ЕВРОПЕЙСКИ ПАРЛАМЕНТ

2004 *2009*

Документ за разглеждане в заседание

A6-0403/2007

22.10.2007

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ПРЕПОРЪКА

относно предложението за решение на Съвета относно приемане, от името на Европейската общност, на протокола за изменение на Споразумението ТРИПС, съставен в Женева на 6 декември 2005 г. (8934/2006 – C6-0359/2006 – 2006/0060(AVC))

Комисия по международна търговия

Докладчик: Gianluca Susta

Легенда на използваните знаци

*	Процедура на консултация *мнозинство от подадените гласове*
**I	Процедура на сътрудничество (първо четене) *мнозинство от подадените гласове*
**II	Процедура на сътрудничество (второ четене) *мнозинство от подадените гласове за одобряване на общата позиция* *мнозинство от всички членове на Парламента за отхвърляне или изменение на общата позиция*
***	Одобрение *мнозинство от всички членове на Парламента, освен в случаите по членове 105, 107, 161 и 300 от Договора за ЕО и член 7 от Договора за ЕС*
***I	Процедура на съвместно вземане на решение (първо четене) *мнозинство от подадените гласове*
***II	Процедура на съвместно вземане на решение (второ четене) *мнозинство от подадените гласове за одобряване на общата позиция* *мнозинство от всички членове на Парламента за отхвърляне или изменение на общата позиция*
***III	Процедура на съвместно вземане на решение (трето четене) *мнозинство от подадените гласове за одобрение на съвместния проект*

(Посочената процедура се базира на правното основание, предложено от Комисията.)

СЪДЪРЖАНИЕ

Страница

ПРОЕКТ НА ЗАКОНОДАТЕЛНА РЕЗОЛЮЦИЯ НА ЕВРОПЕЙСКИЯ ПАРЛАМЕНТ

относно предложението за решение на Съвета относно приемане, от името на Европейската общност, на протокола за изменение на Споразумението ТРИПС, съставен в Женева на 6 декември 2005 г.
(8934/2006 – C6-0359/2006 – 2006/0060(AVC))

(Процедура на одобрение)

Европейският парламент,

– като взе предвид предложението за решение на Съвета,

– като взе предвид протокола за изменение на Споразумението ТРИПС, съставен в Женева на 6 декември 2005 г.,

– като взе предвид искането за одобрение, представено от Съвета съгласно член 300, параграф 3, алинея втора, заедно с член 133, параграф 5и член 300, параграф 2, алинея първа, изречение първо от Договора за ЕО (C6-0359/2006),

– като взе предвид член 75 и член 83, параграф 7 от своя правилник,

– като взе предвид препоръката на комисия по международна търговия и становището на комисия по правни въпроси (A6-0403/2007),

1. дава своето одобрение за изменение на споразумението;

2. възлага на своя председател да предаде позицията на Парламента на Съвета и Комисията, както и на правителствата и на парламентите на държавите-членки.

EXPLANATORY STATEMENT

Background

The TRIPS Agreement adopted in 1994 extends the basic legal principles of the World Trade Organisation to the area of intellectual property and increases minimum protection standards for intellectual property.

The significant costs associated with the introduction of higher intellectual property protection standards in developing countries generated intense discussion, particularly as to whether increased patent protection under the rules of the TRIPS Agreement impeded access to affordable medicines in poor countries.

The WTO Ministerial Conference held in Doha in 2001 culminated in the adoption of the 'Doha Declaration', which stressed that the TRIPS Agreement could and should be interpreted and implemented in a manner supportive of WTO members' right to protect public health and, in particular, to promote access to medicines for all.

In addition to affirming existing 'flexibilities' in the TRIPS Agreement, the declaration recognised that countries with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing and instructed the Council for TRIPS to find an 'expeditious solution' to this problem.

After long and difficult negotiations, the Council for TRIPS reached an agreement which was adopted by a decision of the general Council of the WTO on 30 August 2003.

This decision spells out the circumstances under which countries with insufficient or no manufacturing capacity in the pharmaceutical sector can make effective use of compulsory licensing and import generic versions of drugs still under patent, subject to a large number of conditions in both the exporting and importing country.

