



January 31, 2003

Ms. Gloria Blue
Executive Secretary
Trade Policy Staff Committee
Office of the U.S. Trade Representative
Via E-mail: FR0060@ustr.gov

Dear Ms. Blue:

The National Association of Manufacturers (NAM) welcomes the opportunity to provide comments on the second public draft of the Free Trade Area of the Americas (FTAA) Agreement, as requested by USTR in its Dec. 27, 2002 *Federal Register* notice. The NAM represents 14,000 companies in all sectors of manufacturing, including 10,000 firms of small and medium size.

The NAM's comments will concentrate most heavily on the draft intellectual property chapter, but also will cover FTAA provisions related to market access, rules of origin, customs procedures, standards, and transparency.

Intellectual Property Provisions

Beyond the benefit of tariff cuts, improved intellectual property protections are among the most important benefits the FTAA can deliver to U.S. manufacturers. NAM urges that the FTAA trading partners at least meet, and preferably exceed, the intellectual property protection standards set out in the Trade Promotion Authority (TPA) negotiating objectives of the Trade Act of 2002. The FTAA Agreement should require each participating country to incorporate and enforce most, if not all, of the following intellectual property provisions.

- *Ensure Patent Protection for Inventions in All Fields of Technology*

The FTAA should guarantee the availability of patent protection for products and processes in all areas of technology. Relative to the standards reflected in the Uruguay Round's Trade-Related Aspects of Intellectual Property Rights (TRIPS) Agreement and the North American Free Trade Agreement (NAFTA), this means that FTAA members should take on the obligation to grant comprehensive protection for all biotechnological inventions, including plant and animal inventions. The FTAA should ensure that patents, without exception, could protect all new, useful and non-obvious inventions.

The FTAA should not be used as a mechanism to bypass the mandate of TRIPS to make patents available for inventions in all technological areas. Certain proposals are

being advanced that would characterize an invention that is new, non-obvious and useful, but is the result of a “discovery” as unpatentable subject matter. The theory of these proposals is that the isolation, characterization and commercial application of a chemical compound from a natural source (for example, a plant) is not deserving of patent protection. Such an approach would fundamentally alter the mandate of the TRIPS Agreement and the NAFTA Agreement to ensure patent protection for all inventions that meet the criteria of being new, useful and non-obvious. It would also conflict with more than 100 years of established U.S. patent law precedent that holds that the means of production of an invention is immaterial to its patent eligibility.

We have also seen certain countries in the FTAA take unreasonable positions regarding eligibility of inventions that incorporate new uses of previously known compounds. The Andean Pact countries have adopted a standard – upheld by their regional tribunal – that denies patents on process inventions that are new, useful and non-obvious if the process involves use of a previously disclosed product. There is no authority under TRIPS for a country to deny patents on a non-obvious process invention, even if it uses a previously disclosed product. The FTAA should expressly prohibit Members from making end-runs around the requirements of TRIPS, including, if necessary through explicit language prohibiting such practices.

- *Establish a Standard of National Exhaustion of Patent Rights*

Under the TRIPS Agreement, patent holders are to enjoy the exclusive right to import products covered by their patents. Several countries nevertheless permit importation of patented products once the product has lawfully been placed in the commerce of a third country. These practices have a significant trade-distorting effect, given the often widely disparate economic conditions found among the FTAA Member economies.

The legal fiction of international exhaustion was created to permit unauthorized importation of products procured outside the jurisdiction of the patent, whether legitimately from the patent owner or illegitimately from a party not authorized to sell or export the product. International exhaustion works to override explicit contractual or legal restrictions prohibiting export of patented products, and conflicts with the provisions of the Paris Convention that demand that countries treat patents as independent legal instruments.

Patents, unlike other forms of protection, must be specifically procured in each jurisdiction and are limited territorially to that jurisdiction. Patents are independent legal instruments bound to the country or territory in which they have been granted. Indeed, under Article 4bis of the Paris Convention on Industrial Property, patents are to be considered independent in the fullest sense of the word. The NAM notes the recent rejection by the Court of Appeals for the Federal Circuit¹ of foreign doctrine to the effect that a sale of a product in one country under a license to the patent for that product in that country constitutes a first-sale exhaustion of rights, thus clearing the way for unrestricted importation of that same product into any other country even if the product is patented in

¹ *Jazz Photo Corp. v. U.S. International Trade Commission*, 264 F.3d 1094 (Fed. Circ. 2001) (Newman, J.).

that other country, not previously sold in that other country, and not licensed for sale in that other country by that importer. Under these latter circumstances, the patent holder in the other country typically has restricted the terms of use or sale of the product in order to prevent parallel importation.

