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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 Korea.

Very truly yours,

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

VMJD: me

The United States – Korea Trade Promotion Agreement

Report of the
United States Industry Trade Advisory Committee for Chemicals, Pharmaceuticals, Health/Science Products and Services [ITAC-3]
April 24, 2007

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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 - Korea 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 - Korea TPA have been met. We are especially pleased with the agreements that were reached covering rules of origin. Most of the members of our committee are very pleased with the agreement on intellectual property rights (IPR) negotiated for our sector. We are pleased that all tariff lines eventually go to zero and note that most of the lines in our sector go to zero upon implementation. Furthermore, we are delighted to report that USTR took note of our sensitivities and negotiated suitable phase out periods that should allow our industries adequate time to adjust to this new competition.

We were very pleased that the United States made negotiating a Free Trade Agreement with South Korea a priority and hope that this agreement can serve as a template for future agreements, both in this region and other important areas of the world.

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 our 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

In a letter to Ambassador Schwab and Secretary Gutierrez, dated June 19, 2006, ITAC-3 emphasized the following points. We continued to press on these issues as the negotiations progressed.

Importance

From the perspective of our industrial sectors, South Korea is a very significant trading partner with the United States. In fact, it was one of our target countries.

We then took the opportunity to state our negotiating objectives as detailed below:

Tariffs:

ITAC 3 supports a comprehensive and balanced agreement based on full reciprocity in tariff levels. Except for the product categories described below (see "Ancillary Issues"), we support immediate elimination of all tariffs in our sector upon full implementation of the agreement provided that South Korea offers the same concessions in its tariff levels. However, to the extent that South Korea requests staging of its tariff phase-outs on particular products covered by ITAC 3, the US should request similar staging periods for the same or other products on a trade weighted basis as appropriate, to ensure reciprocity in market access under the agreement.

We reserve the right to nominate a list of import sensitive items that should receive the maximum phase out period offered.

We were delighted to learn that Tiffany Smith will be leading the NAMA tariff negotiations. She has proven to be a very effective negotiator on past agreements and we are confident that she will effectively and competently carry forward these discussions, which are so vital to our industries.

Non-Tariff Barriers:

ITAC 3 supports the complete elimination of all NTBs, especially those involving Pharmaceuticals, Medical Devices and Agricultural Biotechnology, upon implementation of the agreement.

ITAC 3 supports elimination of all NTBs on health care services and health education, including licensing and cross-border movement of personnel in health care fields, such as nursing and medicine.

Rules of Origin:

Product specific rules of origin in free trade agreements are a vitally important aspect for the chemicals sector. The rules we support 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 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 "value content" rules of origin. We find "value content" rules of origin to be burdensome and inefficient.

ITAC-3 strongly supports harmonizing rules of origin across all trade agreements. We therefore strongly support the use of the recently concluded rules in the Andean Free Trade Agreement for product-specific Rules of Origin concerning chapters 28 – 40, the General Rules of Origin and Origin Procedures, and the Customs Administration and Trade Facilitation rules, without substantial change, as the model for this agreement except for the special exception to the Chemical Reaction Rule concerning 2930.20 that was incorporated into the Andean agreement.

We also believe that origin rules for both preferential and non-preferential purposes should be the same in this and all trade agreements.

It is vitally import that the rules effectively eliminate the potential for transshipment of goods so that the full benefits of the agreement accrue to the parties.

We are pleased to that Jay Eizenstat provided leadership for this part of the negotiations. ITAC 3 members have an excellent relationship with Jay, having worked closely with him on several other FTAs to refine the origin rules affecting our sector. It is a pleasure to work with an individual that truly understands our needs.

Intellectual Property Rights:

Strong protection for IPR is vital for our sector. We strongly advocate that the US-Korea FTA should reflect U.S. standards in this area. The FTA should require not only that the parties adopt patent restoration and data exclusivity rights, but also the limits applied under US law.

In the case of crop protection chemicals, we advocate at least 10 years of data protection based on current US law and regulatory practices under FIFRA.

In the case of pharmaceuticals, we advocate that IP rights be based on current US law and regulatory practices as interpreted by the Patent Office and US FDA as appropriate. More specifically, strong patent protection and 5 years of data protection for pharmaceuticals are crucial elements of any agreement. The absence of patent linkage in Korea is also a significant concern, and should be addressed in the FTA. If linkage is to be part of the FTA, there must be reasonable and timely means to challenge questionable patents, restrictions on the types of patents that can enter the linkage system as is the case with US law, and incentives for the swift resolution of patent disputes, all of which are essential elements of the current US patent linkage system. The FTA also needs to remedy the cumbersome and protracted process of Korea's judicial system which takes an average of 6 to 12 years to litigate patent dispute claims.

