



## INTERNATIONAL UPDATE

### The Customs Practice of Sidley Austin LLP

Sidley's Washington, D.C.- and Brussels-based customs practice is well versed in the full range of customs issues facing companies and industries. Our attorneys address the most current and pressing issues in trade policy, while also being adept at the "nuts and bolts" of customs issues.

Our members have served in numerous U.S. government, European Commission and international organization roles. Through our representation of prominent trade associations, foreign sovereigns and multinationals, we stay at the front lines of customs reform, trade facilitation, and the challenging integration of the new customs mission of cargo security.

A substantial part of our practice is in the trade compliance arena. We have assisted companies in the development of import compliance programs. We also regularly conduct internal reviews and devise remedial measures as warranted.

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### U.S. Trade Negotiators Seek Public Comment on Elimination of Import Duties on Pharmaceutical Products

Over 9,000 pharmaceutical and chemical intermediates enjoy duty free treatment under the customs regime of the United States and other countries that participate in the World Trade Organization (WTO) Pharmaceutical Agreement. The Office of the U.S. Trade Representative (USTR) is seeking public comment on the possible expansion of the list of products subject to this reciprocal duty free treatment. Companies in the pharmaceutical industry interested in submitting comments on this issue must do so by April 9, 2010.

With the creation of the WTO in 1995, the United States and sixteen of its trading partners agreed to the reciprocal elimination of import duties on approximately 7,000 pharmaceutical products and chemical intermediates. This so-called "zero-for-zero" pharmaceutical initiative has been expanded in subsequent rounds of negotiation to include additional international nonproprietary names (INNs) and chemical intermediates. USTR estimates that the agreement covers over \$60 billion in U.S. imports and over \$25 billion in U.S. exports of goods. The zero-for-zero initiative, together with the guarantees of patent protection created by the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), constitute some of the most significant gains for any global industry arising out of international trade negotiations.

The **Pharmaceutical Appendix** to the Harmonized Tariff Schedule of the United States enumerates the products and chemical intermediates that are eligible to enter duty free as a result of these negotiations. The Pharmaceutical Appendix consists of three tables. Table 1 lists active pharmaceutical ingredients and dosage-form products by their INNs from the World Health Organization (WHO). Prefixes and suffixes that could be associated with the INNs in Table 1, potentially resulting in multiple permutations in derivatives, are enumerated in Table 2. Chemical intermediates intended for the manufacture of pharmaceuticals are listed in Table 3.

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In anticipation of a new round of WTO negotiations in April 2010 concerning the list of products subject to reciprocal duty free treatment, the USTR published a **notice** on March 12, 2009 inviting public comments. Specifically, the USTR requests input on (1) the expansion of the pharmaceutical active ingredients included on the list; (2) prefixes and suffixes that could be associated with an active ingredient in order to designate its salt, ester or hydrate form; and (3) the expansion of the chemical intermediates intended for the manufacture of pharmaceutical active ingredients included on the list. In particular, the USTR will be reviewing the INNs on the most recent WHO lists (*i.e.*, lists 94–99) for inclusion on the list.

As noted above, comments on the list of products subject to reciprocal duty free treatment must be submitted to the USTR by April 9, 2010. To ensure consideration, comments must include the specific information detailed in the USTR's notice inviting comments. Sidley Austin has a team of professionals with expertise in the WTO Pharmaceutical Agreement who would be pleased to assist companies in assessing the risks and opportunities that the new round of negotiations presents, and in developing input to the comments that the pharmaceutical industry prepares for the USTR on this issue.

**If you have questions about any of these items, please contact your regular Sidley Austin LLP contact.**

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