EIROPAS PARLAMENTS

2004 *2009*

Juridiskā komiteja

2004/0258(COD)

7.6.2005

ATZINUMS

Sniegusi Juridiskā komiteja

Starptautiskās tirdzniecības komitejai

par priekšlikumu Eiropas Parlamenta un Padomes regulai par patentu obligāto licencēšanu attiecībā uz farmaceitisko produktu ražošanu eksportam uz valstīm, kurās ir sabiedrības veselības aizsardzības problēmas
(COM(2004)0737 – C6-0168/2004 – 2004/0258(COD))

Atzinumu sagatavoja: *Giuseppe Gargani*

PA_Leg

ĪSS PAMATOJUMS

The aim of the regulation proposed by the Commission is to enable manufacturers of generic pharmaceutical products to produce and sell patented pharmaceutical products intended for export to countries in need of such products which either have no manufacturing capacity, or are not self-sufficient, in the relevant sector.

The regulation aims to implement at Community level the WTO General Council decision of 30 August 2003 on the implementation of paragraph 6 of the Declaration on the TRIPs agreement and public health.

By waiving WTO members' obligations under Article 31(f) of the WTO agreement on Trade Related Aspects of Intellectual Property Rights (the TRIPS agreement), this decision allows WTO members to grant compulsory licences for the production and sale of patented pharmaceutical products intended for export to third countries with insufficient or no manufacturing capacity in the pharmaceutical sector.

Uniform implementation of the decision within the Community is needed to ensure that the conditions for the granting of compulsory licences for export are the same in all EU Member States, to avoid distortion of competition for operators in the EU single market and to apply uniform rules to prevent re-importation into the territory of the European Union of pharmaceutical products manufactured under compulsory licences.

The European Union, therefore, proposes to take a stand as one of the international players with the greatest commitment to ensuring that the citizens of the most disadvantaged countries have access to pharmaceutical products at lower prices.

In view of the objectives set forth by the Commission, your rapporteur can only warmly welcome this proposal for a regulation.

However, it should be remembered that the measures contained in the proposal in question constitute, objectively speaking, a reduction in the protection usually accorded to intellectual property rights through the TRIPS agreement.

Consequently, while fully supporting the principle of solidarity with the disadvantaged which underlies the proposal, it is perfectly reasonable to allow patent holders the opportunity to be involved in the procedure laid down for the granting of compulsory licences for the manufacture and sale of pharmaceuticals intended for export to WTO countries with public health problems.

The amendments tabled by your rapporteur aim, therefore, to protect the legitimate economic, industrial and commercial interests of pharmaceutical patent holders. This would be achieved by giving them the right to submit comments to the competent national authority in order to ensure, by providing for both parties to have a say in the proceedings, that the decision taken minimises any loss of rights in relation to intellectual property. Provision is made also for the right holder to be involved in any proceedings to ascertain whether there has been an infringement of the ban on re-importing into the European market pharmaceutical products

manufactured under a compulsory licence.

Finally, your rapporteur has sought to avoid giving manufacturers of generic pharmaceuticals under compulsory licences an unfair competitive advantage. Article 16 of the proposal refers to two possible procedures which may be used to enable importing countries to control the quality of the pharmaceuticals exported: a marketing authorisation for the European market (under Article 6 of Directive 2001/83/EC) or the scientific opinion procedure (under Article 58 of Regulation (EC) No 726/2004). In both cases, provision is made for derogations from the usual data protection and caducity rules.

However, in the case of marketing authorisation, this procedure would allow the authorised person to enter the EU market on conditions in which he would not otherwise be allowed to do so. Even on the understanding that such authorisation was granted only for export purposes, it would have the effect of reducing legal certainty and creating an unfair advantage for manufacturers of generic pharmaceuticals who, at the end of the period laid down for the protection of data relating to the patented product, could obtain marketing authorisation for the EU market before they could otherwise expect to do so.