Moreover, we believe that Korea should reverse the burden of proof in certain process patent enforcement actions when confirmatory information on the accused infringer's process is

not available. This change would be in line with United States law set out in 35 USC 295. Finally, we are concerned that the Korean provisions for restoring patent term due to regulatory and patent office delays do not appear to be adequate and consistent with U.S. law and practice.

We also will be looking for practical, science-based approaches to the establishment of IPR protection for agricultural biotechnology. The agreement needs to emphasize enforcement of IP rights and adherence to the principles of the WTO and the existing TRIPS agreement as they relate to IP.

In addition, we encourage USTR to obtain strong commitments from South Korea to take effective action at its borders to address trade in pirated and counterfeited goods.

ITAC members recognize and strongly support the USG negotiators leading this effort, including Victoria Espinel and Karen Hauda.

Pharmaceuticals & Medical Devices:

As you know, this area presents some special challenges to our negotiators. We have created an informal subcommittee to work with your staff on this issue, chaired by our Vice Chairman, Robert Branand. The committee is made up of seasoned executives representing both pharmaceuticals and devices. We hope that you will call on their expertise to be sure that the outcome of these talks will be consistent with the needs of these important industries.

South Korea currently imposes price controls on Pharmaceuticals and Devices through its government-administered insurance reimbursement system. This system needs to establish clear, transparent rules for decision making; enforce reasonable time frames for decision making; ensure that data requirements are sensitive to and encourage medical innovation; ensure a balanced opportunity for the primary suppliers and developers of technology to participate in decision making; and establish a meaningful appeals process.

Given the history of significant problems in this sector, ITAC members were extremely concerned about the Ministry of Health and Welfare's recent announcement in May of sweeping new pharmaceutical pricing policies in Korea. Both the substance of the new proposals and the way they were put forward -- with virtually no consultation with stakeholders -- is of significant concern. ITAC members expect that the KORUS FTA will improve the environment in which they do business in Korea. The Korean government's recent announcement represents the "old way" of doing business in Korea and is a significant step backwards.

Going forward, the NHI's policies and procedures for listing and reimbursing medicines need to be improved to strengthen recognition of the value of innovative medicines. Currently, the Korean pharmaceutical reimbursement system, for which the NHI is in effect a monopolist single purchaser, lacks transparency and clear, fair, criteria in determining the value of innovative medicines, and systematically undervalues such medicines. Korea's current reimbursement policies in fact represent a disguised industrial policy that not only hinders

foreign companies wishing to expand business and investment in Korea, but also actively disincentivizes local R&D.

A more objective process for establishing the guidelines and conditions under which drugs can be reimbursed would improve access to innovative medical discoveries that are developed abroad and would benefit Korean patients significantly. Even when new drugs are approved in Korea, the conditions under which doctors and nurses can prescribe them are often sharply limited by the Government. Sound science, internationally recognized good medical practice, and the best interests of Korean patients, not local protectionism, should drive such decisions.

Transparency is a crucial shortcoming of the Korean system. In general, the Korean Government's decision-making processes relating to innovative medicines and drug policy lack transparency and do not ensure meaningful consultation with foreign companies regarding major policy or rule changes affecting them. Such decisions can lead to major changes in access to breakthrough U.S. medicines, with important consequences for Korean patients. The lack of independent appeal mechanisms contributes to arbitrary decision-making and a troubling lack of accountability.

The system must also make sure that there is no disadvantage built in for imported products.

We were very pleased to learn that Jeffrey Dutton will be working this important issue. We have a long history with Jeff and truly appreciate his attention to detail, which will be a vitally important aspect of work in this important area for our sector.

Data Recognition & Exclusivity:

The right to market many of the products in our sector is subject to various government controls requiring the submission of voluminous data files. It is important that the FTA establish the fact that the authorities in Korea should recognize data meeting US standards.

In the case of pharmaceuticals, the negotiating text should be based on current US law and regulatory practices as currently interpreted by the US FDA. For instance, contrary to U.S. law, the three-year exclusivity provision applies to a same or similar product rather than the new condition of use of the product. The current text would prevent the marketing of competing versions of a product even for off-patent uses. In addition, the phrase "same or similar product," used in both the three- and five-year exclusivity provisions, is overly vague and could allow exclusivity to be broadly applied to all products in a therapeutic class—a blatant diversion from U.S. law under which exclusivity applies strictly to products with the same active ingredient including any ester or salt of the active ingredient in the case of five-year exclusivity, or specifically to the new condition of use in the case of three-year exclusivity.

