



Asia 1: Patentability and patent systems

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			
		Pharmaceutical products	Patentability exceptions New use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Brunei WTO review, Other source°	Chapter 72 Laws of Brunei  <i>Emergency (Patents) Order 1999 Not yet in force as of 2001.</i>	Yes. Registration of patents granted in UK, Malaysia and Singapore.		No	Experimental use
Cambodia Patent Law	Law on the Patents, Utility Models Certificates and Industrial Designs 2002	No. Patents excluded until 2016	Not explicitly excluded	No	Experimental purposes
China Patent Law, WTO review	Patent Law of PRC 1992	Yes	2 <sup>nd</sup> use patents allowed	Yes, under Article 13 of the Chinese Regulations on Drug Registration	Scientific research or experimentation
India Patent Law	Patents Act 1970 Patents (Amendment) Act 1999 Patents (Second Amendment) Act 2002 Patents Ordinance 2004	Yes, with mailbox provision	2 <sup>nd</sup> use excluded, but effect of patents ordinance to be clarified	Yes	
Indonesia Patent Law, WTO review	Patents Act, Law no. 14-2001	Yes	Not explicitly excluded	No	Experimental use Use for research, education and analysis
Laos Other source°	Patents, Petty Patents and Industrial Designs Decree <i>New patents law being drafted WTO Accession process</i>	No  <i>Yes under draft law</i>			Experimental use
Malaysia Patent Law, WTO review	Patents Act 1983 (Latest amendment 2002)	Yes	2 <sup>nd</sup> use patents allowed	Yes	"The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done only for scientific research"

Philippines WTO review	Intellectual Property Code (Republic Act No. 8293)	Yes	Not excluded  * Specifically permitted for certain new medical applications	No	Private and non-commercial use Scientific research and experiment
Singapore Patent Law, WTO review	Patents Act 1994, amended 1995	Yes	Not excluded	No	Private and non-commercial use "Experimental purposes relating to the subject-matter of the invention"
Sri Lanka WTO review	Intellectual Property Code 1979 (Last amended 2000)  <i>Intellectual Property Bill 2003, not yet enforced as of 2004</i>	No	Not excluded		Broad provision: Patent owner's rights "extend only to acts done for industrial or commercial purposes and, in particular, not to acts done only for scientific research"
Thailand Patent Law, WTO review	Patents Act 1999	Yes	Not excluded	Yes	Broad provision: "Any act for the purpose of study, research, experimentation or analysis, provided that it does not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner"  Reverse-engineering of products specifically permitted under Trade Secrets Act 2002.
Vietnam Patent Law	Civil Code on Protection of Industrial Property (cif 1 July 1996) Decree63/CP 1996, Decree06/2001, Decree 54/2000	Yes	Not excluded	No	Use for purposes which are not commercial
Pakistan Patent Law	Patents Ordinance 2000 Patents (Amendment) Ordinance, 2002	Yes, post-2005, with mailbox provision	New and 2 <sup>nd</sup> use both excluded  Mere change in "physical appearance of a chemical product where the chemical formula remains the same" also excluded	No	Experimental purposes Teaching purposes in educational or research institutions

Asia 2: Doha flexibilities - PI, CL, GU

Country Sources consulted	Provision/Mechanism			
	Exhaustion regime	Compulsory license grounds	Government use	Data protection
Brunei WTO review, Other source°	No provision under existing law  <i>International, under Emergency Order</i>	No provision  <i>Emergency Order provides for compulsory licensing scheme on grounds of: Failure to work domestically Demand not met on reasonable terms Anti-competitive practices</i>	No.  <i>Yes, under Emergency Order.</i>	No provision (only common law).  Stated in WTO review that data protection measures will be included in new Medicines Act.
Cambodia Patent Law	International	Failure to exploit*  * This ground may only be invoked after 3 years from grant or 4 years from filing	Yes, For public interest including national security, nutrition, health, and on finding of anticompetitive practices  * Patent owner may request Ministry hearing to vary terms of the decision authorizing the exploitation	No provision, but accession agreement appears to include commitment for 5-year data exclusivity.  A separate law on the Protection of Undisclosed Information and Trade Secrets is planned for adoption by the National Assembly in 2004 and promulgation in 2005.
China Patent Law, WTO review	National	Public interest Emergency/extraordinary state of affairs Refusal to deal Dependent patents  * Under Implementing Regulations, all grounds seem subject to delay of 3 years after grant.  ** Patent holder is entitled to judicial review as to "legal validity" of licensing decision within 3 months of notification. Unclear as to whether this would suspend execution of CL.	No explicit provision	Yes Data exclusivity of 6 years, under Implementation Provisions of Drug Administration Law (2002), as follows: "Within six years from the date on which a manufacturer or distributor was granted marketing approval of a pharmaceutical product utilized new chemical entities, if any second applicant applies for market authorization using the said undisclosed data without the permission of the prior applicant, the competent authority for drug administration shall not grant the market authorization, except for that the second applicant submits his own data"

