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April 24, 2007

Ambassador Susan C. Schwab
United States Trade Representative
Executive Office of the President
600 17th Street, NW
Washington DC 20508

Dear Ambassador Schwab:

Pursuant to Section 2104 (e) of the Trade Act of 2002 and Section 135 (e) of the Trade Act of 1974, as amended, I am pleased to transmit the report of the United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services (ITAC 3) on the Trade Promotion Agreement between the United States and Panama.

Very truly yours,

V.M. (Jim) DeLisi, Chairman
ITAC 3

VMJD: me

The United States – Panama Trade Promotion Agreement

Report of the
United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services [ITAC-3]
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United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services [ITAC-3]

Advisory Committee Report to the President, the Congress and the United States Trade Representative on the United States - Panama Trade Promotion Agreement.

1. Purpose of the Committee Report

Section 2104 (e) of the Trade Act of 2002 requires that advisory committees provide the President, the U.S. Trade Representative, and Congress with reports required under Section 135 (e)(1) of the Trade Act of 1974, as amended, not later than 30 days after the President notifies Congress of his intent to enter into an agreement.

Under Section 135 (e) of the Trade Act of 1974, as amended, the report of the Advisory Committee for Trade Policy and Negotiations and each appropriate policy advisory committee must include an advisory opinion as to whether and to what extent the agreement promotes the economic interests of the United States and achieves the applicable overall and principle negotiating objectives set forth in the Trade Act of 2002.

The report of the appropriate sectoral or functional committee must also include an advisory opinion as to whether the agreement provides for equity and reciprocity within the sectoral or functional area.

Pursuant to these requirements, the United States Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services hereby submits the following report.

2. Executive Summary of Committee Report

Most of our members believe that the negotiating objectives and priorities of ITAC-3 regarding the United States - Panama TPA have substantially been met. We are very pleased with the rules of origin that were included in this agreement. We are also pleased that all tariff lines eventually go to zero and note that most of the lines in our sector go to zero upon implementation.

Shawn Brown of the Generic Pharmaceutical Association advocates for modifications to the patent and data/market protection provisions for pharmaceuticals, so that brand pharmaceutical companies receive no greater IP/data protection than those IP rights accorded under current U.S. law. He is also concerned that the intellectual property chapter fails to achieve a suitable balance in promoting innovation and ensuring access to affordable medicines.

III. Brief Description of the Mandate of ITAC-3

ITAC – 3, the United States Industry Trade Advisory Committee on Chemicals, Pharmaceuticals, Health/Science Products and Services, in addition to counting a representative of the environmental community and the health service sector amongst its members, represents the following product sectors and subsectors:

Adhesives and Sealants
Specialty Chemicals
Industrial Chemicals
Organic Chemicals
Inorganic Chemicals
Crop Protection Chemicals
Pharmaceuticals
Biotechnology
Dyes and Pigments
Paints and Coatings
Petrochemicals
Fertilizers
Printing Inks
Electronic Chemicals
Public Health
Rubber and Rubber Articles
Soaps and Detergents
Plastics and Compounded Products
Composite Materials
Biocides
Forest and Paper Product Chemicals
Rare Earth Metals
Radioactive Chemicals
Enzymes, Vitamins, and Hormones
Cosmetics, Toiletries, and Fragrances
Photographic Chemicals and Film
Catalysts
Animal Health Products
Medical Devices & Equipment

The sector coverage as listed above for ITAC 3, includes the products and substances classified in the U.S. Harmonized Tariff Schedule (HTS) Chapters 28 – 40, as well as other specific chemicals found in HTS Chapters 13, 14, 15, 22, 23, 25, 27, 55 and 71 as well as medical equipment found in HTS Chapters 28, 30, 34, 38, 40, 42, 61, 63, 84, 85, 87, 90 and 94.

IV. Negotiating Objectives and Priorities of ITAC-3

ITAC-3 emphasized the following points prior to, and during the negotiations.

Importance

From the perspective of our industrial sectors, Panama is not a significant trading partner with the United States. We continue to urge the Administration to devote its energies to negotiating FTA's with strategic trading partners, such as South Korea. However, we want to reemphasize the twin priorities of implementation and enforcement of this and other free trade agreements.

