EXECUTIVE OFFICE OF THE PRESIDENT
THE UNITED STATES TRADE REPRESENTATIVE
WASHINGTON, D.C. 20508

February 18, 2010

The Honorable Benyamin Ben-Eliezer
Minister of Industry, Trade and Labor
Jerusalem, Israel

Dear Minister Ben-Eliezer:

I have the honor to acknowledge receipt of your letter of February 18, 2010, which reads as follows:

"In connection with the 2009 Special 301 Out-of-Cycle Review, I have the honor to confirm the understandings reached between the Government of Israel and the Government of the United States of America (collectively, the "Parties") as follows:

A. Data Protection

1. The Government of Israel (hereinafter GOI) shall publish an Exposure Bill within 90 days of this letter (and shall submit a Bill to the Knesset no later than 90 days after the Exposure Bill is published), that would extend the term of protection for pharmaceutical confidential test and other data submitted for obtaining marketing approval against unfair commercial use.

a. The Bill shall provide that protection against unfair commercial use shall consist of a term of protection for confidential pharmaceutical test and other data submitted to the Israel Ministry of Health (hereinafter MOH) in connection with an application to obtain marketing approval for a medical preparation containing a "New Chemical Entity". The term of protection available shall expire no later than six and one half (6.5) years after the date the said medical preparation containing a "New Chemical Entity" first received final marketing approval in any recognized country, or, if the first worldwide filing of the application for marketing approval of the medical preparation containing a "New Chemical Entity" occurs in Israel, six (6) years after the date that marketing approval is granted in Israel for that medical preparation containing a "New Chemical Entity".

b. The Bill shall provide that its provisions shall apply to all applications pending at the time the Bill comes into force.

c. The Bill shall leave all other provisions of the current law intact.

2. The concerns regarding MOH delays in the examination of applications for registration of pharmaceutical preparations have been remedied as follows: In 2007, the MOH promulgated guidelines that require the issuance of marketing approvals within 12 months of the submission of an application. Said guidelines were recently reviewed by Israel's Supreme Court in the context of a petition complaining of, *inter alia*, delays in the grant of marketing approvals for pharmaceutical preparations. The Supreme Court found that the MOH was processing applications within the 12 month timeframe, in most instances, and would likely be able to reduce that time frame further in the near future given the recent hiring of additional examiners. In addition, on May 12, 2009, the GOI issued Government Decision No. 183 instructing that the Pharmacists Regulations (Medical Preparations) be amended so as to require marketing approvals to issue within 270 days from their submission. The GOI has promulgated regulations that are scheduled to be published on March 1, 2010 that amend the Pharmacists Regulations (Medical Preparations) to incorporate Decision No. 183. The Parties shall review the implementation of these regulations two (2) years after entry into force of the legislation.

B. Patent Term Extension

The GOI shall publish an Exposure Bill within 90 days of this letter (and shall submit a Bill to the Knesset no later than 90 days after the Exposure Bill is published), that shall amend Israel's patent term extension (PTE) law to reflect the following:

1. The number of reference countries shall be reduced to include only five (5) European Union (EU) reference countries (*i.e.*, France, Germany, Italy, Spain, and the United Kingdom) as well as the United States. Accordingly, Australia, Austria, Belgium, Denmark, Finland, Greece, Iceland, Ireland, Japan, Luxembourg, Norway, Portugal, Sweden, Switzerland, and The Netherlands shall be removed from the list of reference countries.

2. If an applicant files a PTE application in Israel within the required timeframe of 90 days from the date of marketing approval, the application shall be eligible for examination, notwithstanding that reference PTE Orders have not yet been granted in at least two reference countries. The application shall remain valid until such time as reference PTE Orders have been granted (either as an interim or final PTE Order) in the United States and at least one EU reference country, but no later than the

expiration of the underlying Basic Patent in Israel. However, if a reference PTE has not been granted (either as an interim or final PTE Order) in the United States and at least one EU reference country prior to the expiration of the underlying Basic Patent in Israel, then no PTE (interim or final) shall be granted in Israel in respect of that Basic Patent. Challenges to a pending PTE application, other than in respect of non-satisfaction of the "two state" requirement, may be commenced upon conclusion of the aforesaid examination, and any opposition filed must be decided finally prior to the expiration of the underlying Basic Patent.

