellectual Property Law through a Human Rights Lens (forthcoming), https://papers.ssrn.com/sol3/papers.cfm?abstract_id=2670225, 12–15.

5 For background position papers during the negotiations, see, e.g., “Statement of Views of the European, Japanese and United States Business Communities” (1988); US Draft Text, 28
Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.6

In essence, the vaguely worded provision requires WTO Members to protect the submission of undisclosed test data of pharmaceutical and agro-chemical products that contain new chemical entities (left undefined, and thus differing interpretations may be permissible) and involve considerable effort against unfair commercial use.7 Test data protection is thus a reward for the production of data in accordance with standard protocols and procedure, rather than the normal reward for creativity of innovation.8 In this regard, test data protection is similar to the EU’s protection of databases rather than a typical IPR.

Article 39(3) requires two distinct obligations: protect data against unfair commercial use and against disclosure,9 unless it is necessary to protect the public or unless steps are taken to protect against unfair commercial use. While the obligation against disclosure by the health authorities is relatively straightforward, the requirement to protect against “unfair commercial use” is opaque. In what can only be termed “constructive ambiguity,” the drafters of the TRIPS provided no guidance or other information as to the meaning of the term. Thus, it is unclear how protection should occur, what the limit of such protection is or what the time period is for

October 1987, Article 31(1); EC Draft Text, MTN.GNG/NG11/W/68, 29 March 1990, Article 28; Switzerland Draft Text, NG11/W/73, 14 May 1990, Article 241(1); Communication from India, MTN.GNG/NG11/W/37, 10 July 1989, p. 18.
6 Protected data includes health and safety testing in regard to humans, animals and plants, as well as environmental impact tests and other information the relevant authorities may require that includes manufacturing, storage and packaging tests. See Carlos M. Correa, “Unfair Competition under the TRIPS Agreement: Protection of Data Submitted for the Registration of Pharmaceuticals” (2002) 3(1) Chicago Journal of International Law 69, 73.
7 Article 39 does not use the terms “trade secret” or “undisclosed information” perhaps because “[t]he difficulty of finding a common and acceptable understanding of what those notions mean favoured the adoption of a more neutral terminology, which does not characterize the contents of the information, but only its ‘undisclosed’ nature.” See the United Nations Conference on Trade and Development and the International Centre for Trade and Sustainable Development, Resource Book on TRIPS and Development (Cambridge University Press, 2005), 521.
8 On this point, see Correa, above n. 6, 72.
9 Thus, information that is in the public domain is not within the scope of the protection.
such protection. The question at the forefront of this debate is whether and to what extent Article 39(3) requires Members to preclude their drug regulatory authorities from using and relying on test data submitted by the originator in the examination of a generic product for a certain period of time. This question should be resolved through recourse to the VCLT, namely, Articles 31 and 32, which dictate that the interpretation should first and foremost be in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose of the agreement.

Most governments and commentators do not believe that the provision requires test data exclusivity. In this view, there is nothing in Article 39(3) that requires WTO Members to prevent the health authorities from allowing generic applicants to rely on test data submitted by the originator in order to obtain marketing approval.10 To those holding this view, WTO Members must merely adequately protect eligible “undisclosed test or other data” against “unfair commercial use” and “disclosure” by providing in their laws protection against misappropriation of test data.11 In this regard, it is not unnecessarily “unfair” for the generic manufacturer to benefit from use of the preexisting test data but rather a “legitimate exploitation of an externality created during legitimate competition in the

10 See UNCTAD, “The TRIPS Agreement and Developing Countries,” p. 48 (UN, UNCTAD/ITE/1 1996), http://unctad.org/en/docs/ite1_en.pdf (“authorities are not prevented . . . from using knowledge of such data, for instance, to assess subsequent applications by third parties for the registration of similar products”).

Another argument proponents of this view make is based on the connection between Article 39(3) and Article 39(1) of TRIPS with reference to Article 10 bis of the Paris Convention. The former seeks to guard against “unfair commercial practices,” which does not mean the same thing as “unfair competition” in the market in the absence of exclusive rights, as used in Article 39.1 TRIPS with a reference to Article 10 bis of the Paris Convention on the Protection of Industrial Property. Proponents of such a view argue that interpreting Article 39(3) as requiring test data exclusivity would render moot Article 39(1). Furthermore, proponents of this view argue that Article 39 only illustrates and provides examples of but does not add to Article 10 bis of the Paris Convention.

Moreover, while it is clear that the use of the test data will provide a benefit to the generic company, it is less clear whether such governmental use should be deemed “commercial.” Governmental use is not normally associated with commerce, but rather is administrative in nature. In other words, the purpose of Article 39(3) is to prevent the unfair use of data by competitors – through, for instance, dishonest practices – not to restrain use by governments in assessing a subsequent application for marketing approval. In fact, one can even question whether the regulatory authority or even the generic applicant engages in “use” of the data – certainly, the regulatory authority does not use the data when granting marketing authorization on the basis of approval in another jurisdiction.

