Compulsory Licensing and Government Use Authorization

Asian Regional Course for Judges on Intellectual Property and Public Health 2021

Compulsory License and Government Use

A compulsory license is an authorization given by a national authority to a natural or legal person for the exploitation of the subject matter protected by a patent, without the consent of the patent holder. A compulsory license may be issued in order to attain various public policy objectives, including the protection of public health.

A government use authorization is an act by the government authorizing a government department to exploit a patented invention without the consent of the patent holder by itself or through a contractor, public or private.

The grant of compulsory license or government use is subject to the compliance with certain conditions under Article 31 of the TRIPS Agreement.

Article 31

> Where the law of a Member allows for other use of a subject matter of a patent without the authorization of the right holder, including use by the government or third parties authorized by the government, the following provisions shall be respected:
>
> (a) authorization of such use shall be considered on its individual merits;
>
> (b) such use may only be permitted, if prior to such use, the proposed user has made efforts to obtain the authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time. This requirement may be waived by Member 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;
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> (c) the scope and duration of such use shall be limited to the purpose for which it was authorized, and in the case of semi-conductor technology shall only be for public non-commercial use or to remedy a practice determined after judicial or administrative process to be anti-competitive;
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> (d) such use shall be non-exclusive;
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> (e) such use shall be non-assignable, except with that part of the enterprise or goodwill which enjoys such use;
>
> (f) any such use shall be authorized predominantly for the supply of the domestic market of the Member authorizing such use;
>
> (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 which led to it cease to exist and are unlikely to recur. The competent authority shall have the authority to review, upon motivated request, the continued existence of these circumstances;

(h) the right holder shall be paid adequate remuneration in the circumstances of such case, taking into account the economic value of the authorization;

(i) the legal validity of any decision relating to the authorization of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(j) any decision relating to the remuneration provided in respect of such use shall be subject to judicial review or other independent review by a distinct higher authority in that Member;

(k) Members are not obliged to apply the conditions set forth in subparagraphs (b) and (f) where such use is permitted to remedy a practice determined after judicial or administrative process to be anti-competitive. The need to correct anti-competitive 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 which led to such authorization are likely to recur;

(l) where such use is authorized to permit the exploitation of a patent ("the second patent") which cannot be exploited without infringing another patent ("the first patent"), the following additional conditions shall apply:

(i) the invention claimed in the second patent shall involve an important technical advance of considerable economic significance in relation to the invention claimed in the first patent;

(ii) the owner of the first patent shall be entitled to a cross-licence on reasonable terms to use the invention claimed in the second patent; and

(iii) the use authorized in respect of the first patent shall be non-assignable except with the assignment of the second patent.

The concerns of developing countries about the possible impact of patents in the pharmaceutical sector led the WTO to adopt, in November 2001, the Doha Declaration on the TRIPS Agreement and Public Health, which confirmed, *inter alia,* that the granting of compulsory licenses was one of the clearly admitted flexibilities under the TRIPS Agreement and that WTO Members were free to determine the reasons for the granting of such licenses.

Thus, while article 31 refers to some specific grounds for issuing compulsory license or government use authorization (national emergency, anti-competitive practices, public non-commercial use, dependent patents), it does not limit the ability of a country to allow for issuing compulsory licenses to remedy a different situation. It does not limit in any way the capacity of governments to grant compulsory licenses or undertake government use.

The TRIPS Agreement also does not limit the purpose for which a compulsory license or government use authorization may be granted. Hence, it can be conferred to import or locally produce a patented product. In some cases, such as compulsory licenses to remedy abuse of a market dominant position or to protect public health, importation

may be the only or the main way to comply with the purposes for which the authorization is given.

Compulsory licenses and government use can be utilized in relation to any of the rights conferred by a patent, including the manufacture, importation or exportation of patent-protected products, as well as in relation to all kinds of products including medicines, vaccines and diagnostic kits. Pursuant to the Doha Declaration an amendment to the TRIPS Agreement has been adopted through Article 31 *bis* to establish a system that seeks to allow exportation under a compulsory license to countries with non-existent or insufficient pharmaceutical manufacturing capacity. However, the system requires the observance of a number of procedural and administrative requirements which has made it cumbersome and economically unviable for generic manufacturers who could produce and export relevant patented medicines under such a system.

