



**October 9, 2015**

## **What's New in the TPP Intellectual Property Text?**

### **Pharmaceutical Provisions<sup>1</sup>**

The TPP negotiations concluded in Atlanta this week. Today, WikiLeaks published the complete TPP Intellectual Property Chapter<sup>2</sup>, dated Monday, October 5, 2015 – the date that the 12 Pacific Rim nations announced a final TPP deal. The leaked text does not contain negotiating country brackets, indicating rules are no longer subject to debate. However, it still has to go through legal scrubbing as there are still drafters' and negotiators' notes, which may clarify the meaning of some provisions. The interpretation of this Chapter is also likely to depend on provisions in other TPP chapters.

This analysis only covers some of the main obligations of the intellectual property measures relating to pharmaceutical or regulated products in the concluded text.

References to Articles are to those in this leaked text, unless otherwise indicated.

#### **Patent Term Adjustment (Article QQ.E.14)**

Patent term adjustments (typically called extensions) significantly delay market entry of generic medicines and restrict access to affordable medicines.

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<sup>1</sup> Burcu Kilic & Peter Maybarduk, Public Citizen's Global Access to Medicines Program & Sanya Smith Reid, Third World Network, More information and analysis is available at: [www.citizen.org/tppa](http://www.citizen.org/tppa).

<sup>2</sup> <https://wikileaks.org/tpp-ip3>

1. Each Party shall make best efforts to process applications for marketing approval of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays.
2. With respect to a pharmaceutical product (50) that is subject to a patent, each Party shall make available an adjustment(51) of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.(52)
3. For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations provided that the Party continues to give effect to this Article.
4. With the objective of avoiding unreasonable curtailment of the effective patent term, a Party may adopt or maintain procedures that expedite the examination of marketing approval applications.

FN 50: A Party may comply with the obligations of this paragraph with respect to a pharmaceutical product or, alternatively, with respect to a pharmaceutical substance.

FN 51: For greater certainty, a Party may alternatively make available a period of additional sui generis protection to compensate for unreasonable curtailment of the effective patent term as a result of the marketing approval process. The sui generis protection shall confer the rights conferred by the patent, subject to any conditions and limitations pursuant to Paragraph 3.

FN 52: Notwithstanding Article QQ.A.10bis, this Article shall apply to all applications for marketing approval filed after the date of entry into force of this Article for that Party.

The first paragraph of this text follows the wording of the previously leaked texts (October 2014<sup>3</sup> and May 2015<sup>4</sup>) and encourages countries to process patent applications and applications for marketing approval of pharmaceutical products in an efficient and timely manner.

The relevant provision in the November 2013 WikiLeaks text provided patent term adjustments not only for patents covering new pharmaceutical products but also for patents that cover methods of making or using pharmaceutical products. The scope of this provision is now narrower than it was. And it is also narrower than the relevant provision in the Korea-U.S. Free Trade agreement.

<sup>3</sup> <https://wikileaks.org/tpp-ip2/>

<sup>4</sup> <http://keionline.org/node/2308>



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The earlier version of the provision provided limitations on the period and applicability of patent term extensions. These limitations were similar to, though not entirely the same as; those found in the U.S. Patent Act, i.e., a party may limit extensions to one per pharmaceutical product. The current version of the text does not prescribe limitations, but rather allows Parties to provide for conditions and limitations within their own legal system and practice and encourages Parties to adopt or maintain procedures that expedite the examination of marketing approval applications.

### **Regulatory Review Exception (Article QQ.E.15)**

Without prejudice to the scope of, and consistent with, QQ.E.4, each Party shall adopt or maintain a regulatory review exception (53) for pharmaceutical products.

FN53: For greater certainty, consistent with QQ.E.4, nothing prevents a Party from providing that regulatory review exceptions apply for purposes of regulatory reviews in that Party, in another country, or both.