A further argument against an interpretation requiring test data exclusivity is that during the course of the negotiations, this quasi-IPR was

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12 Correa, above n. 6, 77.
13 Paris Convention on the Protection of Industrial Property (WIPO) of 20 March 1883, as amended, www.wipo.int/treaties/en/text.jsp?file_id=288514. In particular, Article 39(1) reads: “In the course of ensuring effective protection against unfair competition as provided in Article 10 bis of the Paris Convention (1967), Members shall protect undisclosed information in accordance with paragraph 2 and data submitted to governments or governmental agencies in accordance with paragraph 3.”
14 Correa, above n. 6, 78.
discussed, debated and rejected by the negotiating parties. More specifically, the negotiating parties rejected a US proposal and subsequent bracketed text in the Brussels Draft tabled at the Brussels Ministerial Meeting 1990, which would have obligated protection of all test data without approval of the right holder for a period of not less than five years (the US proposal also allowed for payment of reasonable compensation). Instead, Members agreed in the TRIPS Agreement to provide more limited protection to “unfair commercial practices.” Thus, as Reichman succinctly states, “the collocation of clinical test data within the provisions regulating unfair competition negated any inference that the TRIPS drafters had imposed an exclusive intellectual property right on this subject matter and indirectly confirmed the implications to be drawn from the deletion of the U.S.-EU bracketed proposal between 1990 and 1991.” In another publication, Reichman adds that “to ignore the clear evolution of the text in favour of quasi-exclusive rights in regulatory data, in a form that was proposed but ultimately excised from the 1994 Final Act, would in effect amount to imposing unbargained-for trade concessions under a discredited ‘TRIPS plus approach’ that has no legal foundation whatsoever.” Such a view is sensible and has textual support, as Article 3.2 of the WTO’s Dispute Settlement Understanding (DSU) provides that “[r]ecommendations and rulings of the DSB [Dispute Settlement Body] cannot add to or diminish the rights and obligations provided in the covered agreements.”

Again, the question becomes what is a legitimate benefit to a generic manufacturer and what is a benefit based on an “unfair commercial practice” – the point being, it is not the existence of the benefit that matters for Article 39(3) but whether the benefit was fair or unfair. The distinction is unstated in TRIPS and thus a reasonable interpretation would provide Members with some discretion on the matter.

On the other hand, the United States, EU and others hold a much different position and maintain that Article 39(3) requires test data exclusivity.  

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17 Reichman, above n. 2, 18–19.  
To these parties, Article 39(3) mandates test data exclusivity. For instance, on the coming into force of TRIPS the US Trade Representative stated that Article 39(3) means:

[T]he data will not be used to support, clear or otherwise review other applications for marketing approval for a set amount of time unless authorized by the original submitter of the data. Any other definition of this term would be inconsistent with logic and the negotiating history of the provision.\(^{20}\)

More specifically, these parties argue that the drafters intentionally used differing language in Article 39(1) and Article 39(3) – simply stated, “unfair competition” does not equate to “unfair commercial use.” In Article 39(1), the reference to Article 10\(^{22}\)bis of the Paris Convention relates to behavior among competitors, with the article defining unfair competition as “any act of competition contrary to honest practices in industrial or commercial matter.” This has been referred to as “practices such as false allegations on competitors’ products or services, acts which may cause confusion about the origin and nature of products or services, undue advantage of the goodwill of another’s enterprise, parasitism, etc. as regulated in the EC’s Member States’ national laws.”\(^{21}\) By contrast, Article 39(3) refers not to the behavior among competitors but to a governmental function of protecting certain types of test data so as not to provide unfair competitive advantages to generic manufacturers seeking

\(^{20}\) Office of the General Counsel, US Trade Representative, “The Protection of Undisclosed Test Data in Accordance with TRIPS Article 39.3,” unattributed paper for submission in bilateral discussions with Australia (May 1995). This view, however, can be contrasted with that of the US Government Accountability Office, which later admitted to “different interpretations of the obligations under TRIPS 39(3), and exactly what practices can be considered a fulfillment of this obligation.” US Government Accountability Office, “U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification,” GAO Report 07–1198 (2007), www.gao.gov/products/GAO-07-1198. The EU, which reads Article 39(3) as establishing test data exclusivity, has also stated: “It must be admitted that the following of Article 39.3 does not, from a prima facie reading, appear to impose data exclusivity during a certain period of time. This lack of clarity is the obvious result of a difficult negotiation process where divergences of views arose between developing and industrialized countries as to the necessity of EC/US like type of data protection as well as among industrialized countries on the length of the data exclusivity period.” See European Commission, “Legal Issues Related to Compulsory Licensing under the TRIPS Agreement: An EU Contribution” (2006), http://trade.ec.europa.eu/doclib/docs/2006/may/tradoc_122031.pdf, accessed 22 February 2017.

marketing approval their products. To this group, therefore, there is little other choice but for drug marketing authorities to refuse to accept or rely on test data submitted by the originator in an application for generic marketing approval. Finally, this group generally believes that because the TRIPS Agreement does not set any time limit to the period of exclusivity, Article 39(3) would not prevent a country from providing test data exclusivity for an unlimited period of time.

Article 39(3) has never been interpreted by the WTO DSB, although in 2000 the United States did file a complaint against Argentina in relation to the provision. The countries reached a mutually agreeable solution in 2002 and a panel was never established. Argentina did not amend its laws as part of the solution or enact test data exclusivity.

