Trade Facts

Office of the United States Trade Representative ***www.ustr.gov***
Bipartisan Agreement on Trade Policy: Intellectual Property
May 2007

Intellectual Property

- The Administration's agreement with the Congressional leadership preserves a strong overall level of protection for intellectual property in developing country free trade agreements, including those most recently notified to the Congress.

- Within this overall framework of strong intellectual property protection, the agreement reached with the Congressional leadership aims to incorporate certain flexibilities. These modifications are aimed at further ensuring that developing country free trade agreement partners are able to achieve an appropriate balance between fostering innovation in, and promoting access to, life-saving medicines. The results are fully in line with this Administration's long-standing trade policy objectives in the area of intellectual property.

- In particular, the agreement with the Congressional leadership entails the following elements related to intellectual property, medicines, and health:

    - Clarification that the period of protection for test data for pharmaceuticals by developing country FTA partners will generally not extend beyond the period that such protection is available for the same product in the United States, coupled with a provision that will encourage our partners to process marketing approval applications for innovative drugs in a timely manner.
    - Clarification that developing country FTA partners may implement exceptions to normal rules for protecting test data if necessary to protect public health.
    - A more flexible approach, for developing country partners, to restoring patent terms to compensate for processing delays. This flexibility is accompanied by new provisions stipulating that trading partners will make best efforts to process patent and marketing approval applications expeditiously.
    - More flexibility in terms of the types of procedures that developing country partners may implement to prevent the marketing of patent-infringing products.
    - Integration within the intellectual property chapter of a recognition that nothing in the chapter affects the ability of our FTA partners to take necessary measures to protect public health by promoting access to medicines for all, and a statement affirming mutual commitment to the 2001 Doha Declaration on the TRIPS Agreement and Public Health.

- While the agreement on pending FTAs with developing countries incorporates various flexibilities with respect to pharmaceutical-related IPR provisions, the intellectual property chapters of these agreements continue to represent an enhancement of IPR protection for pharmaceutical products in those markets, compared to the status quo situation. In particular, these FTAs:

    - Contain provisions protecting against unfair commercial use of test and other data submitted in connection with product approval. These provisions, even as modified by the Administration-Congress agreement, provide assurances that our developing country FTA partners will satisfy their obligations under the TRIPS Agreement.
    - Require the establishment of procedures through which patent holders can effectively enforce their rights against pharmaceutical products that infringe patents. While the nature of these procedures is more flexibly defined than in the original negotiated FTA text, it remains the case that the IP chapters establish a firm basis for preventing the marketing of patent-infringing products.

- Limit grounds for patent revocation, and improve other important patent rules and procedures.
- Require FTA partners to join major international agreements in such areas as patent and trademark procedure, protection of new plant varieties, and deposit of microorganisms and industrial designs.
- Require FTA partners to make best efforts to process patents and marketing approvals expeditiously, and retain the option that patent term extension may be applied in cases of unreasonable delays.
- Establish trademark-related obligations that will contribute to effective efforts to combat production of and trade in counterfeit drugs.
- Establish civil, criminal, and border enforcement disciplines that will also contribute to combating trade in fake drugs.