Some Possible Grounds for Compulsory License/Government Use

National Emergency

One of the grounds under which a compulsory license can be issued is a situation of national emergency or circumstance of extreme urgency. The Doha Declaration has confirmed that WTO members have the full freedom to determine what would constitute a such a situation or circumstance. This determination is not subject to any notification to the WTO or assessment by WTO members. There is also no need for a formal declaration of a situation of national emergency. The Doha Declaration has also confirmed that a public health crisis, including HIV/AIDS, TB, malaria and other epidemics can constitute such a situation or circumstance. The reference to epidemics suggests that a public health emergency may not be a short-term problem, but a long-lasting situation. Therefore, a compulsory license or government use authorization can be issued in respect of health technologies to deal with an emergency and the same can be maintained without any time constraints as long as the underlying situation persists.

When a compulsory license or government use authorization is issued on grounds of a situation of national emergency or circumstance of extreme urgency, the requirement to undertake prior negotiation with the patent holder for a voluntary license is waived.

In many cases of national emergency or circumstance of extreme urgency government use may be the simplest and fastest way of addressing a public need as the decision can be taken by the government *ex officio* without the need for a request for a compulsory license from a third party. Even the nature of the use must be non-commercial, this does not prevent the government from appointing a commercial contractor or agent to exploit the patent on behalf of the government. The administrative act authorizing government use of a patent does not need to specify a determined quantity or value of the product to be produced or imported.

Public Interest or Public Health Need

One of the grounds on which a compulsory license or government use authorization may be generally available under national patent laws, subject to the conditions under article 31 of TRIPS, is to make such authorization available for reasons of public interest (as under the German patent law), or to satisfy the objectives of public health (as under the French law). Thus, a compulsory license may be available, e.g., where the patented product on a health technology (such as medicine or vaccine) is not available at affordable price.

Refusal to Deal or Grant Voluntary License

A compulsory license may be granted in cases where the patent owner refuses to grant a voluntary license on reasonable commercial terms. Such compulsory licenses may be justified on the basis of the nature of the patented product being an essential facility.

Lack of Local Working of the Patented Invention

A compulsory license may also be issued on the ground of lack of local working of the patented invention. Historically, the requirement of local working of a patented invention has been a foundational principle of the patent system, and is of particular significance for developing countries to ensure industrial manufacturing of the patented invention in the country rather than mere importation of the product by the patent holder, to enable technological learning in the process. Provisions allowing grant of compulsory licenses for inadequate local working under the laws of Argentina and Brazil were subjected to a WTO dispute based on a complaint by the US which was subsequently settled after mutual consultations between the parties without any determination of TRIPS inconsistency of such provisions.

Conditions for the Grant of Compulsory License/Government Use

- Compulsory license or government use authorization should be granted taking into consideration the individual merits of the proposed use. Hence, such decisions cannot involve sets of patents defined by its subject matter, title-holder or otherwise. However, this would not be an impediment to establish parameters for the grant of compulsory licenses regarding certain categories of product that are needed to address a specific need such as controlling a specific disease or an epidemic. Likewise, a compulsory license can be extended to all patents relating to a particular product or process (e.g., the patent on the compound chemical formula, as well as patents on compositions, use, etc. of the compound).

- Prior to granting a compulsory license, the proposed licensee should have made efforts to obtain authorization (voluntary license) from the right holder on reasonable terms and conditions. The compulsory license can be granted if such efforts have not been successful within a reasonable period of time. These requirements, however, will not apply where the compulsory license is issued in situations of national emergency or circumstances of extreme urgency, as nationally determined, public non-commercial use (government use), and for licenses granted to remedy anti-competitive practices. In such cases, the right holder must be informed as soon as reasonably practicable about the grant of a compulsory license. The evaluation of whether a voluntary license has been requested or offered on reasonable commercial terms will lie with the competent authority for the granting of the compulsory license. Any decision in this regard should be taken in line

with commercial practice while taking into account the public health objectives that could be attained with the compulsory license. Some national laws establish the period within which the patent owner is bound to indicate its acceptance or refusal to grant a voluntary license on reasonable commercial terms.

