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The Honorable Ronald Kirk
United States Trade Representative
Executive Office of the President
600 17th Street NW
Washington, DC 20508

**RE: Federal Register docket number USTR-2011-0021
Issues for Inclusion in Special 301 Report –
Clean Technology, Energy and Advanced Manufacturing IPR Concerns:
Multilateral Organizations and BRICs**

Dear Ambassador Kirk:

To reinvigorate the U.S. economy and enable sustainable economic growth, the United States must drive exports and create jobs. This in turn requires policies that encourage U.S. industrial growth. The U.S. government can cultivate enabling environments that lead to technology development and improve access to foreign markets for U.S. goods and services. To that end, effective Intellectual Property protection around the world is of critical importance, and is particularly essential with respect to driving an advanced manufacturing agenda and protecting U.S. brands.

Advancing technology requires U.S. companies to innovate constantly and to differentiate American products through effective branding. Thus, expanding the U.S. economy demands strong and predictable IP rights. As the developing world continues to grow, exports have become increasingly central to U.S. companies' business strategies and to the long-term success of the U.S. economy. More than half of U.S. exports originate from IP intensive industries. IP, in other words, serves as a vital trade asset and a driving force behind an innovation based economy. Patents, trade secrets and trademarks are critical but are increasingly under threat.

Below, you will find an overview of our concerns regarding proposals and policies that undermine the IP critical to advanced manufacturing and strong brand protection that NFTC member companies and others face in BRIC countries (Brazil, Russia, India, China) and around the world. First, we highlight those proposals and policies that would result in erosion of IPR in a range of leading international forums and negotiations including the UNFCCC, Rio+20 and WHO. We also highlight cross-cutting concerns with a particular focus on trade secrets and cyber espionage, which are increasingly urgent concerns. Finally, we highlight specific country concerns with a focus on BRIC countries in particular. We are of course aware that non-country specific concerns identified in this document are atypical for a Special 301 Report. We believe, however, that it is important to highlight them in the fashion laid out below and urge you to consider the most appropriate ways to include them in your final Special 301 Report. We would be happy to enter discuss these concerns with you further.

I. International forums and cross-cutting issues

Several threats to U.S. clean technology, energy and advanced manufacturing IP rights exist in a range of international forums and can occur across countries. In most instances, the countries involved are the same and include China, India, Brazil, Venezuela, and Bolivia.

UNFCCC

Global climate change negotiations continue to proceed under the auspices of the United Nations Framework Convention on Climate Change (UNFCCC). In this context, China, India, Bolivia, and Venezuela, as well as several highly active NGOs, have called for compulsory licensing or other forms of “flexibilities” with respect to clean technology and other environmental goods and energy-related IP Rights. These countries and others falsely portray IP rights as “barriers” to international technology transfer despite the proven positive effects such IP rights have in enabling and encouraging innovation and the development, dissemination and deployment of existing and new technologies. Calls to weaken IP rights and to make the discussion about such rights an agenda item have consistently been a negotiating tool used against the United States and other developed countries and have tried to portray the need for IPR weakening as a “moral” rather than science or evidence-based cause.

U.S. companies enjoy a clear competitive advantage in environmental goods and services. Clean technology IP rights are a key driver of U.S. exports, private sector investment, growth and jobs. They are also critical to achieving global climate change and energy-related objectives, and are exhaustively regulated in the WTO TRIPS Agreement. Efforts to weaken clean technology patent rights, or to misappropriate trade secrets, are counterproductive and will stymie innovation, and the development and diffusion of technology. Any efforts to alter or amend the IPR regime in a UNFCCC context, moreover, would undermine the central role that the WTO TRIPS Agreement plays in this respect and cause legal and political confusion, and uncertainty for businesses, innovators, investors and consumers alike.

Calls for IPR weakening were specifically rejected during the high-level COP16 meeting in Cancún in December 2010, where the final Decision remained silent on IP issues despite G77 calls that they be weakened and that “flexibilities” be imposed. Nonetheless, the same issues were raised again during last year’s COP17 meeting in Durban, South Africa (December 2011) where a highly damaging “agenda fight” was only narrowly avoided. There is a real threat that they will continue to be on the negotiating agenda in 2012 and beyond. NFTC and its members ask that the U.S. Government remain vigilant in opposing any weakening of IP rights for environmental goods and services.

RIO+20

In June 2012, world leaders will meet in Rio de Janeiro, Brazil, for the twentieth anniversary of the United Nations Conference on Environment and Development (Rio+20). The RIO+20 Summit agenda suffers from overly broad objectives including: (1) to secure renewed political commitment for sustainable development and global poverty reduction, (2) to assess the progress to date and remaining gaps in the implementation of the major summits on sustainable development, and (3) to address new and emerging challenges towards the sustainable green economy. Several country proposals put forward in December 2011 raise sensitive IPR issues that have no place in the Rio+20 negotiations.

