[1] 1994年発効のNAFTAには、②販売承認手続による特許期間浸食回復のための特許期間延長の条項は含まれておらず、TPP交渉において、本条項に対するカナダの立場は注目される

[2] シンガポールとチリは告知義務があるが、ジェネリック販売開始阻止手段については単に「新薬特許期間においてはジェネリック医薬品の承認をしてはいけない」とのみ規定されている。ジョルダンは告知義務のみが規定されている。

[3]35USC§156
医薬品等 、その使用法または製造方法をクレームする特許権の存続期間は、販売許可のために必要であった政府規制期間(regulatory review period) について、延長が認められる。延長期間は、最大5年 、かつその製品の認可後の存続期間が14年を超えないことを条件 とする。ひとつの特許権について存続期間延長が認められるのは1回だけであり 、また、ひとつの政府規制に対して複数の特許権がある場合でも、ひとつの特許権についてのみ延長が認められる 。

[4]21USC§355(j)(5)(F)
新規化合物（エステルや塩も含む）については、原則として承認後5年間、ANDAが認められず 、既承認医薬についても、新たな臨床試験を含む追加申請が行われた場合等は、原則としてその承認後3年間はANDAが認められない 。すなわち、当該期間においては、最初に医薬品開発を行った者に市場優先が与えられる。なお、その他、オーファンドラッグに関しては7年間 、小児用法に関しては6ヶ月間 、同様の市場優先がその開発者に対し与えられる。

[5]35USC§271(e)(1)
医薬品等の政府規制法による資料準備のため、妥当な範囲(solely for uses reasonably related to the development and submission of information)で行う、特許発明品の製造、使用、販売の申し出、販売および輸入する行為は、侵害を構成しない。すなわち、関連する医薬品の特許権存続期間中に、ジェネリック医薬品メーカーがANDAを提出するために実施する試験等は、特許権侵害に該当しない。なお、本規定は、その立法の経緯となった合衆国巡回控訴裁判所（United States Court of Appeals for the Federal Circuit：CAFC）の事件 の被告であるジェネリック医薬品メーカー・ボーラー（Bolar）社の名前に由来して、ボーラー条項と呼ばれることがある。

[6] 21USC§355(j)(5)(B)(iv)(I)(II)

[7] FDAホームページ参照
http://www.accessdata.fda.gov/scripts/cder/ob/default.cfm

[8] 35USC § 271(e)(2)(A)

[9] 21USC § 355(j)(5)(B)(iii)
なお、ANDAがあるたびに訴訟提起することで市場独占期間を継続させる先発メーカーが後を立たなかったため、このANDA停止がされるのは最初の1回のみとする規則の改正が2003年に行われた 。

資料：米国 FTA 医薬知財条項リスト

①Bolar 関連条項	
Korea FTA (2012)	**Article 18.8.5.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating such information to support an application for meeting marketing approval requirements of that Party, and if the Party permits exportation of such product, the Party shall provide that the product shall only be exported outside its territory for purposes of generating information to support an application for meeting marketing approval requirements of that Party.
	仮訳：桝田作成 Article 18.8.5. 第 3 項を前提として、加盟国が、第三者に対し、医薬品の販売承認申請のために必要な情報を得る目的で、存続期間中の特許対象を使用することを許容している場合には、 その権原のもとで産生された製品は、医薬品の販売承認申請の際に求められる情報を得る目的以外では、その領域内で製造、使用、販売してはならない。そして、加盟国が、そのような製品を輸出することを認めている場合には、加盟国は、医薬品の販売承認申請の際に求められる情報を得る目的以外では、その領域外に輸出してはならない。
Colombia FTA	**Article 16.9.5.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, sold, offered for sale, or imported in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.

Panama TPA	**Article 15.9.5.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.
Peru TPA (2009)	**Article 16.9.5.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, sold, offered for sale, or imported in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.
CAFTA-DR (2009)	**Article 15.9.5.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical or agricultural chemical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.