To render the mechanism established in the decision operational, implementation at national or - as in the case of the European Union - regional level was required.

To that end, in October 2004 the Commission presented, under the co-decision procedure, a proposal for a regulation of the European Parliament and of the Council on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems.

The proposal contained a large number of charges and conditions in addition to the substantial number already envisaged in the WTO decision. The rapporteur, Mr Van Hecke, accordingly directed his efforts to ensuring that the text transposed the WTO decision as faithfully as possible, by seeking to remove all additional conditions which would have rendered the - already extremely complex - mechanism even more complicated, confusing and, in effect, unusable.

On 12 July 2005 the Committee on International Trade adopted the report by a very large

majority, with a couple of abstentions.

In the run-up to the forthcoming WTO ministerial conference in Hong Kong, strengthened by the solid report he had received from the committee, Mr Van Hecke, instead of seeking the report's immediate adoption in plenary, launched, in close cooperation with the shadow rapporteurs of the other political groups, an informal trialogue with the Commission and the Council with a view to achieving interinstitutional agreement on first reading before the Hong Kong conference and thus strengthening the European Union's position in the multilateral negotiations.

In the course of the trialogue, the rapporteur negotiated a compromise on the assumption that the regulation represented only a temporary solution and that the European Parliament would be consulted again when a permanent amendment was adopted, which still seemed to be a distant prospect at that time.

In its report, our committee had specifically asked the Commission to present, at three-year intervals after the entry into force of the regulation, a report on its operation, in order to monitor the use made of the mechanism it introduced.

The text adopted by the Committee on International Trade was more ambitious than the final compromise text, particularly with regard to technology transfer and capacity building in the developing countries, the remuneration of right holders, the simplified and accelerated procedure and the non-suspensory effect of appeals.

Nevertheless, Parliament's input greatly improved the Commission's original proposal.

The compromise reached by the three institutions was eventually adopted by Parliament on first reading on 1 December 2005 and by the Council on 27 April 2006, thus transposing the temporary waiver into Community law.

On 6 December 2005, a few days after Parliament had adopted the regulation, the WTO General Council adopted a decision on a permanent amendment to the TRIPS Agreement.

It was in the light of this permanent amendment that the Commission submitted the present proposal for a Council decision accepting the Protocol amending the TRIPS Agreement.

The European Parliament has to decide whether to give its assent to this proposal.

If the protocol is accepted by the European Union, the European Parliament will be consulted again, under the codecision procedure, on the proposal to amend the regulation transposing the protocol into Community law.

Substance of the proposal

Your rapporteur considers that the issue at stake goes far beyond simply assenting to an international protocol. The problem addressed is of huge political and humanitarian importance: access to medicines in the developing and less-developed countries where they are most needed, but which cannot pay the high prices set by the pharmaceutical industry.

This being so, your rapporteur wishes to make the following comments:

(1) The protocol has been submitted to all WTO members and is open for acceptance until 1 December 2007 or such later date as may be decided by the ministerial conference.

The protocol will enter into force upon acceptance by two-thirds of WTO members. Pending such acceptance, the waiver (the 2003 decision) will continue to be the legal basis.

The European Union has already transposed the waiver into law, and consequently delaying acceptance of the protocol until after 1 December would not create a legal vacuum, but could allow time to assess the effectiveness of the proposed mechanism to be assessed and whether it should be made permanent.

(2) To date, only seven countries (out of the 150 WTO members), or 4.7% of the membership, have accepted the permanent amendment of the TRIPS agreement: the United States, Switzerland, El Salvador, the Republic of Korea, Norway, India and the Philippines.

If the European Union did not accept the protocol by 1 December 2007, it would not be alone, and it is by no means certain that the objective of acceptance by two thirds of the membership (100 countries) could be achieved by that date.

(3) The amendment did not have to be a mere 'cut and paste' of the WTO decision of 30 August 2003, but the opposition of some WTO member states made it impossible to adopt an amendment allowing easier access to medicines.

