Procedure file

Basic information

AVC - Assent procedure (historic) Decision	2006/0060(AVC)	Procedure completed
Intellectual property: agreement on trade-related aspects of rights TRIPS, done at Geneva on 6 December 2005, amending protocol by the WTO Subject 3.50.15 Intellectual property, copyright 6.20.01 Agreements and relations in the context of the World Trade Organization (WTO)		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	INTA International Trade	ALDE SUSTA Gianluca	27/02/2007
	Committee for opinion	Rapporteur for opinion	Appointed
	DEVE Development	The committee decided not to give an opinion.	
	ENVI Environment, Public Health and Food Safety	The committee decided not to give an opinion.	
	JURI Legal Affairs	PSE ROCARD Michel	29/01/2007
Council of the European Union	Council configuration	Meeting	Date
	General Affairs	2830	19/11/2007
European Commission	Commission DG	Commissioner	
	Trade	MANDELSON Peter	

Key events

27/04/2006	Initial legislative proposal published	COM(2006)0175	Summary
20/06/2006	Legislative proposal published	08934/2006	Summary
14/12/2006	Committee referral announced in Parliament		
22/10/2007	Vote in committee		Summary
22/10/2007	Committee report tabled for plenary, 1st reading/single reading	A6-0403/2007	
23/10/2007	Debate in Parliament		
24/10/2007	Results of vote in Parliament		

24/10/2007	Decision by Parliament	T6-0459/2007	Summary
19/11/2007	Act adopted by Council after consultation of Parliament		
19/11/2007	End of procedure in Parliament		
29/11/2007	Final act published in Official Journal		

Technical information

Procedure reference	2006/0060(AVC)
Procedure type	AVC - Assent procedure (historic)
Procedure subtype	International agreement
Legislative instrument	Decision
Legal basis	EC Treaty (after Amsterdam) EC 133; EC Treaty (after Amsterdam) EC 300-p2/3-a1/2
Stage reached in procedure	Procedure completed
Committee dossier	INTA/6/36159

Documentation gateway

Initial legislative proposal		COM(2006)0175	27/04/2006	EC	Summary
Legislative proposal		08934/2006	20/06/2006	CSL	Summary
Committee draft report		PE390.562	08/06/2007	EP	
Committee opinion	JURI	PE390.411	28/06/2007	EP	
Committee report tabled for plenary, 1st reading/single reading		A6-0403/2007	22/10/2007	EP	
Text adopted by Parliament, 1st reading/single reading		T6-0459/2007	24/10/2007	EP	Summary

Additional information

National parliaments	IPEX
European Commission	EUR-Lex

Final act

Decision 2007/768
OJ L 311 29.11.2007, p. 0035 Summary

Intellectual property: agreement on trade-related aspects of rights TRIPS, done at Geneva on 6 December 2005, amending protocol by the WTO

PURPOSE: to accept, on behalf of the EU, the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

PROPOSED ACT: Council Decision.

CONTENT: the purpose of this Council Decision is to accept, on behalf of the EU an amendment to the WTO TRIPS Agreement. It is the first ever such amendment to TRIPS and has come about due to the chronic shortages of pharmaceutical products in certain developing countries. Initially agreed in 2003 in the form of a ? provisional waiver? there was an understanding that the ?waiver? should at a later stage become an amendment to the TRIPS Agreement in the form of a Protocol in order to make it more permanent.

In amending TRIPS, WTO Members have committed themselves to exporting patented medicines to third countries with no manufacturing capacity in the pharmaceutical sector, by making use of compulsory licences. At the same time, substantial safeguards against trade diversion and re-importation have been set out. A statement, issued by the chair of the General Council describes Members? ?shared understanding? on how the Decision is interpreted and implemented. The Decision may only be used in good faith and is to be used for the purpose of public health problems only. It may not be used for industrial or commercial policy objectives. The statement also notes that the medicines must not get into the wrong hands.

To guarantee that the system is aimed at the neediest, developed countries in the WTO ? including all of the EU Member States ? have taken a commitment not to use the system as importers. Similarly, high income developing countries have made a statement that they would not use the system except in exceptional circumstances. The system does, however, allow all WTO members to act as exporters.

To recall, the Commission in 2004 proposed the adoption of a Regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems. The purpose of this Regulation is to give practical meaning to the implementation of the system described above. Its adoption is imminent. (Please refer to 2004/0258(COD)).