Commentators have attempted to find a middle ground position between the two extremes outlined above, but these proposals lack a strong textual basis. For instance, Taubman argues that based on legitimate expectations of IP protection and a “fair relationship between competitors” any interpretation of Article 39(3) that would result in competitors using or benefiting from test data should be deemed “unfair and fit to be legally suppressed” if such use/benefit would be “likely systemically to deter submission and future production of such data.” Taubman believes this reading of Article 39(3) “reconciles utilitarian policymaking

22 The EU perhaps overstates its case by making statements such as: “Both the logic and the negotiation history of Article 39.3 of TRIPS leave no doubt that providing data exclusivity for a certain period of time was the envisaged way to protect data against unfair use as prescribed by Article 39.3.” European Union Commission, Questions on TRIPS and Data Exclusivity, at 3; European Commission, “Legal Issues,” 20.
23 The EU suggests but essentially dismisses the possibility of a payment by the generic manufacturer to the originator so as to ensure against “unfair commercial use.” Ibid.
24 It is worth noting that the TRIPS Agreement does not set out the temporal starting point for data exclusivity (if in fact it applies) – left unstated is therefore whether the date of filing or the date of marketing approval is the relevant point in time or whether this is left to the discretion of Members who only have to provide effective data exclusivity period for a long enough period to be considered sufficient protection against unfair commercial use.
26 Ibid.
with legitimate claims of limited exclusive rights, because they are strictly limited by public interest, and are defensible in terms of actual public welfare, while offering data originators fair commercial opportunities.”\(^{28}\) Correa disagrees, pointing to the fact that such an interpretation is not in line with the VCLT and existing WTO jurisprudence, which states that “legitimate expectations” can only be found in the text (and negotiating history indicates the negotiating parties did not accept a period of exclusivity for test data but rather an unfair competition rule). Moreover, Correa further points out that 85 percent of the global market for prescription drugs is in the developed world, and therefore whether a developing country applies test data exclusivity would not deter investment in test data.\(^ {29}\) Other commentators argue that Article 39(3) sets up (or should set up) a system of compensation,\(^ {30}\) whereby generic manufacturers must compensate the originator of the test data for use within a set period of time. Regardless of the potential merits of such a system, there is no textual basis for a compensatory system in Article 39(3). To the contrary, the US proposal including compensation as an option does not appear in the final text, indicating that Members considered and rejected such an approach.

### 6.2.2 Domestic Legislation

When included as part of domestic legislation, test data exclusivity differs in application among its adherents. In all countries with test data exclusivity, the regime is meant to strike a balance between the economic interests of the R&D-based pharmaceutical industry, on the one hand, and ethical considerations and the interests of the generic producers, on the other hand.\(^ {31}\) But there is no consensus on the outcome of this balance, with

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\(^{28}\) Ibid., at 606.


\(^{31}\) Although it must be stated that Congress justified the introduction of marketing exclusivity to encourage "the development and testing of unpatentable pharmaceuticals," apparently with the burgeoning market for biologics in mind. See Allergan Inc. v. Alcon Labs., 324 F.3d 1322, 1325 (Fed. Cir. 2003), cert. denied, 540 US 1048 (2003). Likewise, in the EU the fact that some countries in the common market did not adequately protect pharmaceutical
differences even appearing in the two most ardent proponents of test data exclusivity, the EU and United States, with the former protecting data for up to eleven years, while the latter offers five years’ protection. Others applying five years’ protection include Australia and New Zealand, while Japan and China provide six years’ protection and Switzerland grants a ten-year period of exclusivity. Likewise, regimes differ on the rigidity of test exclusivity and on the scope of exceptions.

It is worth noting again that test data exclusivity is viewed in these countries as a reward for the production of data that are useful to society. The sui generis right provides protection separate from and regardless of patent protection. But it does not automatically provide the beneficiary with any additional profits beyond that of the patent. In the majority of instances, the period of test data exclusivity runs concurrently with and ends prior to the expiration of patent protection. In fewer cases, test data exclusivity does indeed extend beyond the period of patent protection, such as when marketing authorization is only sought well into the period

32 The EU provided for test data exclusivity in 1987 and currently operates one of the more stringent regimes. The EU provides for an eight-year period of test data exclusivity plus an additional two years’ market exclusivity and an additional one year for new indications that show significant clinical benefits over existing therapies. EU Directive 2004/27/EC of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use.

33 Test data exclusivity for pharmaceuticals first appeared in 1984 when the United States expanded its protection regime for pesticides (dating from 1972), providing for five years of exclusivity for new pharmaceutical chemical entities and three years for new clinical research and/or indications for pharmaceutical drugs. The regime has since expanded to provide for a period of four years’ test data exclusivity and a concurrent period of twelve years’ market exclusivity for biologic products. See US Biologics Price Competition and Innovation Act of 2009, www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/UCM216146.pdf, accessed 8 March 2017.


35 In Bayer v. Canada (Attorney General) 243 NR 170 (1999), the General Court of Appeal held that the health authority does not request or examine undisclosed information during an application by a generic for marketing approval, but rather ensures the generic product is the same as the original – thus, the data are not used and the exclusivity period is irrelevant. However, if the health authority uses the data when assessing the generic application, it would be bound to protect such information for the five-year period as per Canadian law and NAFTA. The TRIPS consistency of this ruling is not beyond question. See Basheer, above n. 30, 31.
of patent or when the product has not received patent protection. It is in these cases where test data exclusivity can negatively impact on the costs of pharmaceuticals, but for the data exclusivity a generic competitor could be on the market. The impact of such provisions thus differs from product to product depending on the time period when the data exclusivity extends beyond patent protection.