Oman FTA (2009)	**Article 15.8.5.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating such information, and if the Party permits exportation, the Party shall provide that the product shall only be exported outside its territory for purposes of meeting marketing approval requirements of that Party.
Bahrain FTA (2006)	**Article 14.8.5.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent solely to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than to meet requirements for approval to market the product once the patent expires, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.
Morocco FTA (2006)	**Article 15.9.6.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in its territory other than for purposes related to generating information to meet requirements for approval to market the product, and if the Party permits exportation, the Party shall provide that the product shall only be exported outside its territory for purposes of meeting marketing approval requirements of that Party.
Australia FTA (2005)	**Article 17.9.6.**Consistent with paragraph 3, if a Party permits a third person to use the subject matter of a subsisting patent to generate information necessary to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to generating information to meet requirements for marketing approval for the product, and if the Party permits exportation,

	the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.
Singapore FTA (2004)	**Article 16.7.5.**If a Party permits the use by a third party of the subject matter of a subsisting patent to support an application for marketing approval of a pharmaceutical product, that Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of that Party other than for purposes related to meeting requirements for marketing approval, and if the Party permits exportation, the product shall only be exported outside the territory of that Party for purposes of meeting marketing approval requirements of that Party.
Chile FTA (2004)	**Article 17.9.4.**If a Party permits the use by a third party of the subject matter of a subsisting patent to support an application for marketing approval or sanitary permit of a pharmaceutical product, the Party shall provide that any product produced under such authority shall not be made, used, or sold in the territory of the Party other than for purposes related to meeting requirements for marketing approval or the sanitary permit, and if export is permitted, the product shall only be exported outside the territory of the Party for purposes of meeting requirements for issuing marketing approval or sanitary permits in the exporting Party.
Jordan FTA (2001)	**Article 4.19.** If a Party permits the use by a third party of a subsisting patent to support an application for marketing approval of a product, the Party shall provide that any product produced under this authority shall not be made, used or sold in the territory of the Party other than for purposes related to meeting requirements for marketing approval, and if export is permitted, the product shall only be exported outside the territory of the Party for purposes of meeting requirements for marketing approval in the Party or in another country that permits the use by a third party of a subsisting patent to support an application for marketing approval of a product.
②医薬品の販売承認審査による特許期間浸食回復のための特許期	

間延長	
Korea FTA (2012)	**Article 18.8.6.**(b)With respect to patents covering a new pharmaceutical product21 that is approved for marketing in the territory of the Party and methods of making or using a new pharmaceutical product that is approved for marketing in the territory of the Party, each Party, at the request of the patent owner, shall make available an adjustment of the patent term or the term of the patent rights of a patent covering a new pharmaceutical product, its approvedmethod of use, or a method of making the product to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of that pharmaceutical product in the territory of that Party. Any adjustment under this subparagraph shall confer all of the exclusive rights, subject to the same limitations and exceptions, of the patent claims of the product, its method of use, or its method of manufacture in the originally issued patent as applicable to the product and the approved method of use of the product.22 仮訳：桝田作成 Article 18.8.6.(b 加盟国内で販売承認を得た新薬および、加盟国内で販売承認を得た新薬の製造・使用方法をカバーする特許権に関し、特許権者の請求に応じて、その加盟国内での、その医薬品の最初の商業的使用に関する販売承認手続きの結果として、実質特許期間が不当に削減されたことに対して、特許権者に補償をする目的で、新薬の製品、その承認された使用方法、製造方法をカバーする特許権の特許期間または特許権の存続期間を調整する機会を提供する。 このサブパラグラフにおけるいかなる調整に対しても、同一の制限と例外があることを条件として、その製品および承認された使用方法に該当する当初に登録された特許権に関し、その製品、使用方法、または製造方法の特許請求の範囲についてのすべての排他的権利が与えられる。
Colombia FTA	**Article 16.9.6.**(a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. The Parties shall cooperate and provide assistance to one another to achieve these objectives. **Article 16.9.6.**(c) With respect to any pharmaceutical product that is covered by a patent, each Party may make available a restoration of the

