

Shannon S.S. Herzfeld

SENIOR VICE PRESIDENT
INTERNATIONAL AFFAIRS

March 16, 2000

PhRMA

Mr. Jon Rosenbaum
Assistant U.S. Trade Representative
for Trade and Development
Chairman of the GSP Subcommittee
of the Trade Policy Staff Committee
Office of the U.S. Trade Representative
600 17th Street, N.W., Room 518
Washington, D.C. 20508.

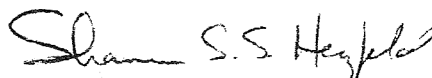
Re: Pre-Hearing Statement and Request to Appear at the GSP public hearings for the Dominican Republic, 65 Fed. Reg. 11104 (March 1, 2000).

Dear Mr. Rosenbaum:

On behalf of the Pharmaceutical Research and Manufacturers of America (PhRMA) and its member companies, I am pleased to submit our pre-hearing statement and request to appear at upcoming April 13 - 14 public hearings to review the status of the Dominican Republic as a beneficiary of the General System of Preferences (GSP) program.

PhRMA appreciates the continued vigilance of Washington agencies, and the particular efforts of the Ambassador Manatt and the staff of the U.S. Embassy in Santo Domingo to monitor this volatile situation, and to advance U.S. commercial interests.

Sincerely,



Shannon S.S. Herzfeld

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cc: Mr. Joseph Papovich, Assistant USTR
Mr. Peter Allgeier, Associate USTR

Pharmaceutical Research and Manufacturers of America

Written Statement

Mr. Chairman and other Members of the GSP Committee, my name is Susan Kling Finston. I am Assistant Vice President for Intellectual Property with the Pharmaceutical Research and Manufacturers of America (PhRMA). PhRMA represents America's leading research-based pharmaceutical and biotechnology companies, which are devoted to inventing medicines that allow patients to lead longer, happier, healthier and more productive lives. Investing more than US\$ 26 billion in 1999 in discovering and developing new medicines, PhRMA companies are leading the way in the search for new cures.

On behalf of the PhRMA and its member companies, I am pleased to appear before you in support of the accepted petition submitted by the International Intellectual Property Alliance (IIPA) for review of the Dominican Republic's status as a beneficiary developing country under the General System of Preferences (GSP) program. PhRMA hereby joins in support of IIPA's request, made in its June 19, 1999, submission to the U.S. Trade Representative (USTR), "that the eligibility of the Dominican Republic as a GSP beneficiary developing country be reviewed, and that its GSP benefits be suspended or withdrawn, in whole or in part, if requisite improvements are not made by the Dominican Republic to remedy the deficiencies . . . which adversely affect U.S. copyright owners." PhRMA further requests that damage to the U.S. research-based pharmaceutical industry be included in this review.

Background

The Dominican Republic has a rich and long-standing tradition of protecting industrial property. As in the U.S., patent rights are provided under the Constitution of the Dominican Republic, which includes the right to "exclusive property for the time and in the way determined by the law, of inventions and discoveries. . . ." (Article 8, numeral 14, Constitution of the Dominican Republic.) The Dominican Republic first became a signatory to the *Paris Convention on Industrial Property* in 1890, and since 1911 it has had a patent law in force. In fact, it was not until the 1980's that patent infringement and unfair commercial use of protected confidential data began to pose significant threats to commerce in the Dominican Republic.

Patent infringement of patented pharmaceutical products in the Dominican Republic occurs mainly through unauthorized copying and reliance on protected confidential data. The failure to safeguard confidential protected data from unfair commercial use violates the Dominican Republic's obligations under the WTO TRIPS Agreement, which it ratified in 1995. In spite of its domestic law and international commitments, the Dominican Republic's Department of Drugs and Pharmacy within the Department of Health continues to approve the import, export, manufacture, marketing and/or sale of pharmaceutical products which are unauthorized copies of patented products registered in the Dominican Republic. On January 28, 2000, the Legal

Counsel to the President of the Dominican Republic issued a formal opinion authorizing the Secretary of Health to issue all health registrations for pharmaceutical products without consideration of opposition by patent holders. This action has provided further support to the Secretary of Health to continue the policy of providing marketing approval to infringing products.

PhRMA also remains concerned by ongoing legislative consideration in the Dominican Republic of an industrial property bill that would continue this practice and establish as law additional forms of patent infringement. We believe that the current Dominican Industrial Property Bill, if adopted without amendment, would stand as the worst new law in the Western Hemisphere. As stated in PhRMA's March 9 letter on this subject, neighboring countries are following closely the progress of issues in the Dominican Republic. In fact, the draft industrial property bill has become a tool for those in the U.S. and elsewhere who are attempting to weaken the fabric of the WTO TRIPS Agreement generally. If the Government of the Dominican Republic is permitted to move forward with this legislation, the negative precedent will harm prospects for effective patent protection in the region and the larger developing world.