National laws that create the legal fiction of international exhaustion of patent rights do not represent sound public policy and work to seriously prejudice the interests of the patent owner. Policies permitting international exhaustion operate to create a market in arbitrage of patented product with numerous undesirable effects. One such effect is that products will be diverted from their target markets. This raises the prospect of improperly labeled products or counterfeit products. Another undesirable effect of international exhaustion is to divert products to the markets capable of providing the highest price for the patented articles. This practice works to prejudice countries with economic conditions not capable of supporting the higher prices that can be obtained for the patented product in other markets.

The FTAA agreement should reaffirm the principle of territorial integrity of patents reflected in Article 4bis of the Paris Convention by explicitly prohibiting policies of international exhaustion of patent rights. The FTAA should instead provide that the act of placing a patented product on the market of one country cannot and will not exhaust the patent holder's rights in another country.

A number of proposals seek to establish either an unfettered discretion for FTAA members to define their policies on international exhaustion, or would impose a regional or global exhaustion policy on all FTAA members. We strongly oppose such proposals. The concept of regional exhaustion, such as is followed by the European Community, is premised on the economic equivalence of the intellectual property rights in all members of the common market. The FTAA is not creating a common market, and the economic value and attributes of intellectual property rights varies tremendously within the members of the FTAA. For example, the value and effectiveness of a United States patent can in no way be equated to the value and effectiveness of an Argentine or Uruguayan patent. A policy of regional or international exhaustion is thus entirely inappropriate for the FTAA. Given the widely divergent economic value of intellectual property rights, particularly patent rights, within the region, it is essential to preserve the ability of patent owners to manage these independent rights. The only effective way to do this is to provide through the FTAA that patent owners may take legally enforceable steps to preserve the full enforceability of patents in an FTAA Member, regardless of the acts that are performed in relation to patents in other FTAA Members.

- *Provide for Patent Term Restoration for Patent Office Delays*

For patent protection to provide an appropriate incentive for innovation, a sufficient period of protection must be provided to allow companies to recoup their research and investment expenses. The TRIPS standard for patent term requires a minimum of 20 years from the filing date of the application. However, the law of most countries fails to account for the fact that many countries' patent offices are overloaded with work, and thus the pendency of patent applications can last for many years,

significantly decreasing the effective term of the resultant patents. US law recognizes the problem with this approach and provides for the restoration of patent terms to account for significant delays on behalf of the patent office processing. The backlog in many offices in the FTAA countries makes this an important and needed provision.

- *Provide Patent Term Restoration to Recover Regulatory Review Time*

In a number of highly regulated technological areas, including pharmaceuticals, agricultural chemicals, and medical devices, significant barriers exist in bringing a product to market. The barriers faced by these industries result in extended delays commercializing the patented product. The United States, the European Union, Japan, and several other countries recognize this fact and provide a restoration of lost term to patent owners that have faced extensive delays in reaching the market due to regulatory approval procedures. In addition, the United States patent system preserves an effective patent term for innovators by providing patent term restoration in the event of undue patent office delays in granting the patent.

The FTAA should incorporate an obligation to grant patent term restoration to ensure that patent owners will enjoy an effective period of patent protection in all FTAA countries. The restoration should be made available so that patent owners are guaranteed an effective term of protection for patented inventions that cannot be commercialized due to delays in regulatory approval procedures or who faced undue administrative delays in obtaining the patent. The extension model should reflect the findings of the initial market in which the delays were incurred, so that the patent owner throughout the FTAA region will enjoy a generally consistent patent term.

- *Place Limitations of the Grounds for Patent Revocation*

The laws of many countries provide for the invalidation or revocation of a patent based on issues not addressed by the patent office when the patent was granted. Simply stated, NAM believes that a patent office or a court should only be able to invalidate or revoke a patent for reasons related to the conditions for patentability used to grant the patent.