	patent term or patent rights to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party. Any restoration under this subparagraph shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent.
Panama TPA	**Article 15.9.6.**(a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. The Parties shall cooperate and provide assistance to one another to achieve these objectives. **Article 15.9.6.**(c) With respect to any pharmaceutical product that is covered by a patent, each Party may make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party.
Peru TPA (2009)	**Article 16.9.6.**(a) Each Party shall make best efforts to process patent applications and marketing approval applications expeditiously with a view to avoiding unreasonable delays. The Parties shall cooperate and provide assistance to one another to achieve these objectives. **Article 16.9.6.**(c) With respect to any pharmaceutical product that is covered by a patent, each Party may make available a restoration of the patent term or patent rights to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party. Any restoration under this subparagraph shall confer all of the exclusive rights of a patent subject to the same limitations and exceptions applicable to the original patent.
CAFTA-DR (2009)	**Article 15.9.6.**(b) With respect to any pharmaceutical product that is covered by a patent, each Party shall make available a restoration of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term resulting from the marketing approval process related to the first commercial marketing of the product in that Party.

Oman FTA (2009)	**Article 15.8.6.**(b) With respect to patents covering pharmaceutical products or their method of use: (i) each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of the product in that Party; and (ii) where a Party approves the marketing of a new pharmaceutical product based on evidence of prior approval in another territory, including information on safety and efficacy submitted in connection with that approval, the Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term in the Party as a result of the marketing approval process in the other territory and in the Party. (c) For purposes of this paragraph, effective patent term means the period from the date of approval of the product until the original expiration date of the patent.
Bahrain FTA (2006)	**Article 14.8.6.** (b) With respect to any pharmaceutical product that is covered by a patent: (i) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process related to the first commercial use of the product in that Party; and (ii) where a Party approves the marketing of a new pharmaceutical product on the basis of information concerning the safety or efficacy of a same or a similar product in another territory, such as evidence of prior marketing approval, the Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term in the Party as a result of the marketing approval process in the other territory and in the Party. For purposes of this paragraph, effective patent term means the period from the date of approval of the product until the original expiration date of the patent.
Morocco FTA (2006)	**Article 15.10.3.**With respect to patents covering pharmaceutical products, each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing

	approval process.
Australia FTA (2005)	**Article 17.9.8.**(b) With respect to a pharmaceutical product17-17 that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.
Singapore FTA (2004)	**Article 16.8.4.(a)** With respect to any pharmaceutical product that is subject to a patent: (a) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process;
Chile FTA (2004)	**Article 17.10.2(a)** 2. With respect to pharmaceutical products that are subject to a patent, each Party shall: (a) make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process;
Jordan FTA (2001)	**Article 4.23.(a)** With respect to pharmaceutical products that are subject to a patent: (a) each Party shall make available an extension of the patent term to compensate the patent owner for unreasonable curtailment of the patent term as a result of the marketing approval process.
医薬品のテストデータの保護	
Korea FTA	Article 18.9.1.(a) If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the origination of which involves a considerable effort, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the territory of the Party, authorize another to market a same or a similar product based on: (i) the safety or efficacy information submitted in support of the marketing approval; or (ii) evidence of the marketing approval,

	for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the territory of the Party. (b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person that previously submitted the safety or efficacy information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on: (i) the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval of the new product in the territory of the Party. (c) For purposes of this Article, a new pharmaceutical product is one that does not contain a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product, and a new agricultural chemical product is one that contains a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product. Article 18.9.2.(a) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of the pharmaceutical product containing the previously approved chemical entity, other than information related to bioequivalency, the Party shall not, without the consent of a person that previously submitted such new clinical information to obtain marketing approval in the territory of the Party, authorize another to market a same or a similar product based on: (i) the new clinical information submitted in support of the marketing approval; or (ii) evidence of the marketing approval based on the new clinical