The regulatory review exception, widely known as the Bolar exception in the United States, helps speed generic medicines to market. It is a safe harbor provision that permits the generics manufacturer to make small batches to apply for marketing approval before the patent expires without risk of liability for infringement.

QQ.E.4. mimics the language of Article 30 of TRIPS and permits Parties to adopt a regulatory review exception: “Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.”

The earliest version of this provision limited the application of the provision to testing conducted with the intent of seeking domestic regulatory review only. The final provision adopts a generalized and flexible approach. It reflects Canada and New Zealand’s existing regime with respect to the early regulatory review exception and applies to products submitted for domestic regulatory review as well as products submitted for regulatory review in foreign jurisdictions.



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## Pharmaceutical Data Protection/Protection of Undisclosed Test or Other Data (Market exclusivity) (Article QQ.E.16)

1. (a) If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product (54), the Party shall not permit third persons, without the consent of the person who previously submitted such information, to market the same or a similar(55) product on the basis of:
  - (i) that information; or
  - (ii) the marketing approval granted to the person who submitted such information

for at least five years(56) from the date of marketing approval of the new pharmaceutical product in the territory of the Party .

FN 54: Each Party confirms that the obligations of Article QQ.E.16, and QQ.E.20 apply to cases in which the Party requires the submission of undisclosed test or other data concerning: (a) only the safety of the product,(b) only the efficacy of the product, or (c) both.

FN 55: For greater certainty, for purposes of this Section, a pharmaceutical product is “similar” to a previously approved pharmaceutical product if the marketing approval, or, in the alternative, the applicant’s request for such approval, of that similar pharmaceutical product is based upon the undisclosed test or other data concerning the safety and efficacy of the previously approved pharmaceutical product, or the prior approval of that previously approved product.

FN 56: For greater certainty, a Party may limit the period of protection under Article QQ.E.16.1 to 5 years, and the period of protection under Article QQ.E.20.1 (a) to 8 years.

Exclusivity rules delay generic drug registration for a specified period of time, by limiting the ability of generics manufacturers and regulatory authorities to make use of an originator companies’ data and grant generics marketing approval.

The provision mirrors the language in the Australia-U.S. Free Trade Agreement (AUSFTA) and it allows for ‘at least five years<sup>5</sup>’ of market exclusivity for new pharmaceutical products. The Parties shall not permit third parties to market the same or similar product using the same test or other data concerning the safety and efficacy of the product. It is important to mention that market exclusivity means that Parties can accept generic medicine applications during those five years, but cannot grant the marketing approval before 5 years pass from the date of marketing approval in the territory of the Party.

<sup>5</sup> The footnote 57, clarifies that 'at least' doesn't mean have to do more than 5 or 8 years.



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The provision distinguishes between the information required and permitted. If a Party relies on required undisclosed test or other data to grant a marketing approval, paragraph (a) applies. If a Party relies on the marketing approval conferred in a foreign country paragraph (b) applies.

The WikiLeaks text of November 2013<sup>6</sup> conferred exclusivity for any ‘information’ submitted in support of marketing approval, even if it is disclosed and in the public domain. The scope of exclusivity is more limited now, provided only for ‘undisclosed test or other data’.

Products that are considered to be the same as or similar to the reference product are also excluded from relying on its protected data. Footnote 56 clarifies that a pharmaceutical product can be a ‘similar’ to a previously approved pharmaceutical product if the marketing approval of that similar pharmaceutical product is based upon the information concerning the safety or efficacy of the previously approved pharmaceutical product, or the prior approval of the reference product.

Peru’s Annex incorporates the concurrent period concept from the U.S.-Peru FTA. Peru has the option of starting the exclusivity clock from the date of U.S. marketing approval (or first approval in another TPP Party), rather than from the date of marketing approval in Peru. This applies, however, only so long as Peru approves a product within 6 months of the date an application is filed with the Peruvian authorities. In practical terms, this can shorten the exclusivity period in Peru, if the originator takes a long time to apply for marketing approval in Peru.

