Industrial Property Committee

Strategic vision 2017

Preserve and improve the standard of protection of Industrial Property of the Pharmaceutical Industry of Innovation.

Yuri Vázquez

AMIIF
Innovación para la vida

Agenda 2017

Industrial Property Committee

Issues	Activities	Time-line
NAFTA	Re-negotiation	First trimester 2017
Agreements with EUROPE	Modernization TLCUEM y AELC	First semester 2017
Legislative reforms	Through reforms in domestic law strengthen the standard of protection of IP rights	During 2017
Academy	Calendar; issues and speakers. SEPI y Schools	First semester 2017
Linkage Gazette	Integration of the patents list	✓ FEBRERO 2017 AGOSTO 2017

Action plan

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NAFTA

✓ **1. Identify scenarios and imminent risks in toral issues** (*RDP; Patents criteria; Imports; Bids*) **for:**

✓ **2. Set Postures**: *"RE-NEGOTIATION OF NAFTA Risks and Opportunities from AMIIF perspective"*
✓ **We asked PhRMA and BiO to have a position.*

3. Work out a strategy that involve:

i) Authorities (SE/IMPI),
ii) Allies in the E.U. (PhRMA; BiO);
iii) Embassies;
iv) Private sector (CONCAMIN / CCE) and
v) Academy (SEPI / Schools);

4. Implementation of specific actions; Feasible solutions and their follow-up.

Re-negociación NAFTA

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CURRENT POSSIBLE SCENARIOS

Reasonable position of the U.S.
Unreasonable position:

Re-negotiation with TPA (Trade Promotion Authority): Modifying sections and adding chapters.
* Re-negotiation without TPA: Negotiating rules of origin.

3. Denounce: U.S. / Mexico.

Lack of disciplines in:
- Foreign investment; (Mexico must preserve openness in goods and services and protect foreign investment, import substitution)
- Public sector purchases;
- **Industrial property.**

4. That the U.S. violates WTO obligations / rules.

NUESTROS ASOCIADOS

Re-negociación NAFTA

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Possible risks

I. Regulatory Data Protection in Mexico is granted directly as a consequence of article 1711 in NAFTA (both for small molecules and biologics). Without NAFTA, the Mexican Government would be able to cease granting this protection immediately.

II. While not deriving from NAFTA other forms of protection, including a linkage system between patents and marketing authorizations and patentability criteria allowing use and formulation claims have been implemented in Mexico under considerations that NAFTA obligations imply high IP Protection standards.

III. Mexico eliminated a local manufacturing site requisite in 2008 (which forced Marketing Authorizations to be linked to a site established in the Country, and was seen as a protectionist measure). The elimination of NAFTA could end up justifying a re-enactment of this requirement.

IV. An imposition of import taxes could take place in retaliation to U.S. tax measures. This would negatively impact the R&D business models in which Mexico is mainly an import market.

V. Government procurement procedures in Mexico (including medicines) are favorable to products coming from countries covered by Free Trade Agreements. This benefit would be lost, and medicines coming from the U.S. could be subject to different standards, competing with countries with which Mexico does not currently have an Agreement (e.g. China; India and Korea).

VI. Mexican Laws establish the possibility of strict price controls, which are currently not applied. An exit from NAFTA could be an incentive to apply these provisions, or impose reference pricing towards lower income countries.

VII. R&D companies currently benefit from “equivalency agreements” in which marketing authorizations granted by certain foreign offices (including the FDA) are considered in local applications. Whereas this is not a NAFTA obligation, the provisions were enacted in an open trade environment with the U.S.

VIII. IP enforcement standards could also be lowered.