The European Commission, in accordance with Article 133 of the EU Treaty, negotiated on behalf of the European Community for the adoption of the Protocol. Further, upon adoption of the Regulation on compulsory licensing of patents, the Community will have an exclusive competence over this matter and Member States will, as a result, not be able to accept the Protocol individually. The President of the Council will be authorised to designate the person empowered to deposit the instrument of acceptance of the Protocol with the WTO Director General. The Protocol will be binding on its Member States. For these reasons the Commission proposes to the Council that it adopt the proposed Decision.

Intellectual property: agreement on trade-related aspects of rights TRIPS, done at Geneva on 6 December 2005, amending protocol by the WTO

The Council adopted common guidelines on the draft decision aiming to accept, on behalf of the EU, the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

This amendment would make permanent a waiver decision on compulsory licences originally adopted in 2003 and will allow any WTO Member to export pharmaceutical products made under a compulsory licence for the purpose of supplying developing countries with insufficient manufacturing capacities. It will ensure a legally secure, predictable, effective and sustainable solution for those countries which want to use the system to get affordable medicines they need.

Intellectual property: agreement on trade-related aspects of rights TRIPS, done at Geneva on 6 December 2005, amending protocol by the WTO

The Committee on International Trade adopted the recommendation drafted by Gianluca SUSTA (ALDE, IT) requesting Parliament?s assent on the proposal for a Council decision on the acceptance, on behalf of the European Community, of the Protocol the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which aims to facilitate access to affordable medicines for populations in developing countries in their efforts to control diseases of public health importance, including HIV, tuberculosis and malaria. The report was adopted by 24 votes for, none against and 3 abstentions.

MEPs were awaiting Council undertakings on when developing countries may use the flexibility provided for under the TRIPS agreement to produce or import generic substitutes for patented medicines.

In its resolution of 12 July 2007 (see RSP/2007/2595), the European Parliament called on the Council to adopt a Joint Policy Statement with Parliament to the effect that the Member States remain free to use all exceptions from the TRIPS Agreement under their domestic patent laws to authorise production and export "to address public health needs in importing Members". Parliament also urged the Council to restrict the Commission's negotiating mandate to ensure that it does not negotiate pharmaceutical-related "TRIPS-plus" provisions affecting public health and access to medicines in Economic Partnership Agreements with the African, Caribbean and Pacific states and other future and regional agreements with developing countries.

In the absence of a response from the Portuguese Presidency to the European Parliament?s requests, MEPs postponed the vote on the assent procedure on three occasions.

The Portuguese Presidency sent a draft declaration to MEPs stating that the European Parliament's requests in particular regarding technological transfer and research were being taken into account.The Presidency should make a statement in Plenary highlighting the additional measures to be taken to improve access to medicine.

The Council has also decided not to include "TRIPS-plus" provisions in the Economic Partnership Agreements with the ACP states and other future and regional agreements with developing countries.

Intellectual property: agreement on trade-related aspects of rights TRIPS, done at Geneva on 6 December 2005, amending protocol by the WTO

The European Parliament adopted a resolution drafted by Gianluca SUSTA (ALDE, IT) on the proposal for a Council decision on the acceptance, on behalf of the European Community, of the Protocol the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) which aims to facilitate access to affordable medicines for populations in developing countries in their efforts to control diseases of public health importance, including HIV, tuberculosis and malaria. It gave its assent to the acceptance of the protocol.

Intellectual property: agreement on trade-related aspects of rights TRIPS, done at Geneva on 6 December 2005, amending protocol by the WTO

PURPOSE: the acceptance, on behalf of the European Community, of the Protocol amending the Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement, done at Geneva on 6 December 2005.

LEGISLATIVE ACT: Council Decision on the acceptance, on behalf of the European Community, of the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.

CONTENT: the Council adopted a Council Decision on the acceptance, on behalf of the European Community, of the Protocol amending the World Trade Organisation?s (WTO) agreement on the Trade-Related Aspects of Intellectual Property Rights (TRIPS), in order to improve access to pharmaceutical products for least developed countries.

This Protocol, adopted in Geneva in December 2005, aims to help developing countries in the fight against HIV/AIDS, Tuberculosis and Malaria by providing access to vital medicines at the lowest possible prices. This Protocol, which will enter into force as soon as it has been approved by two-thirds of the WTO members, will allow WTO members to export patent medicines to third countries which do not have the production capacity in the pharmaceutical sector, by making the waiver decision permanent for the compulsory licences initially adopted in 2003.

The amendment will bring to a close a process initiated by the Declaration on the TRIPS Agreement and Public Health presented by the Ministers during the Ministerial Conference of the WTO held in Doha in November 2001.