Despite the potential to raise the cost of and delay access to medicines, test data exclusivity is now part of the national legal system of more than fifty countries, and the list grows every year. Test data exclusivity is far from the new international standard, however, and many countries remain committed to resisting its spread. Among this group of countries is Argentina, which crafted its regime so as to avoid even the most stringent interpretation of Article 39(3) and industry pressure. More specifically, Argentina maintains a restrictive approach requiring the submission of test data only for the registration of new chemical entities. Moreover, where pharmaceutical products already on the market in Argentina or in other jurisdictions meet certain predefined standards, the health authority can rely on the prior registration and avoid the need for the submission of test data.

Test data exclusivity is now regularly included as a matter of course in FTAs concluded by the United States, EU and European Free Trade Association (EFTA). Test data exclusivity has even been included in accession commitments of a number of countries wishing to accede to the WTO, including most notably China and perhaps, rather oddly, Cambodia (an LDC). The next subsection reviews the commitments made in FTAs and

36 IFPMA, above n. 19.
templates of demandeur countries so as to illustrate the trend of increasing protection beyond that which is required by the TRIPS Agreement.

6.2.3 The Expansion of Test Data Exclusivity in Free Trade Agreements

The incorporation of test data exclusivity in FTAs began in 1994 with the NAFTA. More specifically, Article 1711 of NAFTA provides for a period of five-year data exclusivity from the date of marketing approval, but also provides that a party can approve a drug by “relying” on the date of marketing approval of another party, in which case the period of exclusivity would run concurrently with that of the original party. This approach subsequently served as the original post-TRIPS template for test data exclusivity in FTAs.

In the past decade the reach of test data exclusivity has changed immensely with its inclusion in IP chapters of FTAs negotiated by, among others, the United States, EU and EFTA. In most cases, the demandeur requests and/or requires the partner country to match the level of protection in its domestic law. For example, US FTAs generally match its domestic standard by seeking a five-year period of exclusivity for a new pharmaceutical product (ten years for a new agricultural chemical product). For instance, Article 17.10.1(a) of the Australia-United States FTA (AUSFTA) reads:

If a Party requires, as a condition of approving the marketing of a new pharmaceutical product, the submission of undisclosed test or other data concerning safety or efficacy of the product, the Party shall not permit third persons, without the consent of the person who provided such information, to market a same or similar product on the basis of (1) such...
Several issues are worth noting. First, unlike the TRIPS Agreement, the wording of the FTA provision relates to marketing exclusivity but acts to prohibit third parties (i.e., generic manufacturers) from relying on test data for a period of time and gaining marketing approval. Second, and again unlike the TRIPS Agreement, the provision delineates the time period for such test data exclusivity – in the above example, five years from the date of marketing approval for the originator product. Third, while the starting point for the period of data exclusivity is unstated in the TRIPS Agreement, the FTA makes clear that the starting date is not the date of filing the request but rather the date of marketing approval in the country. The fourth issue to note is the subtle deviation in wording from the TRIPS Agreement, which requires protection of a product “which involves a considerable effort” and containing “new chemical entities,” arguably enlarging protection to every “new pharmaceutical product,” which perhaps includes, for instance, a new application or method of a known chemical entity, new dosage, combinations, administration, indications and the like. The effect of this linguistic shift is immense, as it allows an applicant for a new pharmaceutical product to obtain protection even in the case of old and well-known products (irrespective of whether any effort was spent in generating the data).

In some FTAs, such as the US-Jordan FTA and the KORUS FTA, there is an additional provision that limits test data exclusivity to a period of three

42 See also US FTAs with Singapore (Article 16.8.1), Bahrain (Article 14.9.1) and Oman (Article 15.9.1), and CAFTA-DR-US (Article 15.10.1).
43 The exception to US FTA practice are the FTAs with Peru, Colombia and Panama, which do not provide a set period of protection but only state that protection must be for a “reasonable period” of time.
44 But see that the term “new product” is loosely defined as “one that does not contain a chemical entity that has previously been approved by the Party.” AUSFTA, Article 17.10.1(d). See also US FTAs with Morocco (Article 15.10.1); Central America FTA–Dominican Republic (Article 15.10.1(c), Bahrain (Article 14.9.1(c)), Oman (Article 15.9.1(c)) and KORUS (Article 18.9.1(c)). See also the US-Jordan FTA (Article 4.22 (note 10)) and others that include “protection for new uses for old chemical entities for a period of three years” within the definition of “new chemical entity.”
years from the date of obtaining marketing authorization for pharmaceutical products that contain a chemical entity that has been approved earlier for marketing in another pharmaceutical product (whereas for pharmaceutical products that do not contain a previously approved chemical entity the term of protection is five years from the date of obtaining marketing authorization). 46

Most US FTAs contain an additional provision that explicitly states that the period of test data exclusivity period remains intact even after the expiration or invalidation of the patent. Article 17.10.3 of the AUSFTA provides an example of the US template in this regard:

When a product is subject to a system of marketing approval . . . 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 . . . in the event that the patent protection terminates on a date earlier than the end of the term of protection. 47

The reason for this provision is both simple and clear – test data exclusivity is regarded as a right separate from and in addition to patent rights. Thus, the expiration or invalidation of patent rights has no effect on test data exclusivity.

