Access to Affordable Medicines: A Comparison of Provisions of the TRIPS Agreements and Selected Bilateral Trade Agreements

PROVISION	TRIPS	US	CHILE	SINGAPORE	CAFTA - DR	MOROCCO	AUSTRALIA	BAHRAIN	NAFTA	JORDAN
Bolar	Not mentioned but allowed based on WTO dispute settlement panel Canada-EU.	Required - 35 U.S.C. § 271 (e)(1) Export allowed under 21 U.S.C. § 382.	If Party permits 3rd party use of subject matter of subsisting patent to support application for marketing approval or sanitary permit of pharmaceutical product, any products produced under that authority may only be made, used or sold in the territory of the Party for purposes of meeting requirements for marketing approval or sanitary permits. If export is permitted, products may only be exported for purposes of meeting requirements for marketing approval or sanitary permits in exporting Party. Art. 17.9:4	If Party permits 3rd party use of subject matter of subsisting patent to support application for marketing approval, any products produced under that authority may only be made, used or sold in the territory of the Party for purposes of meeting requirements for marketing approval. If export is permitted, products may only be exported for purposes of meeting requirements for marketing approval of that Party. Art. 16.7:5	If Party permits 3rd party use of subject matter of subsisting patent to support application for marketing approval of pharmaceutical product, any products produced under that authority may only be made, used or sold in the territory of the Party for purposes of meeting requirements for marketing approval once the patent expires. If export is permitted, products may only be exported for purposes of meeting requirements for marketing approval of that Party. Art. 15.9:5	If Party permits 3rd party use of subject matter of subsisting patent to support application for marketing approval of pharmaceutical product, any products produced under that authority may only be made, used or sold in the territory of the Party for purposes of meeting requirements for marketing approval. If export is permitted, products may only be exported for purposes of meeting requirements for marketing approval of that Party. Art. 15.9:6	If Party permits 3rd party use of subject matter of subsisting patent to support application for marketing approval of pharmaceutical product, any products produced under that authority may only be made, used or sold in the territory of the Party for purposes of meeting requirements for marketing approval. If export is permitted, products may only be exported for purposes of meeting requirements for marketing approval of that Party. Art. 17.9:6 If patent granted adjustment of terms, Australia may permit export by 3rd party of pharmaceutical product covered by that patent for the purpose of meeting marketing approval requirements of Australia or another territory. 5/18/04 Side Letter IP Understanding	If Party permits 3rd party use of subject matter of subsisting patent to support application for marketing approval of pharmaceutical product, any products produced under that authority may only be made, used or sold in the territory of the Party for purposes of meeting requirements for marketing approval once the patent expires. If export is permitted, products may only be exported for purposes of meeting requirements for marketing approval of that Party. Art. 14.8:5	No provision.	If Party permits 3rd party use of subject matter of subsisting patent to support application for marketing approval of pharmaceutical product, any products produced under that authority may only be made, used or sold in the territory of the Party for purposes of meeting requirements for marketing approval. If export is permitted, products may only be exported for purposes of meeting requirements for marketing approval of that Party or in another country that permits 3rd party use of a subsisting patent to support application for marketing approval. Art. 4:19 Parties permitting export for purposes of obtaining market approval in another country must require manufacturer to certify that products will be exported only in quantities needed to meet the requirements Bfor obtaining marketing approval in the destination country. U.S.-Jordan MOU on IPR Issues.

