



Highlights of [GAO-07-1198](#), a report to congressional requestors

## Why GAO Did This Study

The WTO Agreement on Trade-Related Intellectual Property (TRIPS) requires all 151 World Trade Organization (WTO) members to provide baseline protections, including 20-year patents for innovative pharmaceuticals. The Trade Act of 2002 granting Trade Promotion Authority (TPA) to the President outlined three negotiating objectives related to intellectual property (IP). The first two aim to strengthen IP rights and enforcement abroad. The third calls for respect of the WTO Doha Declaration on TRIPS and Public Health, which addresses access by developing countries to patented medicines, particularly in epidemic and emergency situations.

This report (1) describes the Declaration and its interpretation by the United States and other nations; (2) analyzes how USTR has balanced respect for the Doha Declaration with the other two IP objectives in negotiating free trade agreements; and (3) evaluates the extent of public health input by agencies and the private sector. We reviewed official WTO and U.S. government documents, interviewed U.S. and foreign government officials, and obtained private sector views.

## What GAO Recommends

If Congress disagrees with USTR's interpretation and implementation of TPA guidance with regard to IP and public health, it should specify more clearly its intentions for U.S. trade policy and public health policy input.

To view the full product, including the scope and methodology, click on [GAO-07-1198](#). For more information, contact Kireb Tager at (202) 512-4347 or [YagerL@gao.gov](mailto:YagerL@gao.gov).

## INTELLECTUAL PROPERTY

# U.S. Trade Policy Guidance on WTO Declaration on Access to Medicines May Need Clarification

## What GAO Found

The 2001 Doha Declaration on TRIPS and Public Health was adopted by WTO members to stress the importance of implementing the TRIPS Agreement in a manner supportive of public health. The U.S. interprets the Declaration as a political statement that recognizes the severity of public health crises while affirming the importance of IP protection. It maintains that the Declaration neither changes existing TRIPS obligations, nor creates new rights and does not assign public health greater priority than IP protection. USTR says the Declaration clarifies flexibilities already in TRIPS, including the flexibility to compulsorily license patents under certain circumstances. USTR recognizes these as being allowed for WTO members, including those facing public health crises, but only in a fashion that will not unduly harm patent holders. Some developing countries assert they provide broad discretion to ensure access to medicines when IP regulations present barriers to affordable care.

USTR balances respect for the Doha Declaration with TPA's other two IP negotiating objectives by actively promoting high levels of IP protection for pharmaceuticals while making targeted allowances for developing country partners. USTR believes that this longstanding U.S. pursuit of high IP protections for pharmaceuticals creates incentives for investment in research and development of new treatments, ultimately enhancing public health. With regard to the TPA objective of respecting the Doha Declaration, USTR's key policy change was to not insist upon two provisions it sees as relevant to the Declaration in FTAs with developing country trading partners. Otherwise, USTR has continued to pursue other pharmaceutical related IP protections that it does not consider related to the Doha Declaration. Reactions to USTR's record are mixed. The pharmaceutical industry considers these types of FTA provisions critical for preserving incentives for research and innovation. However, some academics, experts, nongovernmental organizations (NGOs), and generic producers have expressed concerns that these provisions may delay entry by cheaper generic products. In response to similar concerns in Congress, a bipartisan agreement was reached with the Administration to revise four recent FTA's prior to their submission for Congressional approval.

U.S. interagency and private sector input into trade negotiations related to public health have remained limited since Congress enacted TPA. The Department of Health and Human Services (HHS) and other agencies generally endorse USTR's view that strong IP protection promotes public health and access to medicines, and interagency input has been primarily technical in nature. Within the formal private sector trade advisory system, a public health representative was recently added to 2 of the 16 private sector advisory committees, but not until USTR had concluded nine trade agreements. USTR did obtain some public health views through other formal and informal means during this period.