(4) The WTO decision of 30 August 2003 was supposed to provide an 'expeditious solution' to the crisis in access to medicines faced by developing countries with little manufacturing capacity, but there is no proof of the decision's efficacy.

To date, only Canada, Norway, China, Korea, India and the European Union have adopted legislation transposing the decision into their own law. In the last four years, not one importing country has notified the Council for TRIPS that it intends to use the mechanism to import cheaper life-saving medicine.

Conclusions

It seems, therefore, that the mechanism is not particularly effective, and does not provide a satisfactory means of resolving the problem of accessing medicines at affordable prices.

The European Parliament can now decide whether to:

- give its assent,
- withhold its assent, or
- postpone its assent.

One of the questions raised is whether it would be preferable to ascertain the effectiveness of the mechanism introduced by the 2003 decision and carry out a review of the use made of the

flexibilities offered by the TRIPS Agreement before making it permanent.

Postponing its assent would enable the European Parliament to ascertain whether at least two thirds of Member States accepted the protocol by 1 December and, if not, to consider whether, in the near future, the European Union ought to launch an initiative at the WTO to revise the decision with a view to making it a more genuinely effective instrument; ascertain the effectiveness of the mechanism; and ascertain whether the bilateral agreements currently being negotiated by the Commission (in particular, the economic partnership agreements with the ACP countries and other agreements negotiated with less-developed countries) contain higher levels of intellectual property protection than those contained in the TRIPS Agreement.

This would also enable the European Union to make every effort, in the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property set up by the WHO in 2006, to encourage the use of the flexibilities legally provided for under the TRIPS agreement.

However, in view of the fact that, in the present circumstances, it would probably be very difficult to renegotiate the protocol, your rapporteur considers that the European Parliament could give its assent if it received a firm Council commitment to:

- State that the mechanism created by the WTO Decision of 30 August 2003 and the Protocol to the TRIPS Agreement represents, at best, only a small part of the solution to the problem of access to medicines at affordable prices.

- Adopt a Joint Policy Statement with the European Parliament to the effect that EU Member States are free to use the Article 30 exception provision of the TRIPS Agreement under their domestic patent law to authorise production and export 'to address public health needs in importing Members', and mandate the European Commission to refrain from taking action to interfere with these proceedings.

- Mandate the European Commission
  - not to negotiate pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines in the Economic Partnership Agreements (EPAs) with the ACP countries and other future bilateral and regional agreements with poor developing countries
  - to refrain from requesting adherence to or acceptance of the obligations of the Patent Cooperation treaty and the Patent Law Treaty, to refrain from incorporating the terms of Directive 2004/48/EC on the enforcement of intellectual property rights and to not introduce disciplines such as nonoriginal database protection in the EPAs with the ACP countries.

- State that the European Union supports the developing countries which use the so-called flexibilities built into the TRIPS Agreement in order to be able to provide essential medicines at affordable prices under their domestic public health programs.

- Mandate the European Commission to explore new solutions such as 'pool procurement strategies' which could be used by countries or groups of countries to find viable and long-lasting solutions to the problem of access to medicines at affordable prices and stimulate

direct investment in local production facilities within a region.

- Mandate the European Commission to pro-actively support the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property process at the WHO.

- Recognise that the European Union must take additional measures as a matter of urgency with a view to encouraging the transfer of technology, research, capacity strengthening, regional supply systems and help with registration, in order to facilitate and increase the production of pharmaceutical products by the developing countries themselves. The EU must commit to a specified level of funding to upgrade or construct pharmaceutical production facilities owned by local persons in developing (including Least Developed) Countries, and increase its aggregate funding to public private partnerships pursuing research and development of medicines of special relevance to developing countries.

28.6.2007

OPINION OF THE COMMITTEE ON LEGAL AFFAIRS

for the Committee on International Trade

on the proposal for a 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
(8934/2006 – C6-0359/2006 – 2006/0060(AVC))

Draftsman: Michel Rocard

AVC

SHORT JUSTIFICATION

The Committee on Legal Affairs was asked to draw up an opinion for the Committee on International Trade, the committee responsible, on the proposal for a 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.