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Market exclusivity (NCE) 5 Years	Article 39.3 does not establish ME but requires protection against unfair commercial use of data submitted for marketing approval of pharmaceutical products. Article 70 provides, with respect to existing subject matter: Where a product is the subject of a patent application in a Member, exclusive marketing rights shall be granted, for 5 years after obtaining marketing approval in that Member or until product patent is granted or rejected in Member, whichever period is shorter, provided that, subsequent to the entry into force of the WTO Agreement, a patent application has been filed and a patent granted for that product in another Member and marketing approval obtained in such other Member.	5 years ME for new active ingredients. 21 U.S.C. §355 (j)(5)(D)(ii)	ME for products that utilize new chemical entities, which products have not been previously approved, for a period of at least five years from approval for the pharmaceutical product. Art. 17.10:1 [Shorter time periods may be available for certain products for systems in place at date of implementation. Art. 17.10:1 n.25]	ME for a pharmaceutical product to prevent the marketing of the "same or similar product" for a period of at least five years from approval for the pharmaceutical product. Art. 16.8:1 [Shorter time periods may be available for certain products for systems in place at date of implementation. Art. 16.8:1 n.16-14] If marketing approval based on grant of approval of "same or similar product" in another country, Party will defer approval to 3rd parties for at least five years from approval in the territory of the Party or the territory of other country, whichever is later. Art. 16.8:2 Marketing exclusivity can extend beyond the term of a patent.	ME for new pharmaceutical products for at least 5 years from date of approval in the Party. Art. 15.10:1(a) If approval is based on previous approval in another country, third parties not allowed to obtain authorization or market the product for at least five years from approval in Party's territory to person who received approval in other territory. [That is, until data holder in the other Party ends five years of protection in the CAFTA country.] Art.15.10:1(b) A new product is "one that does not contain a chemical entity that has been previously approved" in the Party. Art. 15.10:1(c) [Shorter time periods may be available for	ME for new pharmaceutical product for at least 5 years from date of approval in the Party. A new product is "one that contains a new chemical entity that has not been previously approved" in the Party. Art. 15.10:1 Market exclusivity can extend beyond the term of a patent. Arts. 15.10:1 and 2 nn. 12 and 13.	ME for new pharmaceutical product prevents marketing of "same or similar product" for at least 5 years from the date of marketing approval in the Party. Art. 17.10:1(a) A new product is "one that does not contain a chemical entity that has been previously approved for marketing in the Party." Art. 17.10:1(d) If Party allows approval on the basis of approval in another country, the Party will not permit marketing of the "same or similar product" for at least 5 years from the date of marketing approval by the Party, or the other territory, whichever is later. Art. 17.10:1(c) [Parties may retain systems in place for protecting data from unfair commercial use at date of entry into force. Art. 17.10:2 n.17-26] Marketing exclusivity can extend beyond the term of a patent. Art. 17.10:3	ME for new pharmaceutical product prevents marketing of same or similar products for at least 5 years from the date of marketing approval in the Party. Art. 14.9:1(a) If using data from another country, the Party will not permit marketing of the "same or similar product" for at least 5 years from the date of marketing approval of the new product by the Party. Art. 14.9:1(b) 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." Art. 14.9:1(c) Marketing exclusivity can extend beyond the term of a patent. Art. 14.9:3	Provides data protection for products utilizing new chemical entities at least five years from the date on the Party granted approval to the data submitter. Art. 1710:6	Does not establish ME. Requires protection of data for new chemical entities against unfair commercial use. When reliance is on approval in another country, will protect for at least as long as the other country does. Art. 4:22 and n.11.

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				Art. 16.8:3	certain products for systems in place at date of implementation. Art. 15.10:1(a) n.15]					
Registration Period			[Implementing legislation establishes a period of 12 months to register in Chile after the first registration anywhere in the world. Data holder risks losing enforcement of the ME if it does not market the product for 12 months after the registration of the product in the Party.]		The CAFTA Party may require the data holder to seek approval in the CAFTA Party within 5 year of approval in first territory in order to receive protection. Art. 15.10:1(b)					
Mkt. 3 Years						Permits at least three more years from the date of approval in the Party when new clinical information is needed for approval in the Party (or evidence of prior approval in another Party that required new information). Art. 15.10.2	Permits at least 3 more years when new clinical information (other than information related to bio equivalency) needed for approval in the Party (or evidence of prior approval in other Party that required new information) from date of marketing approval by the Party or the other territory, whichever is later. Art. 17.10:2	For a pharmaceutical product with a chemical entity that has been previously approved for marketing in another pharmaceutical product, third person without consent would not be authorized to market the "same or similar product" based on new clinical information for at least 3 years from the date of marketing approval in the Party. Art. 14.9:2(a) For products specified in Art. 14.9:2(a),		Provides for protection for at least three years for new uses for old chemical entities. Art. 4:22 and n.10.

