

**KEI note on Language in FTA's on Patents Exceptions (3-Step Test and Compulsory Licensing)**

FTA (Date Coming into Force)	General exceptions (nearly identical versions of the TRIPS Article 30 3-Step Test)	Compulsory Licensing (topics covered in Article 31 and 40 of the TRIPS)
<p><b>NAFTA (1994)</b></p>	<p>Art. 1709 (Patents):</p> <p>6. A Party 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 into account the legitimate interests of other persons.</p>	<p>Art. 1709 (Patents):</p> <p>10. Where the law of a Party allows for use of the subject matter of a patent, other than that use allowed under paragraph 6, without the authorization of the right holder, including use by the government or other persons authorized by the government, the Party shall respect the following provisions:</p> <p>(a) authorization of such use shall be considered on its individual merits;</p> <p>(b) such use may only be permitted if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and such efforts have not been successful within a reasonable period of time. The requirement to make such efforts may be waived by a Party in the case of a national emergency or other circumstances of extreme urgency or in cases of public non-commercial use. In situations of national emergency or other circumstances of extreme urgency, the right holder shall, nevertheless, be notified as soon as reasonably practicable. In the case of public non-commercial use, where the government or contractor, without making a patent search, knows or has demonstrable grounds to know that a valid patent is or will be used by or for the government, the right holder shall be informed promptly;</p> <p>(c) the scope and duration of such use shall be limited to the purpose for which it was authorized;</p>

		<p>(d) such use shall be non-exclusive;</p> <p>(e) such use shall be non-assignable, except with that part of the enterprise or goodwill that enjoys such use;</p> <p>(f) any such use shall be authorized predominantly for the supply of the Party's domestic market;</p> <p>(g) authorization for such use shall be liable, subject to adequate protection of the legitimate interests of the persons so authorized, to be terminated if and when the circumstances that led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, on motivated request, the continued existence of these circumstances;</p> <p>(h) the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorization;</p> <p>(i) the legal validity of any decision relating to the authorization shall be subject to judicial or other independent review by a distinct higher authority;</p> <p>(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial or other independent review by a distinct higher authority;</p> <p>(k) the Party shall not be obliged to apply the conditions set out in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anticompetitive. The need to correct anticompetitive practices may be taken into account in determining the amount of remuneration in such cases. Competent authorities shall have the authority to refuse termination of authorization if and when the conditions that led to such authorization are likely to recur;</p>
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		(l) the Party shall not authorize the use of the subject matter of a patent to permit the exploitation of another patent except as a remedy for an adjudicated violation of domestic laws regarding anticompetitive practices.
<b>Jordan (2001)</b>	Art. 4 (Intellectual Property Rights), Paragraphs 17-21 (Patents): N/A	<p>Art 4 (Intellectual Property Rights):</p> <p>20. Neither Party shall permit the use of the subject matter of a patent without the authorization of the right holder except in the following circumstances:</p> <p>(a) to remedy a practice determined after judicial or administrative process to be anti-competitive;</p> <p>(b) in cases of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that such use is limited to use by government entities or legal entities acting under the authority of a government;</p> <p>or</p> <p>(c) on the ground of failure to meet working requirements, provided that importation shall constitute working.</p> <p>Where the law of a Party allows for such use pursuant to sub-paragraphs (a), (b) or (c), the Party shall respect the provisions of Article 31 of TRIPS and Article 5A(4) of the Paris Convention.</p>
<b>Australia (2004)</b>	<p>Art. 17.9 (Patents):</p> <p>3. A Party 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.</p>	<p>Art. 17.9 (Patents):</p> <p>7. A Party shall not permit the use[17-15] of the subject matter of a patent without the authorisation of the right holder except in the following circumstances:</p> <p>(a) to remedy a practice determined after judicial or administrative process to be anticompetitive under the Party's laws relating to prevention of anti-competitive practices;[17-16] or</p> <p>(b) in cases of public non-commercial use, or of national emergency, or other circumstances of extreme urgency, provided that:</p> <p>(i) the Party shall limit such use to use by the government or third persons authorised by the government;</p> <p>(ii) the Party shall ensure that the patent owner is provided with reasonable compensation for such use; and</p>