We have previously outlined several elements in the bill that are inconsistent with the Dominican Republic's multilateral obligations, and provide additional description of the deficiencies (see Tab B). PhRMA appreciates the strong and continuing support that the Office of the U.S. Trade Representative, the Department of State, the Commerce Department and in particular the U.S. Embassy in Santo Domingo have provided in opposing this legislation in the face of political pressure from activist groups. We understand that Ambassador Manatt has continued his strong focus on this issue, as the legislation moves towards forward in the Chamber of Deputies (having passed in the Senate without modification).

Request for Relief

PhRMA asks that the GSP committee review the eligibility of the Dominican Republic as a GSP beneficiary and that benefits be suspended or withdrawn, in whole or in part, if the Dominican Republic does not improve its record on protection of patented pharmaceutical products. More specifically, we ask that the GSP Committee move to withdraw GSP benefits from the Dominican Republic should the legislation under consideration be adopted without amendment.

Tab A -- List of Interested Parties Wishing to Testify

1. Susan Kling Finston
Assistant Vice President, Intellectual Property
Pharmaceutical Research and Manufacturers of America
1100 Fifteenth Street, N.W.
Washington, DC 20005

202-835-3492 telephone

2. Rodney Lopez
General Manager - Merck, Dominican Republic
Calle Manuel de Jeses Troncoso Esq.
Edificio Plaza Alcazar
Apartamento 203
Esquina Calle 2-A, Ens
Piantini
Santo Domingo, Dominican Republic

809-534-2570 telephone

3. Juan Acevedo
Vice President, Bristol Myers Squibb
Puerto Rico Administration
PO Box 364707
San Juan, Puerto Rico 00936-4707
Puerto Rico

787-774-2840 telephone

Tab B -- Deficiencies in the Dominican Republic Intellectual Property Regime

- Inconsistencies with the WTO Agreement on Trade Related Aspects of Intellectual Property Rights (TRIPS)

The Dominican Republic is an original signatory of the *WTO Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS), ratified by the National Congress through Resolution No. 2-95 of 1995. In order to comply with the provisions set forth in TRIPS, the Dominican Republic is reviewing and modifying its prior industrial property laws. Unfortunately, the Industrial Property bill that has been passed by the Senate and which is pending in the Chamber of Deputies contains provisions which are in contradiction with the minimum standards that the member countries of the World Trade Organization agreed to grant to industrial property rights under the TRIPS Agreement.

Given the long history of protection for industrial property in the Dominican Republic, and the fact that the new law reduces the level of patent protection from that of the *status quo*, it appears that the TRIPS inconsistencies in the industrial property bill are not accidental. Argentina's 1996 patent law, and that country's unfettered ability to support pirate activities throughout the region has clearly influenced the drafters of the Dominican Republic's industrial property bill. The bill, if approved without modifications, would include the following major incompatibilities with the TRIPS Agreement:

Compulsory licenses. The draft law includes a provision for compulsory licenses which would operate automatically 180 days after a petition is made, in violation of patent owner rights, and without obligation for the licensee to fulfill technical and economic requirements (Article 40.1). Furthermore, the compulsory license would be issued without the need to prove any fault on the part of the title holder or any national emergency, in contravention of TRIPS Article 31.

Protection of Confidential Data. Protection of Confidential Data is not contemplated, notwithstanding the obligation under TRIPS Article 39.3 to protect confidential information from unfair commercial use. Pharmaceutical products, which must be proven safe and effective before they can be marketed, require production of an extensive amount of confidential data for disclosure to health regulatory authorities. The TRIPS Agreement requires WTO members to protect this data against unfair commercial use by refusing to grant expedited approvals to competitors. In contrast to TRIPS requirements, Article 30, e of the Dominican bill specifically authorizes the use of confidential data by third parties for purposes of obtaining health registration for products.

Exclusions to Patentability. The bill excludes the possibility of patenting distinct uses of previously patented inventions, combinations of existing materials and excludes the patenting of microorganisms and non-biological methods and processes connected with living material (so-called second use patents). The legislation does not protect plant varieties pursuant to Article 27.3 of TRIPS, by this or any other *sui generis* system.

Placement of Bond by Foreigners. Foreigners continue to be required to post bond in order to access local courts. This is a violation of GATT Article III National Treatment requirements, and has been removed from the draft copyright legislation.