	information, for at least three years from the date of marketing approval in the territory of the Party. (b) If a Party requires or permits, in connection with granting marketing approval for a pharmaceutical product of the type specified in subparagraph (a), the submission of evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory, other than evidence of information related to bioequivalency, such as evidence of prior marketing approval based on the new clinical information, the Party shall not, without the consent of the person that previously submitted such new clinical information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on: (i) the new clinical information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval based on the new clinical information in the other territory, for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.
	仮訳：桝田作成 Article 18.9.1. (a)新薬または新規農薬に対して販売承認を付与する条件として、製品の安全性、有効性に関する情報、創作するのに相当の努力を含む情報、の提出を要求または許容している場合には、加盟国の領域内で販売承認を得る目的で先にそのような安全性、有効性の情報を提出した者の承諾を得た場合を除き、医薬品に関しては、加盟国の領域内で販売承認された日から、少なくとも 5 年間、農薬に関しては少なくとも 10 年間は、 他者に対して同一または類似の製品を 1）販売承認を得るために提出された安全性、有効性情報 2）販売承認を証明する事実 に基づいて販売することを許可してはならない。 新薬または新規農薬に対して販売承認を付与することに関連して、他国における製品の安全性、有効性を証明する事実、たとえば他国において先に承認された事実、の提出を要求または許容している場合には、他国において販売承認を得る目的で先にそのような安全性、有効性の情報を提出した者の承諾を得た場合を除き、

	医薬品に関しては、加盟国の領域内で販売承認された日から、少なくとも 5 年間、農薬に関しては少なくとも 10 年間は、 他者に対して同じまたは類似の製品を 1）販売承認を得るために提出された安全性、有効性情報 2）販売承認を証明する事実 に基づいて販売することを許可してはならない。 **Article 18.9.2.は適応拡大におけるデータ保護の取り扱いについて規定(保護期間 3 年)**
Colombia FTA	**Article 16.10.2.**(a) If a Party requires, as a condition for approving the marketing of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where 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. (b) Each Party shall provide that for data subject to subparagraph (a) that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence or bioavailability studies. (c) Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on. (d) A Party need not apply the provisions of subparagraphs (a), (b), and (c) with respect to a pharmaceutical product that contains a chemical entity

	that has been previously approved in the territory of the Party for use in a pharmaceutical product.
Panama TPA	**Article 15.10.2.** (a) If a Party requires, as a condition for approving the marketing of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where 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. (b) Each Party shall provide that for data subject to subparagraph (a) that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them.17 Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence or bioavailability studies. (c) Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on.

	(d) A Party need not apply the provisions of subparagraphs (a), (b), and (c) with respect to a pharmaceutical product that contains a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product.
Peru TPA (2009)	**Article 16.10.2.**(a) If a Party requires, as a condition for approving the marketing of a pharmaceutical product that utilizes a new chemical entity, the submission of undisclosed test or other data necessary to determine whether the use of such products is safe and effective, the Party shall protect against disclosure of the data of persons making such submissions, where 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. (b) Each Party shall provide that for data subject to subparagraph (a) that are submitted to the Party after the date of entry into force of this Agreement, no person other than the person that submitted them may, without the latter's permission, rely on such data in support of an application for product approval during a reasonable period of time after their submission. For this purpose, a reasonable period shall normally mean five years from the date on which the Party granted approval to the person that produced the data for approval to market its product, taking account of the nature of the data and person's efforts and expenditures in producing them. Subject to this provision, there shall be no limitation on any Party to implement abbreviated approval procedures for such products on the basis of bioequivalence or bioavailability studies. (c) Where a Party relies on a marketing approval granted by the other Party, and grants approval within six months of the filing of a complete application for marketing approval filed in the Party, the reasonable period of exclusive use of the data submitted in connection with obtaining the approval relied on shall begin with the date of the first marketing approval relied on. (d) A Party need not apply the provisions of subparagraphs (a), (b), and (c) with respect to a pharmaceutical product that contains a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product.