Malaysia’s Annex permits Malaysia to keep its so called ‘access window’ system. A pharmaceutical company must file a marketing approval request in Malaysia within 18 months after the product is first registered in any country, or forfeit market exclusivity. The ‘access window’ is for new pharmaceutical products, new clinical information/combinations and biologics. However the periods of protection start from the date of first marketing approval in Malaysia.

Brunei’s Annex includes the same access window as Malaysia with the same conditions.

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<sup>6</sup> See, Secret Trans-Pacific Partnership Agreement (TPP) - IP Chapter <https://wikileaks.org/tpp/>



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## Pharmaceutical Data Protection (marketing exclusivity) for New Clinical Information or New Compounds (Article QQ.16.2)

Marketing exclusivity for new forms and uses of old medicines could be considered a form of evergreening. Since marketing exclusivity applies regardless of the patent status of a drug, even off-patent medicines presented in the forms and uses described below would not have a generic competitor.

This section of text now requires countries to choose one of two possible evergreening models to incorporate in their laws. Offering a choice between options which support different objectives seems to have little internal logic and presumably reflects a political compromise. Footnote 58 clarifies that additional exclusivity protection on submission of new chemical information does not extend to pharmaceutical products that receive 8 years data exclusivity (as in the case of Japan).

2. Each Party shall (57):

- (a) apply Article QQ.E.16.1 mutatis mutandis for a period of at least three years with respect to new clinical information submitted as required in support of a marketing approval of a previously approved pharmaceutical product covering a new indication, new formulation or new method of administration; or alternatively,
- (b) apply Article QQ.E.16.1 mutatis mutandis for a period of at least five years to new pharmaceutical products that contain a chemical entity that has not been previously approved in the Party.(58)

FN57: A Party that provides a period of at least 8 years of protection pursuant to QQ.E.16.1 is not required to apply Article QQ.E.16.2.

FN 58: For the purposes of this QQ.E.16.2(b), a Party may choose to protect only the undisclosed test or other data concerning the safety and efficacy relating to the chemical entity that has not been previously approved.

### Option (a): Three years additional exclusivity for new clinical information:

A *new indication of a known medicine* refers to a new use of that medicine. Depending on how "indication" is defined, this could mean the use of a known medicine for treatment of another disease or use of the known medicine for the same disease but for a different population of patients such as children. Option (a) provides 'at least three years' of Article 16.QQ.1-style market exclusivity for new clinical information supporting a new indication.

For example, the HIV medicine zidovudine (AZT) was first discovered as an anti-cancer medicine in 1964. In 1987 it was approved by the U.S. Food and Drug Administration for the treatment of



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HIV.<sup>7</sup> This is a new indication. AZT cost about USD7,000 per person per year at the monopoly price (new HIV indication) when it was introduced<sup>8</sup> while the price of the generic version (cancer indication) had fallen to USD70 per person per year by June 2013<sup>9</sup>. This is an example of the kind of price differences which could occur in TPP countries if they choose this implementation option of providing three-year monopolies for new indications.

The approval for previously known medicines for use in children may also be considered a new indication.<sup>10</sup> Whether data/marketing exclusivity for new indications would apply for versions of the same medicine used in the treatment of children would depend on the definition used by the medicine regulatory authority concerned. Pediatric versions would also be considered new formulations of known medicines<sup>11</sup>.

*A new formulation of a known medicine* refers to a different version of the same medicine including salts, esters, ethers, polymorphs, thermodynamically stable versions, different dosage forms, etc. For instance, imatinib mesylate is a new formulation of the drug imatinib which is used in the treatment of chronic myloid leukemia. In this case it is a salt (mesylate) form of imatinib. A further formulation of imatinib would be the imatinib mesylate b or the beta crystalline form of imatinib mesylate. These are different salt formulations of the old medicine imatinib. Swiss MNC Novartis sold its version of imatinib mesylate b for USD 2666 per person per month in India while the generic version of imatinib mesylate b cost less than USD 200 per person per month.<sup>12</sup>