India Patent Law	International	<p>Failure to work domestically*  Public demand not being met on reasonable terms*  Product not supplied to public at "reasonably affordable price"*  Dependent patents</p> <p>* These grounds may only be invoked 3 years from grant or 4 years from filing.</p>	<p>Yes,  For national emergency/  extreme urgency, and for  public non-commercial use</p>	<p>No provision, although discussion  underway</p>
Indonesia Patent Law, WTO review	No explicit provision	<p>Failure to exploit*  Patent implemented in a manner that  "contravenes the public interest"  Dependent patents</p> <p>* This ground may only be invoked 36 months after date of patent issue, and requires a court hearing.</p>	<p>Yes,  For national defense or  security, or "an urgent need  for the sake of public interest"</p>	<p>No provision</p> <p><i>* However, WTO response states that data protection will be provided for under the draft Law on Trade Secrets.</i></p>
Laos Other source °	No explicit provision	<p>Public interest  Failure to exploit  Anti-competitive practices  Dependent patents</p>	<p>No  Yes, under draft law</p>	<p>No provision</p>
Malaysia Patent Law, WTO review	International	<p>Failure to work domestically*  Failure to meet public demand on  reasonable terms*  Inter-dependent patents</p> <p>* These grounds may be invoked only after 3 years from grant or 4 years from date of filing</p>	<p>Yes,  For public interest including  national security, nutrition,  health, and on finding of  anticompetitive practices</p> <p>* Patent owner may request  Ministry hearing to vary  terms of the decision  authorizing the exploitation</p>	<p>No provision (only common law and  Official Secrets Act 1972)</p>

Philippines WTO review	National	Public interest, including national security, nutrition, or health National emergency Failure to exploit, or in cases of "public non-commercial use of the patent by the patentee, without satisfactory reason" Anti-competitive practices Refusal to license	No	Yes, but only under Food, Drug and Cosmetic Act and general business confidentiality regulations  No specific provision in patent legislation.  * For agricultural chemical products, the Pesticide Regulation provides data exclusivity for 8 years from data of approval. No other applications may be filed during this time-frame.
Singapore Patent Law, WTO review	International	Failure to exploit domestically* Failure to supply on reasonable terms* Dependent patents**  *These grounds may only be invoked 3 years from grant or 4 years from filing. ** Requires court hearing	Yes, For "services of the Government", national security purposes, public non-commercial use during emergency	Yes Data exclusivity of 5 years under Medicines Act 1998 and Control of Plants Act 1998.  * Stated in WTO interview that later applicants must provide new data even after 5 years.
Sri Lanka WTO review	Unclear: language suggests national exhaustion	No provision		No However, draft legislation will include provisions for data protection. As stated in WTO interview, later applicants will be required to submit new data.
Thailand Patent Law, WTO review	Unclear: National exhaustion implied but not specified.	Failure to exploit domestically* Public demand not being met on reasonable terms* Dependent patents*  * These grounds may only be invoked 3 years from grant or 4 years from filing.	Yes, For "any service for public consumption", national defense, environmental preservation, or to "prevent or relieve" severe food shortages	Yes, under Trade Secrets Act 2002.  No specific provision in patent law.  * Stated in WTO interview that the issue of whether later applicants may rely on previous test data will be determined "on a case by case basis"
Vietnam Patent Law	International (incl. products placed on market under CL Article 52.1(b) Decree	Failure to exploit Public interest, including national security, "prevention and treatment of diseases", or "other urgent needs of society" Refusal to deal	No	Yes, under Decree no. 54/2000/ND-CP

	63-CP)	<p>* No emergency provisions</p> <p>** Under Decree No. 06/2001/ND-CP, CLs may not be applied for until 3 years from grant or 4 years from filing</p>		
Pakistan Patent Law	International	<p>Failure to exploit*</p> <p>* This ground may only be invoked 3 years from grant or 4 years from filing.</p>	<p>Yes,</p> <p>For public interest, including health, nutrition, or national security, and on finding of anticompetitive practices</p> <p>* Patent owner may request hearing to vary terms of the decision authorizing the exploitation</p>	<p>Yes, under Trade Marks Ordinance 2001, Rules of Business 1973, Official Secrets Act 1923, Civil Servants Rules 1964.</p> <p>* According to interpretation stated in WTO interview, later applicants would probably have to provide new data.</p>

Latin America and the Caribbean 1: Patentability and patent systems

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Argentina Patent Law, WTO Review	Law 24.481, 1996	Yes, with mailbox provision	Not excluded  * Combinations of known inventions or mixtures of known products excluded unless non-obvious	Yes, under Undisclosed Information Law No. 24.766, 1996.	Private and non-commercial use, including scientific research Teaching purposes  Other uses broadly interpreted by reproduction of Article 30 text which authorizes the provision of "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."
Barbados Patent Law, WTO Review	Patent Act no. 18/2001	Yes	Not excluded	No	Scientific research
Belize Patent Law, WTO Review	Patent Act Chapter 253/2000 Patents Bill 2000	Yes	Not excluded	No	Experimental purposes
Brazil Patent Law, WTO Review	Industrial Property Law, No. 9.279, 1996 (amended 2001, Law no. 10.196)	Yes, as of 2004 Mailbox provision * Patents have to be passed by Health Ministry	Not excluded	Yes	Experimental use Use related to studies, or scientific/technological research Private and non-commercial use Use of patented self-reproducing biological material
Chile Patent Law,	Law No 19.039, 1991	Yes	New use excluded "except where the qualities	No	Experimental use Non-commercial use