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								permits at least 3 more years when new clinical information needed for a product previously approved based on that new information in another territory (other than information related to bioequivalency) from date of marketing approval by the Party based on the new clinical information. Art. 14.9:2(b)		
Patent Extensions – Hatch-Waxman			Provides for extensions for delays in the marketing approval process. [There is no time frame to trigger request for extension.] Art. 17.10:2(a)	Patent extensions allowed for delays in marketing approval process. [There is no time frame to trigger request for extension.] Art. 16.8:4(a)	For pharmaceutical products covered by a patent, compensates for delays in the marketing approval process related to the first commercial marketing of the product in that Party. Art. 15.9:5(b) [There is no time frame to trigger request for restoration, only says unreasonable curtailment of the effective patent term.]	Patent extensions available for delays in marketing approval process. Art. 15.10:3 [There is no time frame to trigger request for extension.]	For pharmaceutical products covered by a patent, compensates for delays in the marketing approval process. Art. 17.9:8(b) [There is no time frame to trigger request for extension.]	For pharmaceutical products covered by a patent, compensates for delays in the marketing approval process related to the first commercial use of the product in that Party. Art. 14.8:6(b)(i) When a new pharmaceutical product is authorized based on data for “a same or a similar” product in another territory, compensates for approval delays in the other territory or in the Party. Art. 14.8:6(b)(ii) The “effective patent term” is the period from approval of the product until the original expiration date of the patent. Art. 14.8:6(b) If the patent approved	Patent extensions available for delays in regulatory approval processes. Art. 1709:12 [There is no time frame to trigger request for extension.]	Patent extensions available for pharmaceutical products for delays in marketing approval process. Art. 4:23(a) [There is no time frame to trigger request for extension.]

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								in another territory was the basis for approval in the Party, the Party shall extend the term of a patent granted under such procedure by the same time that was extended in the first territory Art. 14.8:7		
Patent Extensions - PTO	No provision.	35 U.S.C. §154	Allows extensions in cases of delay in granting a patent of >5y from filing or >3y from request of examination, whichever is later (delays due to patent applicant need not be included in the delays of government to act). Art. 17.9:6	Allows extensions in cases of delay in granting a patent of >4y from filing or >2y from request of examination, whichever is later (delays due to patent applicant, including in filing of documents, need not be included in the delays of government to act). Art. 16.7:7 and n.16-13 If a Party grants a patent based on an examination of the invention in another country, the Party could grant the patent owner an extension of up to 5 years if there was a delay in the first Party where it was examined and that Party has extension the term due to the delay. Art. 16.7:8	Allows for extensions in cases of delay in granting a patent of >5y from filing or >3y from request of examination, whichever is later (delays due to patent applicant need not be included in the delays of government to act). Art. 15.9:6(a)	Allows for extensions in cases of delay in granting a patent of >4y from filing or >2y from request of examination, whichever is later (delays due to patent applicant need not be included in the delays of government to act). Art. 15.9:7	Allows for extensions in cases of delay in granting a patent of >4y from filing or >2y from request of examination, whichever is later (delays due to patent applicant or opposing third person need not be included in the delays of government to act). Art. 17.9:8(a)	Allows for extensions in cases of delay in granting a patent of >4y from filing or >2y from request of examination, whichever later (delays due to patent applicant need not be included in the delays of government to act). Art. 14.8.6(a)		