Several US FTAs also effectively prohibit generic manufacturers from using evidence of registration of the originator drug in another country to prove the safety and efficacy of their version so long as the originator applies for marketing approval within five years of registering the product in a country other than a party to that particular FTA. 48 In other words, a generic manufacturer is prevented from relying on the data used in the originator’s application for marketing approval in another country for a certain time period even where the originator has not sought marketing approval in that jurisdiction; thus, the jurisdiction does not have access to that particular drug until the expiration of the data exclusivity period. Depending on how the originator times its entry into the market, the effect

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46 See, e.g., KORUS FTA, Article 18.9.2(a) and Article 18.9.1(a) in conjunction with 18.9.1(c), respectively. While neither party currently implements such practice, the KORUS also provides five years of test data exclusivity where the generic applicant seeks as a basis for registration information or evidence of prior marketing approval in such other territory. Ibid., at Article 18.9.1(b).
47 See also US FTAs with Singapore (Article 16.8.1), Morocco (15.10.1, note 11), Oman (Article 15.9.3) and the KORUS FTA (Article 18.9.4).
48 These provisions are found in US FTAs with Singapore (Article 16.8.2), AUSFTA (Article 17.10.1(c)), Morocco (Article 15.10.1), CAFTA-DR-US (Article 15.10.1(b)), Bahrain (Article 14.9.1(b)), Oman (Article 15.9.1(b)) and KORUS (Article 18.9.1(b)).
of the provision could result in ten years of test data protection. For example, an originator could wait almost five years after registering a drug in one of the FTA countries before submitting the marketing approval application in another FTA-member country. It would then be entitled to five years of exclusivity from that date in the secondary country.

The United States softened its approach in FTAs with Peru, Colombia and Panama in a manner that may hasten the registration of pharmaceuticals in these secondary markets. More specifically, if any of these countries uses US FDA approval as the basis for granting marketing approval in their jurisdiction to US originators, the period of exclusivity is to run concurrent with the period in the United States so long as approval is granted within six months of the date of application. Thus, no matter when the test data is registered in the FTA-partner country, the exclusivity period will expire when it expires in the United States. These agreements also contain an explicit exception to test data exclusivity for measures to protect public health in accordance with the Doha Declaration and subsequent implementing protocols.

The “pullback” seen in the above FTAs did not last, as is evident in the recently negotiated (but not in force) TPP, with the “megaregional” FTA reverting to the protection commonly seen in US FTAs. More specifically, the TPP provides for the protection of undisclosed test data for “new pharmaceutical product[s]” (as opposed to new chemical entities) for a period of five years from the date of approval in another jurisdiction with protection extending even if the jurisdiction grants marketing approval on the basis of registration in another territory. In addition, the TPP is the first US agreement to specifically include biologics through a complicated formula that ultimately provides eight years’ protection.  

49 The latter exception also appears in the KORUS FTA (Article 18.9.3).


51 Ibid., at 18.47(1)(b).

52 Ibid., at 18.51. There, the United States has proposed a twelve-year data exclusivity term for biologics to match its domestic legal framework, and the failure to achieve this period has caused much discussion and debate among US industry and politicians. See Zachary Brennan, “Final TPP Agreement Draws Ire from Both Sides over Biologics Exclusivity” (Regulatory Affairs Professional Society (RAPS), 5 October 2015), www.raps.org/Regulatory-Focus/News/2015/10/05/23325/Final-TPP-Agreement-Draws-Ire-from-Both-Sides-over-Biologics-Exclusivity/; Jenny Leonard, “Hatch: TPP Biologics Commitments Would Not Require Side Letters” (9 September 2016) 34(35) Inside U.S. Trade,
The other two major proponents of test data exclusivity are the EU and EFTA. While earlier FTAs negotiated by these trade blocs followed the United States in adopting a five-year protection periods,53 the negotiating strategy later shifted upward in the EU and EFTA FTAs to a period of protection of eight years for pharmaceutical products.54 The language used in the provision, however, more closely resembles Article 39(3) of the TRIPS Agreement than the standard US provision. For instance, Article 20(29) of the CETA provides protection for a period of eight years from the date of the granting of the originator’s marketing approval against disclosure for “new chemical entities . . . if the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.”55

More recent EFTA FTAs shift to a new model that instead of setting a period of protection applies a cost-sharing or compensatory liability scheme. For example, Annex XIII, Article 3 of the EFTA-Korea FTA states:

The Parties shall prevent applicants for marketing approval for pharmaceutical and agricultural chemical products from relying on undisclosed test or other undisclosed data, the origination of which involves considerable effort, submitted by the first applicant to the competent authority for marketing approval for pharmaceutical and agricultural chemical products, utilizing new chemical entities, for an adequate number of years from the date of approval, except where approval is sought for original products. Any party may instead allow in their national legislation applicants to rely on such data if the first applicant is adequately compensated [emphasis added].56


53 See, e.g., EU FTAs with Korea (Article 10.36) and Peru-Colombia (Article 231); EFTA FTAs with Colombia (Article 6.11.2).
54 See, e.g., EFTA agreements with Hong Kong (Annex XII, Article 4.2), Montenegro (Annex VI, Article 6.2) and Serbia (Annex VI, Article 5.2).
55 Generic applicants can, however, make use of test data after a period of six years. CETA, 20.29. The CETA does not require changes to existing Canadian law. Government of Canada, Regulations amending the Food and Drug Regulations (Data Protection), Canada Gazette Part II, vol. 140, 2006, 1493–502.
56 See also Article IV, Annex V of the EFTA–Lebanon FTA, which grants a period “of at least six years [protection], except where approval is sought for original products, or unless the first applicant is adequately compensated” (emphasis added).
Two things are worth noting. First, the EFTA FTAs are fairly stringent in that they usually require data exclusivity (as opposed to market exclusivity), providing for eight years’ protection and contain few exceptions. In many respects, the EFTA position is even more onerous and less flexible than US FTAs. Second, EFTA FTAs are noteworthy in that they provide for an alternative to exclusivity in the form of a compensatory option requiring “adequate” compensation. The provision highlighted in the extract above is similar, but slightly more onerous than the EFTA-Tunisia FTA, which requires five years’ protection or adequate compensation and also includes two safeguards in that the provision explicitly provides that the parties could disclose data “as far as necessary, to protect public health against harmful effects of the products” and that the term of protection “not exceed the period applying to the identical product in the country of origin or in the exporting country.” Perhaps even more interestingly, the EFTA-Korea protects undisclosed test data involving new chemical entities that involved considerable effort for “an adequate number of years” – thus, the agreement leaves the term of protection to the “relevant laws and regulations of the Parties.” The provision also allows for “adequate compensation” in lieu of exclusionary protection.