*A new method of administration* refers to a change in the means by which an active ingredient is delivered into a patient's body. For example, according to Doctors Without Borders, 'Valganciclovir is primarily used as treatment and prevention of an infection caused by

<sup>7</sup> [http://d2pd3b5abq75bb.cloudfront.net/2012/07/16/14/39/31/171/UTW\\_13\\_ENG\\_Jul2010.pdf](http://d2pd3b5abq75bb.cloudfront.net/2012/07/16/14/39/31/171/UTW_13_ENG_Jul2010.pdf)

<sup>8</sup> <http://www.avert.org/history-aids-1987-1992.htm>

<sup>9</sup> [http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF\\_Access\\_UTW\\_16th\\_Edition\\_2013.pdf](http://d2pd3b5abq75bb.cloudfront.net/2013/09/11/10/25/44/896/MSF_Access_UTW_16th_Edition_2013.pdf)

<sup>10</sup> Eg

<http://www.accessdata.fda.gov/scripts/cderworld/index.cfm?action=newdrugs:main&unit=4&lesson=1&topic=7>

<sup>11</sup> For example, nevirapine syrup. Invented in 1990, by the late 1990s, the hemihydrate or syrup form of this medicine was also known. It is this syrup version that is used for the pediatric treatment of HIV. So this is a syrup formulation of nevirapine. By 2008, an extended release form of Nevirapine was also formulated

<sup>12</sup> <http://www.lawyerscollective.org/news/archived-news-a-articles/126-novartis-case-background-and-update-supreme-court-of-india-to-recommence-hearing.html>



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cytomegalovirus (CMV) in organ transplant patients. But CMV also affects people living with HIV and, if left untreated, can cause blindness and death.<sup>13</sup>

Ganciclovir can be taken intravenously, orally<sup>14</sup> or via an ophthalmic gel.<sup>15</sup> These can be said to be new methods of administration of ganciclovir. Roche, the originator, marketed Valganciclovir for USD 8500 (the monopoly price) for a 4 week course of treatment in the US and for USD 5950 in India.<sup>16</sup> The generic price in India for a 4 week course of treatment was approximately USD 1000.<sup>17</sup>

### Option (b): New combinations

Under option (b), a Party would provide five years exclusivity if a known product were combined with a new chemical entity that has not been previously approved. This kind of exclusivity would possibly apply to fixed combinations.

For example, Kaletra, a second line combination HIV medicine (lopinavir and ritonavir) is sold as a single tablet by Abbott. Ritonavir was originally marketed on its own under the brand name Norvir by Abbott in 1996<sup>18</sup>. Later Abbott worked on lopinavir and the combination of the two medicines was approved for marketing in 2000 by the U.S. FDA.<sup>19</sup> In recent years generics have been available in some middle-income countries at about 10-20% the price of Abbott's monopolized products in countries of comparable income levels.

<sup>13</sup> <http://www.msf.org/article/victory-access-medicines-valganciclovir-patent-rejected-india>

<sup>14</sup> Via its L-valine ester (Valganciclovir),

<http://www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/PediatricAdvisoryCommittee/UCM255409.pdf>

<sup>15</sup> [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2009/022211s000\\_sumr.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2009/022211s000_sumr.pdf)

<sup>16</sup> <http://www.msf.org/article/victory-access-medicines-valganciclovir-patent-rejected-india>

<sup>17</sup> <http://www.livemint.com/Companies/gDdz0mQiHJV54JiCQcZvkN/Roche-prepares-to-defend-local-patent-for-Valcyte.html>

<sup>18</sup> <http://www.prnewswire.com/news-releases/abbott-receives-us-fda-approval-for-heat-stable-norvirr-ritonavir-tablets-84147727.html>

<sup>19</sup> [http://www.accessdata.fda.gov/drugsatfda\\_docs/nda/2010/022417s000\\_MedR.pdf](http://www.accessdata.fda.gov/drugsatfda_docs/nda/2010/022417s000_MedR.pdf)



### Public Health Safeguards (Article QQ. E.16.3)

3. Notwithstanding paragraphs 1 and 2 above and Article QQ.E.20, a Party may take measures to protect public health in accordance with:

- (a) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");
- (b) any waiver of any provision of the TRIPS Agreement granted by WTO Members in accordance with the WTO Agreement to implement the Declaration and in force between the Parties; and
- (c) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.