- *Provide a “Grace Period” Preventing the Loss of Patent Rights to the Patent Holder for Disclosures from the Inventor Prior to Patent Expiration*

The patent law in virtually all countries dictates that patents are granted to inventions which are novel, useful (sometimes expressed as industrially applicable), and non-obvious (sometimes expressed as possessing inventive step). With regard to novelty, it is often measured as of the date of application, and many countries prevent patenting if there is any public disclosure by anyone even one day before the filing date (this is called “absolute novelty”). The US has an exception to this rule, permitting the patenting of inventions where the application is filed within one year of any public disclosure (so long as the inventor can establish that the invention was made prior to any public disclosure). Some Latin American countries have a similar exemption, but most do not. A proposal being discussed at the global patent harmonization talks taking place at the World Intellectual Property Organization (WIPO) in Geneva (known as the Substantive Patent

Law Treaty or SPLT talks) would allow patents to be granted even if there is a prior public disclosure of the invention, so long as it emanated from the inventor, and is limited to one year prior to the application date. Adoption of such a provision in the FTAA would be the fairest for all, allowing developing countries, with less knowledge of the rigidity of absolute novelty systems, to protect their inventions despite an inadvertent disclosure.

- *Promote Accession to the Patent Cooperation Treaty and Other International IP Treaties*

The Patent Cooperation Treaty (PCT) is an excellent vehicle for obtaining global patent protection, allowing for the filing of a single application, in the home country language, to be treated as the equivalent of an application filed in each country of the treaty. The treaty allows time for informed and orderly decision making, allowing for completion of filing of the application, including the preparation of translations, hiring of local associates, and the payment of filing fees, up to 30 months from the first filing date, after the application is published and receives an international search and examination. There has been exponential growth in the usage of this treaty, and it has been a boon for patent applicants in all types of industries worldwide. Countries have found that, after adherence to the PCT, the number of patent applications rise, increasing the likelihood that innovative technologies will be introduced in their countries, and making it easier for local innovative industries to protect their inventions. While there have been some notable successes in Latin America (for example, Mexico), there remain a number of countries that are not among the over 116 current PCT members. Greater participation in the Patent Cooperation Treaty in the region could reduce duplicative search and examination efforts by their patent offices. If the lack of technical expertise is a barrier to participation in the Patent Cooperation Treaty, the World Intellectual Property Organization and the current members of the Treaty in the hemisphere should provide technical assistance.

As a general proposition, the FTAA countries should strive to create a mechanism to facilitate the grant of patents and registration of trademarks in multiple countries. Members should cooperate and share the work products from other members to reduce their workload and avoid unnecessary duplication and costs of examination processes. Once one country has examined, for example, the patentability of an invention, it should share this information with other FTAA members, which can then rely more directly on these results in granting patents or registering trademarks in their country. In order to make this mechanism work most effectively, however, the FTAA countries would need to harmonize certain aspects of their legal standards regarding patents and trademarks.

The creation of a work-sharing mechanism would not be difficult or unprecedented. Recent developments in information and communication technology have made it possible to share information electronically in a cost-effective manner. In fact, the U.S. Patent and Trademark Office (PTO) have built an electronic pipeline to the European Patent and Japanese Patent Offices, which enable them to exchange search and examination information. PTO should build upon its current efforts and initiate pilot or feasibility projects with selected FTAA Members to start to build work-sharing capacity.

The TRIPS Agreement does not incorporate other procedurally beneficial multilateral instruments in the field of intellectual property law. These instruments include the Patent Cooperation Treaty, the Budapest Convention for the Deposit of Microorganisms, the Trademark Law Treaty, the Protocol to the Madrid Convention on the International Registration of Marks, and the proposed WIPO Patent Law Treaty. FTAA members should agree to adopt the standards in these predominantly technical instruments within a reasonable period of time.

- *Provide a period of at least five, and preferably ten, years during which a third party cannot refer to or rely on confidential data submitted to regulatory agencies consistent with the provisions of TRIPS Article 39 (3)*

Article 1711(6) of NAFTA provides as follows: no person – other than the one who submitted confidential test data to obtain marketing approval for a product – may, without the original submitter's permission, rely on such data in support of an application for product approval during a reasonable period of time after the approval. Article 39(3) of the TRIPS Agreement contains a similar provision. However whereas the TRIPS Agreement does not define the phrase "reasonable period of time," NAFTA states that a reasonable period of time is a period of not less than five years. During the five-year period, generic producers may not rely on the innovator's test data package in obtaining marketing approval for their own version of the product. Such parties always have the option of undertaking the expense of compiling their own data on the safety and efficacy of the product.