The shift to a cost-sharing compensatory approach is interesting for many reasons, not least because in a number of ways it replicates the debate between Taubman and Correa noted earlier in this chapter. While such a method accomplishes the goal of rewarding current and encouraging future standardized tests and the production of societally useful data, it is debatable whether “adequate compensation” from a developing country would make much difference to the equation. On the other hand, payment of even a token amount would recognize the costs involved in the production of the data and shield against attacks of the generic unfairly benefiting through misappropriation of information.

What is clear is that the misappropriation approach as argued by many developing countries at the WTO is failing at the bilateral and regional levels. Both developed and developing countries are agreeing to recognize and protect test data for a set period of time. The question becomes whether a compensatory, cost-sharing approach as that of the EFTA model

57 This is in contrast to EU FTAs, which normally require market exclusivity as opposed to the more stringent data exclusivity or a combination of the two, with data exclusivity for five years and an additional period of market exclusivity. See, e.g., EU FTAs with Georgia (Article 187(5)) and Moldova (Article 315(5)).
58 EFTA-Tunisia FTA, Annex V, Article 4.
59 EFTA-Korea FTA, Annex XIII, Article 3, including note 2.
60 Ibid.
would be a better or fairer result than the more blunt exclusive property approach as seen in the US and EU models. Several issues would need to be taken into account in answering that question, namely, how does one calculate adequate compensation? Would cost figures need to be calculated as well as potential loss of profit? How can the system be designed to provide compensation but not unduly burden generic applicants at the risk of increasing the price of the medicine? How would the system apply in regard to the issuance of a compulsory license?

6.3  Test Data Exclusivity in Hong Kong

For many years, Hong Kong not only did not provide for test data exclusivity but approved applications from generic manufacturers simply where similar products had been approved or commercialized in another jurisdiction. This is no longer the case and now Hong Kong provides test data exclusivity for a period of eight years as provided in the Guidance Notes on Registration of Pharmaceutical Products/Substance, which reads:

Clinical and scientific documentation substantiating the safety and efficacy of the product (except for generic products applications received on or after 1 Oct 2012 and their originator products have been registered in Hong Kong for over 8 years . . .) [emphasis in original].

Hong Kong only recently raised its term of protection from a period of five to eight years. The reason for the increase in the term of protection is Annex XII, Article 4, of the HK-EFTA FTA (2011), which requires:

1. The Parties shall protect undisclosed information in accordance with Article 39 of the TRIPS Agreement.


Reichman, above n. 2, 35 (“a reasonable royalty model could be adopted . . . which would oblige generic producers to pay a flat percentage of gross sales, or a flat percentage above marginal costs of production, as a tithe for the right to rely on the originators’ test data results for a specified period of time, to last no longer than five years”). The lingering question is how to ensure this does not provide for under- or overcompensation.

2. For pharmaceuticals, including chemical entities and biologics… that require marketing approval by a competent authority, the Parties shall prevent applicants for marketing approval for such products from relying on, or referring to, undisclosed test data or other data submitted to the competent authority by the first applicant for a period, counted from the date of marketing approval, of at least eight years for pharmaceuticals ...

3. Reliance on or reference to such data may be permitted:
   (a) in order to avoid unnecessary duplication of tests of agrochemical products involving vertebrate animals, provided that the first applicant is adequately compensated; or
   (b) where a written consent from the first applicant is presented.

Several issues are worth noting. First, the provision is not limited to “new chemical entities” but to “pharmaceuticals.” In this regard, it is unlike and goes beyond the typical EFTA agreement in a manner that is more restrictive.64 Second, while the eight-year term of test data exclusivity is in line with EFTA agreements, it is beyond those of the United States and therefore to the extreme end of exclusivity. Third, the protection applies to chemical entities and biologics, making this agreement one of the first globally to explicitly protect biologics. Fourth, the provision allows for adequate compensation instead of the eight-year waiting period but only applies it to certain agrochemical products. Here again, this is a departure from EFTA practice, which regularly applies this provision to pharmaceuticals. Overall therefore this provision is more restrictive than the usual EFTA template on test data exclusivity.

Moreover, it is worth highlighting that the agreement requires test data exclusivity as opposed to market exclusivity. This means that in practice, the period of market exclusivity extends beyond the eight-year period. This is the case since the regulatory review process in Hong Kong takes on average up to one year to complete, meaning the effect of data exclusivity actually will actually extend market exclusivity to an average of nine years.65

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64 The only way around this is to rather creatively read Article 4(1), which states that “[t]he Parties shall protect undisclosed information in accordance with Article 39 of the TRIPS Agreement,” in such a way as to restrict application of the provision to chemical entities.