Chemical Tariff Harmonization Agreement

ITAC-3, and its predecessor, the Industry Sector Advisory Committee for Chemicals and Allied Products [ISAC-3], has long supported the Chemical Tariff Harmonization Agreement (CTHA) initiated in the Uruguay Trade Round. Accordingly, we particularly favor increased trade

relationships with current CTHA signatory countries as well as other nations that have chemical producing industries.

Over the long term, the U.S. chemical sector generally favors, with appropriate staging, a multilateral agreement on the elimination of chemical tariffs by the world's chemical producing nations. The pharmaceuticals sector supports immediate tariff elimination in accordance with the multilateral understanding on elimination of pharmaceutical tariffs. The negotiation by the current Administration of TPAs with key chemical producing countries can provide the catalyst to bring the tariff elimination objective into focus in the current round of multilateral negotiations under the auspices of the World Trade Organization. Until the Doha Development Agenda is successfully concluded, we support continuing efforts to achieve the elimination of chemical tariffs through selective bi-lateral and regional TPAs, and as part of countries' accessions to the WTO, as desirable alternatives, so long as they do not undercut efforts to achieve the ultimate goal of a level trading field and broad multilateral tariff elimination.

Staging of Market Access Provisions

ITAC-3 favors realistic and balanced staging timetables in all TPAs for the elimination of tariffs and non-tariff barriers. ITAC-3 also favors immediate tariff elimination for the pharmaceutical sector in all TPAs in accordance with the multilateral consensus contained in the Understanding on Elimination of Pharmaceutical Tariffs.

Rules of Origin

The rules of origin for chemicals under free trade agreements are a vitally important aspect for the chemicals sector.

We have proposed that the rules of origin in free trade agreements for chemical products (Harmonized Tariff Schedule Chapters 28-40) be based on the position taken by the United States in its submission to the World Customs Organization's Committee on Rules of Origin. These rules are hierarchical in nature, starting first with the concept of "tariff shift" as the test for determining whether there has been a substantial transformation of a product that will confer origin. Where a product, good, or substance does not meet the tariff shift rule, the second test should be the chemical reaction rule. If, following these two tests, the product's origin is still in doubt, a third set of tests based on additional rules for mixtures, purification, separation, and so forth are prescribed.

ITAC-3 is not in favor of a "value content" rule of origin. We find these rules of origin to be burdensome and inefficient.

ITAC-3 strongly supports harmonizing rules of origin in as many trade agreements as possible.

Investment

The industry members of ITAC-3 believe that the inclusion of a chapter in any free trade agreement providing for strong investment protection rules for U.S. companies is a priority.

Among the elements that we advocate that should be covered in an investment chapter are:

- The defining of investment in a comprehensive manner;
- The guarantee of the better of either MFN or national treatment;
- The provision for and the assurance of the free transfer of profits and capital;
- The adequate dealing with issues affecting the movement of key personnel;
- The disciplining of the use of performance requirements;
- The prohibition of expropriation except in the case of a public purpose and only with the payment of prompt, adequate and effective compensation;
- The guarantee that investment will receive fair and equitable treatment, with full protection and security, consistent with the principles of international law; and
- The assurance that investors have access to an effective mechanism in the agreement for the settlement of investor-state disputes within the provisions of the FTA that are consistent with the "Model BIT", NAFTA, Chile, and Singapore.

Mr. Waskow, of Friends of the Earth, has urged that the mandate in the Trade Act of 2002, requiring that foreign investors should receive no greater substantive rights than U.S. citizens are accorded under U.S. law, should be complied with. He further advocates that environmental and other public interest protections be fully protected in the text of the Agreement and that foreign investors should not be permitted to bypass the domestic judicial systems of the parties to any free trade agreement.

Labor and Environment Provisions

ITAC-3 has advocated that U.S. negotiators should consider with great care the pursuit of these objectives. The importance of labor and environment, and other issues such as human rights, must not be denied by any industry sector. However, all of the industry sector members of ITAC-3 believe that the complex and global issues of labor and environment are best dealt with in the international institutions that already exist to examine these issues—in the case of labor, the International Labor Organization, and, for the environment, the various multilateral environmental agreements (MEAs) and the WTO Committee on Trade and Environment, which seeks to determine how trade agreements and environmental agreements should interact. Approaching these issues in a piecemeal fashion through bilateral free trade agreements is, in the judgment of the industry sector ITAC-3 members, inadvisable.