		<p>(iii) the Party may not require the patent owner to provide undisclosed information or technical know-how related to a patented invention that has been authorised for use in accordance with this paragraph.</p> <p>--</p> <p>[17-15] "Use" in this paragraph refers to use other than that allowed under paragraph 3 and Article 30 of the TRIPS Agreement.</p> <p>[17-16]With respect to sub-paragraph (a), the Parties recognize that a patent does not necessarily confer market power</p>
<b>Chile (2004)</b>	<p>Art. 17.9 (Patents):</p> <p>3. Each Party 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.</p>	<p>Art. 17.9 (Patents): N/A</p> <p>Art. 17.1 (General Provisions):</p> <p>13. Nothing in this Chapter prevents a Party from adopting measures necessary to prevent anticompetitive practices that may result from the abuse of the intellectual property rights set forth in this Chapter.</p> <p>Preamble:</p> <p>Recognizing the principles set out in the Declaration on the TRIPS Agreement on Public Health, adopted on November 14, 2001, by the WTO at the Fourth WTO Ministerial Conference, held in Doha, Qatar</p>
<b>Singapore (2004)</b>	<p>Art. 16.7 (Patents):</p> <p>3. Each Party 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.</p>	<p>Art. 16.7 (Patents):</p> <p>6. Neither Party shall permit the use[16-11] of the subject matter of a patent without the authorization of the right holder except in the following circumstances:</p> <p>(a) to remedy a practice determined after judicial or administrative process to be anticompetitive under the competition laws of the Party;[16-12]</p> <p>(b) in the case of public non-commercial use or in the case of a national emergency or other circumstances of extreme urgency, provided that:</p>

		<p>(i) such use is limited to use by the government or third parties authorized by the government;</p> <p>(ii) the patent owner is provided with reasonable and entire compensation for such use and manufacture; and</p> <p>(iii) the Party shall not require the patent owner to transfer undisclosed information or technical "know how" related to a patented invention that has been authorized for use without the consent of the patent owner pursuant to this paragraph. Where a Party's law allows for such use pursuant to subparagraphs (a) and (b), the Party shall respect the provisions of Article 31 of the TRIPS Agreement.</p> <p>--</p> <p>[16-11] AUse" in this provision refers to use other than that allowed in paragraph 3.</p> <p>[16-12] The Parties recognize that an intellectual property right does not necessarily confer market power upon its owner.</p>
<p><b>CAFTA (2005)</b></p>	<p>Art. 15.9 (Patents):</p> <p>3. A Party 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.</p>	<p>Art. 15.9 (Patents): N/A</p> <p>Understandings Regarding Certain Public Health Measures  (<a href="https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file697_3975.pdf">https://ustr.gov/sites/default/files/uploads/agreements/cafta/asset_upload_file697_3975.pdf</a>):</p> <p>The obligations of Chapter Fifteen do not affect a Party's ability to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.</p> <p>In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the "TRIPS/health solution"), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.</p>

		With respect to the aforementioned matters, if an amendment of a pertinent provision of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) enters into force with respect to the Parties and that amendment is incompatible with Chapter Fifteen, our Governments shall immediately consult in order to adapt Chapter Fifteen as appropriate in the light of the amendment.
<b>Bahrain (2006)</b>	<p>Art. 14.8 (Patents)</p> <p>3. Each Party 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.</p>	<p>Art. 14.8 (Patents): N/A</p> <p>Side Letter on Public Health (<a href="https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset_upload_file447_6296.pdf">https://ustr.gov/sites/default/files/uploads/agreements/fta/bahrain/asset_upload_file447_6296.pdf</a>):</p> <p>The obligations of Chapter Fourteen of the Agreement do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.</p> <p>In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the "TRIPS/health solution"), Chapter Fourteen does not prevent the effective utilization of the TRIPS/health solution.</p>
<b>Morocco (2006)</b>	<p>Art. 15.9 (Patents):</p> <p>3. Each Party 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.</p>	<p>Art. 15.9 (Patents): N/A</p> <p>Side Letter on Public Health (<a href="https://ustr.gov/sites/default/files/uploads/agreements/fta/morocco/asset_upload_file258_3852.pdf">https://ustr.gov/sites/default/files/uploads/agreements/fta/morocco/asset_upload_file258_3852.pdf</a>):</p> <p>The obligations of Chapter Fifteen of the Agreement do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS,</p>

		<p>tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.</p> <p>In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and public health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the "TRIPS/health solution"), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.</p> <p>With respect to the aforementioned matters, if an amendment of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights enters into force with respect to the Parties and a Party's application of a measure in conformity with that amendment violates Chapter Fifteen of the Free Trade Agreement, our Governments shall immediately consult in order to adapt Chapter Fifteen as appropriate in the light of the amendment.</p>
<p><b>Oman (2006)</b></p>	<p>Art. 15.8 (Patents):</p> <p>3. Each Party 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.</p>	<p>Art. 15.8 (Patents): N/A</p> <p>Side Letter on Public Health (<a href="https://ustr.gov/sites/default/files/uploads/agreements/fta/oman/asset_upload_file44_8808.pdf">https://ustr.gov/sites/default/files/uploads/agreements/fta/oman/asset_upload_file44_8808.pdf</a>):</p> <p>The obligations of Chapter Fifteen of the Agreement do not affect the ability of either Party to take necessary measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency.</p> <p>In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman's statement</p>

