

Brussels, 16 June 2008  
CAB24/PM/RN/sa A(08)694 – D(08)738

Mr James Love  
US Co-Chair  
Ms Jill Johnstone  
European Co-Chair  
TACD  
London

*Dear Mr Love and Ms Johnstone,*

Thank you for your letter of 17 March 2008 where you are addressing the important issue of access to medicines and compulsory licensing.

Let me first underline that the issue of access to affordable pharmaceutical products in developing countries is essential to attain the proposed EU development goals and in this respect we believe it is important that trade policies and development policies go hand in hand.

We fully support the use of the "flexibilities" built into the TRIPS Agreement and recognised by paragraphs 4, 5 and 6 of the Doha Declaration as well as the additional flexibilities for least-developed countries made available pursuant to paragraph 7 of the Doha Declaration, in order to be able to provide essential medicines at affordable prices under their domestic public health programmes.

We also recognise that WTO members have the right to grant compulsory licenses and the freedom to determine the grounds upon which such licenses are granted. The point is that, from a policy perspective, including from the point of view of ensuring sustainable and long-term access to affordable medicines, recourse to compulsory licences is something that has to be carefully assessed and applied.

We fully understand Thailand's concern to offer affordable medicines to its population, especially its poorest citizens. This is something that can be achieved through a mix of policy measures, of which compulsory licensing is just one.

The Commission does not question Thailand's right to issue compulsory licences (as made clear in our correspondence), but we have doubts, from a policy point of view, on a *systematic* recourse to compulsory licences that could eventually be detrimental to the overall objective of the patent system, *i.e.* innovation and the development of new medicines.

That is why the Commission encourages negotiations for voluntary agreements between potential licensees and patent holders on reasonable terms and conditions.

Turning to your request for access to a number of documents which we have treated as a request under Regulation (EC) No 1049/2001<sup>1</sup> regarding public access to European

---

<sup>1</sup> OJ L145, 31.05.2001, page 43.

Parliament, Council and Commission documents ("the Regulation"), we understand that you would like to access all correspondence between the EC and the government of Thailand on the issue of compulsory licensing of medicine patents in Thailand and, secondly, between the EC and pharmaceutical companies or trade associations or their representatives on the issue of compulsory licensing of medicine patents in Thailand. I note that you have sent a similar request to Susan Schwab.

Concerning your request for correspondence between the EC and the Thai authorities, I am able to attach nine letters (listed in annex).

As to the request concerning correspondence with industry, I can inform you that there has been no correspondence between industry and the Directorate General for Trade or myself on the particular issue of compulsory licensing in Thailand. We can, however, confirm that the pharmaceutical industry on several occasions have raised their concern orally about the policy applied by Thailand in respect of compulsory licensing.

Let me add a little more detail regarding the EU position on the use of compulsory licensing of patents by developing countries, and, in particular, the various actions taken by the Commission.

As stated above, the Commission is fully supportive of the Doha Declaration on the TRIPS Agreement and Public Health. In this spirit, it has also taken active part in the WTO process to amend the compulsory licensing provisions of the TRIPS Agreement. The Commission has confirmed this attachment by implementing the waiver decision on compulsory licensing into Community legislation through Regulation 816/2006 of 17 May 2006. In addition, on 30 November 2007 the European Union deposited its instrument of acceptance of the Protocol amending the TRIPS Agreement. This amendment will allow developing countries without manufacturing capacities in the pharmaceutical sector to benefit from exported generic medicines.

However, the question of compulsory licensing legislation is only one element in finding solutions to the challenge of access to affordable medicines. The Commission is active in a range of areas:

- For instance, the Commission supports local production capacity through various projects. Local production can indeed promote competition and make pharmaceutical products more affordable. It is important to encourage technology transfer to ensure that locally produced pharmaceutical products meet internationally agreed standards. Technology transfer, leading to local production of affordable key pharmaceuticals, and commodities in prevention, treatment and care of HIV/AIDS, malaria and tuberculosis are one of the objectives of a specific initiative dedicated to Aid for poverty-related diseases (HIV/AIDS, Tuberculosis and Malaria). Specific projects have also been funded in Africa and Asia.
- In the context of its co-operation with the World Health Organisation (WHO), the European Medicines Agency provides scientific opinions for the evaluation of certain medicinal products for human use exclusively intended for markets outside the Community. Through WHO, the Commission also supports the strengthening of National drug regulatory authorities in various countries in Africa, Caribbean and Pacific. The Commission is a major funder of pharmaceutical and health-oriented/clinical research including health systems research and capacity building in

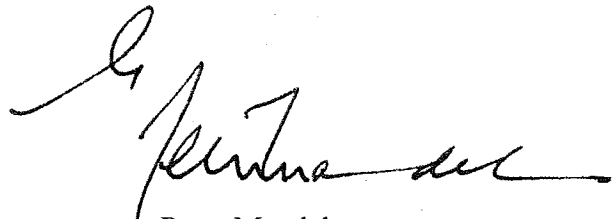
various sub-Saharan African countries through the European & Developing Countries Clinical Trials Partnership (EDCTP).

- In the research field the Commission is supporting research projects and innovative initiatives in respect of poverty related diseases under the current seventh Framework Programme for Research (FP7 - 2007-2013).
- The Commission also encourages pharmaceutical companies to adopt schemes such as tiered-pricing under which medicines are sold in poor and developing countries at considerably lower prices than in developed countries. On the Commission's proposal, the Council adopted Council Regulation (EC) No 953/2003 which offers manufacturers and exporters of tiered-priced medicines related to HIV/AIDS, malaria, tuberculosis and related opportunistic diseases reinforced protection at the border against import into the EU market where higher prices prevail.

You have also asked for a list of all compulsory licenses issued within the EU since 2001. In this regard, it should be noted that the Commission itself could grant compulsory licenses only in the context of its antitrust policy (see below). In the EU, patent law remains a national competence of the Member States; requests for compulsory licences are handled by each of the Member States with regards to patents which are valid on their territory. For further details on such compulsory licences you should therefore refer to the administration of the EU Member States.

At EU level the only area where issues of compulsory licensing can arise is in relation to the EU Treaty's competition rules (Article 82 of the EC Treaty) where a business abuses their monopoly rights and where the Commission may order the grant of compulsory licenses of IP rights on competition grounds. Since 2001 this occurred in 2 cases, the IMS-case<sup>2</sup> and the Microsoft-case<sup>3</sup>. The first case concerns copyright and the second case the issue of interoperability of the Microsoft Windows system.

Finally, I take note of your request for a meeting with the Commission services, where there is an on-going dialogue on issues including with civil society. My services stand ready to meet with you again in the future.



Peter Mandelson

Enc: Copies of correspondence between the EU and the government of Thailand

Cc: Ms Susan C Schwab (United States Trade Representative)

---

<sup>2</sup> Commission Decision 2002/165/EC

<sup>3</sup> Commission Decision, 24 March 2004 (Case COMP/C-3/37.792 *Microsoft*), C(2004)900 final.