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Mr. Douglas Bell
Chairman, Trade Policy Staff Committee
Office of the US Trade Representative
Executive Office of the President
600 17th Street NW
Washington, DC 20508

Re: Request for Comments Concerning the Proposed Transatlantic Trade and Investment Partnership, 78 Fed. Reg. 19566 (April 1, 2013)

Novartis Corporation appreciates this opportunity to provide comments as the Office of the United States Trade Representative prepares for negotiations on the proposed Transatlantic Trade and Investment Partnership (TTIP). Novartis Corporation is part of the Novartis Group of companies, which has approximately 120,000 employees globally and sells products in more than 140 countries. In addition to pharmaceuticals, Novartis Group companies manufacture and distribute eye care products, generics, vaccines, consumer health products and animal health products. Novartis Group companies have 26,000 employees in the United States and conduct much of their R&D here.

We wish to highlight several topics where we believe the TTIP can be of particular value to Novartis, including market access issues, the importance of maintaining high patent standards, the importance of rigorous regulatory standards in the biopharmaceutical sector and cooperation between the European Union and the United States on improving regulatory standards in third countries.

Market Access Issues

Although many pharmaceutical and intermediate product tariffs between the US and the EU were eliminated under the Uruguay Round's "zero for zero" initiative and the various updates, where tariffs still exist on biopharmaceutical products and intermediates, the tariffs should be eliminated under TTIP immediately upon entry into force of the agreement.

Biopharmaceutical products face unique challenges when gaining access to foreign markets. Manufacturers must meet exacting regulatory approval standards as well as dealing with uncertain (and often non-transparent) government pricing and reimbursement determinations. Add to these hurdles the fact that, under most national healthcare systems, purchases of innovative medicines are subject to government procurement procedures and requirements. Consistent with past US free trade agreements, including a separate chapter in TTIP on pharmaceuticals will be instrumental in making sure the agreement addresses the unique

circumstances facing our sector in a coherent and comprehensive manner. Creation of a Medicines and Medical Devices Committee or working group, as under the KORUS agreement and the Korea-EU free trade agreement, should also be a high priority for the TTIP, to provide a mechanism to enable our industry to work directly with US and EU officials on future competitive concerns as they arise.

Enhancing Intellectual Property Standards

The TTIP negotiations offer both the US and the EU the opportunity to harmonize their own national practices and to set new, higher standards for patentability that can offer a model for improving bilateral and multilateral approaches to intellectual property protection. The US and EU should use the high standards in their own markets as benchmarks when negotiating IP protections in agreements with other trading partners and establish a joint working group to address enforcement of IP standards in third countries.

Novartis wishes to affirm the principles and approaches in this area outlined by PhRMA, as follows:

- Clearly provide that the scope of patent eligible subject matter includes medical process inventions and plant or non-human animal inventions;
- Impose no limits on improvement inventions beyond the normal standards applied to determine patentability;
- Clarify “novelty” in the following ways:
    - A claimed invention shall be found novel if each and every element or step of the claimed invention was not explicitly or inherently disclosed in the prior art;
    - To inherently anticipate a claimed invention, the subject matter disclosed in the prior art must necessarily and unconditionally possess the undisclosed features, properties or attributes of the claimed invention;
    - Compositions comprised of novel forms, structures or complexes of a molecule known in the prior art shall be considered novel if the compositions as claimed are not identically described in the prior art;
- Stipulate that determinations of whether an invention is not obvious should be made on a case-by-case basis without reference to *per se* rules;

- Elucidate that broad disclosures of compounds do not anticipate all specific molecules within their scope absent specific teachings or directions to one of ordinary skill in the art;

- Provide greater clarity regarding what constitutes adequate disclosure of the invention and the nature of what additional information can later be presented to support the patent application.

Achieving Regulatory Compatibility across the Atlantic

The TTIP negotiations offer the opportunity to eliminate regulatory differences and redundant requirements that detract from efficiency in undertaking global drug development, review and evaluation. A first priority in this area would be for the EMA and FDA to work together to develop a common approach to the handling and disclosure of data contained in non-clinical and clinical study reports submitted by an applicant to obtain marketing approval.

Novartis supports recommendations from PhRMA and the European Federation of Pharmaceutical Industries and Associations for specific work on regulatory compatibility between the US and EU, including the following:

- Provide mutual recognition of each other's Good Manufacturing Practices and Good Clinical Practices inspections.

- Grant sponsors the right to receive parallel scientific advice upon request for all medicines.

- If successful, formally adopt the current pilot program between the US and EU agencies to conduct parallel assessment of Quality by Design applications.

Work in the following areas would be consistent with ongoing workstreams in the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH):

- US and EU agencies should work together to achieve greater regulatory compatibility in the scope, content and timing of submission of pediatric plans, so that companies are required to prepare only a single plan for submission in both territories.

- Seek greater collaboration on pharmacovigilance issues including post-market testing and risk management requirements and format and deadlines for adverse event reporting through a specific "cluster" on this topic.

- Revise existing guidance to reduce the requirements for duplicative local bridging requirements.

- Develop a harmonized structural framework and methodology for benefit-risk assessments (agencies would retain authority to make different risk-benefit judgments under their individual approval schemes).

- Develop a harmonized approach to post-approval variation submissions for manufacturing changes.

Improving Regulatory Standards in Third Countries

Novartis recommends that the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA) work closely together during the TTIP negotiations to develop strategies to ensure the uniform quality, safety and efficacy of medicines offered in other markets. Our industry's objective is to ensure the public health, safety and welfare of the patients who rely on our products, and to ensure that adequate procedures are in place to allow patients to have full confidence in the medicines they buy through authorized channels. The TTIP could make a major contribution to the competitiveness of the pharmaceutical sector by promoting cooperation among US and EU trading partners to ensure the quality, safety and efficacy of medicines. Since no uniform international standard is in place to ensure the quality of medicines, enhanced cooperation between FDA and EMA to develop an approach to preventing substandard medicines from entering the US and EU marketplaces is critical. Substandard medicines endanger patient care, which in turn raises health care costs. The US and EU should encourage more vigilance by other national drug authorities to prevent the presence of substandard medicines in the market in the first instance would be the desired policy response.

Novartis believes that outcomes from the TTIP negotiations should be ambitious. The US and the EU should aim to achieve new levels of protection for intellectual property rights and regulatory compatibility that raise the bar internationally and lead to the creation of new norms that can be incorporated in future trade agreements among willing partners. With the US and the EU in the lead internationally in developing innovative drugs and healthcare solutions, it is very much in our collective interest to pursue this goal.

Thank you for the opportunity to submit these views.

Sincerely,
Tracy Haller