The provision provides safeguards for Parties to take measures to protect public health in accordance with the TRIPS Agreement and Doha Declaration. The provision borrows the language from May 10 Agreement and the previous FTAs (Peru US FTA, Korea-US FTA).

Public Citizen, Third World Network and other observers including Carlos Correa<sup>20</sup> have suggested expanded language to provide a clear operational path for health exceptions to marketing exclusivity. The actual provision provides little specific guidance, but nevertheless references all TPP exclusivity provisions. This should mean Parties may provide health exceptions to marketing exclusivity for biologics.

Chile has preserves the health and other exceptions<sup>21</sup> in its law, which Chile can use to override the biologics exclusivity.<sup>22</sup>

<sup>20</sup> "...this language has little or no practical effect. It would not limit in any manner the obligations imposed by the agreement. The referred to Declaration only confirms the flexibilities allowed by the TRIPS Agreement in relation to public health matters (such as compulsory licenses and parallel imports), but it is unlikely to provide a sufficient legal basis to derogate from the obligations established by the TPP", Carlos M. Correa. Intellectual Property in the Trans-Pacific Partnership: Increasing the Barriers for the Access to Affordable Medicines. South Centre Research Paper No. 62, September, 2015, <http://www.southcentre.int/research-paper-62-september-2015/>, ,....

<sup>21</sup> Eg in addition to health, for non-commercial public use, national emergency, other circumstances of extreme urgency declared by the competent authority and national security, termination of the exclusivity is allowed. Compulsory licences, anticompetitive practices by the originator company, failure to commercialise it in Chile for more than 12 months after getting marketing approval in Chile etc result in the protection under this paragraph not applying, [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=270135](http://www.wipo.int/wipolex/en/text.jsp?file_id=270135), [http://www.ifpma.org/fileadmin/content/Publication/IFPMA\\_2011\\_Data\\_Exclusivity\\_En\\_Web.pdf](http://www.ifpma.org/fileadmin/content/Publication/IFPMA_2011_Data_Exclusivity_En_Web.pdf), [http://www.wipo.int/wipolex/en/text.jsp?file\\_id=338935](http://www.wipo.int/wipolex/en/text.jsp?file_id=338935).

<sup>22</sup> Annex to IP Chapter 4-Chile



## Patent Linkage (Article QQ.E.17)

Patent linkage is a regulatory mechanism that links medicine marketing approval to patent status. Under some forms of linkage, even spurious patents may function as barriers to generic medicine registration. Patent linkage can facilitate abuse, since the financial benefits to patent holders of deterring generic market entry may outweigh risks of penalties.

Earlier TPP drafts included a U.S. proposal that would have required countries to automatically block generic market entry in case of alleged patent infringement. The text is more permissive now, and provides countries with two options:

1. If a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting the safety and efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval by the Party or in another territory, that Party shall provide: (59)
  - (a) a system to provide notice to a patent holder(60) or to allow for a patent holder to be notified prior to the marketing of such a pharmaceutical product, that such other person is seeking to market that product during the term of an applicable patent claiming the approved product or its approved method of use;
  - (b) adequate time and opportunity for such a patent holder to seek, prior to the marketing (61) of an allegedly infringing product, available remedies in subparagraph (c); and
  - (c) procedures, such as judicial or administrative proceedings, and expeditious remedies, such as preliminary injunctions or equivalent effective provisional measures, for the timely resolution of disputes concerning the validity or infringement of an applicable patent claiming an approved pharmaceutical product or its approved method of use.