CAFTA-DR (2009)	**Article 15.10.1.**(a) If a Party requires, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, the submission of undisclosed data concerning safety or efficacy, the Party shall not permit third persons, without the consent of the person who provided the information, to market a product on the basis of (1) the information, or (2) the approval granted to the person who submitted the information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party.15 (b) If a Party permits, as a condition of approving the marketing of a new pharmaceutical or agricultural chemical product, third persons to submit evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval, the Party shall not permit third persons, without the consent of the person who previously obtained such approval in the other territory, to obtain authorization or to market a product on the basis of (1) evidence of prior marketing approval in the other territory, or (2) information concerning safety or efficacy that was previously submitted to obtain marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date approval was granted in the Party's territory to the person who received approval in the other territory. In order to receive protection under this subparagraph, a Party may require that the person providing the information in the other territory seek approval in the territory of the Party within five years after obtaining marketing approval in the other territory. (c) For purposes of this paragraph, a new product is one that does not contain a chemical entity that has been previously approved in the territory of the Party. (d) For purposes of this paragraph, each Party shall protect such undisclosed information against disclosure except where necessary to protect the public, and no Party may consider information accessible within the public domain as undisclosed data. Notwithstanding the foregoing, if any undisclosed information concerning safety and efficacy submitted to a Party, or an entity acting on behalf of a Party, for purposes of obtaining marketing approval is disclosed by such entity, the Party is

	still required to protect such information from unfair commercial use in the manner set forth in this Article. **Article 15.10.2.** Where a Party permits, as a condition of approving the marketing of a pharmaceutical product, persons, other than the person originally submitting safety or efficacy information, to rely on evidence or information concerning the safety and efficacy of a product that was previously approved, such as evidence of prior marketing approval in the territory of a Party or in another country, that Party: (a) shall implement measures in its marketing approval process to prevent such other persons from marketing a product covered by a patent claiming the previously approved product or its approved use during the term of that patent, unless by consent or acquiescence of the patent owner; and (b) shall provide that the patent owner shall be informed of the request and the identity of any such other person who requests approval to enter the market during the term of a patent identified as claiming the approved product or its approved use.
Oman FTA (2009)	**Article 15.9.1.** (a) If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market a same or a similar product based on: (i) the safety or efficacy information submitted in support of the marketing approval; or (ii) evidence of the marketing approval, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the territory of the Party. (b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person that previously submitted the safety or efficacy information to obtain marketing approval in the other territory,

	authorize another to market a same or a similar product based on: (i) the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval in the other territory, for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval of the new product in the territory of the Party. (c) For purposes of this Article, a new pharmaceutical product is one that does not contain a chemical entity that has been previously approved in the territory of the Party for use in a pharmaceutical product and a new agricultural chemical product is one that contains a chemical entity that has not been previously approved in the territory of the Party for use in an agricultural chemical product. **Article 15.9.2.** (a) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information that is essential to the approval of a pharmaceutical product, other than information related to bioequivalency, the Party shall not, without the consent of a person that previously submitted such new clinical information to obtain marketing approval in the territory of the Party, authorize another to market a same or a similar product based on: (i) the new clinical information submitted in support of the marketing approval; or (ii) evidence of the marketing approval based on the new clinical information, for at least three years from the date of marketing approval in the territory of the Party. (b) If a Party requires or permits, in connection with granting marketing approval for a pharmaceutical product of the type specified in subparagraph (a), the submission of evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory, other than evidence of information related to bioequivalency, such as evidence of prior marketing approval based on the new clinical information, the Party shall not, without the consent of the person that previously submitted such new