65 The regulatory agency does not release records on this matter. The author established the stated period of time through informal conversations and interviews with pharmaceutical company representatives and lawyers who represent applicants and have experience with the system.
According to Shaikh’s ranking of thirty-five FTAs involving twenty-three jurisdictions according to their “access to medicine,” the HK-EFTA FTA ranks fairly low at twenty-fourth – with strong scores for proximity to Article 39(3) of TRIP and strength of test data exclusivity but weak on duration of test data exclusivity and inclusion of exceptions/access enabling provisions. Even more worrying, however, is that in the survey of domestic laws on test data exclusivity Hong Kong ranked dead last among the twenty-three jurisdictions surveyed. Thus, and rather curiously, Hong Kong’s domestic legislation lacks many of the exceptions and flexibilities that are included in the HK-EFTA FTA. While it is in Hong Kong’s interest to provide for an access-oriented regime, it is in fact proving to be the most restrictive regime of any jurisdiction.

Having agreed to a period of eight years of restrictive data exclusivity in the EFTA FTA, there is little Hong Kong can now do in regard to length of protection. Why Hong Kong would agree (or even demand) such a provision is unknown, but it makes little sense for the jurisdiction. Most notably, the main justification for test data exclusivity protection is to ensure that there is a sufficient period of marketing exclusivity to allow the originator drug companies to recoup R&D costs. This justification is of little relevance to Hong Kong, for a number of reasons. First, given the size of the market, it is unlikely that its protection of test data (or otherwise) would affect the decision-making of a company on whether it should proceed with clinical tests. Second, such protection will not stimulate the development of a pharmaceutical industry or in any way benefit Hong Kong companies. Third, the extended period of protection is burdensome for the healthcare budget.

Moreover, and as importantly, the extended period of exclusivity appears unwarranted in Hong Kong given that generic applicants often delay regulatory filings until even after the patent term has expired. The requirement will also likely extend protection well beyond the expiration of the patent, as Hong Kong is rare in requiring that prior to filing an application for marketing approval containing a new chemical or

67 Ibid.
biological entity, the product must have received prior registration in at least two specified countries. This indicates that Hong Kong identifies itself as a secondary market for innovative drugs and not as a market that drives innovative products. Even more, it does not appear that Hong Kong undertook any economic or health impact analysis prior to its implementation of an eight-year period of test data exclusivity. Hong Kong is not alone in this regard, as there is a dearth of empirical evidence on the effect of test data exclusivity in general. That being said, the evidence that does exist indicates that test data exclusivity extends the period of effective protection for originator drugs, thereby delaying generic competition, and increases the cost of drugs to consumers and governmental purchasers. The evidence also reveals that test data exclusivity has not led to an increase in pharmaceutical-related foreign direct investment (FDI) and that it may actually result in the delay of registration of drugs in secondary markets.

This last point – that test data exclusivity could delay drug registration in secondary markets – has been understudied in the literature but may be more important than the impact on the introduction of generic pharmaceuticals. This is not only because originators can delay their application for marketing approval in such markets, but also because some FTAs restrict generic manufacturers from referencing the marketing approval from another jurisdiction. In the past, such references have been used by marketing authorities to approve generic drugs even in the absence of registration by the originator in the relevant market. In the restrictive FTAs, however, the result could be that the drug is not available in the

69 “The Guidance Notes on Registration of Pharmaceutical Products/Substances,” Note 8 (D)(g), above n. 63.
jurisdiction for a considerable length of time. This is particularly the case where neither the domestic law nor the FTA requires the originator to apply for marketing approval within a certain period of time following the first approval or filing in another jurisdiction. The benefit of such practice for the originator is that it can delay the introduction of the drug into a lower-priced market until its period of exclusivity (and with it, higher prices and profits) ends in the primary markets.

In order to prevent gaming of the system in such a manner, secondary jurisdictions should require both in domestic law and as a safeguard in FTAs a provision that requires originators to submit applications for marketing approval within a certain period of time – e.g., six months – following submission or approval in another jurisdiction. In the Hong Kong context, the jurisdiction should amend existing the regulations so as to require originators to apply for registration within a certain time frame after gaining marketing authorization in the original market (or receiving approvals in two jurisdictions to mimic existing rules regarding submission) in order to be able to make use of the full eight-year protection period. Should an originator not meet the timeline, then test data exclusivity should run from the time of the date of the first grant of marketing approval. Because such a requirement does not exist in the EFTA-Hong Kong FTA, an amendment to that treaty would also be required.

Hong Kong should also take numerous other steps to minimize the potential harm that test data exclusivity could bring to the health system while maintaining good-faith compliance with its international commitments. For instance, one important step Hong Kong could take to liberalize and simplify its regime is by granting marketing approval to pharmaceuticals that have been approved in other select jurisdictions, perhaps by amending the existing rule such that when a product has been registered in two listed jurisdictions, marketing approval is automatically granted on application in Hong Kong. In this regard, Hong Kong would not “use” or “require” any originator data in the granting of marketing approval, and thus Article 39(3) of the TRIPS Agreement would not apply.72

Hong Kong could also amend the regulations such that when it requires the submission of test data, it will explicitly limit protection of the test data to that which is necessary in order to gain marketing approval. This

72 Reichman, above n. 2, 19 (“WTO Members have no duty to ‘require... the submission of undisclosed test or other data’ and they may rely upon the health and safety decisions of other jurisdictions, or on the published medical literature, or a combination of both, without incurring liability under Article 39.3”).
limitation would be in accordance with Article 39(3) of the TRIPS Agreement, which requires protection for data that are necessary for marketing approval. Where companies voluntarily submit information or submit excess information that is not needed for the granting of marketing approval, such information should not be subject to the data exclusivity regime. Such an interpretation should also be consistent with Article 4(1) of Annex XII of the HK-EFTA FTA, which calls on the Parties to “protect undisclosed information in accordance with [TRIPS] Article 39.”