The solution proposed by your rapporteur, therefore, is to drop the marketing authorisation procedure, given that the scientific opinion procedure guarantees the possibility of controlling the quality of pharmaceutical products intended for export.

GROZĪJUMI

Juridiskā komiteja aicina par jautājumu atbildīgo Juridisko komiteju savā ziņojumā iekļaut šādus grozījumus:

Komisijas ierosinātais teksts[1]	Parlamenta izdarītie grozījumi
Grozījums Nr. 1 8. panta 5. punkta 2. daļa	
Interneta adresi nosūta kompetentajai iestādei.	*Tīmekļa vietnes* adresi nosūta kompetentajai iestādei ***un tiesību subjektam***.
Pamatojums	
The other party concerned, i.e. the right holder, should have access to this information.	

[1] OV vēl nav publicēts.

Grozījums Nr. 2
8.a pants (jauns)

8.a pants

1. Pieteikuma iesniedzējs viena mēneša laikā pēc kompetentajai valsts iestādei iesniegtā obligātās licences pieteikuma paziņo tiesību subjektam par šo pieteikumu.

2. Pieteikuma iesniedzējs informē kompetento iestādi par šo paziņojumu. Ja pieteikuma iesniedzējs neinformē tiesību subjektu, obligātās licences piešķiršanas procedūru aptur.

3. Tiesību subjekts var iejaukties obligātās licences piešķiršanas procedūrā:

(a) iesniedzot savus komentārus par 7. pantā minēto pierādījumu esamību un faktiskajiem apstākļiem;

(b) paziņojot savu viedokli par noteikumiem un nosacījumiem, kas nosaka obligātās licences piešķiršanu;

(c) iesniedzot savus komentārus par atbilstību 8. panta 2., 3., 6. un 9. punktā minētajiem nosacījumiem;

(d) iesniedzot priekšlikumus un komentārus attiecībā uz 8. panta 4. punktā minētajām prasībām par saskaņā ar obligāto licenci ražoto produktu marķējumu, apzīmējumiem un iepakojumu.

Pamatojums

Granting a compulsory licence involves a significant curtailment of intellectual property rights. For that reason, it is essential to have a system that allows both sides to be heard and enables the right holder to participate in the procedure brought before the competent national authority. This will enable him to protect his legitimate rights by submitting his own observations on the terms and conditions for the grant of the compulsory licence.

Grozījumu iesniedza *Marie Panayotopoulos-Cassiotou*

Grozījums Nr. 3
10. panta 1. punkta e) apakšpunkts

(e) licences derīguma termiņš;	(e) licences derīguma termiņš ***un izsniegšanas nosacījumi***;

Pamatojums

In order to be consistent with Recital 7 which states that 'compulsory licences issued under this regulation should therefore impose clear conditions upon the licensee as regards the acts covered by the licence'.

Grozījums Nr. 4
12. panta 2.a punkts (jauns)

	2.a Par produktu aizturēšanu vai ražošanas apturēšanu attiecīgās dalībvalsts kompetentā iestāde nekavējoties informē tiesību subjektu. Tiesību subjekts var sniegt kompetentajai iestādei par produktiem jebkuru informāciju, kuru uzskata par vajadzīgu.

Pamatojums

Enabling the right holder to supply the relevant information could be extremely helpful for the national authority responsible for monitoring infringements of the ban on reimporting products into the Community. Moreover, the right holder is directly damaged by any fraudulent use of the compulsory licence.

Grozījumu iesniedza *Marie Panayotopoulos-Cassiotou*

Grozījums Nr. 5
14. panta 3. punkts

3. Pēc licences izbeigšanas ***saprātīgā laika posmā*** licences īpašnieks nodrošina, lai jebkuru produktu, kas ir viņa īpašumā, uzraudzībā, varā vai kontrolē, uz sava rēķina novirzītu uz tām valstīm, kam tas ir nepieciešami, vai citādi, kā izlēmusi kompetentā iestāde, apspriežoties ar tiesību subjektu.	3. Pēc licences izbeigšanas ***kompetentajai iestādei ir tiesības noteikt saprātīgu laika posmu, kurā*** licences īpašnieks nodrošina, lai jebkuru produktu, kas ir viņa īpašumā, uzraudzībā, varā vai kontrolē, uz sava rēķina novirzītu uz tām valstīm, kam tas ir nepieciešami, vai citādi, kā izlēmusi kompetentā iestāde, apspriežoties ar tiesību subjektu.

