

Korea Exchange of Letter on Data Protection

EXECUTIVE OFFICE OF THE PRESIDENT

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

WASHINGTON, D.C. 20508

March 12, 2002

Mr. Park Sang-Ki

Director General

Bilateral Trade Bureau

Ministry of Foreign Affairs and Trade

Seoul, Korea

Dear Director General Park:

The following is the understanding of the U.S. Government regarding Government of Korea's position on data protection issue:

The Government of Korea is committed to being in full compliance with its obligation under Article 39.3 of the WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS).

Effective February 11, 1999, through a new provision in Article 5, paragraph 11, of the Pharmaceutical Safety and Efficacy Review Regulation, the Government of Korea ensures the protection of undisclosed test or other data submitted to the Government of Korea against unfair commercial use. The legal effect of this amendment to Article 5 is as follows:

- This protection applies to all new pharmaceutical chemical products for which undisclosed information must be submitted as a condition for obtaining marketing approval.
- That is, a subsequent applicant cannot rely on pharmaceutical test data submitted by others for a period of the six-year period, counted from the date of marketing approval of the new drug, unless the subsequent applicant has obtained permission of the original applicant or original developer.
- During the six-year period, a subsequent applicant must submit a full dossier for marketing approval. The data submitted by the subsequent applicant must meet the same criteria for approval as applied against the data of the original applicant. After the six-year period, the subsequent applicant is only required to submit the bioequivalence test data.
- The amendment of the Ministerial Regulation of the Pharmaceutical Affairs Act went into effect on January 1, 1995, and applies to all data submitted on or after that date.

Under the Agrochemical Management Act, the Government of Korea provides the same protection for agricultural chemical products as described above for pharmaceutical products, except that subsequent applicants are denied the possibility to rely on the test data submitted by others until fifteen years have passed since the approval of the original product.

Under Article 127 of the Korea Penal Code, public officials or former public officials who have disclosed legally confidential information that was obtained during the course of their duties are subject to penal servitude or

imprisonment or probation years, or suspension of qualifications or probation years.

Under Article 2 of the Korean State Compensation Law the Government of Korea is liable for damages to public officials in respect of trade secrets and causes loss either intentionally or through negligence.

Article 72-9 of the Pharmaceutical Affairs Law the KFDA Commissioner may make publicly undisclosed data under circumstances where it is necessary to protect the public interest and this is consistent with and no broader than Article 39.3 of the TRIPS Agreement. A similar provision exists in Article 27 of the Pharmaceutical Management Act.

I would appreciate your confirmation that the U.S. understands that the Government of Korea's position is accurate.

Sincerely,

[Signature]

Barbara Weisel

Deputy Assistant U.S. Trade Representative

For Bilateral Asian Affairs

MINISTRY OF FOREIGN AFFAIRS AND TRADE

REPUBLIC OF KOREA

March 13, 2002

Ms. Barbara Weisel

Deputy Assistant USTR for Bilateral Asian Affairs

Office of the United States Trade Representative

600 17th Street, NW

Washington, D. C. 20508

U.S.A.

Dear Ms. Weisel:

This letter is to confirm that the description and interpretation of Korean law and relations set forth in your letter dated March 12, 2002 is accurate.

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Sincerely yours,

Park Sang-Ki

Director General

Bilateral Trade Bureau

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