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Elizabeth Kendall
Assistant U.S. Trade Representative, Intellectual Property and Innovation (Acting)
Office of the United States Trade Representative
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SENT VIA EMAIL

RE: NAFTA Renegotiation

Dear Ms. Kendall:

Recently you encouraged industry to provide issues that people felt should be addressed in the upcoming re-negotiations of the North American Free Trade Agreement (NAFTA). I write on behalf of Intellectual Property Owners Association (IPO) to suggest such issues. We appreciate the opportunity to submit comments.

IPO is an international trade association representing companies and individuals in all industries and fields of technology who own, or are interested in, intellectual property rights. IPO's membership includes around 200 companies and more than 12,000 individuals who are involved in the association either through their companies or as inventor, author, law firm, or attorney members. IPO membership spans more than 30 countries. IPO advocates for effective and affordable IP ownership rights and provides a wide array of services to members, including supporting member interests relating to legislative and international issues; analyzing current intellectual property issues; information and educational services; and disseminating information to the general public on the importance of intellectual property rights.

The upcoming review of our trading relationship with Canada provides an opportunity to address a number of intellectual property implementation and enforcement challenges pursuant to NAFTA. An updated NAFTA must strengthen and modernize protections for U.S. innovation.

1. **Effective Patent Dispute Resolution Procedures:** Canada's Patented Medicines (Notice of Compliance) Regulations must be carefully balanced to avoid prejudice to patent owners. The PMNOC regulations should continue to provide for patent linkage and effective injunctive relief by providing for a 30-month stay during the litigation. The resolution procedures are designed to allow for early resolution of patent disputes before infringing follow-on products are allowed on the market. The Comprehensive Economic and Trade Agreement (CETA) Regulations now contemplate proceedings that are full actions, which will include document productions, oral discovery, discovery motions, and potentially third-party discovery.

Despite the Canadian Federal Court's best efforts to move actions to trial within two years or less in the mid-2000's, they have been unsuccessful. In order for the parties to obtain a proper, fair and full trial, the minimum patent stay period should be 30-months. Generic competitors typically capture the entire market within three months from product launch.

IPO addressed several other concerns related to proposed amendments to the PMNOC regulations in comments to the Department of Industry (attached).

2. **Data Protection:** The CETA Regulations provide a patent term restoration regime that is wholly inadequate (up to a maximum of a two-year extension with limitations on the timing of a regulatory submission) which is unfair to patent owners. The upcoming NAFTA negotiations should contemplate rectifying this by allowing for a five-year patent extension term without limitations, or alternatively, providing for additional data protection up to at least 12 years.

3. **Patentability Standards:** Canada has maintained an unreasonable and heightened patent utility standard which has significantly weakened patent rights for the innovative pharmaceutical industry and has been inconsistent with Canada's international obligations and the practices of other countries, including the U.S. The Supreme Court of Canada recently rejected Canada's "Promise Doctrine" in a unanimous decision. If implemented fully, the ruling will represent a significant step toward addressing Canada's more than decade-long departure from its NAFTA obligations and restoring certainty and predictability to Canada's patent system. How the lower Canadian courts will interpret this and related utility issues in the future remains uncertain, given their role in developing the Promise Doctrine.

   The recently launched renegotiation of NAFTA presents an opportunity to urge prompt and full implementation of the Supreme Court ruling, to clarify and reinforce the baseline patent utility standard, and to prevent any further backsliding by Canada. This would not only provide greater certainty to innovators in North America, but would also help reinforce long-standing baseline patentability standards globally. Such reinforcement is critical to counter increasing efforts by some countries and multilateral organizations to erode intellectual property rights. We ask that the USTR encourage full implementation of the Supreme Court on utility ruling in the upcoming NAFTA negotiations.

4. **Repeal of the Price Medicines Price Review Board:** Policies imposed by Canada's PMPRB artificially lower the prices of patented medicines, which disincentivizes innovators from bringing new life saving medicines to market. U.S. innovators, who often bear high research and development costs, are unfairly treated because other nations do not appropriately price to reasonably re-coup the US innovators' investment in research and development costs. The PMPRB was created following the successful enactment of NAFTA in 1993, but there is no reasonable basis for tying pricing to patents, unreasonably suppressing prices.

5. **Investor State Dispute Mechanisms:** IPO is deeply concerned that the NAFTA negotiating objectives omitted a critical enforcement tool – investor-state-dispute-settlement (ISDS). ISDS must be included in an updated NAFTA as it is the only way to ensure that other countries treat U.S. investors fairly, do not seize property without compensation and do not impose unfair localization requirements. U.S. investors have previously faced these problems in Canada, requiring the use of ISDS.

   Without access to ISDS mechanisms in NAFTA and any future agreements that the Administration is considering, we are left to the whim of domestic decision-making by our trading partners, which can be extremely biased in favor of domestic industry, as can be seen in our case. The state-to-state mechanisms that exist in these agreements are no doubt powerful, but there is a significant capacity question to consider with so many U.S. companies and industries requesting help from the U.S. government in disputes with trading partners. We must have our own tools to address these sorts of disputes, and ISDS is one we need.

NAFTA renegotiation provides a crucial means of ensuring a more predictable environment for innovation in North America. We ask that USTR make full use of this opportunity to protect the intellectual property rights of our members and other innovative U.S. companies. Thank you for the opportunity to provide our suggestions.

Sincerely,

Mark W. Lauroesch
Executive Director