		<p>accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively the “TRIPS/health solution”), Chapter Fifteen does not prevent the effective utilization of the TRIPS/health solution.</p> <p>With respect to the aforementioned matters, if an amendment of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) enters into force with respect to the Parties and a Party’s application of a measure in conformity with that amendment violates Chapter Fifteen of the Agreement, our Governments shall immediately consult in order to adapt Chapter Fifteen as appropriate in the light of the amendment.</p>
<p><b>Peru (2007)</b></p>	<p>Art. 16.9 (Patents):</p> <p>3. Each Party 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.</p>	<p>Art. 16.9 (Patents): N/A</p> <p>Art. 16.13 (Understandings Regarding Certain Public Health Measures):</p> <p>1. The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).</p> <p>2. The Parties have reached the following understandings regarding this Chapter.</p> <p>(a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party’s right to protect public health and, in particular, to promote access to medicines for all.</p> <p>(b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman’s statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively, the</p>



		<p>“TRIPS/health solution”), this Chapter does not and should not prevent the effective utilization of the TRIPS/health solution.</p> <p>(c) With respect to the aforementioned matters, if an amendment of the TRIPS Agreement enters into force with respect to the Parties and a Party’s application of a measure in conformity with that amendment violates this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the amendment.</p>
<p><b>Colombia (2011)</b></p>	<p>Art. 16.9 (Patents):</p> <p>3. Each Party 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.</p>	<p>Art. 16.9 (Patents): N/A</p> <p>Art. 16.13 (Understandings Regarding Certain Public Health Measures):</p> <p>1. The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).</p> <p>2. The Parties have reached the following understandings regarding this Chapter.</p> <p>(a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party’s right to protect public health and, in particular, to promote access to medicines for all.</p> <p>(b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman’s statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively, the “TRIPS/health solution”), this Chapter does not and should not prevent the effective utilization of the TRIPS/health solution.</p>

		<p>(c) With respect to the aforementioned matters, if an amendment of the TRIPS Agreement enters into force with respect to the Parties and a Party's application of a measure in conformity with that amendment violates this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the amendment.</p>
<p><b>Korea (2011)</b></p>	<p>Art. 18.8 (Patents):</p> <p>3. Each Party 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.</p>	<p>Art. 18.8 (Patents): N/A</p> <p>Art. 18.11 (Understanding Regarding Certain Public Health Measures):</p> <p>1. The Parties affirm their commitment to the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2).</p> <p>2. The Parties have reached the following understandings regarding this Chapter:</p> <p>(a) The obligations of this Chapter do not and should not prevent a Party from taking measures to protect public health by promoting access to medicines for all, in particular concerning cases such as HIV/AIDS, tuberculosis, malaria, and other epidemics as well as circumstances of extreme urgency or national emergency. Accordingly, while reiterating their commitment to this Chapter, the Parties affirm that this Chapter can and should be interpreted and implemented in a manner supportive of each Party's right to protect public health and, in particular, to promote access to medicines for all.</p> <p>(b) In recognition of the commitment to access to medicines that are supplied in accordance with the Decision of the General Council of 30 August 2003 on the Implementation of Paragraph Six of the Doha Declaration on the TRIPS Agreement and Public Health (WT/L/540) and the WTO General Council Chairman's statement accompanying the Decision (JOB(03)/177, WT/GC/M/82) (collectively, the "TRIPS/health solution"), this Chapter does not and should not prevent the effective utilization of the TRIPS/health solution.</p>

		(c) With respect to the aforementioned matters, if an amendment of the TRIPS Agreement enters into force with respect to the Parties and a Party's application of a measure in conformity with that amendment violates this Chapter, the Parties shall immediately consult in order to adapt this Chapter as appropriate in the light of the amendment.
<b>Panama (2011)</b>	<p>Art. 15.9 (Patents):</p> <p>3. A Party 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.</p>	<p>Art. 15.9 (Patents): N/A</p> <p>Art. 15.10 (Measures Related to Certain Regulated Products): Pharmaceutical Products</p> <p>2. [...]</p> <p>(e) Notwithstanding subparagraphs (a), (b), and (c), a Party may take measures to protect public health in accordance with:</p> <p>(i) the Declaration on the TRIPS Agreement and Public Health (WT/MIN(01)/DEC/2) (the "Declaration");</p> <p>(ii) 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</p> <p>(iii) any amendment of the TRIPS Agreement to implement the Declaration that enters into force with respect to the Parties.</p>