WTO Review	<i>New draft law proposed</i>		of the subject matter are essentially altered or where its use solves a technical problem that did not previously have an equivalent solution"		Teaching purposes
Costa Rica WTO Review	Patent Law No 7979/2000 Law 6867 of 1983 amended 2000	Yes	Not excluded * Combinations of known inventions or mixtures of known products excluded unless non-obvious	Yes	Experimental use Private and non-commercial use
Dominican Republic WTO Review	Law No. 20-00 on Industrial Property, 2000		New use excluded	Yes	Private and non-commercial use Teaching purposes Scientific or academic purposes Use of patented self-reproducing biological material
Guatemala Patent Law, WTO Review	Decree 57/2000	Yes	Not excluded	No	Experimental use Private and non-commercial use Educational purposes Scientific or academic research Use of patented self-reproducing biological material
Honduras Patent Law, WTO Review	Decree 12-99E Industrial Property Law, 2000	Yes	Not excluded	No	Experimental use Scientific research Private and non-commercial use Educational use
Jamaica WTO Review	Draft Patents and Designs Act, 2001	<i>Yes, upon enforcement of draft legislation</i>			
Nicaragua Patent Law, WTO Review	Law on Patents, Utility Models and Industrial Designs, no. 354 2000	Yes	Not excluded	No	Private and non-commercial use Teaching purposes Scientific or academic research Use of patented self-reproducing biological material
Paraguay Patent Law, WTO Review	Patent Law No 1.630/2000	Yes	Not excluded	Yes, but only within 30days before patent expiry	Exclusively non-commercial experimentation Teaching purposes Scientific or academic research
Trinidad and Tobago Patent Law, WTO Review	Patent Act (Consolidation), 1996 (2000)	Yes	Not excluded	No	Experimental use Private and non-commercial use

Uruguay Patent Law, WTO Review	Patent Law No 17.164/1999	Yes	New use and 2nd use excluded	Yes* * However, must be carried out within one year before patent expiry	Private and non-commercial use Educational purposes Scientific or academic research
Bolivia Patent Law, WTO Review	Decision 486 of the Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486  Article 21 states: "Products or processes already patented and included in the state of the art... may not be the subject of new patents on the sole ground of having been put to a use different form that originally contemplated by the initial patent"	No	Experimental use Private and non-commercial use Teaching purposes
Colombia Patent Law, WTO Review	Decision 486 of the Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486	No	Experimental use Private and non-commercial use Teaching purposes
Ecuador Patent Law, WTO Review	Intellectual Property Law, 1998 Decision 486 of the Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486	No	Experimental use Private and non-commercial use Academic purposes
Peru Patent Law, WTO Review	Decree No. 823 on Industrial Property, Decision 486 of Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486	No	Experimental use Private and non-commercial use Teaching purposes
Venezuela Patent Law, WTO Review	Industrial Property Law, 1955 Decision 486 of Andean Community	Yes	New / 2 <sup>nd</sup> use excluded under Decision 486	No	Experimental use Private and non-commercial use Teaching purposes Scientific or academic research  Use of patented self-reproducing

					biological material
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Latin America and the Caribbean 2: Doha flexibilities - PI, CL, GU

Country	Provisions/Mechanism			
Sources consulted	Exhaustion regime	Compulsory license grounds	Government use	Data protection
Argentina Patent Law, WTO Review	International  * Including products placed on market under CL	Failure to exploit* Anti competitive practices, including excessive prices and refusal to supply domestic market on reasonable terms Dependent patents  *This ground may only be invoked after 3 years from grant or 4 years from filing	Yes, For national security or health emergency	Yes, under Undisclosed Information Law No. 24.766, 1996.  No data exclusivity provisions, and according to WTO interview, later applicants may rely on previous test data
Barbados Patent Law	National	Failure to exploit* Dependent patents*  *These grounds may only be invoked after 3 years from grant or 4 years from filing	Yes, For national security, health, nutrition, other public interests, or on finding of anticompetitive practices	Yes, under Protection Against Unfair Competition Act ,1998  According to WTO review later applicants must submit new data
Belize Patent Law, WTO Review	National	Failure to exploit Refusal to license Dependent patents	Yes, For public interest including national security, nutrition or health, or on finding of anticompetitive practices * The Minister must have a hearing with the patent holder	No provision (common law only)  According to WTO interview, this issue will be addressed in a new draft law.

