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## **MOTION FOR A RESOLUTION**

further to Questions for Oral Answer B6-0134/2007

pursuant to Rule 108(5) of the Rules of Procedure

by Georgios Papastamkos and Maria Martens on behalf of the EPP-ED Group

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by Gianluca Susta, Johan Van Hecke and Ignasi Guardans Cambó on behalf of the ALDE Group

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on the TRIPS Agreement and access to medicines

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#### B6-0288/2007

### European Parliament resolution on the TRIPS Agreement and access to medicines

## The European Parliament,

- having regard to its resolutions of 20 June 2007 on the Millennium Development Goals the midway point<sup>1</sup>, of 23 May 2007 on Economic Partnership Agreements<sup>2</sup>, and of 30 November 2006 on AIDS<sup>3</sup>,
- having regard to the proposal for a Council decision accepting, on behalf of the European Community, the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005 (COM(2006) 175 fin.)<sup>4</sup>,
- having regard to Regulation No 816/2006<sup>5</sup> of the European Parliament and of the Council
  of 16 May 2006 on compulsory licensing of patents relating to the manufacture of
  pharmaceutical products for export to countries with public health problems,
- having regard to the Agreement on Trade-Related Aspects of Intellectual Property Rights (hereinafter 'TRIPS Agreement') adopted in April 1994,
- having regard to the Doha Declaration on the TRIPS Agreement and Public Health adopted on 14 November by the Ministerial Conference of the World Trade Organization (WTO) (hereinafter 'Doha Declaration')<sup>6</sup>,
- having regard to the Decision of the General Council of the WTO of 30 August 2003 (hereinafter 'WTO Decision') adopted pursuant to Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health,
- having regard to the Protocol amending the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), done at Geneva on 6 December 2005 (hereinafter 'Protocol',
- having regard to Rule 108(5) of its Rules of Procedure,
- A. whereas over 95% of the 39.5 million people in the world suffering from HIV/AIDS live in developing countries, mostly in Africa; whereas there are an estimated 15 million HIV/AIDS orphans globally, 12.3 million of them living in Sub-Saharan Africa,
- B. whereas before the entry into force in 1994 of the TRIPS Agreement the ability of some middle-income developing countries to produce low-cost generic medicines increased,

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<sup>&</sup>lt;sup>1</sup> Texts Adopted, P6\_TA(2007)0274.

<sup>&</sup>lt;sup>2</sup> Texts Adopted, P6\_TA(2007)0204.

<sup>&</sup>lt;sup>3</sup> Texts Adopted, P6\_TA(2006)0526.

<sup>&</sup>lt;sup>4</sup> OJ C ... / Not yet published in OJ.

<sup>&</sup>lt;sup>5</sup> OJ L 157, 9.06.2007. page 1.

<sup>&</sup>lt;sup>6</sup> WT/MIN(01)/DEC/W/2, 14 November 2001.

- and even very poor states started to become able to obtain certain low-cost generic medicines on the world market, whether such products were on or off patents,
- C. whereas the Doha Declaration reconfirmed the so-called flexibilities built into the TRIPS Agreement and amplified them further by establishing legal machinery to enable countries lacking the capacity to manufacture generic substitutes for costly patented medicines under domestically issued compulsory licenses to obtain imports from countries able and willing to assist them without interference from the relevant patent holders,
- D. whereas this solution, initially embodied in a waiver known as the WTO Decision, could be rendered permanent in the form of a Protocol to the TRIPS Agreement whose acceptance is currently under consideration by the European Parliament,
- E. whereas Article 30 of the TRIPS Agreement allows members to 'provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties'; whereas, because the assisting country would export needed medicines to the importing country, there should be no significant economic impact on the local market of the exporting country,
- F. whereas no country has so far made an official notification to the Council for TRIPS of intent to use the mechanism created by the WTO Decision to import cheaper medicines,
- G. whereas the procedural and substantive requirements that govern the issuance of compulsory licenses by importing (where applicable) and exporting countries, as well as the conditions and notifications connected with that licensing, constitute the principal potential obstacles to effective use of the WTO Decision,
- H. whereas the European Union has already transposed the WTO Decision into internal law, and consequently delaying acceptance of the Protocol until after 1 December 2007 would not create a legal vacuum,
- I. whereas the European Union should expressly endorse full implementation in the developing countries of the flexibilities in the TRIPS Agreement as recognized in the Doha Declaration 'to promote access to medicines for all',
- J. whereas the implementing Regulation for the WTO Decision pays scant attention to issues of technology transfer and capacity-building,
- K. whereas through the EPA negotiations and other bilateral or regional FTAs, the European Union proposes to include new intellectual property WTO+ obligations on ACP and other poor developing countries and LDCs, including the adherence to or the acceptance of the obligations of the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT), and the incorporation of the terms of Directive 2004/48/EC on the enforcement of intellectual property rights; whereas the EU also sets conditions on the way that parties can determine their regime of exhaustion,
- 1. Stresses that access to affordable pharmaceutical products in poor developing countries