NFTC and its members are concerned about proposals advanced by Brazil, Bolivia and India in particular that portray IP rights as a barrier to technology transfer and dissemination and call for compulsory licensing and other forms of IP “flexibility”. Their proposals, as in the case of parallel efforts in the UNFCCC, would harm a wide range of U.S. industries and technologies and would be counterproductive from an economic, sustainability, and development perspective. Suggestions that IP rights form a threat to the dissemination and diffusion of technology are unsubstantiated and are contradicted by economic and market evidence. Accordingly, NFTC members believe that U.S. leadership at RIO+20 will be key to prevent adoption of any new mandates that ultimately would erode IPRs for environmental goods and services.

WHO

Global recognition of the need to address Non-Communicable Diseases began in 2000, with the endorsement of a Global Strategy for the Prevention and Control of Noncommunicable Diseases (NCDs). More recently, the UN has adopted a 2008-2013 NCD Action Plan. While these efforts are generally laudable and merit U.S. and industry support, a variety of interests, ranging from certain G77 governments to key anti-IP NGOs and others, were able to push problematic language into the final Political Declaration of a September 2011 High-level Meeting of the UN General Assembly on the Prevention and Control of NCDs.¹ A specific NCD strategy and work plan is scheduled for adoption in May 2012, and individual member countries are tasked to develop national action plans on the subject which could include further IPR-related actions. As in other international forums, China, India and Brazil appear to be the main driving force.

The UN language as adopted sets a harmful precedent and threatens to create international legal ambiguity that will provide an opening for anti-IP NGOs and countries to construe the NCD mandate broadly. Weakening intellectual property rights related to health technologies, including medicines, diagnostics and medical technologies would be highly counterproductive in light of the urgent need for additional investments and more extensive global trade and investment in relevant NCD-related technologies, services and goods.

NFTC also wants to draw your attention to the work currently taking place within the WHO’s Consultative Expert Working Group on Research and Development: Financing and Coordination (CEWG). The CEWG is currently preparing a report that may recommend, among other measures, that Member States enter into a globally binding treaty to regulate the financing and coordination of health focused R&D. U.S. companies are deeply committed to innovation in public health for the benefit of the developed and developing world. However, we understand that a binding R&D treaty, as currently contemplated by the CEWG and certain other stakeholders, could seek to undermine IP rights and the innovation and technology diffusion that they enable, rather than promote them. As a result, important innovations in health technologies of particular relevance to developing countries and emerging markets would be put at risk, and critical competitive advantages that U.S. industries and workers have spent years to develop may be lost. A dangerous precedent in terms of IPR erosion for other sectors and industries could be set. Once again, China, India and Brazil appear to support such an approach.

¹ Specifically, that Declaration now calls on UN members to the “full use of trade-related aspects of intellectual property rights (TRIPS) flexibilities” with respect to “affordable, safe, effective and quality medicines and diagnostics and other [medical] technologies”.

In the interests of global public health, as well as the U.S. economy's global competitiveness, U.S. exports and the high-value U.S. jobs that IPR, technological development and manufacturing help create, it is crucial that the U.S. Government protect and promote intellectual property in this sector. As we have emphasized in separate correspondence with your office, we also believe the United States must resist efforts to create through this particular forum what amounts to new international regimes aimed at generating revenue from industry. We urge you to review proposals made by the CEWG and support efforts that preserve incentives for innovation while rejecting any proposal, including those to negotiate a global R&D treaty, that would undermine such incentives or diverge from longstanding methods of revenue related institutional policymaking.

WTO

The December 2011 WTO Ministerial Meeting agreed to extend a moratorium on so-called TRIPS "non-violation" cases that has been in force since the Uruguay Round WTO Agreements were first entered into in 1995. "Non-Violation Nullification and Impairment" disputes are allowed in other areas of WTO law and, in the IP area, could be a powerful additional tool to help address challenges against the value of U.S. innovation and advanced technology around the world.

The moratorium was originally foreseen to be in place for no more than five years. Fifteen years, meanwhile, have passed, and the moratorium continues to be extended by unanimous consent. We believe it is important to send a clear signal and work with governments around the world to end the moratorium, which removes an entire legal claim from the WTO Agreements in disputes with other industrialized and major emerging economies (Least Developed and Low Income Developing Countries are exempt) and harms U.S. IPR interests.

