



UNITED STATES
PATENT AND
TRADEMARK OFFICE

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Administrator for External Affairs
Washington, DC 20231
www.uspto.gov

Mr. Carl B. Feldbaum
President
Biotechnology Industry Organization
1225 Eye Street, N.W., Suite 400
Washington, DC 20005-5958

Dear Mr. Feldbaum:

Thank you for your letter of May 6, 2002, regarding the ongoing discussions at the World Intellectual Property Organization (WIPO) in Geneva, Switzerland with respect to substantive patent law harmonization and the efforts of the United States Patent and Trademark Office (USPTO) in this regard.

We are very interested to hear the view of the Biotechnology Industry Organization (BIO) on the wide variety of issues being discussed at WIPO as we assess our positions on these issues. The most recent meeting of the Standing Committee on the Law of Patents took place at WIPO after we received your letter. I would like to note a few of the issues in light of the most recent meeting.

As you had suggested in your letter, a number of delegations did propose amendments that would enter the entirety of the standards of Article 27.3 of the TRIPS Agreement into the draft Substantive Patent Law Treaty (SPLT). Indeed, the U.S. delegation vigorously opposed these amendments. However, due to the support for these amendments from all European Union countries, as well as many Latin American and other developing countries, it is likely that the next draft SPLT documents will include this language, albeit in square brackets.

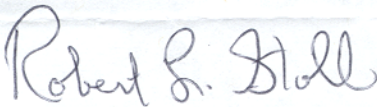
We do appreciate your statement, however, that the standard of TRIPS Article 27.2 is "logical and workable." We will keep this in mind as to future discussions. In addition, many developing countries at the meeting supported amendments allowing requirements in the SPLT with respect to "genetic origin" of living materials. The United States again vigorously opposed these amendments, but due to the specific request of their supporters, the next SPLT documents may include such provisions.

As to the last issue addressed in your letter, the U.S. delegation did reaffirm that it considers the United States standard as to timing of deposits to be the "best practice" in regard to the SPLT. Many other delegations, however, expressed a contrary view.

As evidenced by the activities at the meeting, the USPTO and BIO do share the same viewpoint on many items. The US delegation was very disappointed with the lack of progress at the meeting, particularly due to the controversial issues mentioned above. Indeed, the discussion raised the fundamental issue of whether the ideal of "deep harmonization" as to the best laws and practices for a patent system, which remains a prerequisite for United States participation in these talks, is shared by many other delegations.

We are glad to hear your strong support for the efforts to negotiate a new treaty. However, in light of the most recent discussions, a review of the goals of the SPLT is necessary, and this review could call into question the very purpose of these discussions. We appreciate your interest in this matter and hope to work with BIO in the future as to developments in the international forum with respect to creating a truly global patent system.

Sincerely,

A handwritten signature in cursive script that reads "Robert L. Stoll". The signature is written in dark ink and is positioned above the printed name.

Robert L. Stoll