Technical Barriers to Trade:

Commitments in this area are a vital component to ensuring that standards and regulations do not erode the enhanced market access achieved under the FTA. Strict compliance with rights and obligations under the WTO TBT Agreement should be the base line of this chapter in the FTA. We also support obligations that extend beyond the TBT Agreement to reflect South Korea's standards and regulatory process. The agreement should contain strong transparency provisions, including advanced notice and a meaningful opportunity for private sector interests to participate in the development of South Korea's standards and technical regulations procedures.

We also believe that this agreement needs to include provisions for private sector engagement in the development of IP policy and the subsequent enforcement of that policy. It would be helpful if it also has a strong emphasis on the enforcement of IP rights, the timely adjudication of those rights, and on imposing stricter IP penalties to combat theft, piracy, and illegal commercialization of foreign technology.

It should also have increased efforts to educate the public and raise awareness about the damage done by counterfeiting and piracy by increasing the allocation of government resources toward combating piracy and counterfeiting.

It would be helpful if the agreement required adherence to the obligations in the TRIPS Agreement Art. 39 guidelines especially concerning protecting undisclosed information, particularly in safety and efficacy studies, against unfair commercial use. However, we believe that Art. 39 should not preclude reliance on previous government findings for safety and efficacy to support the approval of generic pharmaceuticals as well as the use of bio-equivalence studies conducted in other territories to grant market approval of a generic drug.

This FTA should also challenge South Korea to help reduce the costs and simplify patent registration procedures through the development of regional patenting schemes.

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.

Ancillary Issues:

One of our members is very concerned about the possible inclusion of an elastomeric fiber exemption under the de minimis rules for textiles. This limitation, treating elastomeric fibers differently than all other yarns/fibers, severely restricts the economic growth opportunities for American cotton and man made fiber producers, yarn and fabric manufacturers, and apparel makers.

It is important that plastics manufactured goods (products falling under HTS 3916-3926) be treated as import sensitive. Chapter 39 includes plastics resins/polymers (HTS 3901-3914) as well as intermediate and finished plastics goods (HTS 3916-3926, "plastics products"). While the US has an overall bilateral trade deficit with South Korea in Chapter 39 products, the deficit in plastics product trade largely accounts for this imbalance. In fact, the bilateral deficit in plastics product trade with South Korea has grown rapidly in recent periods. In 2005, it was approximately $423 million, a 104 percent increase from the $121 million deficit observed in 2004. This member is very concerned that immediately eliminating tariffs (which are generally lower than South Korea's tariffs applied on the same or comparable plastics products) could exacerbate the deteriorating trade position in this segment. For this reason, US negotiators should seek the longest possible phase-out of tariffs on imports of products falling under HTS 3916-3926.

We also specifically requests that imports of polyethylene terephthalate film, sheet and strip (PET Film) (HTS 3920.62.0000) from Korea be treated as import sensitive. Based on affirmative findings of dumping and injury, these products are currently subject to an antidumping duty order. Importantly, in a recent review of the antidumping duty order, the International Trade Commission declined to revoke the order, citing *inter alia*, increased imports from South Korea despite the existence of the order and excess capacity that exceeds demand in the South Korean market. (*See Polyethylene Terephthalate (PET) Film from Korea*, Inv. No. 731-TA-459 (Second Review), USITC Pub. 3800 (Sept. 2005). For this reason, these products

should be treated as import sensitive and any duty reductions should be staged over the maximum period possible.

We are also concerned about Korean imports of Bottle Grade PET resins (HTS 3907.60.0010, CAS # 25038-59-9) and the impact those imports could have on the U.S. PET industry. The EU PET Industry faced significant exports of PET from Korea in the late 90's which resulted in an anti-dumping action taken by the EU against Korea. Bottle Grade PET imports from Korea in 2005 more than tripled the 2004 levels, to over 30,000 MT. According to the ITC, from January to March, 2006, Bottle Grade PET imports from Korea are running at 9,400 MT, which is just under the entire imports from Korea in 2004. The PET Industry in the U.S. is concerned about the continued increase of imports from Korea keeping in mind their past dumping actions in other markets. Bottle Grade PET resin imports should also be treated as import sensitive and any duty reductions should be staged over the maximum period possible.

We believe that in addition to the chapter 39 items specified above that there are two tariff lines that are important to the US Pigments industry that are import sensitive - 320417 and 292143. These two lines should be allowed the maximum staging permitted by the agreement so that US Industry will have time to adjust to this new competition.