The FTAA agreement should build upon and clarify the data protection provisions of NAFTA. Confidential test data must be given a minimum of five years of protection against use (either direct or indirect) by third parties in expedited regulatory approval procedures. Furthermore, the agreement should state clearly that the term "rely" includes not only reliance on the actual test data but also reliance on the fact that a product has obtained marketing approval -- either in the country where marketing approval is sought or in a foreign country. This is particularly important given the trend in many countries of relying on conclusions of safety and efficacy without requiring provision of a dossier of test data. The protections must not be made contingent on patent protection, and should extend protection to new indications for previously approved chemical entities.

We also remain strongly opposed to any effort to equate the obligation to protect test data submitted to gain marketing approval for a regulated product from unfair commercial use to an obligation to protect confidential business information against unauthorized disclosure. Certain suggestions have been made that these two standards are the same, which, if adopted, would conflict with the obligations of TRIPS and NAFTA.

- *Provide "Patent Linkage" between the Regulatory Agency and Patent Enforcement Efforts*

The interrelationship between regulatory agencies, which must approve the use and sale of certain products, such as pharmaceuticals and agricultural chemicals, and those entities charged with patent enforcement, is not strong in many countries. As a result, the health

authority might approve a generic product despite the existence of a patent, or even pending litigation relating thereto. Under U.S. law, if a generic company seeks to obtain approval to market a product before the innovator's patent expires, the innovator is notified, and if the innovator initiates a lawsuit, the regulatory agency will not approve the generic product for up to 30 months, or until the patent issues are resolved, whichever comes first. Other countries, such as Canada, have similar provisions. China is perhaps the most recent country to provide such "patent linkage." Such linkage is necessary to more effectively protect the innovator's intellectual property, and to prevent market disruption by products which might be approved, only to be withdrawn after adverse court action.

- *Establish Deterrent Penalties for Copyright Infringement*

Many NAM companies own commercially important copyrights associated with their products. We acknowledge that many other U.S.-based industries, including the motion picture, recording, software and publishing industries, have made clear the importance of truly effective and enforceable protection for copyrighted material. NAM wishes to add its voice in support of strong and effective standards for protection of copyrighted material.

- *Provide Effective Trademark and Brand Name Protection for Highly Regulated Products*

Countries in the FTAA region are already obliged by the TRIPS Agreement to protect trademark rights. The authority in TRIPS and in NAFTA for governments to restrict trademark rights is narrowly circumscribed. Even so, some of our companies have faced serious challenges around the world to preserving their trademark interests in their products. These challenges have included restrictive labeling conditions imposed by regulation or practice that prevent the normal use of a brand name in conjunction with a regulated product.

One of the central functions of trademark rights is to ensure that the public is aware of the source of the goods that they purchase. For products whose quality is paramount, such as pharmaceuticals, this function is of critical importance. Accordingly, we are concerned that restrictive practices regarding the use of trademarks in association with regulated products will seriously conflict with public health and consumer interests, in addition to undermining the valuable commercial interests of our companies. For these reasons, we strongly support inclusion of provisions in the FTAA that would specifically prohibit the imposition of restrictions and conditions on use of brand names of regulated products such as pharmaceuticals.

- *Eliminate Provisions Unrelated to Free Trade or Intellectual Property Concerns, such as Those Related to Genetic Resources, Traditional Knowledge or Folklore*

Such provisions do not aid in enhancing trade, are unrelated to intellectual property, and most importantly, are best addressed in other forums such as the World Intellectual Property Organization (WIPO). Several proposals have been advanced that would impose special disclosure requirements for patent applications directed to inventions

involving or derived from “genetic resources” or that use “traditional knowledge.” These proposals suggest that patent applicants, among other things, identify the genetic origin of living materials that are disclosed in the application or relate in some undefined way to the invention, or confirm that the genetic resources or traditional knowledge was used with informed consent of the owners of the resources or knowledge. The sanction of an applicant not complying with these vaguely defined obligations would be loss of the patent.

The premise of many of these proposals is that intellectual property owners do not comply with national or international obligations associated with the use of genetic resources, or that there is a conflict in property interests between those possessing genetic resources and those that develop patentable inventions. Neither premise has any basis in fact.

The NAM is not aware of any examples where there has been an unauthorized use of a genetic resource, or where there has been a refusal to share benefits that have been agreed upon as a condition of access. Rather, in the few examples that are known, the companies have committed to share benefits and delivered on those commitments notwithstanding the absence of any commercial or other success in use of the genetic resources.

