NOTICE OF INTENT TO SUBMIT A CLAIM TO ARBITRATION UNDER SECTION B OF CHAPTER 11 OF THE NORTH AMERICAN FREE TRADE AGREEMENT

SIGNA S.A. de C.V.

Investor

v.

GOVERNMENT OF CANADA

Party

Pursuant to Articles 1116 and 1119 of the North American Free Trade Agreement (NAFTA), the Investor, **Signa S.A. de C.V.**, serves notice of intention to submit a claim to arbitration for breach of the Party's obligations under the North American Free Trade Agreement.

A Name and Address of the Disputing Investor

Signa S.A. de C.V.
Av Industria Automotriz S/N Of.
Esq. Alfredo Nobel
Fraccionamiento Industial Toluca
Toluca, Edo. De Mexico, Mexico

B Breach of Obligations

1. The Investor alleges that the Party has breached its obligations under:

   (i) NAFTA Article 1105; and
   (ii) NAFTA Article 1110.

2. Other relevant provisions of the North American Free Trade Agreement include:

(i) Article 1709(7) which states:

> 7. Subject to paragraphs 2 and 3, patents shall be available and patent rights enjoyable without discrimination as to the field of technology, the territory of the Party where the invention was made and whether products are imported or locally produced.

(ii) and such other provisions in the NAFTA that may be relevant.

C Issues and Factual Basis of the Claim

Facts

1. The Investor Signa, is a company incorporated on December 7, 1961 under the laws of Mexico. It is a manufacturer of pharmaceutical chemicals based in Toluca, Mexico, and has invested in its factories, equipment and technologies for the purpose of being able to produce and sell pharmaceutical chemicals, including specifically the chemical ciprofloxacin hydrochloride.

2. The Investor is a joint venture partner with Apotex, Inc. of Ontario, Canada for the production of pharmaceutical dosage forms for sale in Canada based on the Investor's chemicals, including the chemical ciprofloxacin hydrochloride.

3. Cyprofloxacin hydrochloride is a wide-spectrum antimicrobial pharmaceutical used to treat a wide variety of pathogens. It is one of the largest selling pharmaceuticals in Canada.

4. In order for Signa S.A. de C.V. to make sales in Canada, its joint venture partner Apotex must have a health and safety certification known as a "Notice of Compliance" from Health and Welfare Canada. Ciprofloxacin hydrochloride satisfies the safety and health requirements of the Government of Canada's Regulations under the *Food and Drugs Act*. However, the Government of Canada, in violation of its obligation under NAFTA, will not issue a Notice of Compliance due to the improper requirements of the *Patented Medicines (Notice of Compliance) Regulations*.

5. The *Patented Medicines (Notice of Compliance) Regulations* were promulgated on March 12, 1993. These Regulations provide, in essence, as follows:

i. A person who purports to hold one or more patents in relation to a medicine may file with the Minister a Patent List, which sets out the patents purported to be relevant to the medicine.

ii. Once a Patent List has been filed in relation to a medicine, a generic producer cannot then obtain a Notice of Compliance without serving upon the person who has filed the Patent List a Notice of Allegation which alleges, with respect to each patent, either that it is invalid or that it will not be infringed. Once the Notice of Allegation has been served on the person who has filed a Patent List, that person has 45 days within which to file and serve an Application for an Order of Prohibition. If such an Application is filed and served, then the Minister is prohibited from issuing the Notice of Compliance to the generic manufacturer until the Application is disposed of by the Courts or for a further 30 months, whichever is shorter. In practice, it is virtually impossible to have the matter adjudicated in substantially less than 30 months. Moreover, this 30 month period is subject to extension.

6. In substance, the *Patented Medicines (Notice of Compliance) Regulations* thus provide that by merely purporting to have a relevant patent, a person can obtain a mandatory prohibition against a generic competitor for a period of about 3 years, without any preliminary judicial consideration whatsoever as to the merits of the case, or the issues of irreparable harm and balance of convenience that would otherwise be adjudicated before any injunction could be issued.