Labor and Environment Provisions:

ITAC-3 has advocated that U.S. negotiators should consider with great care the pursuit of this objective. 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 fundamentally misguided 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.

Mr. Waskow of Friends of the Earth has urged that the Environment chapter explicitly require

the Parties to the agreement to fully and effectively implement their obligations under any multilateral environmental agreement to which they are a party. He has also urged that the obligations in the agreement regarding improvement of and non-derogation from environmental standards be made subject to the dispute resolution process.

Attachment

US - Korea Trade Summary Sheet for 2005

Chapter	Description	US Exports to Korea	US Imports from Korea	US Balance
28	Inorganic Chemicals	$333,231,563	$52,472,467	$280,759,096
29	Organic Chemicals	$1,975,656,293	$604,416,602	$1,371,239,691
30	Pharmaceuticals	$205,068,364	$17,804,676	$187,263,688
31	Fertilizers	$179,435,457	$1,418,096	$178,017,361
32	Colorants, Paints, Etc	$120,808,022	$65,315,222	$55,492,800
33	Cosmetics & Essential Oils	$148,253,838	$33,126,895	$115,126,943
34	Soaps, Etc	$93,077,299	$26,753,766	$66,323,533
35	Starches, Glues & Enzymes	$28,276,292	$12,834,414	$15,441,878
36	Explosives	$13,500,586	$5,340,285	$8,160,301
37	Photographic Material	$52,535,737	$32,267,801	$20,267,936
38	Miscellaneous Products	$420,588,650	$139,918,915	$280,669,735
39	Plastics & Articles	$866,639,852	$1,008,527,203	-$141,887,351
40	Rubber & Articles Thereof	$88,959,595	$906,631,290	-$817,671,695
	Medical Devices *	$431,192,671	$229,136,404	$202,056,267
	Total	$4,957,224,219	$3,135,964,036	$1,821,260,183

Actual US Dollars
Source: USITC Dataweb
Exports: US Domestic Exports
Imports: Imports for Consumption, customs value
* Medical Devices, except those in 28 - 40 are found in 84, 85, 87, 90 & 94

V. Advisory Committee Opinion on Agreement

Most members of ITAC-3 support the approval of this Agreement in the form it was originally sent to Congress and posted on our secure website. 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:

Preamble: No Comment

Chapter 1: Initial Provisions

No comment.

Chapter 2: National Treatment and Market Access for Goods

Tiffany Smith's group did an excellent job negotiating the tariff sections that affect our sector.

a. Korean Schedule: We are very pleased that most of the Korean Tariffs on U.S. goods will be removed upon implementation of the agreement. In addition, we are pleased that eventually everything will be tariff free in our sector. The phase out schedule is reasonable.

b. U.S. Schedule: We are very pleased that USTR was able to accommodate our sensitivities in this negotiation allowing for 10 year staging in some instances to allow US producers time to adjust to this new competition.

Chapter 3: Agriculture

No Comment

Chapter 4: Textiles & Apparel

No Comment

Chapter 5: Rules of Origin

We are very pleased with the rules of origin that are included in this agreement. ITAC-3 worked very closely with 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 Korea. We applaud Mr. Eizenstat for a job well done!

It is our hope that the chemical rules of origin contained in the Korea 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 would also support the use of these rules of origin in other trade preference programs such as GSP.

Chapter 6: Customs Administration

We support the language in this agreement as adopted in previous FTA's. These strong provisions are important to ensure that trade is not encumbered by onerous and non-transparent customs procedures.

Chapter 7: Sanitary & Phytosanitary Measures

No Comment

Chapter 8: Trade Remedies

ITAC 3 supports the efforts of our negotiators that resulted in maintaining our trade remedy laws and procedures.

Chapter 9: Government Procurement

No Comment

Chapter 10: Investment

ITAC 3 is pleased to note that this agreement contains strong provisions that should protect US investors and investments in Korea. There is a broad definition of investment, guarantees of prompt and fair compensation in the case of expropriation, a ban on performance requirements, a commitment to national treatment as well as free transfer of capital. All of these issues are vitally important to our sectors which tend to be very capital intensive.

Chapter 11: Services

Annex II – Formatting Note for Investment/Services: No Comment
Korea Annex I – Reservations to Investments/Services: No Comment
Korea Annex II - Reservations to Investments/Services: No Comment
US Annex I - Reservations to Investments/Services: No Comment
US Annex II - Reservations to Investments/Services: No Comment

ITAC 3 supports the establishment of a Working Group to facilitate the ease and speed of authorization, licensing or certification of service suppliers. This committee is especially important in the areas of professional services, such as medicine and nursing, where there is an immediate need for the mutual parties to get prompt information of standards and criteria for education, licensing and certification, knowledge of the scope of practice

for providers, as well as understanding of the regulatory body and authority that oversees the medical and nursing service providers. When possible, the Working Group may want to consider including international medicine and nursing certifying organizations, specializing in preparing health care providers for international deployment. Where parties agree, each party should encourage relevant bodies within its territory to develop temporary licensing procedures for professional services.