Moreover, we note that by definition, there cannot be a conflict in ownership interests between patented inventions and genetic resources. To qualify for a patent, an invention must be new, useful and non-obvious. Under U.S. patent law standards, and under standards in all other FTAA countries, a patent may not be granted on a naturally occurring substance that would give rights in the substance as it exists in nature. Genetic resources thus, by definition, cannot be covered by patent rights. Likewise, a patented invention, by definition, involves some inventive contribution.

In light of these points, there is no place in the FTAA for provisions that would impose special disclosure requirements for inventions involving living materials, particularly where non-compliance would serve as a basis for declaring the patent invalid. Such standards will do nothing to ensure compliance with national genetic resource management regimes, and will provide unjustified opportunities for third parties to challenge patents on inventions that clearly meet patentability requirements.

Let us clarify that we are not advocating that patent rights extend to know native plants and known native folk-medicine herbal remedies.² Regrettable confusion has existed on this question in general, notwithstanding the bedrock principle that patent protection can never extend to widely known practice. Rather, we are saying that patent protection must be provided for the identification, isolation, and purification of the active, effective, and unharmed chemical component – aside from the numerous other chemical components in any given plant – for treatment of a particular disease.

We are aware that a number of governments have proposed to include provisions in the intellectual property chapter of the FTAA that would protect “traditional knowledge.” As innovators, we certainly support efforts that will respect the intellectual property, as

² An erroneously granted patent for medicinal use of turmeric was reversed upon reexamination.

well cultural and other interests of traditional communities. We are also supportive of practices that reward cooperation with these communities, including by sharing benefits where an innovator has worked with and used traditional knowledge from a local community.

Many of the proposals that we have reviewed and have been offered in the name of protecting traditional knowledge do not seem focused on that task. Instead, these proposals either simply declare that rights must be provided, or state that intellectual property rights must be made “subordinate” to these rights. We do not believe it is feasible or realistic for the FTAA to attempt to define rights for traditional communities through these simple references or declarations. We would also have serious concerns with any effort to subordinate intellectual property rights to other types of intangible rights.

We note that several other multilateral organizations, including WIPO, are grappling with the practical difficulties of creating enforceable rights for these communities. These difficulties include problems in defining what the rights are to cover, who “owns” the rights, whether they are transferable or alienable, how those rights are to operate, and how those rights might interact with not only intellectual property rights, but general property and other rights created by law. We also are not aware of any national regime that might serve as a precedent or basis for such a standard. As such, we do not believe it is feasible or realistic to include specific obligations regarding traditional knowledge or genetic resources into the IP chapter of the FTAA.

- *Improve IP Enforcement Procedures*

Several countries have failed to establish a legal environment that permits intellectual property owners to effectively enforce their rights. A number of specific measures required by TRIPS have not been implemented in a number of FTAA Members. The FTAA should be used to further refine the nature of obligations in the area of enforcement procedures to ensure that efficient and effective procedures are available in all FTAA members to enforce rights. In particular, the obligations of Article 50 of TRIPS to provide for preliminary relief options for intellectual property owners must be implemented in a more favorable manner than has been the experience in many FTAA countries.

A monitoring system should be set up to ensure full implementation of intellectual property obligations. In addition, a mechanism should be set up to foster cooperation in enforcement efforts, particularly in eliminating counterfeit products at the border. This program could be supplemented with additional technical assistance and funding from the United States.

- *Provide for IP Technical Assistance*

The NAM urges that the U.S. Government continue to play a strong role in ensuring adequate training and technical assistance to build the capacity for FTAA members to benefit from the eventual FTAA and to implement trade commitments.

In the area of intellectual property protection, this means that the United States (in part through the U.S. Patent and Trademark Office or PTO and the U.S. Agency for International Development or USAID), and in combination with other international organizations, should continue to offer up substantial assistance to build capacity for drafting and updating relevant IP legislation and regulations, enforcing IP protections (through, for instance, the training of judges, prosecutors and investigators), and granting patents and registering trademarks. Improvements in these areas will lead to a more stable and business-friendly environment for foreign and domestic goods and services providers.

Ideally, costs of assistance from the U.S. should be underwritten in a comprehensive USAID program, complemented with in-kind contributions from technical agencies such as USPTO and the Customs Bureau. Otherwise, management of the technical assistance projects may be delegated to the technical agencies. NAM companies are prepared to support these efforts to provide technical assistance.