The industry members of ITAC-3 also indicated that it is a fundamentally misguided strategy to include labor and environmental provisions in future trade agreements in such a way as to lead to the imposition of trade sanctions. If we were to pursue this formula, those members felt that the

U.S. would ultimately be choosing a market closing, not a market-opening strategy. Important trading partners would turn away from this strategy, and U.S. efforts to create more open markets would fail. The industry members have urged that the chemical and pharmaceutical industries, and their respective trade associations, get more actively involved in numerous discussions with interested parties about the relationship that should exist between trade and the environment. They believe that dialogues of this nature are the best means of providing the basis for exploring constructive approaches on a multilateral level.

V. Advisory Committee Opinion on Agreement

Most members of the ITAC-3 support the approval of this Agreement in the form it was originally sent to Congress. We reserve the right to modify/withdraw our support should there be any changes. We would appreciate your special attention to our particular areas of concern.

The following specific comments are inserted in accordance with the numeration and titles in the Agreement text:

Chapter 1: Initial Provisions

No comment.

Chapter 2: General Definitions

No Comment

Chapter 3: National Treatment and Market Access for Goods

We are pleased that all tariff lines eventually go to zero. We wish that the USTR had been able to close a tariff deal closer to that which it negotiated with Australia where almost all tariff lines were reduced to zero upon implementation of that agreement. We are disappointed in the number of lines in our sector that are the subject of extended staging, but recognize the struggle that the USTR faced in this area and therefore accept what has been done.

Chapter 4: Rules of Origin Procedures

We are very pleased with the rules of origin that are included in this agreement. ITAC-3 worked very closely with Mr. Jay Eizenstat of the Office of the USTR to obtain rules for our sector that ensure that chemical products subject to, and taking advantage of, this agreement are truly territorial to the parties to it, namely the US and Panama. We applaud Mr. Eizenstat for a job well done!

It is our hope that the chemical rules of origin contained in the Panama TPA are followed in future TPAs and not those unfortunately found in the agreements with Jordan,

Morocco, Israel and Bahrain, which all contain a GSP-based rule. We continue to urge the USTR to work to secure more practical rules in ongoing free trade negotiations in other parts of the world.

We are aware that the United States intends to seek a Free Trade Area for the entire Middle East Region [MEFTA]. We support this concept but strongly urge that the language on rules of origin employed with Israel, Jordan, Morocco, and now Bahrain, not be used as a template for any future negotiations.

Chapter 5: Customs Administration and Trade Facilitation

No Comment

Chapter 6: Sanitary and Phytosanitary Measures

No Comment

Chapter 7: Technical Barriers to Trade

No Comment

Chapter 8 Trade Remedies

No Comment

Chapter 9 Government Procurement

No Comment

Chapter 10: Investment

No Comment

Chapter 11: Cross-Border Trade in Services

No Comment

Chapter 12: Financial Services

No Comment

Chapter 13: Telecommunications

No Comment

Chapter 14: Electronic Commerce

No Comment

Chapter 15: Intellectual Property Rights:

Our ITAC supports Intellectual Property Rights protection consistent with US Law.

Most of our members fully support the important intellectual property provisions that the FTA contains regarding pharmaceutical products. Strong intellectual property protection abroad is a core goal of U.S. trade policy and has a direct impact on U.S. jobs and U.S. workers. U.S. negotiating objectives as set forth in the Trade Promotion Authority legislation include a requirement to obtain IP protection consistent with U.S. standards. This objective has been achieved in the Panama FTA. As in the United States, the Panama agreement provides a five-year period of data exclusivity, requires linkage and the restoration of patent term resulting from unreasonable curtailment of that term by marketing approval process or unreasonable patent office delays. These provisions reflect the critical nature of intellectual property rules as an engine of pharmaceutical innovation and an incentive that helps facilitate the access of Panamanian patients to innovative medicines. These provisions are critical to maintaining the broad support of our ITAC for this agreement.