WIPO

At the World Intellectual Property Organization (WIPO), the work programs of Committees are being driven by an increasingly negative agenda that is focused on exceptions and limitations to intellectual property, rather than its effective protection and enforcement. As in other forums, at WIPO, a group of emerging countries continues to argue, without supporting evidence, that IPR are a barrier to access to new products and services and that, therefore, IPR must be weakened or eliminated. At the WIPO Standing Committee on Patents, Brazil has even proposed that a manual be developed, to instruct countries as to how they can limit and weaken IP rights. We are concerned that the WIPO Secretariat's publications and capacity-building activities often reflect the IP-skeptic perspectives of certain members as well. In contrast, WIPO officials should promote the value of intellectual property, and communicate its critical role as a tool underpinning innovation, technology diffusion, economic growth, and social and economic advancement. The Secretariat must adopt a practical and evidence-based – rather than political – approach when talking about IP-related challenges and opportunities.

Trade secrets

Apart from issues arising in international forums and the country-specific issues described below, NFTC believes that the issue of trade secrets presents a cross-cutting threat to advanced manufacturing and technology sectors -- as well as branded consumer products -- and is worth separate mention as well. Trade secrets are a key form of Intellectual Property protection and are vital to the well-being and competitiveness of many of America's most important industrial and services industries and sectors. At the international level, they are protected under Article 39.2 of the WTO Agreement on Trade-Related Intellectual Property Rights (TRIPS) in particular, which provides that natural and legal persons shall have the possibility of preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent "in a manner contrary to honest commercial practices".

Trade secrecy is also protected through international harmonization of technical and regulatory requirements to eliminate or mitigate Technical Barriers to Trade (TBTs) as governed under the TBT Agreement in the WTO and TBT Chapters in U.S. FTAs.

As a result of the IP, regulatory and procurement policies of certain countries, however, trade secrets and the value that they provide are increasingly under threat. Cyber-based economic espionage in particular constitutes a drain on U.S. wealth and places targeted companies at a major competitive disadvantage. Additionally, non-transparent or arbitrary regulatory policies may threaten trade secrecy for consumer goods. Trade policymakers and governments must consider more effective ways to respond to threats – including from cyber-attacks and unfair regulatory and technical requirements – and ensure effective protection of trade secrets.

II. Country-Specific Issues

China

Patent Subsidies: The Chinese government subsidizes the development of home-grown patented technologies by providing financial support to certain domestic firms to fund filing of foreign patent applications.² To qualify for the subsidy, enterprises must be incorporated in China³, thus resulting in the "less favorable treatment" of foreign enterprises operating in China who continue to be ineligible for the subsidy as a result of their incorporation abroad. China plans to dramatically expand the program, aiming to generate 2 million patent filings a year by 2015.⁴ China's patent subsidy program discriminates against foreign SMEs operating in China, violating China's commitments as a member of the WTO and under TRIPS Article 3.1 in particular, and hurting U.S. industry as a result.

MOFCOM import-export rules: China's Ministry of Commerce (MOFCOM) Technology Import-Export Administrative Regulations require companies filing patent applications to register most technology transfer and license agreements. This includes patent assignments, assignments of rights to apply for patents, and patent licenses. The rules do not specify penalties

2 See Notice of the Ministry of Finance on Issuing the "Interim Measures for the Administration of Special Funds for Subsidizing Foreign Patent Applications", C.J. No. 567 (2009) and Notice on the Submission of Applications for Special Subsidies for Foreign Patent Filings in 2010, Ministry of Finance and State Intellectual Property Office, 19 May 2010.

3 See Instructions for Completing the "Application Form for Special Subsidies for Foreign Patent Filings in 2010, at para. 2(2)(a).

4 SIPO, National Patent Strategy 2011-2020 (available in English at <http://graphics8.nytimes.com/packages/pdf/business/SIPONatPatentDevStrategt.pdf>).

for noncompliance but a registration certificate is necessary to engage in various commercial activities requiring government authorization, including foreign exchange and customs importation. A failure to register a patent-related agreement in a timely manner can significantly impede commercialization efforts.