- ***Clarify Conditions for Compulsory Licensing***

Both the TRIPS Agreement and NAFTA permit the issuance of compulsory licenses as long as certain procedural and substantive safeguards are respected. Neither the TRIPS Agreement nor NAFTA, however, regulate the grounds for issuing a compulsory license. As a result, several countries have adopted laws that would permit the issuance of compulsory licenses under circumstances that effectively undermine the normal exercise of patent rights. Some countries, for example, permit the issuance of compulsory licenses if the patent holder charges an above-market price for the patented product.

The FTAA agreement should define with specificity the circumstances under which a compulsory license may be issued. Compulsory licenses should only be permitted in cases of national emergency or to remedy fully adjudicated findings of misuse of the patent rights to cause harm to competition in a market. In the latter case, there should be a clear obligation to find that the anti-competitive behavior is most effectively remedied through the severe sanction of a compulsory license. The negotiations on compulsory licensing should reflect standards defined through negotiations in the area of competition and should ensure that "anticompetitive behavior" is not defined in such a way as to undermine the normal exercise of patent rights.

We believe defining the criteria that may serve as a basis for issuing compulsory licenses will materially improve and harmonize practices in FTAA member countries. Moreover, we do not believe additional conditions or provisions are necessary to define the authority of FTAA Members to take action to address public health emergencies. For these reasons, we strongly oppose provisions being incorporated into the TRIPS Agreement that would reserve for governments of the FTAA a broad discretion over the grounds for imposing compulsory licenses. Such a general authority – such as a general authority to grant compulsory licenses for any “public health” need – would seriously undermine, if not eliminate, the value of a patent.

Further, the FTAA is not the appropriate forum to debate any of the issues presented in paragraph 6 of the Doha Ministerial declaration, and NAM opposes any attempt to insert them here.

Market Access Provisions

Beyond NAFTA, the United States is largely excluded from the interlocking network of free trade agreements that are currently in force in the region or currently are being negotiated between Latin American countries and countries outside the region. The FTAA provides a needed opportunity to ensure market access of U.S. products and services on equal or preferential terms compared to those accorded to our major trading partners. To this end, the FTAA should:

- *Eliminate Tariffs*

The NAM wants the market access benefits for U.S. manufactured exports to come on line as early as possible. Tariff elimination should be comprehensive and as front-loaded as feasible.

At least 25 manufacturing sectors represented in the NAM desire their entire sectors to have tariffs eliminated immediately upon entry into effect of the regional trade agreement.

Among the sectors that the NAM would like to see included in the immediate tariff-elimination basket are the following: chemicals; construction & mining equipment; copper & copper alloy brass mill products; cosmetics; crop protection chemicals; distilled spirits; electrical equipment; energy products; environmental products; fertilizer; fish & seafood products; information technology & electronics products; gems & jewelry; medical equipment; paint & coatings; paper products; pharmaceuticals; printing, publishing & converting technologies; processed foods; soda ash; sporting goods; steel products; toys; wood machinery; and wood products.

These sectors include the 10 sectors that obtained limited zero-for-zero tariff elimination agreements in the WTO's Uruguay Round. Because the Uruguay Round zero-for-zero's often use a positive list approach, additions to those agreements usually cannot keep pace with rapid changes in technology. As a result, many important and innovative products are not covered by the zero-for-zero initiative. Furthermore, only a limited number of countries have signed on to the zero-for-zero agreements, which allows many countries to "free ride" on the initiatives, that is, they can export products tariff-free to the United States, while they subject imports from the United States to tariffs. Trade distortion results not only from this tariff imbalance but also from tariff preferences that several FTAA countries have negotiated among themselves, excluding the United States.

The FTAA agreement should immediately eliminate tariffs on all goods traded within the Hemisphere in the previously mentioned sectors. Furthermore, FTAA parties should be encouraged to participate in the zero-for-zero modality of the WTO non-

agricultural market access negotiations by proposing their own sectors for inclusion and engaging constructively on U.S.-proposed sectors.

- *Eliminate Government Measures, such as Price Controls and Reference Pricing, which Deny Full Market Access for U.S. Products in Foreign Markets*

Despite the significant progress made in the Uruguay Round negotiations and NAFTA to lower trade barriers, protectionist, discriminatory, or otherwise arbitrary government policies continue to adversely affect market access in the region.

