

Policy of the European Commission on Intellectual Property Matters

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Selected matters

- Patents
 - Regulation on compulsory licensing
- Trademarks
 - Amendment of the Fee Regulation
- Design
 - Amendment of the Design Directive (spare parts)
- Copyright
 - Collective management

Regulation on compulsory licensing

- Proposal for a regulation on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems
2004/0258 COM of 29 October 2004
- May become adopted in **October/November 2005** for the entering into force on the 20th day following its publication

Background

- 14 November 2001
 - Doha Declaration on the TRIPS Agreement and public health
 - Recognizing the right to grant compulsory licenses
- 30 August 2003
 - Decision of WTO General Council on the implementation of paragraph 6 of the Doha declaration
 - Waive certain conditions concerning the grant of compulsory licenses, Art. 31(f) TRIPS
 - Foresee an amendment of TRIPS to replace the decision

Why Community legislation?

- Active role of the Community
- Uniform rules within the Community
 - Avoid distortion of trade in the internal market
 - Prevent re-importation
- Regulation ensures direct and immediate application in each member state without need for separate national implementation

The proposal

- Patents and SPC's
- Manufacture and sales of pharmaceutical products
- Intended for export to eligible WTO members affected by public health problems

The proposal (cont.)

- Available only if negotiations with the patent holder have failed
- To reach a license agreement
 - On reasonable commercial terms and conditions
 - Within a reasonable period of time – taking into consideration situations of extreme urgency

The proposal (cont.)

- Compulsory license is granted upon application
- The application must i.a. include
 - Identification of the pharmaceutical product
 - Identification of the relevant patents and SPC's
 - Evidence of negotiations with the patent holder
 - The importing WTO member state, including evidence of a request from that member state to supply the product in certain amounts
 - The amount of product which the applicant applies to manufacture

The proposal (cont.)

- The competent authority shall verify that the importing member state has made a notification to the WTO pursuant to the Decision, which
 - Specifies the pharmaceutical products and amounts required
 - Confirms that the member state is an eligible member state
 - Confirms that the member state, if the pharmaceutical product is subject to patent in that member state, has or intends to grant a compulsory license for import according to Art. 31 TRIPS

The proposal (cont.)

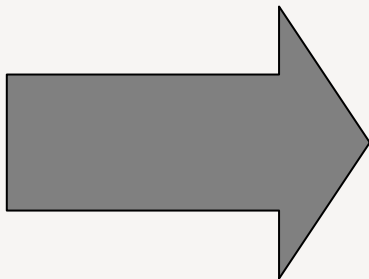
- Terms of the license
 - Non-exclusive and non-assignable
 - Limited to manufacture and export in accordance with the application
 - The pharmaceutical products must be clearly indentified (through labelling or marking) as being manufactured subject to the Regulation and the packaging shall be distinguished from that of the patent holder.
 - Communication via a website of the manufacture and the distinguishing features of the product

The narrow perspective

- Reasonable (and necessary?) from a humanitarian point of view
- Limited in scope
- Thus, not providing any significant setback to the development of an efficient, uniform intellectual property system supporting innovation
- Compliance with an obligation according to international law

The wider perspective

- Recital 5: "This Regulation is intended to be part of the wider European and international action to address public health problems faced by least developed countries"
- Priorities of the UK presidency: "Europe's Role in the World"



Does the intellectual property system have a north-south challenge?

Amendment of Fee Regulation (EC 2869/95)

- The fees of the Office shall be fixed at such level that the revenues thereof is sufficient for the budget of the Office to be balanced, Art. 139 (2) CTMR
- Background for the proposal
 - Increased revenues (renewal fees)
 - Cost reductions (efficient costs management and e-services)

The original proposal (3 December 2004)

All amounts in EURO	Actual	Proposal
Basic filing	975	600
Basic e-filing	N/A	500
Registration	1,100	950
Opposition	350	550
Revocation/invalidation	700	1,000
Appeal	800	1,200
Basic renewal	2,500	1,750

The adopted proposal (20 September 2005)

All amounts in EURO	Actual	Proposal	Adopted
Basic filing	975	600	900
Basic e-filing	N/A	500	750
Registration	1,100	950	850
Basic renewal	2,500	1,750	1,500
Basic e-renewal	N/A	N/A	1,350

Implementation of the adopted proposal

- Approved in the Committee on Fees, etc.
- Commission must formally adopt and publish the proposal
- Entering into force is foreseen before 1 November 2005
- Transitional rules
 - According to Art. 2 of the original proposal
 - Renewal fees can be paid from 1 October 2005, Art. 47(3) CTMR

Design Directive (98/71/EC)

- Harmonization of substantive law in the member states
- No agreement with respect to design protection of "must match" spare parts ("a component part used for the purpose of the repair of a complex product so as to restore its original appearance")
- "Freeze plus", Art. 14
- Analysis of the consequences of the directive and suggest the changes needed to complete the internal market, Art. 18

The actual situation

- 15 member states have design protection for spare parts
- 9 member states have a repair clause, allowing design protection on new products but leaving the possibility for alternative parts in the aftermarket
- 1 member state provides for a repair clause combined with a term of protection of 5 years and a fair and reasonable compensation (not implemented)

Conclusion of the analysis

- Excluding design protection in the aftermarket for spare parts is the only effective one to achieve an internal market
- "The main purpose of design protection is to grant exclusive rights to the appearance of the a product, but not a monopoly over the product as such"

The proposal for amendment

- New Art. 14(1):
"Protection as a design shall not exist for a design which constitutes a component part of a complex product used within the meaning of Article 12(1) of this Directive, for the purpose of the repair of that complex product so as to restore its original appearance."
- Corresponds to Art. 110(1) CDR
- Implementation: 2 years from adoption

Confusion as to the origin of spare parts

- An obligation on member states to ensure that the consumers are duly informed about the origin of spare parts, Art. 14 (2)
- The implementation must be made in the context of
 - Art. 6(1)(c) Trademark Directive
 - Art. 4(1)(I) Block Exemption EC 1400/2002

Collective management of copyrights

- Online music market
- Revenue gap between EU and USA
 - EU forecast 2005 € 106.4 million
 - US forecast 2005 € 498.3 million
- Reasons?
 - No effective structure for the collective management of online music services

The study

- Study on a Community Initiative on the Cross-border collective management of copyright
 - Commission Staff Working Document of 7 July 2005
- General objective of the initiative
 - Opening up an unexploited market
 - Strengthening the confidence of copyright owners

The proposal

- To give right-holders the choice to authorise collecting societies of their choice to manage their online rights for the entire EU.