	clinical information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on: (i) the new clinical information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval based on the new clinical information in the other territory, for at least three years from the date of marketing approval based on the new clinical information in the territory of the Party.
Bahrain FTA (2006)	**Article 14.9.1.** (a) If a Party requires or permits, as a condition of granting marketing approval for a new pharmaceutical or new agricultural chemical product, the submission of information concerning safety or efficacy of the product, the Party shall not, without the consent of a person that previously submitted such safety or efficacy information to obtain marketing approval in the Party, authorize another to market a same or a similar product based on: (i) the safety or efficacy information submitted in support of the marketing approval; or (ii) evidence of the marketing approval; for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval in the Party. (b) If a Party requires or permits, in connection with granting marketing approval for a new pharmaceutical or agricultural chemical product, the submission of evidence concerning the safety or efficacy of a product that was previously approved in another territory, such as evidence of prior marketing approval in the other territory, the Party shall not, without the consent of a person that previously submitted the safety or efficacy information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on: (i) the safety or efficacy information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval in the other territory; for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of marketing approval of the new product in the Party. (c) For purposes of this Article, a new pharmaceutical product is one that

	does not contain a chemical entity that has been previously approved in the Party for use in a pharmaceutical product and a new agricultural chemical product is one that contains a chemical entity that has not been previously approved in the Party for use in an agricultural chemical product. **Article 14.9.2.** (a) If a Party requires or permits, as a condition of granting marketing approval for a pharmaceutical product that includes a chemical entity that has been previously approved for marketing in another pharmaceutical product, the submission of new clinical information, other than information related to bioequivalency, the Party shall not, without the consent of a person that previously submitted such new clinical information to obtain marketing approval in the Party, authorize another to market a same or a similar product based on: (i) the new clinical information submitted in support of the marketing approval; or (ii) evidence of the marketing approval based on the new clinical information; for at least three years from the date of marketing approval in the Party. (b) If a Party requires or permits, in connection with granting marketing approval for a pharmaceutical product of the type specified in subparagraph (a), the submission of evidence concerning new clinical information for a product that was previously approved based on that new clinical information in another territory, other than evidence of information related to bioequivalency, such as evidence of prior marketing approval based on the new clinical information, the Party shall not, without the consent of the person that previously submitted such new clinical information to obtain marketing approval in the other territory, authorize another to market a same or a similar product based on: (i) the new clinical information submitted in support of the prior marketing approval in the other territory; or (ii) evidence of prior marketing approval based on the new clinical information in the other territory; for at least three years from the date of marketing approval based on the new clinical information in the Party.
Morocco FTA (2006)	**Article 15.10.1.** If a Party requires, as a condition of approving the marketing of a new

	pharmaceutical or agricultural chemical product, the submission of: (a) safety and efficacy data, or (b) evidence of prior approval of the product in another territory that requires such information, the Party shall not permit third persons not having the consent of the person providing the information to market a product on the basis of the approval granted to the person submitting that information for at least five years for pharmaceutical products and ten years for agricultural chemical products from the date of approval in the Party's territory. For purposes of this paragraph, a new product is one that contains a new chemical entity that has not been previously approved in the Party's territory. **Article 15.10.2.** If a Party requires the submission of (a) new clinical information that is essential to the approval of a pharmaceutical product (other than information related to bioequivalency), or (b) evidence of prior approval of the product in another territory that requires such new information, the Party shall not permit third persons not having the consent of the person providing the information to market a pharmaceutical product on the basis of such new information or the approval granted to the person submitting such information for at least three years from the date of approval in the Party. A Party may limit such protection to new clinical information the origination of which involves considerable effort.
Australia FTA (2005)	**Article 17.10.1.**(a) 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 the information, to market the same or a similar product on the basis of that information, or the marketing approval granted to the person who submitted such information, for at least five years from the date of marketing approval by the Party. (b) If a Party requires, as a condition of approving the marketing of a new agricultural chemical product, including certain new uses of the same product, the submission of undisclosed test or other data concerning safety