- The scope and duration of the authorization must be limited to the purpose for which it was authorized. However, national may allow the scope of a compulsory license to be conceived in broad terms and allow for the exercise of the rights of making, using, offering for sale, selling, or importing for these purposes the covered product(s) for the full term of the patent. It may also limit the license to some of such rights or to a period shorter than the life of the patent, or to some claims or fields of use of the patent.
- Beneficiaries of a compulsory license can also export the products produced thereunder (provided that it is predominantly used for supplying the domestic market of the country where the compulsory license has been granted). The limitation on exportation does not apply where the compulsory license is granted to remedy anti-competitive practices.
- The termination of a compulsory license is subject to establishing that the circumstances which led to the grant of the compulsory license have ceased to exist, and even so, the legitimate interests of the beneficiary of the compulsory license is adequately protected. This could be interpreted as meaning that the licensee could not be deprived of her right to the license once she has made serious preparations for putting the invention into use, or established productive or marketing capabilities.
- The right holder is required to be paid adequate remuneration for the compulsory license. Governments have considerable discretion in defining the level and mode of payment, subject to the general rule that the remuneration is adequate in the circumstances of each case, taking into account the economic value of the authorization in conformity with Article 31(h) of the TRIPS Agreement. The level of remuneration, however, should be reasonable and not frustrate the purpose of a compulsory license that is intended to address a public health need, such as ensuring access to pharmaceutical products at the lowest possible price. The remuneration should be determined based on the circumstance of the licensee, the country where it will operate, as well as the purpose of the license. The economic value of the license for determining the remuneration can be based on the size of the market to be supplied (predominantly the domestic market), the newness or maturity of the technology, its rate of obsolescence, the degree of competition by substitute product, and the scope of the patent. In determining the adequacy of the remuneration, factors such as subsidies or other contributions received by the patent holder to develop the invention, the degree to which the development cost has been amortized, and the R&D expenses actually incurred by the patent holder can be taken into account. Based on these factors, royalty guidelines of some governments as well as by the UNDP suggest a royalty rate along a scale base on the price of the generic product. For example, the UNDP guidelines recommend a base royalty rate of 4 per cent of the price of the generic product, with a 2 per cent increase or decrease, depending upon such factors as the degree to which a medicine is particularly innovative or the role of governments in paying for research and development.
- The requirement of a remuneration is waived for a country importing under a compulsory license under article 31 *bis* if the remuneration is paid in the exporting country.
- The right holder should also have the opportunity to seek review by judicial or other "distinct higher authority", of the legal validity of any decision relating to the granting of a

compulsory license. However, such a right will not prevent a country from giving immediate effect to a decision conferring a compulsory license, and thus an injunction on implementation of the compulsory license may be denied. Moreover, the review can be limited to the legal validity of the decision granting compulsory license, but not the terms of the license or the remuneration determined.

National Implementation of Compulsory License/Government Use provisions

Country	Compulsory License		Government Use	
	Grounds	Conditions	Grounds	Conditions
India	Reasonable requirements of the public with regard to the patented invention not satisfied. This includes the following Prejudice to any existing trade or industry or development of new trade or industry Demand for patented article not being met adequately or on reasonable term Export market for patented article manufactured in India not being supplied or developed Prejudice to the establishment or development of commercial activities in India Exclusive grant back conditions,	License can be issued after 3 years from the grant of patent Applicant must demonstrate efforts made to obtain voluntary license on reasonable terms and that negotiations did not succeed within reasonable period (not ordinarily exceeding 6 months) Decision on grant of compulsory license is to taken following notice and hearing of both parties Remuneration must be reasonable having regard to nature of invention, expenses incurred by patentee in making or developing the invention, obtaining and maintaining the patent, and other factors	National emergency Extreme urgency Public non-commercial use	Any time after grant of patent A compulsory license may be granted to any interested person pursuant to a declaration by the government of the necessity for issuing a compulsory license All conditions relating to compulsory license on application by third parties apply, including for remuneration. However, the requirement of notice and hearing of the applicant for license and the patent holder can be waived where this is deemed necessary, including for public health crises relating to HIV/AIDS, TB, malaria or other epidemics.