- and LDCs is essential to attain the proposed EU development goals and would contribute to poverty reduction, increase human security, and promote human rights and sustainable development;
- 2. Believes that the EU policy should aim at maximizing the availability of pharmaceutical products at affordable prices in the developing world;
- 3. Calls on the Council to 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;
- 4. Asks the Commission and the Member States to provide concrete financial support for pharmaceutical-related transfer of technology and capacity building for developing countries and local production of pharmaceuticals in all developing countries, especially LDCs, in discharging the obligations established by Article 66.2 of the TRIPS Agreement;
- 5. Asks the Council to commit to a specified level of funding to upgrade or construct pharmaceutical production facilities owned by local persons in developing countries (including LDCs), and increase the EU aggregate funding to Public-Private Partnerships pursuing research and development of medicines of special relevance to developing countries:
- 6. Asks the Commission to grant funding for R&D on poverty-related, tropical and neglected diseases across a broad spectrum of venues, including Public-Private Partnerships and other possible funding ventures, and to support research institutes willing to cooperate with public health initiatives dedicated to these efforts;
- 7. Asks the Council to support the idea that the mechanism created by the WTO Decision and the Protocol to the TRIPS Agreement represents just a part of the solution to the problem of access to medicines and public health and that other measures to improve health care and infrastructure are equally indispensable;
- 8. Asks the Council to support the developing countries which use the so-called flexibilities built into the TRIPS Agreement and recognized by the Doha Declaration in order to be able to provide essential medicines at affordable prices under their domestic public health programmes;
- 9. Encourages the developing countries to use all means available to them under the TRIPS Agreement, such as compulsory licences and the mechanism provided by Article 30;
- 10. Calls on the Council to adopt a Joint Policy Statement with the European Parliament to the effect that EU Member States remain free to use all exception provisions of the TRIPS Agreement under their domestic patent laws to authorise production and export 'to address public health needs in importing Members' and asks the Council to mandate the Commission to refrain from taking action to interfere with these proceedings;
- 11. Calls on the Council to deliver on the Doha declaration on public health and to restrict the

mandate to the Commission in order not to negotiate pharmaceutical-related TRIPS-plus provisions affecting public health and access to medicines, such as data exclusivity, patent extensions and limitation of grounds of compulsory licenses, in the framework of the negotiation of the Economic Partnership Agreements (EPAs) with the ACP countries and other future bilateral and regional agreements with developing countries;

- 12. Asks the Commission to support disclosure by patent applicants of the source and origin of inventions deriving from biological resources and associated traditional knowledge found in developing countries with a view to promoting the equitable sharing of benefits and technology derived from those resources by supplying countries;
- 13. Calls on the Commission to support 'pool procurement strategies' under Article 31(b) and other strategies which could be used by countries or groups of countries to provide greater buying power and economies of scale in the production of generic medicines at affordable prices and stimulate direct investment in local production facilities within a region;
- 14. Asks the Council to mandate the European Commission to proactively support the work of the Intergovernmental Working Group on Public Health, Innovation and Intellectual Property (IGWG) at the WHO and to report regularly to the European Parliament on its work;
- 15. Encourages pharmaceutical companies to pursue pricing alternatives involving a high-volume, low-margin approach, which could enhance access to medicines;
- 16. Recalls that counterfeiting of medicines is not a patent issue as such; stresses that measures to tackle counterfeiting need to be taken in the area of criminal enforcement (penal sanctions) and drug regulation by reinforcing the regulatory capacity of the national authorities and not by increasing levels of intellectual property protection;
- 17. Calls on LDCs and other poor countries to take the necessary measures to prevent medicines covered by compulsory licensing leaving the country and ensuring that the medicines go to the local population in need;
- 18. Instructs its President to forward this resolution to the Council, the Commission, the Governments of the EU Member States and ACP countries, the WTO and the heads of UNAIDS, UNDP and UNFPA.