Patents and Technical Standards: China’s standard-setting practices continue to be a cause of significant concern to U.S. industry. As part of its National IP Strategy, China has focused on improving its standards-related policies, including regulating “the process of turning a patent into a standard”.⁵ In 2010, the China National Institute of Standardization (CNIS) issued and requested comments from all stakeholders on its Disposal Rules for Inclusion of Patents in National Standards (Disposal Rules). The Disposal Rules appear to eliminate the most problematic aspects of draft regulations previously issued by the Standardization Administration of China, which would have obligated patent owners to grant a royalty-free license or a license with a royalty substantially below market rates. More work, however, is required to align the Disposal Rules with global standards. (For example, infringement of essential patents is based on “commercial feasibility” as opposed to the more customary “technical essentiality.” As a result, possible infringement is broadened to both technical solutions outside the standard and technologies that develop after the standard’s promulgation. It is also unclear whether entities holding patents but not participating in standard setting will be bound by the Disposal Rules even though it is clearly not feasible for innovators to monitor every standard that may be applicable to their patents. And, even if non-participating innovators are aware of a particular standardization effort, as a practical matter they should not be bound by a process in which they did not participate.)

Compulsory licensing: China’s patent law and anti-monopoly law provide the government with broad authority to grant compulsory licenses. The relevant Chinese government agencies have yet to clarify the circumstances under which compulsory licenses may be granted and claim that they have no immediate plans to exercise this authority. Nevertheless, when viewed in the context of China’s overall innovation and IPR strategy, the compulsory licensing provisions are troubling and a source of concern for industry. On October 12, 2011, China’s State Intellectual Property Office (“SIPO”) released a draft amendment to The Measures of Compulsory Licensing for Patents (“Draft Measures”) for public comments. The Draft Measures continue to offer a broad basis for potential compulsory licensing and, thus, fail to resolve our existing concerns.

Technical Barriers to Trade: Companies have experienced ongoing inconsistency of enforcement of important rules for food additives and/or other substances at the ports of entry. These persistent problems threaten trade secrecy as outlined above.

Indigenous Innovation: At the 2010 JCCT, China agreed to: (1) limit the use of indigenous innovation policies in the context of government procurement, i.e., it will not “make the location of the development or ownership of intellectual property a direct or indirect condition for eligibility for government procurement preferences for products and services”; (2) liberalize foreign company access to wind power project supply bids; and (3) actively honor data exclusivity in pharmaceutical marketing approval process. We are encouraged by these developments as well as China’s commitment to delink “its innovation policies” from

5 Outline of the National Intellectual Property Strategy

government procurement preferences following President Hu's visit to the United States in January 2011.⁶ On 23 June 2011, China's Ministry of Finance (MOF) produced a notice to this effect. After MOF's 23 June announcement, many local provinces and cities stopped implementing local IIP policies.

While these actions are promising, the situation on the ground has not changed sufficiently and substantial uncertainties remain. For example, Jiangsu Province, and cities of Nanjing, Shenzhen, and Ningbo all issued notices to apply for accreditation for Indigenous Innovation Products less than a month after the Central Government's Notice. Indigenous Innovation Product Accreditation systems impose onerous and discriminatory requirements on companies seeking to sell into the Chinese government procurement market, and contravene multiple commitments of China's leadership to resist trade and investment protectionism and promote open government procurement policies.

Brazil

IP Cross-Retaliation: We continue to be concerned by calls from Brazil to restrict IP rights in retaliation for long-standing WTO trade disputes. While the WTO recognizes limited IPR suspension rights, even temporary action of this sort will have serious repercussions across industry worldwide. Scientific progress and economic recovery require companies to invest both at home and abroad and to be able to rely on consistent, sustained and predictable IPR legal frameworks.

Trade with Brazil, one of today's fastest growing economies, is vital to U.S. and Brazilian economic success. President Obama has set a goal of doubling exports by 2014. Over half of US exports originate from IP intensive industries. Thus, IP serves as a vital trade asset and a driving force behind our innovation-based economy. While recently Brazil has taken steps to position itself as a regional center for innovation and technology, signaling out IP for retaliation tarnishes its reputation. It sends a profoundly negative message to innovators, both local and foreign, and seriously impedes U.S. companies' ability to invest, as well as Brazilian companies' ability to further climb the innovation and advanced manufacturing chain.

National Industrial Property Institute of Brazil's (INPI) Right to Modify Contracts:

Economic growth through innovation is most efficient when companies are allowed to freely contract for goods and services. INPI's role in approving all IP licensing and technology transfer agreements potentially impinges on that freedom. In particular, INPI frequently establishes limits on royalties and confidentiality clauses and prevents the return of technology at the end of contracts. INPI's authority to interfere dates back to the 1970s and Law 5648/70, establishing INPI and granting it the authority to regulate technology transfer. While the law changed in 1996, formally ending INPI's power to interfere in licensing agreements, INPI continues the practice today.

