

# Congress of the United States

Washington, DC 20510

September 27, 2006

The Honorable David M. Walker  
Comptroller General  
United States Government Accountability Office  
441 G Street, NW  
Washington, DC 20548

Dear Mr. Walker,

We are writing to request a study of the U.S. Trade Representative's interpretation and implementation of the principle trade objectives relating to intellectual property, as established by Congress in the Trade Act of 2002.

The Act elaborated three objectives relating to intellectual property: "to further promote adequate and effective protection of intellectual property rights"; "to secure fair, equitable, and nondiscriminatory market access opportunities for United States persons that rely upon intellectual property protection"; and "to respect the Declaration on the TRIPS Agreement and Public Health, adopted by the World Trade Organization at the Fourth Ministerial Conference at Doha, Qatar on November 14, 2001."

Taken together, these three objectives identify priorities and articulate a clear vision for trade negotiations related to intellectual property. By Congressional mandate, the Administration has an obligation to advance this vision through its formal and informal trade promotion activities. We are interested in how these objectives have been interpreted, pursued, and implemented by the Administration since Trade Promotion Authority was granted by Congress in 2002.

In particular, we would like to learn to what extent the third objective, to respect the Doha Declaration on TRIPS and Public Health, has been pursued. In relevant part, the Doha Declaration states that no country should be prevented from exercising its rights to protect public health and promote access to medicines for all. Subsequent elaborations, in 2003 and 2006, have specified mechanisms intended to facilitate such access to medicines. We are interested in understanding how the rights and priorities identified by the Doha objective have been incorporated into trade-related policies, agreements, and practices of the Administration. In your study, please consider the following questions:

- Has the U.S.T.R., through trade agreement provisions, negotiations, preference programs, trade-capacity building, and other efforts, pursued objectives and

principles established under the Doha Declaration and TRIPS Agreement? Have these efforts been successful?

- How has the U.S.T.R. balanced efforts to pursue the Doha objective with the two other intellectual property negotiating objectives outlined by Congress in 2002? How many, if any, provisions negotiated since 2002 expand the Doha protections for access to medicines? How many, if any, provisions of such agreements narrow these protections? What has been the relative impact of each set of provisions?
- If any instruction included in the Trade Act of 2002 has been found to be in conflict with the Doha objective in practice, how has the Administration acted?
- How has the U.S.T.R. promoted the obligations of developed countries as articulated in the Doha Declaration? For example, the Doha Declaration reaffirms “the commitment of developed-country members to provide incentives to their enterprises and institutions to promote and encourage technology transfer to least-developed country members.” Has the U.S.T.R. facilitated such transfer through or in connection with bilateral trade agreements or other mechanisms?
- Have demands of the U.S.T.R., through bilateral trade agreements and other mechanisms, expanded or limited the rights of developing countries as articulated in the Doha Declaration? For example:
  - Has the U.S.T.R. expanded or constrained developing countries’ freedom to independently interpret the TRIPS Agreement according to the Agreement’s objectives and principles under Articles 7 and 8?
  - Have the U.S.T.R.’s activities affected developing nations’ use of compulsory licensing, Bolar provisions, and other provisions endorsed by the World Trade Organization for the protection of public health and the promotion of access to life-saving medicines?
- Which government agencies and private sector groups provide input into and exert influence over the U.S.T.R.’s policies and activities related to intellectual property rights? How does the U.S.T.R. balance and incorporate the concerns of these agencies and private sector groups in its policies and activities, and how have such concerns, once incorporated, affected pursuit of the Doha objective?
- As GAO found in 2002, the U.S.T.R.’s Industry Trade Advisory Committee system has consistently failed to incorporate adequate input from global public health interests. To what extent has this failure been addressed, and has the failure affected implementation of the Doha objective? Does the U.S.T.R. use other mechanisms to assure that input is incorporated from groups advocating the rights and obligations established under the Doha Declaration?
- Has the U.S.T.R. used mechanisms outside formal trade agreements to pursue, implement, and monitor the negotiating objectives related to intellectual property

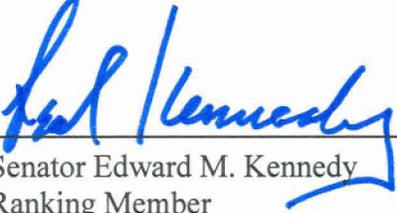
rights, and the Doha objective in particular? Please consider the General System of Preferences, the Special 301 process, trade capacity building activities, the Industry Trade Advisory Committee system, side letters, accessions, and diplomacy. For example:

- Have provisions in “public health side letters” achieved or failed to achieve the Doha policy goal of facilitating access to affordable medicines, including the Doha right to implement compulsory licensing? In practice, have the authorities articulated in these side letters been invoked? If so, to what effect?
- How has advice offered through trade capacity building balanced protection of intellectual property rights with preservation of developing countries’ rights under the Doha Declaration?

We look forward to your response to this request. If you have any questions, please contact David Bowen of Senator Kennedy’s staff at (202) 224-7675 or Naomi Seiler of Representative Waxman’s staff at (202) 225-5420.

With great respect and appreciation, and we look forward to the study.

Sincerely,

  
\_\_\_\_\_  
Senator Edward M. Kennedy  
Ranking Member  
Committee on Health,  
Education, Labor, and Pensions

  
\_\_\_\_\_  
Representative Henry A. Waxman  
Ranking Member  
Committee on Government Reform