FN 59: Drafter's Note: The Parties understand that QQ.A.5 applies to the provisions of this Chapter, including this paragraph. Accordingly, a Party may implement this Article by applying it to any pharmaceutical product that is subject to a patent.

FN 60: For greater certainty, for purposes of this Article, a Party may provide that a "patent holder" includes a patent licensee or the authorized holder of marketing approval.

FN 61: For the purposes of Article QQ.E.17.1(b), a Party may treat "marketing" as commencing at the time of listing for purposes of the reimbursement of pharmaceutical products pursuant to a national healthcare program operated by a Party and inscribed in the Annex attached to the Chapter ## TPP Transparency Annex on Transparency and Procedural Fairness for Pharmaceutical Products and Medical Devices.



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This provision is similar to the “soft” linkage provision of the Peru- US FTA<sup>23</sup>. A Party must either create a system to provide notice to a ‘patent holder’ (really the authorized holder of marketing approval) or allow for notification prior to the marketing of a competing product, or a product for an approved use, claimed under a patent. A Party also needs to provide adequate time and opportunity for a patent holder to seek remedies including judicial and administrative proceedings, preliminary injunctions or equivalent effective provisional measures.

2. As an alternative to paragraph 1, a Party shall instead adopt or maintain an extrajudicial system which precludes, based upon patent-related information submitted to the marketing approval authority by a patent holder or the applicant for a marketing approval, or based on direct coordination between the marketing approval authority and the patent office, the issuance of marketing approval to any third party seeking to market a pharmaceutical product subject to a patent claiming that product, unless by consent or acquiescence of the patent holder.

The second option is similar to the U.S. “hard” linkage system which prevents generics companies from getting marketing approval during the patent term unless by consent or acquiescence of the patent holder. A Party would create an extra-judicial system to prevent the applicant from marketing a product, or a product for an approved use, which are claimed under a patent. This system requires direct coordination between the marketing approval authority and the patent office. The obligation extends to cover the entire term of the patent, unless the patent owner has consented to, or acquiesced in, the use of the information.

Footnote 60 clarifies that a Party could provide protection going beyond the obligations herein and apply this provision to any pharmaceutical product that is subject to a patent.

Although there were discussion and even a proposed measure to exclude biologics from patent linkage, no such exclusion appears obvious from the text.

### **Biologics ( Article QQ.E.20)**

See, Public Citizen & Third World Network Analysis: **Ambiguity Leads to Fallacy: Biologics Exclusivity in the Trans-Pacific Partnership** [http://www.citizen.org/documents/Ambiguity\\_Leads\\_to\\_Fallacy\\_\(Biologics\).pdf](http://www.citizen.org/documents/Ambiguity_Leads_to_Fallacy_(Biologics).pdf)

<sup>23</sup> Peru-US Free Trade Agreement, Article 16.10.03,

<https://ustr.gov/sites/default/files/uploads/Countries%20Regions/africa/agreements/pdfs/FTAs/peru/16%20IPR%20Legal.June%2007.pdf>



### **Market exclusivity & Term of Patent (Article QQ.E.22)**

Subject to Article QQ.E.16.3 (*protection of public health*), when a product is subject to a system of marketing approval in the territory of a Party pursuant to Articles QQ.E.16, QQ.E.20, or QQ.E.13 (*agricultural chemical products*) and is also covered by a patent in the territory of that Party, the Party shall not alter the term of protection that it provides pursuant to Articles QQ.E.16, QQ.E.20, or QQ.E.13 (*agricultural chemical products*) in the event that the patent protection terminates on a date earlier than the end of the term of protection specified in Articles QQ.E.16, QQ.E.20, or QQ.E.13 (*agricultural chemical products*).

Some countries end the exclusivity period when the patent term ends. In other words, exclusivity should not outlast patent protection. USTR aims to defeat this practice with this Article. The Article provides that exclusivity and patent term are independent. This in some cases leads to longer monopoly protection for originator companies.