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Restrictions on patentable subject matter	Art. 27.2 Permits exclusions to protect public order or morality, including to protect human, animal or plant life or health or avoid prejudice to environment. Art. 27.3(a) permits exclusion of diagnostic, therapeutic and surgical methods. Art. 27.3(b) permits exclusions of plants and animals other than micro-organisms, and biological processes for the production of plants and animals other than non-biological or microbiological processes. However, Members required to provide for protection of plant varieties by patent or other means. Parties agreed to review provision after 4 years.		Parties required to make efforts within 4 years of entry into force to propose legislation that would make available patent protection for plants that are new, involve an inventive step and are capable of industrial application. Art. 17.9:2	Permits exclusions contained in TRIPS Arts. 27.2 and 27.3 (a). Art. 16.7.1	Permits exclusions contained in TRIPS Arts. 27.2 and 27.3. Notwith-standing, Parties not providing patent protection for plants as of entry into force required to make all reasonable efforts to make patent protection available. Parties that protect plants and animals as of entry into force required to maintain protection. Art. 15.9.2	Limits exclusions to those necessary to protect public order or morality, including to protect human, animal or plant life or health or avoid prejudice to environment. Art. 15.9.1 Parties required to make patents available for plants and animals. Parties confirmed that patents will be available for any new uses of using a known product, including new uses of a known product for the treatment of humans and animals. Art. 15.9:2	Parties confirm that patents shall be available for new uses or methods of using a known product. Art. 17.9:1 Limits exclusions to (i) those necessary to protect public order or morality, including to protect human, animal or plant life or health or avoid prejudice to environment, and (ii) diagnostic, therapeutic and surgical methods. Art. 17.9:2	Limits exclusions to (i) those necessary to protect public order or morality, including to protect human , animal or plant life or health or avoid prejudice to environment, (ii) animals and (iii) diagnostic, therapeutic and surgical procedures. Art. 14.8:1 Expressly establishes patents for plants, and confirms patents for new uses or methods of using a known product, including products used for particular medical conditions, subject to Art. 14.8:1. Art. 14.8:2	Permits exclusions to protect public order or morality, including to protect human, animal or plant life or health or avoid prejudice to environment. Art. 1709:2 Also permits exclusion of diagnostic, therapeutic and surgical methods, plants and animals other than micro-organisms, and biological processes for the production of plants and animals other than non-biological or microbiological processes. However Parties required to provide for protection of plant varieties by patent or other means. Art. 1709:3	Limits exclusions to (i) those necessary to protect public order or morality, including to protect human, animal or plant life or health or avoid prejudice to environment, and (ii) diagnostic, therapeutic and surgical methods. Art. 4:18.
Compulsory licensing	Allowed by Art. 31, subject to 12 listed restrictions.	Yes.	No provision. TRIPS prevails.	Unauthorized use permitted to remedy anticompetitive practice. Art. 16.7:6(a) Allowed in cases of public non-commercial use or national	No provision. TRIPS prevails.	No provision. TRIPS prevails.	Unauthorized used permitted to remedy anticompetitive practices, for public non-commercial use or national emergency or extreme urgency, if use is limited to government or authorized 3rd parties, patent holder receives reasonable compensation, and	No provision. TRIPS prevails.	Allowed by Art. 1709:10 subject to 12 listed restriction (similar to TRIPS).	Unauthorized use permitted to remedy anticompetitive practices, for public non-commercial use or national emergency or extreme urgency if use is limited to government or authorized 3rd parties, or for failure to meet working requirements.

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				emergency or extreme urgency, if use is limited to government or authorized 3rd parties, patent holder receives reasonable and entire compensation, and patent holder is not required to transfer undisclosed information or know-how. Art. 16.7:6(b)			patent holder is not required to provide undisclosed information or know-how. Art. 17.9:7			(including importation). If utilized, TRIPS Art. 31 and Paris Convention should be respected. Art. 4:20
Disclosures of a claimed invention	Must be "sufficiently clear and complete"; "best mode" permitted; information on foreign applications and grants permitted. Art. 29 [Where no provision in agreement, parties not prevented from implementation into national law since "best mode" requirement permitted in TRIPS.]		No provision.	No provision.	"Sufficiently clear and complete" and "sufficiently supported" defined. Arts. 15.9:9, 10. No provision on "best mode". [Best mode was dropped as a requirement.]	Must be "sufficiently clear and complete." Art. 15.9:10 No provision on "best mode".	"Sufficiently clear and complete" and "sufficiently supported" defined. Arts. 15.9:11, 12. No provision on "best mode".	"Sufficiently clear and complete" and "sufficiently supported" defined. Arts. 15.9:9, 10. No provision on "best mode".	No provision.	References "sufficient written description''. Art. 4:21 No provision on "best mode".
Revocation	Parties shall make available opportunity for judicial review of decision to revoke or forfeit patent. Art. 32		May revoke or cancel only when grounds exist that would have justified refusal to grant a patent, *e.g.*, fraud in obtaining a patent. Art. 17.9:5 and n.24.	May only be revoked on grounds that would have justified refusal to grant a patent, or that pertain to the insufficiency of or unauthorized amendments to patent specification, non-disclosure or	May be revoked or cancelled only on grounds that would have justified refusal to grant a patent. Fraud, misrepresentation or inequitable conduct may be a basis for revoking, canceling or holding patent	May be revoked only on grounds that would have justified refusal to grant a patent. Fraud, misrepresentation or inequitable conduct may be a basis for revoking or holding patent unenforceable. Art. 15.9:5	May only be revoked on grounds that would have justified refusal to grant a patent, as well as fraud, misrepresentation or inequitable conduct. Art. 17.9:5	May be revoked only on grounds that would have justified refusal to grant a patent. Fraud, misrepresentation or inequitable conduct may be a basis for revoking or holding patent unenforceable. Art. 14.8:4	May revoke only when grounds exist that would have justified refusal to grant a patent, or the grant of a compulsory license has not remedied the lack of exploitation. Art. 1709:8	No provision.