Even before it has available the studies and research that would enable it to assess the issue, the Committee on Legal Affairs would like to make the following observations:

- in 2005 the European Parliament, represented on this subject at that time by the rapporteur Johan Van Hecke, took part in working out the compromise which it is now asked to make definitive, but requested that, before the compromise was adopted, the temporary mechanism envisaged should be evaluated and that Parliament should be consulted again after the evaluation. The compromise was indeed adopted, but none of this was done;

- we are being asked to approve the proposal although there is no report officially ascertaining the actual usefulness of the WTO decision taken in August 2003;

- since the WTO's adoption of the Protocol on 6 December 2005 - now more than 16 months ago - only 7 of the 150 countries concerned have explicitly accepted the definitive amendment of the TRIPS Agreement, namely the United States, Switzerland, Salvador, Korea, Norway, India and the Philippines, which is astonishingly few;

- over the past three and a half years no importing country has informed the TRIPS Council that it would like to use the mechanism to import less expensive life-saving medicines.

Before any detailed study is made, these purely procedural observations raise major doubts

about the relevance of the proposal made

The Committee on Legal Affairs has therefore decided to address the following conclusions to the Committee on International Trade:

- regrets that the compulsory licensing provisions do not improve the prospects for cheaper drugs for poor countries as much as can be justified in humanitarian terms;

- recognises that it will be several years before pharmaceutical product patents in India, only available since 2005, become subject to the requirements of the compulsory licensing provisions, and that those requirements will only apply to new, patented drugs;

- notes that Regulation (EC) No 816/20061 contains the same provisions, which are extended to more countries than in the TRIPS amendment;

- stresses the need for close co-operation with the Committee on International Trade in its further analysis of the implications of this issue and for dialogue with the Council and the Commission on improvements to the current system.

The Committee on Legal Affairs has nevertheless decided to call on the Committee on International Trade, as the committee responsible, to give assent, in due course, to the proposal for a Council decision on the acceptance, on behalf of the European Communities, of the Protocol amending the TRIPS Agreement, done at Geneva on 6 December 2005.

[1] Regulation (EC) No 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems (OJ L 157, 9.6.2006, p. *1)*

ПРОЦЕДУРА

Заглавие	Протокол за изменение на Споразумението за свързаните с търговията аспекти на правата върху интелектуалната собственост (ТРИПС)			
Позовавания	08934/2006 - C6-0359/2006 - COM(2006)0175 - 2006/0060(AVC)			
Дата на искане на одобрение от ЕП	6.12.2006			
Водеща комисия Дата на обявяване в заседание	INTA 14.12.2006			
Подпомагаща(и) комисия(и) Дата на обявяване в заседание	DEVE 14.12.2006	ENVI 14.12.2006	JURI 14.12.2006	
Неизказано становище Дата на решението	DEVE 10.9.2007	ENVI 14.6.2006		
Докладчик(ци) Дата на назначаване	Gianluca Susta 27.2.2007			
Заместен(и) докладчик(ци)	Johan Van Hecke			
Разглеждане в комисия	8.5.2007	28.6.2007	17.7.2007	12.9.2007
	9.10.2007			
Дата на приемане	22.10.2007			
Резултат от окончателното гласуване	+: –: 0:	24 0 3		
Членове, присъствали на окончателното гласуване	Kader Arif, Francisco Assis, Françoise Castex, Christofer Fjellner, Béla Glattfelder, Ignasi Guardans Cambó, Sajjad Karim, Alain Lipietz, Marusya Ivanova Lyubcheva, Erika Mann, Helmuth Markov, Vural Öger, Georgios Papastamkos, Godelieve Quisthoudt-Rowohl, Tokia Saïfi, Gianluca Susta, Corien Wortmann-Kool, Zbigniew Zaleski			
Заместник(ци), присъствал(и) на окончателното гласуване	Vittorio Agnoletto, Vasco Graça Moura, Małgorzata Handzlik, Glenys Kinnock, Javier Moreno Sánchez, Ivo Strejček			
Заместник(ци) (чл. 178, пар. 2), присъствал(и) на окончателното гласуване	Den Dover, Thijs Berman, Milan Gaľa			
Дата на внасяне	22.10.2007			