Furthermore, as the phrase “considerable effort” in Article 39(3) of the TRIPS Agreement is vague and undefined, Hong Kong could seek to define it in the legislation and interpret it not only in economic terms but so as to include technical and scientific terms. In this regard, while “considerable” may not be capable of being defined, it would be clear that the standard is high.

In addition, although Hong Kong is not likely to issue a compulsory license on a pharmaceutical, it nevertheless should give itself the flexibility to do so should the need arise (in line with Article 39(3) of the TRIPS Agreement). In this regard, it should provide an exception clause to test data exclusivity in both domestic legislation and in the text of its FTAs in the event of an emergency or other crisis that necessitates the issuance of a compulsory license. The reason an exception clause is necessary is that test data exclusivity could impede a generic manufacturer from obtaining marketing approval, even when acting in accordance with a compulsory license. Simply stated, a manufacturer granted authority to produce a generic drug under compulsory license must still obtain marketing approval prior to producing and placing the drug on the market. If test data exclusivity prevents it from using the originator’s data and obtaining the registration, it cannot actually fulfill the terms of the compulsory license and supply the needed drug.73

Moreover, Hong Kong should seek an interpretation or amendment to the HK-EFTA FTA and legislatively provide for the possibility of a generic applicant providing “adequate compensation” in lieu of providing

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73 In the face of mounting criticism, the United States argued that “if circumstances ever arise in which a drug is produced under a compulsory license, and it is necessary to approve that drug to protect public health or effectively utilize the TRIPS/health solution, the data provisions in the PTA would not stand in the way.” Such a response is somewhat problematic, however, as the legal status of “side letters” is unclear and the wording invites dispute between the parties as to what is “necessary.” See Letter from USTR General Counsel John K. Veroneau to Congressman Sander M. Levin, 19 July 2004 (in the context of the US-Morocco FTA).
a blanket eight years of exclusive protection. Although generic manufacturers may not take advantage of this option, providing for the possibility is prudent, in line with the majority of EFTA’s FTAs and would at least provide an avenue for early access to medicines for consumers.

Finally, and in order to better protect originators, Hong Kong should legislatively provide that a generic manufacturer or other third party cannot use pharmaceutical test data as evidence in an independent submission for marketing approval if the data had been acquired through dishonest commercial practice. In so doing, Hong Kong could take a position on the interpretation of Article 39(3) of TRIPS.74

6.4 Conclusion

Test data exclusivity is a reward for the creation of standardized and better data that is beneficial to society. It is separate from and often runs concurrently with patent protection. On the one hand, test data exclusivity makes sense so as to encourage R&D and the proliferation of test data, even where the likelihood of the originator receiving a patent is unlikely or non-existent. In this regard, it seems unfair that a third party can “free ride” and immediately use the originator’s data to produce a rival medicine. On the other hand, test data exclusivity can serve to delay the entry of generic competition onto the market. Where no patent exists or expires during the term of test data exclusivity, it acts as a de facto patent to ensure a minimum period of monopoly for the originator. In some agreements, countries can be prohibited from using test data submitted in another jurisdiction even where the originator has not sought registration in that market.

There is no consensus on the correct interpretation of Article 39(3) of the TRIPS Agreement, and efforts to further define the provision at the WTO so as to provide for test data exclusivity have been rejected by developing counties. While the trend is for providing test data exclusivity in FTAs, this is being demanded by a handful of developed countries and accepted by others as part of a more comprehensive trade bargain – it cannot be said that subsequent state action has not risen to the level where test data exclusivity can be viewed as the new norm or standard. Therefore, the majority view is also likely the correct interpretation of Article 39(3) of the TRIPS Agreement and the most in line with the VCLT – the provision protects against governmental authorities disclosing

74 Such a view would be in line with the majority of WTO Members and commentators. See, e.g., ICTSD-UNTAD, above n. 7, 11–12; Correa, above n. 29, 576–77.
confidential data, with exceptions for the issuance of a compulsory license and to remedy anticompetitive practices.

Test data exclusivity may not be required by the TRIPS Agreement but it has worked its way into the domestic legislation of a number of jurisdictions. This includes Hong Kong, which agreed to eight years’ test data exclusivity as part of the HK-EFTA FTA. Test data exclusivity in Hong Kong and other small jurisdictions seems misplaced, as surely these markets are too insignificant to influence or determine the decision to proceed with trials and other data-generating activities. Of course, one could still argue that a third party should not be able to “free ride” anywhere in the world, not just in the larger developed country markets. This argument is of course moot, as Hong Kong is now required to protect test data irrespective of whether it benefits the jurisdiction. That being the case, Hong Kong could take several steps to safeguard the healthcare system and limit the potential negative effects of test data exclusivity. If such steps are not taken, test data exclusivity will be an expensive and needless burden on an already stretched system.