Parallel imports. Article 30 (d) of the bill authorizes parallel import of products wherever the products have been placed in any market, by any party, even if the product has been placed in the market without the consent of the owner of the patent, or if it has been placed in the market lacking intellectual property protection. This article would go beyond any current doctrine of exhaustion currently in practice in other countries, both in the developed and developing worlds.

Discrimination for imported products. Article 27.1 of the TRIPS Agreement states that patent rights must not be subject to any discrimination between imported or locally manufactured products. Nevertheless, Article 39 of the Intellectual Property bill requires the manufacturing of the product in the Dominican Republic and its importation both at the same time.

These inconsistencies would entail the commercialization of copies of innovative products by companies that have not incurred any expenses or expended efforts in discovering and developing these products. The deficient Dominican bill enables these companies to unfairly compete in the Dominican Republic, and to create a safe-haven that allows Dominican or foreign companies to export their illegal products throughout Central America and the Caribbean.

- Additional deficiencies in the Dominican Republic Industrial Property regime
 - a. There is no linkage between the Dominican patent authorities and the Dominican Department of Health to prevent issuance of third-party health registrations for products with patent protection without the consent of the owner of the patent. Health Registrations may be issued to non-right holders even in cases of formal opposition by the patent owner.

The violation of patents was not a problem in the Dominican Republic until the 1980's. However, since the mid-1980's patent owners of pharmaceutical products

have been suffering the violation of their registered patents. These violations have mainly taken place through the marketing, distribution and/or sale of pharmaceutical products which are mere copies of a patented products and which rely on the protected confidential data developed by the innovator.

The manufacture, import, distribution and sale of a medical product in the Dominican Republic is regulated by the Sanitary Code, Law No.4471 of 1956, as well as by Decree No. 148 of 1998. This Decree establishes a registration procedure to be completed prior the manufacture, import, distribution and/or sale of any product. The Department of Drugs and Pharmacy within the Department of Health perform this "sanitary registration". The "sanitary registration" is an authorization to manufacture, import, distribute, and sell within the territory of the Dominican Republic, and even to export to other countries. The Department of Health continues to approve the import, export, manufacture, marketing and/or sale of numerous medical products, which contain active ingredients protected by registered patents. These pirate products are being freely marketed within the country.

- b. The Legal Counsel to the President, in a formal opinion issued on January 28, 2000, has issued instructions further undermining data exclusivity in the Dominican Republic

The Legal Counsel to the President of the Dominican Republic, in a formal opinion issued on January 28, 2000, and pursuant to the President's instruction, authorized the Secretary of Health to issue all health registrations without taking into consideration any opposition made in view of registered patents. This formal opinion has reinforced the power of the Secretary of Health to issue of health registrations for products which violate locally registered patents.

- c. The Department of Industry and Commerce does not police the issuance of patents and expedition of certifications that refer to previously filed patents.

Additionally, the Department of Industry and Commerce does not act pro-actively to prevent issuance of patents and expedition of certifications that refer to patents previously filed, allowing unlimited infringement of patent rights.

Tab C - - Department of Health Certificates for Unauthorized Copies of Patented Products

Attached are copies of Dominican Republic Department of Health certificates which confirm requests for or issuance of health registration to provide marketing approval for products which are unauthorized copies of pharmaceutical products protected by patents. The companies affected by the attached Department of Health documents include Merck (Simvastatin), DuPont (Losartan), and Pfizer (Sildenafil).



Secretaría de Estado de Salud Pública y Asistencia Social

"Por una Cultura de la Salud"

DDF-450

CERTIFICACION

La funcionaria quien suscribe, DRA. DULCE FIDELINA PICHARDO, Sub-Secretaria de Estado Drogas y Farmacias,

CERTIFICA

Que el estatus de las especialidades farmacéuticas conteniendo SIMVASTATINA, es el siguiente:

NOMBRE DEL PRODUCTO	CASA FARMACEUTICA	No. DE REGISTRO
ARIANEL 10Mg Comprimidos	ROEMMERS, S.A.	98-0269
ARIANEL 20Mg Comprimidos	ROEMMERS, S.A.	99-0804
ARIANEL 5Mg Comprimidos	ROEMMERS, S.A.	98-0768
KAVELOR 10Mg Comprimidos	MERCANTIL FARMACEUTICA, S.A.	99-0930
NOR-VASTINA 10Mg Tabletetas	EDMAR, CXA	99-0138
ROVESTIN 10Mg Comp. Rev.	LABORATORIO ROWE, CXA	95-0574
ROVESTIN 5Mg Comp. Rev.	LABORATORIO ROWE, CXA	95-0573
ZOCOR 10Mg Tabletetas	MERCK SHARP & DOHME	96-0035
ZOCOR 10 y 20Mg Tabletetas	MERCK SHARP & DOHME	94-0220
ZOCOR 20Mg Tabletetas	MERCK SHARP & DOHME	99-0055
ZOCOR 40Mg Tabletetas	MERCK SHARP & DOHME	99-1110

Dado en Santo Domingo Capital de la República Dominicana a los dieciocho (18) dias del mes de Febrero del año dos mil(2000), a solicitud de HEADRICK RIZIK ALVAREZ & FERNANDEZ.