	coercive package licensing, restraining challenges to patent validity Inadequate working of the patent in the terrirtory of India on a commercial scale Hindrance to local working through importation Patented invention is not available to the public at reasonably affordable price Patented invention is not worked in the country			
Indonesia	Patent holder does not manufacture the product or use the process in Indonesia Exercise of the patent right in a manner detrimental to public interest	License on ground of failure to manufacture in Indonesia can be issued three years after the patent has been granted. License can be issued on other grounds at any time after grant of patent Prior unsuccessful negotiation of voluntary license on reasonable terms within reasonable period (12 months) Terms and remuneration to be set in Ministerial Decree granting compulsory license	Patent may be exploited by government where an urgent public interest need is determined to exist by the government. This includes exploitation of patents in the field of pharmaceutical products needed to eliminate widespread disease. The government may authorize a third party to exploit the patent.	Terms and remuneration to be set in a Presidential Decree
Malaysia	No production of the patented product or application of the patented	Compulsory license can be granted after 3 years from the date of grant or 4 years	A government agency or a third person designated by the Minister may exploit the patented invention without the agreement of the owner	Government use shall be subject to payment of adequate remuneration taking into account the economic value of the authorization, and in case of

	process in Malaysia without any legitimate reason No product produced under the patent for sale in the domestic market , or they are sold at unreasonably high prices or do not meet public demand without any legitimate reason	from the date of filing of patent, whichever is later Prior unsuccessful negotiation of voluntary license on reasonable terms within reasonable period (period not explained in statute) Terms and remuneration to be set in the decision. No statutory guidance on factors to consider in determining remuneration	of patent, based on such authorization by the Minister, on grounds of national emergency or public interest requirement as determined by the government, particularly including, among others, health. Authorization can also be given upon determination of anti-competitive exploitation by the patent owner or his licensee.	determination of anti-competitive practice, the need to correct anti-competitive practices.
Pakistan	To prevent abuses which might arise from exercise of rights conferred by a patent, e.g., failure to work.	Compulsory license can be granted after 3 years from the date of grant or 4 years from the date of filing of patent, whichever is later Terms and remuneration to be set in the decision. No statutory guidance on factors to consider in determining remuneration	A government agency or a third person designated by the Federal government may exploit the patented invention without the agreement of the owner of patent, based on such authorization by the Federal government, on grounds of public interest requirement, including, in particular, health, to remedy anti-competitive exploitation of the invention by the patented invention, to remedy refusal to grant voluntary license on reasonable terms, and non-exploitation of the patent in a manner that does not contribute to technological innovation and transfer and dissemination of technology. The requirement of prior negotiation of voluntary license on reasonable terms within reasonable period of time is waived in cases of national emergency, circumstance of extreme urgency, public non-commercial use, and determination of anti-competitive practices.	Government use shall be subject to payment of adequate remuneration taking into account the economic value of the authorization, and in case of determination of anti-competitive practice, the need to correct anti-competitive practices.

The Philippine	Determination of anti-competitive exploitation of the patent Public non-commercial use of the patent by the patentee without adequate reason Non-working of the patented invention in the country on a commercial scale: importation is deemed to constitute working of the patent	Compulsory license on ground of non-working of the invention can be granted after 3 years from the date of grant or 4 years from the date of filing of patent, whichever is later. Compulsory license on other grounds can be granted at any time Requirement of prior unsuccessful negotiation of voluntary license on reasonable terms within a reasonable time applies. The period of time to be considered reasonable is not statutorily explained. The requirement of prior negotiations do not apply to compulsory licenses on ground of anti-competitive practice determination, national emergency or extreme urgency, public non-commercial use, and where demand of patented drugs and medicines in the Philippines is not met adequately and on reasonable terms. Compulsory license shall be subject to payment of adequate remuneration taking into account the economic value of the authorization, and in case of determination of anti-competitive practice, the need to correct anti-competitive practices.	Government or third party authorized by government may make public non-commercial use of the patent on grounds of -National emergency or circumstances of extreme urgency -Requirement of public interest, including, in particular, health -Demand for patented drugs and medicines not being met adequately and on reasonable terms as determined by Department of Health	Decision to set terms and adequate remuneration
Sri Lanka	No grounds specified. The law allows any person to apply for obtaining a non-voluntary license to exploit a patent.	Applicant has to demonstrate unsuccessful prior negotiation within a reasonable period of time to obtain voluntary license on reasonable terms. Compulsory license shall be subject to payment of adequate remuneration taking into account the	Compulsory license may be issued to the government. Possible grounds include national emergency, extreme urgency, public non-commercial use for purposes including health, determination of	Compulsory license shall be subject to payment of adequate remuneration taking into account the economic value of the authorization, and in case of determination of anti-competitive practice, the need to correct anti-competitive practices.