3. If an applicant files a PTE application in Israel within the required timeframe of 90 days from the date of marketing approval, and at such date the application for the underlying Basic Patent is still pending, the PTE application shall remain valid and shall be examined subsequent to the grant of the Basic Patent.

4. For the purpose of calculating the amount of PTE in Israel, the GOI shall use the PTE granted in France, Germany, Italy, Spain, the United Kingdom, and the United States, subject to the following qualifications:

a. If, by the time of the expiration of the Basic Patent in Israel, a reference PTE is granted in fewer countries than specified in paragraph B.4 above, the PTE in Israel shall be calculated using the reference PTEs from the countries that have granted extensions.

b. A reference PTE which results from marketing authorization delays means any period extending the Basic Patent by one or more days, up to the maximum period allowed under the Patent Act.

c. The PTE in Israel shall expire no later than the expiration date of any U.S. reference patent, including any PTE granted in the United States.

5. The Bill shall leave all other provisions of the current law intact.

6. The Bill shall provide that its provisions shall apply to all applications pending at the time the Bill comes into force.

7. Until the Bill comes into force, the GOI shall endeavor to maintain its current administrative procedures concerning the point in time that the Israel Patent Office normally grants a PTE application.

C. Publication of Patent Applications

1. The GOI shall publish an Exposure Bill within 90 days of this letter (and shall submit a Bill to the Knesset no later than 90 days after the Exposure Bill is published), that shall require the publication of patent applications promptly after the expiration of a period of eighteen (18) months from the filing date in Israel's Patent Office.

2. The Bill shall provide, *inter alia*, that where a third party exploits, for purposes of marketing to the public, an invention claimed in a published application, that said third party shall be liable to pay the applicant a reasonable royalty for the exploitation of the said invention during the period between publication as aforesaid until the date said patent application has been "accepted" by the Israel Patent Office, provided that a patent ultimately is issued in respect of the application and that said patent, as issued, would have been deemed infringed by the acts of said third party during the aforesaid time period. Such Bill shall further provide that the cause of action for the exploitation of an invention claimed in a published application shall accrue only upon issuance of said patent.

3. The Bill shall provide that its provisions shall apply to all applications pending at the time the Bill comes into force.

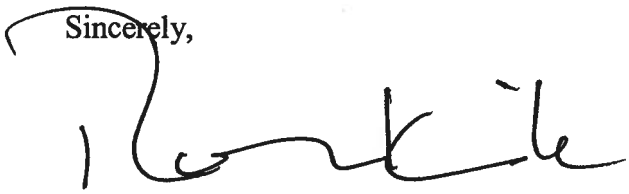
I have further the honor to propose that this letter and your letter in reply confirming that your government shares these understandings represent our governments' mutual understanding of the actions that both governments shall take to address this matter."

I have further the honor to confirm that my government shares the understandings referred to in your letter and that your letter and this letter in reply represent our governments' mutual understanding of the actions that both governments shall take to address this matter.

In recognition of the progress in improving the protection of intellectual property rights that the Government of Israel has made and of the further progress that will result from the actions that the Government of Israel has agreed to take, and with the expectation that these commitments will be implemented fully, I am pleased to share with you that in connection with the conclusion of the 2009 Special 301 Out-of-Cycle Review, Israel shall be lowered upon submission of appropriate legislation to the Knesset from the Special 301 Priority Watch List to the Watch List. If appropriate legislation has not been submitted prior to the issuance of the 2010 Special 301 Report, that report will only reflect that Israel's listing remains under consideration. Moreover, upon the Government of Israel's enactment of legislation that implements fully its commitments, Israel shall be removed from the Special 301 list.

The United States also reiterates its strong support for Israel's accession to the Organization for Economic Cooperation and Development (OECD). Furthermore, in light of the commitments that Israel has made, the United States foresees no impediments, with regard to intellectual property rights matters, to endorsing a favorable opinion from the OECD Trade Committee on Israel's accession to the OECD.

Sincerely,



Ambassador Ron Kirk