EUROPEAN PARLIAMENT

2004 *2009*

Committee on Legal Affairs

2004/0258(COD)

7.6.2005

OPINION

of the Committee on Legal Affairs

for the Committee on International Trade

on the proposal for a European Parliament and Council regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems
(COM(2004)0737 – C6-0168/2004 – 2004/0258(COD))

Draftsman: Giuseppe Gargani

PA_Leg

SHORT JUSTIFICATION

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.

AMENDMENTS

The Committee on Legal Affairs calls on the Committee on International Trade, as the committee responsible, to incorporate the following amendments in its report:

Text proposed by the Commission[1]	Amendments by Parliament
Amendment 1 Article 8, paragraph 5, subparagraph 2	
The website address shall be communicated to the competent authority.	The website address shall be communicated to the competent authority ***and to the right holder***.
Justification	
The other party concerned, i.e. the right holder, should have access to this information.	
Amendment 2 Article 8 a (new)	

[1] Not yet published in OJ.

	Article 8a
	1. Within a month of applying to the competent national authority for a compulsory licence, the applicant shall notify the right holder of that application.
	2. The notification shall be communicated to the competent authority by the applicant. If the applicant fails to notify the right holder, the procedure for granting the compulsory licence shall be suspended.
	3. The right holder may intervene in the procedure for granting the compulsory licence in order to:
	(a) submit his own comments concerning the existence of the evidence and the factual circumstances referred to in Article 7;
	(b) state his opinion on the terms and conditions governing the grant of the compulsory licence;
	(c) submit his own comments concerning compliance with the conditions laid down in Article 8 (2),(3),(6) and (9);
	(d) submit proposals and comments concerning the requirements laid down in Article 8(4) on the labelling, marking and packaging of products manufactured under a compulsory licence.

Justification

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.

Amendment by Marie Panayotopoulos-Cassiotou

Amendment 3
Article 10, paragraph 1, point (e)

(e) the duration of the licence	(e) the duration of the licence ***and the conditions for the issue thereof***;

Justification

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'.

Amendment 4
Article 12, paragraph 2 a (new)

	2a. The right holder shall be informed without delay, by the competent authority of the Member State concerned, of the suspended release or detention of the products. He may supply that authority with any information which he deems appropriate regarding the products.

Justification

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.

Amendment by Marie Panayotopoulos-Cassiotou

Amendment 5
Article 14, paragraph 3

3. ***Within a reasonable time following termination of the licence,*** the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to countries in need or otherwise as prescribed by the competent authority in consultation with the right holder.	3. ***Following termination of the licence, the competent authority shall be entitled to establish a reasonable period of time within which*** the licensee shall arrange for any product in his possession, custody, power or control to be redirected at his expense to countries in need or otherwise as prescribed by the competent authority in consultation with the right holder.

Justification

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.

Amendment 6
Article 16, paragraph 1

Where the application for a compulsory licence concerns a medicinal product authorised in accordance with Article 6 of Directive 2001/83/EC, the provisions of Article 24(4) and (5) and of Article 14(4) and (5) of Regulation (EC) No 726/2004 of the European Parliament and the Council[1] shall not apply.	***deleted***
For the purpose of the application of this paragraph, and by way of derogation from Article 10(1) of Directive 2001/83/EC, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the product concerned is a generic of a reference medicinal product which is or has been authorised under Article 6 of that Directive or under Article 3 of Regulation (EC) No 726/2004.	

[1] OJ L 136 of 30.4.2004, p.1

Justification

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.

PROCEDURE

Title	Proposal for a European Parliament and Council regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems
References	COM(2004)0737 – C6-0168/2004 – 2004/0258(COD)
Committee responsible	INTA
Committee asked for its opinion Date announced in plenary	JURI 27.1.2005
Enhanced cooperation	no
Draftsman Date appointed	Giuseppe Gargani 20.1.2005
Discussed in committee	6.6.2005
Date amendments adopted	6.6.2005
Result of final vote	for: 12 against: 7 abstentions: 0
Members present for the final vote	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
Substitutes present for the final vote	Brian Crowley, Jean-Paul Gauzès, Evelin Lichtenberger, Manuel Medina Ortega, Marie Panayotopoulos-Cassiotou, József Szájer
Substitutes under Rule 178(2) present for the final vote	