Pamatojums

Given that the competent authority is entitled to terminate a compulsory licence, it must also be able to determine the period of time within which the licensee shall arrange for any product in his possession, custody, power or control to be redirected.

Grozījums Nr. 6
16. panta 1. punkts

Ja obligātās licences pieteikums attiecas uz zālēm, attiecība uz kurām atļauja piešķirta saskaņā ar Direktīvas 2001/83/EK 6. pantu, Eiropas Parlamenta un Padomes Regulas (EK) Nr. 726/2004 [1] 24. panta 4. un 5. punkta un 14. panta 4. un 5. punkta noteikumi nav spēkā.	***svītrots***
Šī punkta attiecināšanas nolūkā un, atkāpjoties no Direktīvas 2001/83/EC 10. panta 1. punkta, pieteikuma iesniedzējam nav jāuzrāda pirmsklīnisks tests un klīnisku izmēģinājumu rezultāti, ja viņš var pierādīt, ka attiecīgais produkts ir patentētas zāles, par kurām ir vai nav piešķirta atļauja saskaņā ar minētās direktīvas 6. pantu vai saskaņā Regulas (EK) Nr. 726/2004 3. pantu.	

[1] OV L 136, 30.4.2004, 1. lpp.

Pamatojums

The proposed provision aims to guarantee the quality of the products in question for the importing country. However, allowing derogations from the rules on data protection and caducity in connection with the market authorisation procedure could give an unfair competitive advantage to manufacturers of generic pharmaceuticals on the European market. By removing the reference to market authorisation, derogations would only be possible in connection with the scientific opinion procedure referred to in Article 58 of Regulation 726/2004/EC, which fully meets the purpose of ensuring the quality of products.

PROCEDŪRA

Virsraksts	Priekšlikums Eiropas Parlamenta un Padomes regulai par patentu obligāto licencēšanu attiecībā uz farmaceitisko produktu ražošanu eksportam uz valstīm, kurās ir sabiedrības veselības aizsardzības problēmas
Atsauces	COM(2004)0737 – C6-0168/2004 – 2004/0258(COD)
Atbildīgā komiteja	INTA
Komiteja, kurai lūgts sniegt atzinumu Datums, kad paziņoja plenārsēdē	JURI 27.1.2005
Ciešāka sadarbība	nē
Atzinumu sagatavoja: Iecelšanas datums	*Giuseppe Gargani* 20.1.2005
Izskatīšana komitejā	6.6.2005
Grozījumu pieņemšanas datums	6.6.2005
Galīgā balsojuma rezultāti	par: 12 pret: 7 atturas: 0
Deputāti, kas bija klāt galīgajā balsojumā	*Maria Berger, Monica Frassoni, Giuseppe Gargani, Piia-Noora Kauppi, Kurt Lechner, Klaus-Heiner Lehne, Antonio López-Istúriz White, Antonio Masip Hidalgo, Aloyzas Sakalas, Francesco Enrico Speroni, Diana Wallis, Rainer Wieland, Nicola Zingaretti, Jaroslav Zvěřina, Tadeusz Zwiefka*
Aizstājēji, kas bija klāt galīgajā balsojumā	*Brian Crowley, Jean-Paul Gauzès, Evelin Lichtenberger, Manuel Medina Ortega, Marie Panayotopoulos-Cassiotou, József Szájer*
Aizstājēji (178. panta 2. punkts), kas bija klāt galīgajā balsojumā	