

Pascal Lamy
Director General
World Trade Organization
Centre William Rappard
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February 18, 2009

RE: SEIZURES OF MEDICINES AS GOODS IN TRANSIT TO DEVELOPING COUNTRIES

Dear Pascal Lamy:

Cc: Mr. Kunio Mikuriya, World Customs Organization

Cc: Mr. Francis Gurry, World Intellectual Property Organization

Cc: Dr. Margaret Chan, World Health Organization

Cc: H.E. Mr. Mario Matus (Chile), Chair, WTO General Council

Cc: H.E. Ms. Karen Tan (Singapore), WTO Council for TRIPS

We are writing about recent initiatives by some WTO members to restrict the movement of goods in transit, on the grounds that the goods infringe on domestic patents or other intellectual property rights. Among the tangible and important examples of this are the recent seizures of in-transit medicines by Dutch customs authorities, including cases where medicines manufactured in India were in route to destinations in Brazil, Colombia and Peru. The details of these cases are further described in the attached letter to Dr. Chan of the World Health Organization.

There are long standing traditions to provide exceptions to patent rights for aircraft and marine vessels in route to markets, and for goods in transport, including, for example, the specific exemption of goods in transit from the provisions of Article 51 of the TRIPS, concerning "Suspension of Release by Customs Authorities."

The TRIPS does not require Article 51 to apply to patented goods, and the exception for goods in transit is discretionary rather than mandatory. In addition TRIPS is part of a larger plan to "reduce distortions and impediments to international trade," and seeks to "ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade." Article 41.1 of TRIPS provides that enforcement procedures "shall be applied in such a manner as to avoid the creation of barriers to legitimate trade and to provide for safeguards against their abuse" and Article 41.2 provides that the procedures shall be "fair and equitable."

Article V of the GATT defines goods in transit, and provides that "There shall be freedom of transit through the territory of each contracting party, via the routes most convenient for international transit, for traffic in transit to or from the territory of other contracting parties." This provision extends to all goods in transit, and provides that "all charges and regulations imposed by contracting parties on traffic in transit to or from the territories of other contracting parties shall be reasonable, having regard to the conditions of the traffic."

With regard to trade in medicines, the 2001 Doha Declaration on TRIPS and Public Health recognized "the gravity of the public health problems afflicting many developing and least-

developed countries” and stressed “the need for the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement) to be part of the wider national and international action to address these problems.” In Paragraph 4 of that Declaration, WTO members agreed that “the [TRIPS] Agreement can and should be interpreted and implemented in a manner supportive of WTO Members’ right to protect public health and, in particular, to promote access to medicines for all.” Among other things, the implementation of the WTO's Decision of 30 August 2003 regarding the export of pharmaceutical products to countries with inadequate manufacturing capacity, already seen as complex, will become even more problematic if patent rights are enforced for goods in transit.

Outside of the WTO, the membership of the World Health Organization has endorsed resolution WHA61.21, which states that “international negotiations on issues related to intellectual property rights and health should be coherent in their approaches to the promotion of public health.” WHA61.21 further calls upon member states to “take into account, where appropriate, the impact on public health when considering adopting or implementing more extensive intellectual property protection than is required by the Agreement on Trade-Related Aspects of Intellectual Property Rights.”

The Dutch seizures of medicines in transit from India to South America were made under the European Union's rules regarding customs measures.¹

We are concerned that these rules, and many other rules being proposed in a plethora of new trade agreements, do not protect legitimate sellers and buyers of generic medicines, when those goods move in global trade.

There are reports that the current drafts of the proposed plurilateral Anti-Counterfeiting Trade Agreement (ACTA) does not provide adequate protections for goods in transit, and we are also concerned about many of the proposals regarding provisional measures and customs practices that are seen in bilateral trade agreements. Whether intentional or not, additional risks to goods in transit are also found in the International Medical Products Anti Counterfeiting Taskforce (IMPACT)’s “Principles and Elements for National Legislation against Counterfeit Medical Products” and World Customs Organization’s “Provisional Standards Employed by Customs for Uniform Rights Enforcement (SECURE).”

There is a difference of opinion regarding an important issue. Should countries be free to aggressively enforce patent and other intellectual property claims against goods in transit, or should goods in transit be protected when they are clearly intended to markets where their use is legitimate?

This issue is particularly relevant to the challenge of providing “access to medicine for all,” a central objective of the Doha Declaration on TRIPS and Public Health, and the World Health Organization's recent Global Strategy on Public Health, Innovation and Intellectual Property Rights.

Article 5 of the Dispute Resolution agreement provides that “the Director-General may, acting in an ex officio capacity, offer good offices, conciliation or mediation with the view to assisting Members to settle a dispute.” Given the importance of this issue, we ask that you explore with

1 COMMISSION REGULATION (EC) No 1172/2007 of 5 October 2007 amending Commission Regulation (EC) No 1891/2004 of 21 October 2004 laying down provisions for the implementation of Council Regulation (EC) No 1383/2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights.

the European Union the extent to which its customs rules and provisions in trade agreements present risks to goods in transit, and undermine the commitments made in 2001 in the Doha Declaration on TRIPS and Public Health concerning access to medicines.

We request a meeting to discuss this issue further.

Sincerely,

BUKO Pharma-Kampagne, Christian Wagner-Ahlfs
Consumers International, Bjarne Pedersen
Consumers Union, Chris Murray
Essential Action, Robert Weissman
HAI Africa, , Patrick Mubangizi
HAI Asia Pacific, Kumariah Balasubramaniam
HAI Europe, Teresa Alves
HAI Global, Tim Reed
HAI Latin America and Caribbean, Roberto Lopez.
Health GAP, Brook Baker
IQsensato, Nicoletta Denticò
Knowledge Ecology International, James Love
Medico International, Thomas Gebauer
Oxfam International, Jenny Heap
Third World Network, Sangeeta Shashikant
U.S. PIRG, Edmund Mierzwinski