			before deciding	
Brazil Patent Law, WTO Review	National	"Abuse of economic power"* Failure to exploit domestically* Demand not met on reasonable terms* Dependent patents Public interest National emergency  * These grounds may only be invoked after 3 years from grant of patent	No explicit provision	Yes  According to WTO interview, the "general rule" is that later applicants may not rely on previous test data
Chile Patent Law, WTO Review	No explicit provision	"Monopolistic abuse of a patent" (anti-competitive practices)	No explicit provision	Yes, under Health Code, and Law No. 19.653 on administrative probity
Costa Rica WTO Review	International	Failure to exploit* Refusal to license* WTO interview cites the existence of other grounds "according to the criteria set out in Article 31 of the TRIPS Agreement"  * These grounds may only be invoked after 3 years from grant or 4 from application.		Yes, under Law on Undisclosed Information, No. 7975, 2000
Dominican Republic WTO Review	International	Failure to work Public interest, including national emergency or national security Anti-competitive practices Dependent patents		Yes  According to WTO interview, later applicants must submit new test data
Guatemala Patent Law, WTO Review	International	Dependent patents	Yes, For public interest, including national emergency, public health, national security, public non-commercial use, or to remedy anti-competitive practices	Yes  A new law (passed but not yet in force) provides for data exclusivity of 5 years, to meet obligations of CAFTA.
Honduras Patent Law, WTO Review	International	Refusal to license* Dependent patents	Yes, for public interest including	Yes

		* This ground may only be invoked after 3 years from grant or 4 years from filing	national security, public health or nutrition	
Jamaica WTO Review			Yes	No provision (only common law)
Nicaragua Patent Law, WTO Review	International	Dependent patents	Yes, For public interest, national emergency, or to remedy anti-competitive practices	Yes  According to WTO interview, later applicants may only use same data if the information is "obtained lawfully" or if the applicant "had access because of disclosure elsewhere in the world".
Paraguay Patent Law, WTO Review	International	Failure to exploit* Health emergency National defense or security Anti competitive practices, including excessive prices, or failure to supply local market on reasonable terms Dependent patents  *This ground may only be invoked after 3 years from grant or 4 years from filing ** Patent owner or other interested parties may request hearing to vary terms of the license	No explicit provision	No provision  <i>Under discussion for inclusion in draft law</i>
Trinidad and Tobago Patent Law, WTO Review	National	Failure to work* Demand not met on reasonable terms* Anticompetitive practices  * These grounds may only be invoked after 3 years from grant or 4 years from filing	Yes, for public interest	Yes  According to WTO interview, data exclusivity extends for a "reasonable period of time" that is "normally not less than 5 years", subject to judicial review.
Uruguay Patent Law, WTO Review	International	Failure to work* Public interest Anti-competitive practices Dependent patents	Yes, For public utility, national security, public health	Yes, but only general protection under unfair competition provisions of Decree-Law No. 14.910 of

		* This ground may only be invoked after 3 years from grant or 4 years from filing	emergencies	1979.
Bolivia Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anti-competitive practices Public interest National emergency National security  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, under Decision 486  WTO response is unclear regarding use of previous data; states only that all applicants must be treated equal under the law, and that: an authority "would be able to make internal use of any information available to it." in determining "whether the later product complied with the requirements of the legislation"
Colombia Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anti-competitive practices Public interest National emergency National security  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, under Decision 486 and Criminal Code
Ecuador Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Public interest, including national emergency and national security Anti-competitive practices Refusal to license  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, in patent legislation  According to WTO interview, later applicants must submit new data
Peru Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anticompetitive practices Public interest National emergency	No explicit provision	Yes, under Decision 486  According to WTO interview, later applicants may not rely

		National security * These grounds may only be invoked after 3 years from grant or 4 years from filing		on previous test data
Venezuela Patent Law, WTO Review	International	Failure to exploit* Demand not met on reasonable terms* Anti-competitive practices Public interest National emergency National security  * These grounds may only be invoked after 3 years from grant or 4 years from filing	No explicit provision	Yes, under Decision 486.  Further, databases are specifically protected under Law on Copyright

Africa 1: Patentability and patent systems

Country Sources consulted	Applicable patent law	Provisions/Mechanisms			
		Pharmaceutical products	Patentability exceptions - new use or 2 <sup>nd</sup> use patents	Early working exception	Other exceptions
Botswana WTO Review, Other Source °	Intellectual Property Act, 1996	Yes		No	Experimental purposes
Egypt Patent Law	Intellectual Property Law 82, 2002	Yes, post-2005 with mailbox provision	Not excluded	Yes	Scientific research purposes Other broad exceptions: "Any other acts by third parties, provided that they shall not unreasonably hamper the normal exploitation of the patent, and shall not be unreasonably prejudicial to the legitimate interests of the patent owner, taking into consideration the legitimate interests of others"  Also: "Use of the result of propagation material, by farmers on their own holdings for private propagating purposes "
Ghana Patent Law	Patents Act, 2003	Yes		No	Experimental purposes
Kenya Patent Law, WTO Review	Industrial Property Act, 2001	Yes	Not excluded	Yes	Broad provision: "The rights under the patent shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research"
Malawi Patent Law	Patents Act, 1992	Yes	Not excluded.  *But inventions "capable of being used as food or medicine" which are "a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients" are specifically excluded	No	None specified