Chapter 12: Financial Services

No Comment

Chapter 13: Telecommunications

No Comment

Chapter 14: Electronic Commerce

No Comment

Chapter 15: Labor

No Comment

Chapter 16: Environment

Side letter – Equivalence: No Comment
Side letter – Submissions: No Comment

Chapter 17: Intellectual Property Rights

ITAC 3 strongly supports intellectual property rights protection consistent with US law.

Most of our members applaud the efforts of USTR that resulted in the very strong chapter on intellectual property rights included in this agreement. These members also fully support the important intellectual property provisions that this FTA contains regarding pharmaceutical products. In particular, Korea's commitments regarding patent linkage, patent term restoration, and data protection appropriately recognize the critical nature of intellectual property rules as an engine for pharmaceutical innovation. Korea's enactment of these rights will help advance its objective of joining the ranks of other developed countries with vibrant, research-based life sciences sectors. Implementation of the intellectual property rights provisions must be monitored closely to ensure they are fully reflected in Korean law to the benefit of Korean patients seeking the most effective cures

Shawn Brown of GPhA suggests that as a developed country, Korea's regulation of its pharmaceutical market should reflect a standard of intellectual property protection similar to that in the U.S. The U.S. Korea agreement fails to fulfill the principle trade-negotiating objective of achieving an agreement that reflects such a standard of IP protection. Rather, this agreement blatantly excludes provisions to ensure affordable access to safe and effective generic medicines. The standard of IP protection in U.S. law carefully balances fostering pharmaceutical innovation with ensuring access to affordable medicine. He agrees that the strength of a pharmaceutical market depends on the security of intellectual property and the protection of the incentive to innovate new products. However, of equal importance to a nation's health and the effectiveness of its pharmaceutical market, 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 18: Pharmaceuticals & Medical Devices

Our members strongly believe that this Chapter contains a number of important improvements to Korea's regulatory system, including commitments regarding access to innovation, imposition of an independent appeals process, increased transparency and accountability, and maintenance of ethical business practices to ensure a level playing field. We look forward to the timely implementation of all of these commitments. We applaud the results that the USTR achieved in this area since we recognized that a great deal of effort had to be expended to achieve this victory.

At the same time, much work remains to address the many challenges innovative pharmaceutical companies face in gaining access to the Korean market on fair terms. Korea continues to move forward with imposition of an entirely new reimbursement system which does not adequately recognize and reward innovation or place a high priority on early patient access to cutting edge, life-saving medicines. It is critical that the U.S. government continue to address these issues as quickly as possible. ITAC-3 members encourage continued interaction with the ITAC-3 Pharmaceuticals and Medical Devices Subcommittee to work with your staff on these issues. We hope that you will call on their expertise to be sure that the outcome of these talks is consistent with the needs of these important industries.

Chapter 19: Transparency

We support the strong provisions in this agreement that will result in greatly enhanced transparency in Korea.

Chapter 20: Competition

No Comment

Chapter 21: Institutional Dispute Settlement

No Comment

Chapter 22: Exceptions

No Comment

Chapter 23: Final Provisions

No Comment

Annexes:

Fisheries Annex: No Comments
Outward Processing Annex: No Comment

VI. Membership of Committee:

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.

Michael D. Boyd
V.P. Public Affairs, International
Schering-Plough Corporation

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

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

Morris A. Chavez, President

Representing the Society of the Plastics Industry

Sushan Demirjian
Director, International Trade
American Chemistry Council

Donald E. Ellison
Government Relations, LLC
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
Director, U.S. Federal Government Relations
S.C. Johnson & Son, Inc.

Matthew T. McGrath, Esq, Partner
Barnes, Richardson & Colburn
Representing Intermune, Inc.

Lloyd N. Moon
Vice President
Chemtura Corporation

Tracey J. Norberg, Esq
V.P. Environment & Resource Recovery
Rubber Manufacturers Association

J. Lawrence Robinson
President
Color Pigment Manufactures Association

George L. Rolofson, PhD
Rolofson Consulting
Representing Gowan Company

Lisa Schroter
Hemisphere Polymer & Chemical Company

Tine K. Hansen-Turton
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