However, GPhA believes the standard of IP protection in U.S. law carefully balances fostering pharmaceutical innovation with ensuring access to affordable medicine; the agreement fails to meet this standard. The strength of a pharmaceutical market depends on the security of intellectual property and the protection of the incentive to innovate new products. Of equal importance to a nation's health and the effectiveness of its pharmaceutical market, however, is the cultivation of a robust generic industry able to provide affordable access to medicines. In free trade agreements, as with U.S. law, these interests must be balanced to provide the greatest benefit to the health of America and to our partners in trade. The implementation of laws, regulations and policies that are founded on unbalanced intellectual property principles will lead to the development of barriers to market access for U.S. generic manufacturers—barriers that do not exist in U.S law, and do not reflect the standard of protection found in U.S. law.

The members of our group that are involved in agricultural chemicals are very pleased that this agreement protects registration data for a period of ten years, based on current US law and regulatory practice under FIFRA. Such data protection is a vital component in maintaining a robust agricultural chemicals industry.

Chapter 16: Labor

No Comment

Chapter 17: Environment:

No Comment

Chapter 18: Transparency:

No Comment

Chapter 19: Administration of Agreement and Trade Capacity Building:

No Comment

Chapter 20: Dispute Settlement:

No Comment

Chapter 21: Exceptions:

No Comment

Chapter 22: Final Provisions:

No Comment

Annexes:

11.9 ITAC 3 supports the encouragement of temporary licensing to alleviate any time-burden in obtaining authorization, licensing or certification of professional services. When possible, the Commission may want to include international medicine and nursing certifying organizations in the development of mutually acceptable standards and criteria, specializing in preparing health care providers for international deployment.

There should not be any tariff provisions for health care services and health education, including licensing and cross-border movement of personnel in health care fields, such as nursing and medicine.

Side Letters:

No Comments

VI. <u>Membership of Committee:</u>

Chairman
V.M. (Jim) DeLisi, President
Fanwood Chemical, Inc.

Primary Vice Chairman
Robert E. Branand, Esq.
Representing National Paint & Coating Assoc.

Secondary Vice Chairman
W. Martin Strauss, Ph.D.
V.P. Consumer Traits & Food Policy
Monsanto Company

Karen L. Bland, Esq.
Representing the Society of the Plastics Industry

Sushan Demirjian
Director, International Trade
American Chemistry Council

Donald E. Ellison
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Representing SACMA

D. Geoffrey B. Gamble, Esq.
Director of International Government Affairs
E.I. DuPont de Nemours & Company

Edward L. Gibbs, President
North Coast Medical Equipment, Inc.

Nancy R Levenson
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Matthew T. McGrath, Esq, Partner
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Chemtura Corporation

Michael D. Boyd
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Shawn M. Brown, Esq.
Director of Policy
Generic Pharmaceutical Association

P. Claude Burkey
Divisional V.P., Global Government
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Abbott Laboratories, Inc.

Morris A. Chavez, President
Hemisphere Polymer & Chemical Company

Tine K. Hansen-Turton
Chief Executive Officer
National Nursing Centers Consortium

Mildred W. Haynes
Manager, Federal Government Relations
3M

Craig S. Kramer
V.P. International Government Affairs
Johnson & Johnson

Adrian Krygsman
Direct Product Registration
Troy Corporation

Rosemary O'Brien
V.P. Public Affairs
C.F. Industries

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Eli Lilly & Company

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J. Lawrence Robinson
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Isi A. Siddiqui, PhD
V.P. Science & Regulatory Affairs
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George L. Rolofson, PhD
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Arthur J. Simonetti
Director, Trade Legislation & Regulation
Honeywell International, Inc.

Lisa Schroter
Director, International Policy
The Dow Chemical Company

Henry P. Stoebenau, President
Efficient Global Trade
Representing AAEI

Marjory E. Searing
V.P. Public Affairs – Japan/Asia & Latin America
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Albert C. (Cal) Sutphin
President
Braden Sutphin Ink Company

David F. Waskow, Esq.
International Program Director
Friends of the Earth

Ford B. West
President
The Fertilizer Institute