Mauritius Patent Law	The Patents, Industrial Designs, and Trademark Act No. 25 of 2002	Yes	Not excluded	No	Research and experimental purposes
Morocco Patent Law, WTO Review	Law no. 17-97 on the Protection of Industrial Property, 2000	Yes	Not excluded	No	Experimental purposes Private and non-commercial use
Mozambique Other Source °	Industrial Property Code: Decree No. 18/99, 2004			No	Non-commercial use
Nigeria Patent Law, WTO Review	Patent Law 1971 Draft Patents and Designs Act 2002	Yes	Not excluded	Yes	Scientific research, including "experimentation on the invention to test the invention or improve it" Private and non-commercial use Teaching purposes
South Africa Patent Law, WTO Review	Patents Act 1978, am. 1997 Medicines Act 1997	Yes	2 <sup>nd</sup> medical use allowed	No	No
Sudan Patent Law  <i>Currently in WTO accession process</i>	Patent Act 1971, Patent Regulation 1981  <i>A new draft bill is under consideration.</i>	No  <i>Draft bill will invoke 2016 transition period</i>	Not excluded	No	Implied but not specified; patent rights "shall only extend to acts done for industrial or commercial purposes"
Swaziland Patent Law, WTO notification	Patents, Designs and Trade Marks Act, 1936 (only provides registration for patents filed in UK or South Africa) <i>New draft law: Patents, Utility Models and Industrial Designs Act No. 6 of 1997</i>				

Tanzania Patent Law	Patents Act 1987 (cif 1994)		Not excluded.	No	Patent rights "shall extend only to acts done for industrial or commercial purposes and in particular not to acts done for scientific research"
Tunisia Patent Law, WTO Review	Law No. 2000-84 on Patents	Yes		Yes, but <i>only</i> for "acts necessary for the manufacture of generic drugs"	Private and non-commercial use Experimental purposes
Uganda Patent Law	Patents Act, 1993  <i>New draft law: Industrial Property Bill 2004</i>		Not excluded	No provision in current law  <i>Yes, in draft law</i>	Scientific research  <i>Draft law adds exception for teaching purposes, permits experimental use for commercial purposes, and provides for exportations to other countries with CL authorizations</i>
Zambia Patent Law	Patents Act	Yes	Not excluded  * But specifically excludes any invention which is "capable of being used as food or medicine which is a mixture of known ingredients possessing only the aggregate of the known properties of the ingredients"	No	None specified
Zimbabwe Patent Law	Patents Amendment Act, 2002		Not excluded	Yes, "Test batches" of a patented product may be produced, but not put on the market, 6 months before patent expiry	None specified

Africa 2: Doha flexibilities - PI, CL, GU

Country Sources consulted	Provisions/Mechanism			
	Exhaustion regime	Compulsory license grounds	Government use	Data protection
Botswana WTO Review, Other Source °	National	Failure to supply on reasonable terms	Yes	
Egypt Patent Law	International	<p>Public non-commercial interest, including "preservation of national security, health, environment and food safety"</p> <p>Emergency/extreme urgency</p> <p>"Support of national efforts in vital sectors for economic, social and technological development"</p> <p>Inadequate quantity or quality, or prohibitive prices of patented medicines</p> <p>Medicines "addressing critical cases, or incurable or endemic diseases", or medicine-related inventions</p> <p>Refusal to license on reasonable terms</p> <p>Anti-competitive practices, including "exorbitant prices", failure to supply local market on reasonable terms</p> <p>Dependent patents</p> <p>Failure to exploit domestically*</p> <p>*This ground may only be invoked after 3 years from grant or 4 years from filing</p> <p>** Patent owner may appeal decisions awarding CLs to third parties within one-month of notification of grant</p>	Yes, For national defense or emergency	Yes  * Authorities must protect test data in support of pharmaceuticals and food-related agrochemical products from disclosure and unfair commercial use for a period "until it is no longer confidential, or a period not exceeding five years, whichever comes first"
Ghana Patent Law	International	<p>Anti-competitive practices</p> <p>Refusal to license</p> <p>Failure to exploit*</p>	Yes For public interest, including national security,	Yes, under Protection against Unfair Competition Act, 2000.

		<p>Dependent patents*</p> <p>* These grounds may only be invoked via a request to the courts after 3 years from grant or 4 years from application</p>	<p>nutrition or health</p> <p>* Language unclear on whether prior negotiations with patent holders are required for non-emergency government use</p>	<p>No specific provision in Patents Act.</p>
<p>Kenya Patent Law, WTO review</p>	<p>International</p>	<p>Failure to exploit* Demand not being met on reasonable terms* Dependent patents</p> <p>* These grounds may only be invoked after 3 years from grant or 4 years from application</p>	<p>Yes</p>	<p>Yes, under Pharmacy and Poisons Act and the Pest Control Products Act</p> <p>No time-limit on data exclusivity currently, but an amending provision is under consideration.</p>
<p>Malawi Patent Law, Other source °</p>	<p>Unclear, possibly international</p>	<p>Failure to work* Demand not being met on reasonable terms* Food- and medicine- related commodities</p> <p>*These grounds may only be invoked after 3 years from grant or 4 years from application</p>	<p>Yes, but terms may not be TRIPS-compliant, and may omit authorization for importation or exportation</p>	<p>No specific provision in patent law</p>
<p>Mauritius Patent Law</p>	<p>International</p>	<p>Failure to exploit* Dependent patents</p> <p>*This ground may only be invoked after 3 years from grant or 4 years from application</p>	<p>Yes* For public interest, including national security, nutrition, health, or on finding of anti-competitive practices</p> <p>* A hearing with the patent owner is required before issuing a CL.</p>	<p>Yes, under The Protection Against Unfair Practices Act, 2002.</p> <p>Data exclusivity for "a reasonable period of time" that is "not less than 5 years", subject to Minister's discretion.</p>
<p>Morocco Patent Law, WTO review</p>	<p>National</p>	<p>Failure to work domestically* Domestic market demand not met* Dependent patents*</p> <p>*These grounds may only be invoked after 3 years from grant or 4 years from application</p>	<p>Yes,* For interests of public health where medicine-related inventions are provided in insufficient quality or quantity, or at abnormally high prices</p>	<p>Yes, under various legislation including General Civil Service Act, and Code of Obligations and Contracts</p> <p>No specific provision in</p>