		economic value of the authorization, and in case of determination of anti-competitive practice, the need to correct anti-competitive practices.	anti-competitive exploitation of patent	The requirement of prior negotiation may be waived in cases of national emergency, extreme urgency or in case of public non-commercial use for purposes including health
Thailand	Non production of the patented product or non-application of patented process in the country without legitimate reasons No product under the patent is sold in the domestic market, or is sold at unreasonably high prices, or does not meet the public demand without any legitimate reason	Compulsory license can be granted after 3 years from the date of grant or 4 years from the date of filing of patent, whichever is later Applicant must demonstrate unsuccessful prior negotiation for voluntary licensing on reasonable terms within a reasonable time Compulsory license is subject to adequate remuneration to be determined by agreement between applicant and patentee or determined by the authority	Any ministry, bureau or department of the government may by themselves or through others exploit the patent To carry out any service for public consumption To prevent or relieve a severe shortage food, drugs, etc.	Subject to payment of remuneration
Viet Nam	Failure to manufacture patented product or apply patented process in the country Failure to reach voluntary licensing agreement within reasonable time Anti-competitive practices banned by competition law	Compulsory license on failure to manufacture or apply the patent will be applicable after the expiry of 4 years from date of filing or 3 years from date of grant of patent, whichever is earlier Subject to payment of compensation depending on the economic value of the right and the compensation bracket set by the government	Public non-commercial purposes, or for disease prevention, treatment. Relevant State agencies may request for license to Ministry of Science and Technology	Subject to payment of compensation depending on the economic value of the right and the compensation bracket set by the government

Examples of Compluslory License/Government Use Authorizations on Pharmaceutical Patents

Compulsory Licenses/ Government Use Authorisation					
Country	Drug	CL/GU	Year (granted/filed)	Ground	Royalty
Brazil	Efavirenz	GU	2007	Public Interest	1.50%
Chile	Hepatitis C medicines	CL (Pending)	2018		
China	FDC of lamivudine/stavudine/nevirapine	CL	2005	Non-availability in the country	
Colombia	Imatinib	CL (Pending)	2014		
Colombia	Hepatitis C medicines	CL (Pending)	2017		
Congo	ARVs	GU	2007		
Congo	ARVs	GU	2014		
Ecuador	Ritonavir	CL	2010	Public Interest	4%
Ecuador	Abacavir/lamivudine	CL	2012	Public Interest	5%

Ecuador	Ritonavir	CL	2013	Public Interest	4%
Ecuador	Abacavir/lamivudine	CL	2013	Public Interest	7%
Ecuador	Abacavir/lamivudine	CL	2013	Public Interest	7%
Ecuador	Etoricoxib	CL	2014	Public Interest	0.2% - 0.4%
Ecuador	Mycofenolate sodium	CL	2014	Public Interest	2%
Ecuador	Sunitinib	CL	2014	Public Interest	
Ecuador	Certolizumab	CL	2014	Public Interest	
Gabon	ARVs	GU	2005		
Gabon	ARVs	GU	2006		
Gabon	ARVs	GU	2013		
Georgia	ARVs	GU	2006		
Germany	Raltegravir	CL	2016	Urgent need, public interest	
Ghana	ARVs	GU	2005	Health Emergency	
Guatemala	ARVs	GU	2005		
Guinea	ARVs	GU	2004		
Honduras	ARVs	GU	2005		
Honduras	ARVs	GU	2008		
Honduras	ARVs	CL	2008		