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				misrepresentation of prescribed, material particulars, fraud and misrepresentation. Art. 16.7:4	unenforceable. Art. 15.9:4					
Measures to prevent abuse	Allowed by Art. 8 for abuse of IPR or practices that restrain trade or adversely affect tech transfer. Article 40 discusses abuses in contractual licensing.		Allowed to prevent anticompetitive practices that may result from abuse of IPR. Art. 17.1:13.	No provision.	Allowed to prevent anticompetitive practices that may result from abuse of IPR. Art. 15.1:15.	No provision.	No provision. [Implementing law has amendments, including requirement that patent holders certify when they seek to use the courts to block generic drugs that the legal action has been commenced in good faith, has reasonable prospects of success and will be conducted without unreasonable delay. If the certificate is false or misleading, or if any undertakings given under the certificate are subsequently broken, the company can be liable for a civil penalty of up to $10 million for each contravention.]	No provision.	Article 1704 provides for laws dealing with abusive or anticompetitive licensing practices or conditions.	No provision.
Linkage to patent	No provision.	Yes. 21 U.S.C. §355 (j)(2)(A)(vii)	The Party shall "**not grant marketing approval** to any third party prior to the expiration of the patent term, unless by consent or acquiescence of the patent owner." Art. 17.10:2(c) Provides for notice of request. Art. 17.10:2(b)	The Party "shall **not grant marketing approval** to any third party prior to the expiration of the patent term, unless by consent or with the acquiescence of the patent owner." Art. 16.8:4(c) Provides for notice of request. Art. 16.8:4(b)	The Party "shall **implement measures** in its marketing approval process **to prevent such other persons from marketing a product** covered by a patent claiming the previously approve product or its approved use during the term of that patent, unless by	The Party "shall **implement measures** in its marketing approval process **to prevent such other persons from marketing a product** covered by a patent during the term of that patent, unless by consent or with the acquiescence of the patent owner." Art. 15.10:4(a)	The Party "shall **provide measures** in its marketing approval process **to prevent those other persons from: (i) marketing a product,** where that product is claimed in a patent; or **(ii) marketing a product for an approved use**, where that approved use is claimed in a patent, during the term of that patent, unless by consent or acquiescence of the patent owner." Art. 17.10:4(a)	The Party "shall **implement measures** in its marketing approval process **to prevent such other persons from marketing a product** covered by a patent claiming the product **or its approved method of use** during the term of that patent, unless by consent or acquiescence of the patent owner." Art. 14.9:4(a)	No provision.	Provides for notice of request. Art. 4:23(b)