		**Terms of license may be amended by court at request of owner or licensee	* Patents may be exploited <i>ex officio</i> only after 1 year from issue of formal notice to patentee	patent legislation.  According to WTO review: "A second applicant wishing to register the same product as a generic product is permitted to use a simplified procedure, i.e. he is not obliged to repeat all the clinical, pharmacological and toxicological studies, but may refer to the data published in the scientific literature"
Mozambique Other Source °		National emergency/extreme urgency "of either an economic or a social nature" Failure to exploit, demand not being met on reasonable terms Refusal to license	Yes	
Nigeria Patent Law, WTO review	National	Failure to work domestically* Demand not met on reasonable terms* National security* Public health and nutrition* Environmental conservation* Dependent patents*  *All grounds may only be invoked after 4 years from grant of patent ** CLs only allowed for imports or locally produced patented products	Yes, For public interest including national security, nutrition, health or environmental protection, and for emergency purposes	Yes
South Africa Patent Law, WTO review	International	Failure to work domestically* Demand not met on reasonable terms Refusal to license Dependent patent  *This ground may only be invoked after 3 years from grant or 4 years from filing	Yes  *However, requires hearing with patentee beforehand	No specific provision in patent law  General confidentiality provisions in common law, Medicines and Related Substance Control Act No. 101 of 1965, and Fertilizers, Farm Feeds, Agricultural Remedies and Stock Remedies Act No. 36 of 1947
Sudan Patent Law	National under current law	Failure to work domestically* Demand not met on reasonable terms*	Yes, on grounds of national defense, national economy,	No specific provision in patent law

	<i>International, under new draft bill</i>	<p>Refusal to license* Interdependent patents</p> <p>*These grounds may only be invoked after 3 years from grant or 4 years from filing</p> <p>** <i>Draft bill will redefine conditions considered under national emergency to include: public health crises, "lack of pharmaceutical products at affordable prices", and insufficient manufacturing capacity for pharmaceuticals.</i></p>	<p>and public health</p> <p>* CLs may be granted for purposes of importation</p>	
Swaziland Patent Law, WTO notification		Public interest, including national security, nutrition, health	Yes	
Tanzania Patent Law	National	<p>Failure to work domestically* Demand not met on reasonable terms* Refusal to license* Dependent patents Public health or defense</p> <p>*These grounds may only be invoked after 3 years from grant or 4 years from filing</p> <p>** All grounds require court proceedings</p>	<p>Yes,* For vital public interests including national security, health, or development of vital sectors of economy.</p> <p>* "The minister shall take his decision... after a hearing to which the patent owner and any licensee shall be invited". Further, patent owners may appeal, but this "shall not suspend the effects of the decision"</p>	No specific provision in patent law
Tunisia Patent Law, WTO review	International	<p>Failure to work domestically* Market demand not sufficiently met*</p> <p>*These grounds may only be invoked after 3 years from grant or 4 years from filing. Court hearing required.</p>	<p>Yes, "To meet the needs of the national economy" or "to safeguard the environment"* Public health interests, including remedy inadequate quality or quantity or excessively high price of drugs or products</p>	<p>No specific provision in patent law.</p> <p>General protection of undisclosed information is provided by various legislation including Labour Code, Penal Code, and Order of the Minister of Public Health 1996 on</p>

			necessary for the production of drugs. National defense or security  * CL on these grounds may only be imposed one year after initial formal notice	the marketing of medicines for human use.  According to WTO review, "clinical data pertaining to subject-matter of a second application is not required because the molecule has already been analyzed"
Uganda Patent Law	National under current law  <i>International, under draft law</i>	Failure to work domestically* Demand not met on reasonable terms* Refusal to license* Anti-competitive practices  *These grounds may only be invoked after 3 years from grant or 4 years from filing. Court hearing required.  <i>Draft law waives requirement for patent holder permission in cases of national emergency/ extreme urgency, or for anti-competitive practices.</i>	Yes, for vital public interests, including national security, public health, public order and morality	No specific provision in patent law
Zambia Patent Law	No explicit provision	Failure to work domestically* Demand not met on reasonable terms* Refusal to license* "Unfair conditions attached by the patentee... to the purchase, hire, license or use of the patented article"* Unlawfully restrictive contract terms, including provisions that are "in restraint of trade" or are "contrary to public policy"* Food- and medicine- related commodities  *These grounds may only be invoked after 3 years from grant or 4 years from filing, and require court hearing	Yes, for "services of the State"* or during "any period of emergency"**  *Disputes over CL decision for "services of the State" or "terms for the use" of an invention in such service may be referred to the High Court "by any party in the dispute"  ** Unclear as to whether dispute proceedings are required during periods of emergency.	No specific provision in patent law