India	Sorafenib tosylate	CL	2012	Availability and Affordability	7%
Indonesia	Nevirapine, lamivudine	GU	2004	Health Emergency	0.50%
Indonesia	Abacavir, didanosine, efavirenz, lopinavir/ritonavir, tenofovir, tenofovir/emtricitabine, tenofovir/emtricitabine/efavirenz	GU	2012	Health Emergency	0.50%
Israel	Lopinavir/ritonavir	GU	2020	National security, essential services and supplies	
Italy	Imipenem/cilastatin	CL	2005	Abuse of dominant position	
Italy	Finasteride	CL	2007	Abuse of dominant position	0%
Ivory Coast	ARVs	GU	2004		
Ivory Coast	Lamivudine, lamivudine/zidovudine, lamivudine/zidovudine/nevirapine, lamivudine/stavudine, lamivudine/stavudine/nevirapine, didanosine, efavirenz, indinavir	GU	2007		
Ivory Coast	ARVs	GU	2007		
Liberia	ARVs	GU	2005		
Malaysia	zidovudine, zidovudine/lamivudine	GU	2003		4%

Malaysia	sofosbuvir	GU	2017		
Mongolia	ARVs	GU	2007		
Mozambique	Efavirenz	GU	2005		
Myanmar	ARVs	GU	2005		
Pakistan	ARVs	GU	2006		
Peru	Atazanavir	CL (Pending)	2014		
Philippines	ARVs	GU	2005		
Philippines	ARVs	GU	2008		
Romania	Hepatitis C medicines	CL (Pending)	2015		
Russia	Lenalidomide	CL	2018	3%	
Russia	Sunitinib	CL	2019	10%	
Sudan	ARVs	GU	2008		
Swaziland	Nevirapine, zidovudine	GU	2005		
Sao Tome and Principe	ARVs	GU	2006		
Chinese Taipei	Oseltamivir	GU	2005		

Tajikistan	Lamivudine, stavudine, zidovudine, nevirapine, efavirenz, tenofovir, didanosine, lopinavir, saquinavir, ritonavir, nelfinavir, abacavir	GU	2005		
Thailand	Efavirenz	GU	2006	0.50%	
Thailand	Lopinavir	GU	2007	0.50%	
Thailand	Clopidogrel	GU	2007	0.50%	
Thailand	Letrozole	GU	2008		
Thailand	Docetaxel	GU	2008		
Thailand	Erlotinib	GU	2008		
Thailand	Efavirenz/emtricitabine/tenofovir, lamivudine/zidovudine/efavirenz	GU	2008		
UK (Sctoland)	Pertuzumab	CL (Pending)	2018		
Ukraine	ARVs	CL	2004		
UK	Trastuzumab/emtansine	CL (Pending)	2015		
USA	Naloxone	CL (Pending)	2018		
Zambia	Lamivudine/stavudine/nevirapine	CL	2004	2.50%	

Zimbabwe	ARVs	GU	2002		
Zimbabwe	ARVs	GU	2003		
Zimbabwe	ARVs	CL	2004		
Zimbabwe	ARVs	GU	2005		

Exercise

- Do you agree with the following statements
  - The TRIPS Agreement lays down specific grounds under which compulsory license may be granted
  - Medicines produced in a country under a compulsory license cannot be exported to other countries
  - A government use authorization must specify a determined quantity or value of the product to be produced or imported.
  - A compulsory license can be issued on a patented medicine on the ground of high (unaffordable) price.
  - A government use authorization can only be used by a department or agency of the government.
- In which cases can the requirement to undertake prior negotiation for a voluntary license before the grant of a compulsory license be waived?
- For how long can a compulsory license or government use authorization be granted in a public health emergency situation?
- In which situations do you think a government use authorization can be more useful than a compulsory license to a third party?
- In your opinion, how should the remuneration to be paid to the patent holder for a compulsory license or government use authorization be determined?
- Can a preliminary injunction be granted on the implementation of a compulsory license or government use authorization if the same is legally challenged?