

	Current legal situation in Mexico	Original expectations for the TPP	Proposal for lower standard in TPP
I) Patent restoration terms	NAFTA contemplates already that member countries may include patent restoration terms based on the delays of regulatory approvals and the granting of patents.	Clear rules, conditions, timing and proceedings were expected to proceed with the restoration of patent terms due to delays in the approval of marketing authorizations or the granting of patent	Country members should conduct best efforts to avoid delays in regulatory approvals and the granting of patents
II) Data package exclusivity	Mexican Courts have properly interpreted international treaties already subscribed by Mexico along with the Mexican Health Regulation and ordered the recognition of data package exclusivity for the data submitted for the approvals of new molecules, formulations and they are studying the protection for new indications and biologics. The protection granted by the Courts addresses to avoid the direct and indirect reliance, banning the regulatory agency to grant the marketing authorization.	Obligation for the country members to establish the protection in the domestic law. It was also expected that the TPP would provide clear definition on the subject matter and the timing of protection, specifically for biologics. Clear definition and protection to avoid the direct and indirect reliance of the data package.	There is no provision recognizing data package exclusivity for biologics. The proposal includes vague definitions of biologic and chemical products that may also impact in a negative manner the current interpretation of the Mexican Courts for data package exclusivity for biologics. The protection would be restricted to five years for small molecules provided that the requirements of considerable efforts and undisclosed information are fulfilled but the proposed protection is limited to prohibit the commercialization of the product in violation of data package exclusivity not to ban the granting of the marketing authorization as the Mexican Courts have established in their rulings. This slight difference seems to be irrelevant, but is not, as once the product is approved, cancelling the authorization or stop the commercialization of the illegal product is troublesome and it would take years of litigation.
III) Patent linkage	The Mexican Linkage Regulation prohibits the approval of the infringing product for compound and formulation patents. The protection of use patents can be obtained through litigation.	Patent linkage to avoid the granting of marketing authorizations in violation of pharmaceutical patents, compound, formulation and use patents.	The proposal establishes that patent linkage should prohibit the commercialization of the product "infringing" the patent" while the current system in Mexico prohibits the unlawful approval of the product, preventing the infringement of the patent prior to launching the infringing product. If the obligation in TPP for patent linkage only prohibits the commercialization of the approved product, the enforcement of the patent and the eventual claim of damages and even stop the commercialization of the product could take years of litigation. In addition, the Mexican Delegation opposes that the patent linkage in TPP would include use patents.