<p>Zimbabwe Patent Law</p>	<p>International, "if the cost of importing" a product "is less than the cost of purchasing from the patentee"</p>	<p>Abuse or insufficient use of patent rights, including failure to work domestically and demand not met on reasonable terms.* Unlawfully restrictive contract terms, including provisions that are "in restraint of trade" or are "contrary to public policy"* Food- and medicine- related inventions, or "any invention capable of substantially improving the technological, social, and economic development of the country" Dependent patents Anti-competitive practices</p> <p>* For these grounds, a CL must be applied for within 6 months of initial attempt to procure a voluntary license</p>	<p>Yes, For "service of the State",* or during "periods of emergency"</p> <p>* Use for "service of the State" shall be made "upon such terms and conditions as may be agreed upon between the Minister and the patentee" or as determined by dispute resolution under Patents Tribunal.**</p> <p>** This condition seems not to apply during periods of emergency</p>	<p>No provision in patent legislation</p>
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## Regional patent organizations

Regional organization	African Intellectual Property Organization (OAPI)	African Regional Intellectual Property Office (ARIPO)	Andean Community
Membership	16 member states: Benin, Burkina Faso, Cameroon, Central African Republic, Congo, Cote d'Ivoire, Equatorial Guinea, Gabon, Guinea, Guinea Bissau, Mali, Mauritania, Niger, Senegal, Chad, Togo	15 member states: Botswana, Gambia, Ghana, Kenya, Lesotho, Malawi, Mozambique, Namibia, Sierra Leone, Sudan, Swaziland, Tanzania, Uganda, Zambia	5 member states: Bolivia, Colombia, Ecuador, Peru, Venezuela
Applicable treaty instrument	Bangui Agreement 1977, revision of 1999	Harare Protocol, 1982	Andean Community Decision 486
Administration of patent system	Common patent legislation and authority; i.e., single body serving as national patent authority. Filing of application with Organization is equivalent to a national filing in each member state and grant of patent will mean registration of national rights in all members, subject to national legislation.	Filing of one application (designating country in which protection is sought), but no automatic national registration. Members may reject patents granted (6 months from date of receipt from ARIPO) on basis they are contrary to national legislation.	Filing and grant, of applications at individual national patent offices.
Pharmaceutical products	Yes	Yes	Yes
Patentability exclusions	No exclusion	Not explicitly excluded	New and 2 <sup>nd</sup> use patents excluded
Opposition system			
Parallel imports	Appears to regional exhaustion? Relevant provision states that patent rights "do not extend to subject matter brought on to the market on the territory of a Member state by the patent holder or with his consent" - Art 8.1(a)		International
Compulsory licensing	Demand not being met on reasonable terms 1999 Revision – includes failure to exploit and dependent patents		Failure to exploit Public interest Emergency or national security considerations Anti-competitive practice
Limits on export under CL			Yes
Government use	Yes		
Early working	Not provided		Not specifically provided
Patent exceptions – others	Experimental use in the course of scientific and technical research		Private and non-commercial Experimental use Acts carried out exclusively for

			teaching or scientific or academic research
Data protection	Protection dishonest use of confidential test or other data (production of which requires considerable effort) which have been communicated to authorities for the purpose of obtaining market authorization.		Reproduces Article 39.3 wording

° Further information about "other sources" used:

Brunei: Unpublished data obtained from ASEAN IPR Project

Laos: Unpublished data obtained from ASEAN IPR Project

Botswana: Luke D, Musungu S, Nkrumah Y, Rossi F. "Report on the Mission to Assess Options for Accessing Low Cost Anti-retroviral (ARV) Medicines in Southern Africa", 2004.

Mozambique: Luke D, Musungu S, Nkrumah Y, Rossi F. "Report on the Mission to Assess Options for Accessing Low Cost Anti-retroviral (ARV) Medicines in Southern Africa", 2004.

Malawi: Lewis-Lettington R, Banda C. "A Survey of Policy and Practice on the Use of Access to Medicines-Related TRIPS Flexibilities in Malawi", DFID Health Systems Resource Center, Sept. 2004

Internet links:

ASIA

China Patent Law available at: [http://www.sipo.gov.cn/sipo\\_English/flfg/zlflfg/t20020327\\_33872.htm](http://www.sipo.gov.cn/sipo_English/flfg/zlflfg/t20020327_33872.htm)

China: Implementing Regulations available at: [http://www.sipo.gov.cn/sipo\\_English/flfg/zlflfg/t20020327\\_33871.htm](http://www.sipo.gov.cn/sipo_English/flfg/zlflfg/t20020327_33871.htm)