Despite this bleak picture overall, however, it appears that attitudes within Brazil are shifting. In a recent court decision, the Second Specialized Chamber held that INPI's authority does not include limiting "the values or percentages to be adopted by the parties, within the scope of their industrial or manufacturing concerns." Specifically, the court explained that Brazil has "prioritized free enterprise and competition in the marketplace, with broad opening to foreign

⁶ US-China Joint Statement. The White House. 19 Jan 2011, at ¶27 available at <http://www.whitehouse.gov/the-press-office/2011/01/19/us-china-joint-statement>

capital.” There are also indications that the attitude within INPI may be changing. INPI’s President Jorge Ávila, for example, has remarked that the policy is being reviewed. We commend Brazil’s apparent policy shift and urge the country to foster a truly open and unrestricted marketplace.

INPI Backlog: Like other major patent offices, INPI is experiencing a serious backlog in its review of patent applications, with an average patent pendency of 8-9 years. Unless this is addressed, the inability to timely obtain issued patents in Brazil will perpetuate a serious drag on innovation and impair the ability to commercialize increasing levels of Brazilian R&D. We applaud INPI’s efforts to improve delivery of services in the IP area, taking the necessary steps to hire examiners and enhance internal processes to reduce patents and trademarks applications backlogs. We are also encouraged by the USPTO’s efforts to cooperate with INPI including the training of examiners. Further measures are, however, needed, to facilitate progress towards dealing with backlog and to support patent quality. This includes a focusing of Brazilian government resources on INPI’s core missions of examining and granting patents, and the elimination of interference of non-INPI government agencies in the patent examination process.

India

National Innovation Act and IPR Policy: The Indian Government is considering a National Innovation Act. (<http://www.dst.gov.in/draftinnovationlaw.pdf>). The Act includes a range of measures to promote innovation (including an annual “Science and Technology Plan” and provisions to aid public/private partnerships, promote innovation financing and establish special innovation zones). It also codifies rules on the protection of confidential information. (To date, lacking a relevant statute, protection of trade secrets in India has relied on common law principles, meaning that the scope of protection is unpredictable.) India – alongside China and Brazil – has historically taken a position that trade secrets (and patents) impede the free exchange of clean technology. Given previously expressed views by India on trade secrets (and innovation more broadly), NFTC strongly believes that efforts in this space should be scrutinized to ensure full TRIPS consistency.

Third party access to ‘Essential Facilities’: Industry generally commends the efforts of the Indian Government’s Committee of the Ministry of Corporate Affairs to formulate a National Competition Policy (“Draft Policy”) for India. The Draft Policy has evolved into a comprehensive and helpful framework for fair competition. Section 5.1(vi) of the Draft Policy, however, which requires dominant infrastructure and IPR owners to grant third party access to ‘essential facilities’ on “agreed reasonable and nondiscriminatory terms”, is at odds with the goal of spurring innovation, ushering more economic reform and increasing competition in India.

The “essential facilities” doctrine has been heavily criticized and its application severely curtailed around the world. A broad international consensus exists that the unconditional, unilateral refusal to license a technology rarely raises competition concerns. In addition, the decision not to license a technology is considered to be the most fundamental right conveyed under the IP rights laws – namely, the right to exclude. To impose a blanket duty to license on IPR owners could effectively nullify IP rights and impair or remove the economic, cultural, social and educational benefits created by them. Such a duty would also “compel firms to reach out and affirmatively assist their rivals, a result that is ‘in some tension with the underlying

purpose of antitrust law.’’⁷ The blanket inclusion of IP rights currently foreseen in India’s Draft Policy, is directly at odds with international competition standards and fundamentally irreconcilable with TRIPS.

Recent court decisions: Finally in India we note a trend where courts have invalidated patents obtained by foreign joint venture partners, in a manner that may have the effect of renegotiating JV agreements in favor of the local player. These proceedings and decisions should be closely monitored.

Russia

WTO Accession and ongoing IPR Reform: Business applauds the successful conclusion of Russia’s WTO Accession process in December 2011, including Russia’s commitment to accede to the Information Technology Agreement. In terms of Russia’s IPR policies, we remain concerned about the ongoing reform of Russia’s IPR laws. The lack of a positive change with respect to the current Russian legal regime for compulsory licensing in particular, continues to be a significant cause of concern.

Australia

“Plain” packaging: Last year, the Australian Government passed legislation that mandates the “plain” packaging of all tobacco products. Government policies to reduce or eliminate the ability of manufacturers to distinguish products from those of competitors set a dangerous precedent with potentially far-reaching implications. We are concerned that Australia’s plain packaging proposal—which mandates the elimination of trademarks of American businesses – violates Australia’s international trade obligations and threatens to undermine the rules-based international trading system.

⁷ *U.S. Antitrust and IP Report*, at 6 (quoting *Trinko*, 540 U.S. at 407-08).