7. With respect to ciprofloxacin hydrochloride, a Patent List was filed by Bayer Inc. (formerly Miles Canada Inc., and hereinafter called "Bayer"). By letter dated November 24, 1995, Apotex, the joint venture partner of Signa, served upon "Bayer", as required by the *Patented Medicines (Notice of Compliance) Regulations*, a Notice of Allegation alleging that the relevant patents are invalid. Bayer filed and served an Application for an Order of Prohibition within 45 days from the date of service of the Notice of Allegation, so that, pursuant to the *Regulations*, a Notice of Compliance cannot now issue, thus preventing Apotex and its joint venture partner Signa, from using ciprofloxacin hydrochloride made by the Investor for a period of about 3 years.

9. As a result of the mandatory prohibition, the Investor has been harmed and continues to be harmed in the following respects:

i. Revenues have been lost and continue to be lost as the result of the consequent inability of the joint venture to sell tablets containing ciprofloxacin hydrochloride made by the Investor. It is estimated that sales by the joint venture would be in excess of three million dollars per month. Over the period of the mandatory prohibition, the losses to the Investor will exceed $25 million for this product alone.

ii. Were it not for the mandatory prohibition, the Investor's ciprofloxacin product would be available on the Canadian market, and in fact would be the first generic entry on the market. Thus the Investor would derive the benefit of being able to establish itself as the first generic product on the Canadian Market. As a result of the mandatory prohibition, the Investor's product will not reach the market ahead of other generic products. The Investor will thus dramatically lose market share and competitive advantage, even if and when the Notice of Compliance is obtained. It is estimated that the present value of the gross profit corresponding to the lost market share would be in the range of $75 million, of which the Investor's share will be about $25 million.

10. In the event that the *Patented Medicines (Notice of Compliance) Regulations* are not soon rescinded, there will be further similar damages in relation to other products.

11. NAFTA Article 1105 includes provisions guaranteeing a minimum standard of international law. This standard includes, but is not limited to the following:

(i) The right not to be denied access to courts of justice or to the competent organs of the State.

(ii) Fair and equitable treatment of an investment;

(iii) The requirement that there be no discrimination in patent law based on the field of technology.

12. The delay caused by the mandatory prohibition is a measure tantamount to an expropriation. NAFTA Article 1110 sets out a process to compensate investors whose investments have been expropriated by another NAFTA Party. These terms have not been complied with by Canada.

Issues

1. The *Patented Medicines (Notice of Compliance) Regulations* and their application to ciprofloxacin hydrochloride constitute a breach of the minimum standard of treatment to the investment of the Investor pursuant to NAFTA Article 1105.

2. The *Patented Medicines (Notice of Compliance) Regulations* and their application to ciprofloxacin hydrochloride do not accord the investments of the Investor treatment in accordance with NAFTA Article 1110.

3. The *Patented Medicines (Notice of Compliance) Regulations* and their application to ciprofloxacin hydrochloride contravene the international law principle of nondiscrimination as to field of patent technology as required by NAFTA Article 1709(7) and the WTO Trip's Code Article 28.

D Relief Sought and Damages Claimed

The Investor claims damages for the following:

1. $25,000,000 (Twenty Five Million Canadian Dollars) for lost profits during the period of the mandatory prohibition for lost sales plus compound interest on the foregone profits;

2. $25,000,000 (Twenty-five Million Canadian Dollars) for the Investor's portion of the value of the long-term loss of market share in the Canadian market;

3. Further damages yet to be determined in relation to delayed market entry and lost market share for other products in the event that the *Patented Medicines (Notice of Compliance) Regulations* are not promptly rescinded.

4. Costs associated with these proceedings, including all professional fees and disbursements;

5. Prejudgement and post-judgement interest at a rate to be fixed by the tribunal; and

6. Such further relief that this tribunal may deem appropriate.

DATE OF ISSUE: March 4 , 1996.

Appleton & Associates
950 Third Avenue
Suite 1700
New York, N.Y.
10022

Ph: (212) 935-9558
Fax: (212) 371-3215

BARRY APPLETON
Counsel for the Investor