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					consent or acquiescence of the patent owner." Art. 15.10:2(a) Provides for notice of request. Art. 15.10:2(b)	Provides for notice of request. Art. 15.10:4(b)	Provides for notice of request. Art. 17.10:4(b)	Provides for notice of request. Art. 14.9:4(b)		
Opposition proceedings to the granting of a patent	No provision.		No provision. [The Chilean legislation allowed for opposition proceedings prior to the granting of a patent. It has been maintained in the implementing law.]	Only allowed after the granting of a patent. Art. 16.7:4	No provision.	Only allowed after the granting of a patent. Art. 15.9:5	No provision.	Only allowed after the granting of a patent. Art. 14.8:4	No provision.	No provision.
Utility	Must be "capable of industrial application" which may be deemed to be synonymous with the term "useful". Art. 27.1 n.5		Must be "capable of industrial application" which may be treated as synonymous with the term "useful". Art. 17.9:1	Must be "capable of industrial application" which may treated as synonymous with the term "useful". Art. 16.7:1	Must be "capable of industrial application" which may be treated as synonymous with the term "useful". Art. 15.9:1	Party shall provide claimed invention is "industrially applicable" if it has specific, substantial and credible utility. Art. 15.9:11(b)	Invention must be "capable of industrial application" which may be treated as synonymous with the term "useful". Art. 17.9:1 Party shall provide that an invention is "useful" if it has specific, substantial and credible utility. Art. 17.9:13	No provision.	Must be "capable of industrial application" which may be deemed to be synonymous with the term "useful". Art. 1709:1	Must be "capable of industrial application." Art. 4:17 TRIPS Art. 27.1 n.5 states that "capable of industrial application" may be deemed to be synonymous with the term "useful".
Side Letters/Other Agreements **[Current as of 4/20/05.]**	Declaration on the TRIPS Agreement and Public Health ("Doha Public Health Declaration") clarifies governments' ability to take advantage of flexibilities of Article 31 of TRIPS. Says TRIPS "can and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to	None.	None.	Side letter on IP enforcement issues.	Understanding on Public Health Measures allows measures to protect public health by promoting access to medicines for all, *e.g.*, for HIV, epidemics, extreme urgency or national emergency. Chapter does not prevent utilization of TRIPS/health	Allows measures to protect public health by promoting access to medicines for all, *e.g.*, for HIV, epidemics, extreme urgency or national emergency. Chapter does not prevent utilization of TRIPS/health solution. If TRIPS amended, governments will	(1) Adds PBS procedures. (2) Makes Bolar applicable to extensions of patent terms.	Allows measures to protect public health by promoting access to medicines for all, *e.g.*, for HIV, epidemics, extreme urgency or national emergency. Chapter does not prevent utilization of TRIPS/health solution. If TRIPS amended, governments will consult to adapt Chapter.	US-Canada MOU re implementation of Doha Declaration. Regarding compulsory licenses, provides for suspension of Art. 1709(10)(f) re use being authorized predominantly for the supply of the Party's domestic market, and for provision of adequate	(1) Letter regarding processing of pending applications for marketing approval. (2) MOU regarding IPR issues.

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	medicines for all." Specifically recognizes Members' right to grant compulsory licenses and the freedom to determine the grounds upon which the licenses will be granted, including right to determine what constitutes a national emergency or other circumstances of extreme urgency. Decision for the implementation of Paragraph 6 of the Doha Public Health Declaration (the "Paragraph 6 Decision") constitutes a waiver of a Member's obligation under TRIPS Article 31(f) to limit unauthorized use to supplying the domestic market. Decision covers patented products or products made using patented processes in the pharmaceutical sector needed to address public health problems, including active ingredients and diagnostic kits. Decision permits WTO Members to export pharmaceutical products made under compulsory licenses within the terms set out in the decision and also to import such products				solution. If TRIPS amended, governments will consult to adapt Chapter.	consult to adapt Chapter.			remuneration. Compulsory licenses under Art. 1709(10)(h). MOU remains in effect as long as WTO decision. If TRIPS amended, governments will consult to adapt understanding.	
Patent Harmonization	No provision.	NA	No provision.	No provision.	No provision.	No provision.	Each Party shall endeavor to reduce differences in law and practice participate in international patent harmonization efforts, including WIPO for a	No provision.	No provision.	No provision.

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							dealing with reform and development of international patent system. Art. 17.9:14			