- *Ensure Fair Market Access for Innovative Products*

The lifeblood of the U.S. industry is its ability to develop and bring to market innovative products. The continued development of these products, however, comes at a price. For example, research-based industries need a period of exclusivity in the market to underwrite the costs of continuing research and development for future innovative products. Under free market conditions, research-based producers can capture this value because consumers are generally willing to pay higher prices for novel, more-effective products. The producers' ability to recover costs is further protected by the availability of patent protection and data exclusivity, which provides original manufacturers with a period of market exclusivity and prevents others from free riding on the development costs incurred by innovative producers.

Several governments have adopted measures that distort the market and diminish the opportunity to recover the R&D and testing costs associated with new products. Canada, for example, has adopted a price control regime targeted specifically at patented pharmaceutical products. Such programs undercut the value of intellectual property rights and undermine future research and development efforts. U.S. companies are inevitably the hardest hit by such programs because they comprise the most innovative segment of the industry. Price control programs also force consumers in countries without price controls – most notably the United States – to bear most of the cost of developing new products. This is unfair. The FTAA agreement should include a set of regulatory principles that ensure that non-market based government interventions, including price controls, do not undermine the value of intellectual property rights or other rights protected by the FTAA and are not applied in a way that discriminates against innovative products.

Rules of Origin Provisions

NAM members seek origin rules that are objective, transparent, easy and inexpensive to administer and comply with, yet sufficiently stringent and enforceable so as to optimally preserve benefits for company operations and workers based in the Americas. In this regard, the FTAA should:

- *Create a single, uniform set of FTAA origin rules*

Comprehensive FTAA origin rules should eventually completely replace sub-regional origin rules for the purposes of determining eligibility for preferential tariffs. Creating hemisphere-wide origin rules that overlay the multiple sets of already-existing sub-regional rules merely adds another layer of complexity to doing business in the Americas. An FTAA that complicates rather than simplifies the conduct of business in the region is not worth pursuing.

- *Limit disruption in transition to FTAA rules*

In creating the new uniform FTAA origin rules, efforts should be made to limit the negative impact on companies that have made investments and developed trading relationships based on the assumption of the permanency of sub-regional origin rules, such as those in effect under the NAFTA. Special, early attention must be given by government origin-rules experts – in coordination with industry specialists – to determining how origin rules can best be applied during the FTAA transition period to avoid disruptions in trade patterns and confusion over which rules apply.

- *Help small and medium business learn about origin rules*

To expand the potential benefits of the FTAA, the agreement should provide significant technical assistance to help small and medium businesses learn how to apply the FTAA's rules of origin. This could include a centralized web site, web-based learning, and national outreach seminars.

- *Allow cumulation for purposes of establishing hemispheric origin*
- *Harmonize and streamline rules of origin*

A simplified, consistent and standardized approach in determining origin, marking, and labeling requirements for hemispheric products is an absolute necessity. Such consistency would benefit all hemispheric producers by facilitating understanding by Customs officials and expediting the clearance of imports without undue delays. For example, with respect to pharmaceutical products, the origin of a product should be defined as the place where chemical reactions, normal dosage formulation, and all other activities heretofore resulting in a change in tariff heading take place.

- *Use the tariff-shift approach and curb the use of value content tests and tracing*

Tariff shift rules to determine origin are simpler and facilitate compliance better than content calculation approaches. We believe that the tariff shift system has particularly proven itself in the existing NAFTA rules, and believe that the FTAA should adopt an origin-rule system that builds on and improves on the approach used within NAFTA. We do not favor value tests, since they can be excessively influenced by minor changes in production process and input values, and are difficult to predict due to fluctuation in exchange rates and factor prices. If value tests cannot be avoided, we do not favor tracing, which can require complex and costly accounting procedures.

Customs Rules

The NAM continues to recommend that additional business facilitation provisions be incorporated into the FTAA agreement itself. These provisions should expand and deepen the initial package of customs-related business facilitation measures to include measures that require legislative approval and would be implemented by a specified deadline. The NAM specifically advocates that the FTAA contain the following binding obligations on national customs offices:

- *Immediately Implement a Two-Step Entry Process that Separates the Release of Merchandise from Final Payment of Duty*

Such procedures contemplate the use of financial guarantees for duty payment, time targets for release of merchandise, and final computation of duty obligations following release.

