Trade & Customs - USA

Trade negotiators seek comment on elimination of pharmaceutical import duties

Contributed by Sidley Austin LLP

April 23 2010

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 US Trade Representative recently sought public comment on the possible expansion of the list of products subject to this reciprocal duty-free treatment (comments were due by April 9 2010).

With the creation of the WTO in 1995, the United States and 16 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 non-proprietary names and chemical intermediates. The Office of the US Trade Representative estimates that the agreement covers over $60 billion in US imports and over $25 billion in US 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, 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 international non-proprietary names from the World Health Organization. Prefixes and suffixes that could be associated with the international non-proprietary names 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.

In anticipation of a new round of WTO negotiations in April 2010 concerning the list of products subject to reciprocal duty free treatment, on March 12 2009 the Office of the US Trade Representative published a notice inviting public comment. Specifically, the notice requested input on:

- the expansion of the pharmaceutical active ingredients included on the list;
- prefixes and suffixes that could be associated with an active ingredient in order to designate its salt, ester or hydrate form; and
- the expansion of the chemical intermediates intended for the manufacture of pharmaceutical active ingredients included on the list.

In particular, the Office of the US Trade Representative will be reviewing the international non-proprietary names on the most recent World Health Organization lists (ie, Lists 94 to 99) for inclusion on the list.

For further information on this topic please contact Robert Torresen or Lisa Crosby at Sidley Austin LLP by telephone (+1 202 736 8000), fax (+1 202 736 8711) or email (rtorresen@sidley.com or lcrosby@sidley.com).

Authors

Robert Torresen

Lisa Crosby