Atentamente,

DRA. DULCE FIDELINA PICHARDO
Sub-Secretaria de Estado Drogas y Farmacias
S.E.S.P.A.S.



Secretaría de Estado de Salud Pública y Asistencia Social

"Por una Cultura de la Salud"

DDF-449

CERTIFICACION

La funcionaria quien suscribe, DRA. DULCE FIDELINA PICHARDO, Sub-Secretaria de Estado Drogas y Farmacias,

CERTIFICA

Que el estatus de las especialidades farmacéuticas conteniendo LOSACOR es el siguiente:

NOMBRE DEL PRODUCTO	CASA FARMACEUTICA	No. DE REGISTRO
ARA II 50Mg Comprimidos	ETHICAL PHARMACEUTICAL, CXA	98-0749
ARA II-D Comprimidos	ETHICAL PHARMACEUTICAL, CXA	98-0450
CORMAC 50Mg Comprimidos	MERCANTIL PHARMACEUTICAL, S.A.	99-0932
COZAAR 50Mg Tabletas	MERCK SHARP & DOHME	97-0389
HYZAAR 50/12.5Mg Tabletas	MERCK SHARP & DOHME	98-0792
LORAX 50Mg Tabletas	ELIPEZA FARMACEUTICA, C.POR A.	PEND. REG.
LOSACOR 25Mg Comprimidos	ROEMMERS, S.A.	PEND. REG.
LOSACOR 50Mg Comprimidos	ROEMMERS, S.A.	97-0729
LOSACOR D, Comprimidos	ROEMMERS, S.A.	99-0998
LOSAFRAN 50Mg Tabletas	LUFRA-FARMACOS, S.A.	REG. PEND.
LOSAFRAN-D, Tabletas	LUFRA-FARMACOS, S.A.	REG. PEND.
NEFROTAL 25Mg Comprimidos	LABORATORIOS ROWE, CXA	97-0584
NEFROTAL 50Mg Comprimidos	LABORATORIOS ROWE, CXA	97-0585
NEFROTAL-H, comprimidos	LABORATORIOS ROWE, CXA	98-0807
PAXON 50Mg Comprimidos	SUED FARMACEUTICA, CXA	98-0643

Dado en Santo Domingo Capital de la República Dominicana a los dieciocho (18) de Febrero del año dos mil (2000), a solicitud de HEADRICK RIZIK ALVAREZ & FERNANDEZ.

Atentamente,

DRA. DULCE FIDELINA PICHARDO
Sub-Secretaria de Estado Drogas y Farmacias.
S.E.S.P.A.S

Recibo S.E.S.P.A.S No.1300
Valor RD\$500.00



Secretaría de Estado de Salud Pública y Asistencia Social
"Por una Cultura de la Salud"

C E R T I F I C A C I O N

La funcionaria quien suscribe, DRA. DULCE FIDELINA RICHARDO Sub-Secretaria de Estado Drogas y Farmacias,

C E R T I F I C A

Que el estatus de las especialidades farmacéuticas conteniendo SILDENAFIL es el siguiente :

NOMBRE DEL PRODUCTO	CASA FABRICANTE	No. DE REGISTRO
MASTER 50mg Comprimidos	ETHICAL PHARMACEUTICAL, C.A.	99-0954
PRONAC 50mg Tableta	LABORATORIO FELTREX, S.A.	99-0955
VIAGRA 100mg Tabletas	FERQUIDO, S.A.	98-0658
VIAGRA 25mg Tabletas	FERQUIDO, S.A.	98-0656
VIAGRA 50mg Tabletas	FERQUIDO, S.A.	98-0657
VIRIDIL 50mg Comprimidos	LABORATORIO ROWE, C.A.	99-0711

Dado en Santo Domingo, capital de la República Dominicana a los dieciocho (18) días del mes de Febrero del año dos mil (2000), a solicitud de MAXIMO GOMEZ P., C. por A.

Atentamente,

DRA. DULCE FIDELINA RICHARDO
Sub-Secretaria de Estado Drogas y Farmacias.
S.E.S.P.A.S.

Anexo : Recibo R.I. No.2513011
Por Valor RDS500.00

Dra.DFP/in