- *Establish an Advance-Rulings Regime and Institute a Process for Reviewing and Appealing Decisions*
- *Eliminate All Non-Tariff Charges Not Dedicated to Offsetting the Cost of Processing Imports on Goods Traded within the Hemisphere, Including Consular Fees and Related Charges*
- *Prohibit Export and Import Price Requirements, Import Licensing Conditioned on the Fulfillment of a Performance Requirement, Voluntary Export Restraints and Discriminatory Export Taxes Not Allowed under the WTO*
- *Establish Simple Procedures for the Temporary Admission of Goods Related to Business Travel*
- *Permit Duty-Free Entry of Commercial Samples and Advertising Materials*
- *Implement Meaningful and Enforceable Transparency Provisions for Both Import Licensing Procedures and for Imposing Any Fees in Connection with Importation or Exportation*
- *Consistently Apply Customs Rules*

The lack of consistency with respect to customs valuation rules has led to arbitrary valuation decisions. This result is partially due to the failure of many countries to implement fully the WTO Customs Valuation Agreement. The FTAA should establish disciplines for the consistent application of agreed-upon customs valuation methodologies and should encourage prompt implementation of the Customs Valuation Agreement.

- *Streamline and Harmonize Customs Clearance Practices*

Such an effort could be part of a broader program to harmonize data, documents and procedures.

Standards Provisions

- *Affirm Market-Based Standards Development*

Broadly, the FTAA should acknowledge the vitality of market-driven standards development and conformity assessment. Duplicative and arbitrary product standards impose unnecessary costs on producers and result in long delays in bringing products to market. The FTAA should encourage the harmonization of standards, testing, labeling and certification processes and ensure that such requirements are not unduly burdensome and do not deviate from internationally accepted norms. As part of this process, where applicable for regulated products, the FTAA should encourage mutual recognition and cooperation in the formal development and implementation of standards, including standards on good manufacturing practices and marketing approval requirements. These standards should be based on internationally accepted norms.

The FTAA should also incorporate a mechanism for expediting the approval processes for critical pharmaceutical products, including cancer and AIDS drugs.

- *Restrict Mutual Recognition Agreements (MRAs) For Non-Federally-Regulated Products*

The use of MRAs should be limited and considered as an alternative for conformity assessment needs – and then only applicable to federally regulated products such as medical devices where industry clearly supports the trade benefits to be gained through implementation. MRAs are not the answer to conformity assessment needs in non-regulated areas; if anything, they serve to encourage the creation of unnecessary product-related regulation.

- *Encourage Voluntary, Market-Driven Standards*

The FTAA should encourage the use of voluntary standards over mandatory government regulations – even when public safety and health, national security and environmental obligations are involved. Such voluntary standards can be best developed with government playing a supporting role in the standards development process. International trade is facilitated when buyers and sellers determine which standards meet their needs.

- *Promote Voluntary, Market-Driven Conformity Assessment*

The FTAA should make clear that international conformity assessment should be voluntary and market-driven, featuring national treatment for imports, with cooperative testing agreements as appropriate between pertinent testing bodies in respective countries. Such accords have already been initiated in several cases with the intent of enabling the shipment of products without repetitive testing. Non-discriminatory, international conformity assessment by means of one standard/one test certification acceptance by the

appropriate authorities – based on Supplier’s Declaration of Conformity or third party certification – is appropriate, as determined by market sector and customer requirements

- *Affirm an Inclusive Definition of “International Standards”*

The FTAA should affirm that the definition of “international standards” in the WTO Technical Barriers to Trade accord is not restricted to only IEC, ISO and ITU standards, but should also include widely-used norms such as some North American safety standards and safety installation practices. Not only is the misinterpretation to the contrary detrimental to electrical industry efforts to sell in global markets, the importance of openness and transparency in standards development are lost when the focus is only on these three standards bodies.

Transparency Provisions

The FTAA should encourage, via specific, binding provisions, the transparent application of the Agreement’s provisions, as well as the transparent administration of all national laws and regulations affecting trade and investment in the hemisphere.

- *Mandate and Facilitate Transparency with respect to Trade-Related Regulation*

The FTAA should strive to make relevant trade and investment regulations as transparent as possible. At a minimum, requirements connected with importation and exportation should be published in a timely fashion and with a sufficient level of specificity to ensure that they can be easily understood.

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To answer questions about particular aspects of the NAM submission, please contact the following individuals:

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