Indonesia Patents Act 2001 available at: <http://www.dgip.go.id>

Singapore Patents Act available at: [http://www.wipo.int/clea/docs\\_new/en/sg/sg013en.html](http://www.wipo.int/clea/docs_new/en/sg/sg013en.html)

Singapore Medicines Act available at: [http://www.wipo.int/clea/docs\\_new/en/sg/sg019en.html](http://www.wipo.int/clea/docs_new/en/sg/sg019en.html)

Singapore Control of Plants Act available at: [http://www.wipo.int/clea/docs\\_new/en/sg/sg018en.html](http://www.wipo.int/clea/docs_new/en/sg/sg018en.html)

Thailand Patent Act available at: [http://www.wipo.int/clea/docs\\_new/en/th/th007en.html](http://www.wipo.int/clea/docs_new/en/th/th007en.html)

Thailand Trade Secrets Act, 1992, available at: [http://www.wipo.int/clea/docs\\_new/en/th/th018en.html](http://www.wipo.int/clea/docs_new/en/th/th018en.html)

India Patent Act and amendments available at: <http://ipindia.nic.in/ipr/patent/patents.htm>

## LATIN AMERICA/ CARIBBEAN

Barbados Patents Act, 2001-18 available at: [http://www.wipo.int/clea/docs\\_new/en/bb/bb016en.html](http://www.wipo.int/clea/docs_new/en/bb/bb016en.html)

Nicaragua Law no. 354, 2000 available at: [http://www.wipo.int/clea/docs\\_new/en/ni/ni011en.html](http://www.wipo.int/clea/docs_new/en/ni/ni011en.html)

Guatemala Decree 57-2000 available (Spanish only) at: [http://www.wipo.int/clea/docs\\_new/es/gt/gt001es.html](http://www.wipo.int/clea/docs_new/es/gt/gt001es.html)

Argentina Law 24.481 available (Spanish only) at: [http://www.wipo.int/clea/docs\\_new/es/ar/ar002es.html](http://www.wipo.int/clea/docs_new/es/ar/ar002es.html)

Belize Patents Bill 2000 available at: [http://www.wipo.int/clea/docs\\_new/en/bz/bz003en.html](http://www.wipo.int/clea/docs_new/en/bz/bz003en.html)

Brazil Law no. 9.279 available at: [http://www.wipo.int/clea/docs\\_new/en/br/br003en.html](http://www.wipo.int/clea/docs_new/en/br/br003en.html)

Brazil Law no. 10.196 available at: [http://www.wipo.int/clea/docs\\_new/en/br/br035en.html](http://www.wipo.int/clea/docs_new/en/br/br035en.html)

Ecuador Intellectual Property Law 1998 available at: [http://www.wipo.int/clea/docs\\_new/en/ec/ec001en.html](http://www.wipo.int/clea/docs_new/en/ec/ec001en.html)

Guatemala Decree no. 57-2000 available (Spanish only) at: [http://www.wipo.int/clea/docs\\_new/es/gt/gt001es.html](http://www.wipo.int/clea/docs_new/es/gt/gt001es.html)

Honduras Decree 12-99E available (Spanish only) at: [http://www.sice.oas.org/int\\_prop/nat\\_leg/Honduras/indice.asp](http://www.sice.oas.org/int_prop/nat_leg/Honduras/indice.asp)

Nicaragua Law no. 354, 2000 available at: [http://www.wipo.int/clea/docs\\_new/en/ni/ni011en.html](http://www.wipo.int/clea/docs_new/en/ni/ni011en.html)

Paraguay Law No. 1.630/2000 available at: [http://www.mic.gov.py/propiedad\\_intelectual/](http://www.mic.gov.py/propiedad_intelectual/)

Trinidad and Tobago Patent Act available at: [http://www.wipo.int/clea/docs\\_new/en/tt/tt036en.html](http://www.wipo.int/clea/docs_new/en/tt/tt036en.html)

Uruguay Patent Law 17.164 available at: [http://www.sice.oas.org/int\\_prop/nat\\_leg/Uruguay/L17164Be.asp](http://www.sice.oas.org/int_prop/nat_leg/Uruguay/L17164Be.asp)

Venezuela Industrial Property Law, 1955 available at: [http://www.sice.oas.org/int\\_prop/nat\\_leg/Venezuela/lips.asp](http://www.sice.oas.org/int_prop/nat_leg/Venezuela/lips.asp)

Decision 486 of Andean community available at: <http://www.comunidadandina.org/ingles/treaties/dec/D486e.htm>

## AFRICA

Egypt Intellectual Property Law 82, 2002 available at: [http://www.egypo.gov.eg/inner/english/Laws\\_1.html](http://www.egypo.gov.eg/inner/english/Laws_1.html)

Morocco Law No. 17-97 available at: <http://www.ompic.org.ma/english/presentation/lois.html>

South Africa Patents Act available at: [http://www.wipo.int/clea/docs\\_new/en/za/za026en.html](http://www.wipo.int/clea/docs_new/en/za/za026en.html)

Tunisia Law no. 2000-84 available at: [http://www.wipo.int/clea/docs\\_new/en/tn/tn001en.html](http://www.wipo.int/clea/docs_new/en/tn/tn001en.html)