**Grand River Enterprises Six Nations, Ltd., et al. v. United States of America[[1]](#endnote-1): challenge of the Master Settlement Agreement (MSA)**

* In 1998, several U.S. States and territories and major U.S. tobacco companies concluded the Master Settlement Agreement (‘MSA’) to settle litigation between U.S. states and certain U.S. cigarette manufacturers. The settlement provided for:
  + compensation of costs related to tobacco diseases and required the tobacco companies to restrict their advertising, sponsorship, lobbying, and litigation activities (particularly those targeting youth);
  + dissolution of three specific tobacco trade groups;
  + public disclosure of the documents disclosed during the litigation;
  + funding of an anti-tobacco education campaign; and
  + an annual payments to the settling states.
* The participating States undertook to adopt escrow and complementary legislation.

##### Eli Lilly v. Canada, NAFTA, UNCITRAL: claim concerning medicine patents

* Claimant commenced the arbitration under NAFTA, Chapter 11 by its Notice of Arbitration on 12 September 2013.
* After several rounds of party submissions, several amicus interventions and a hearing, the tribunal issued its award on 16 March 2017.[[2]](#footnote-1)
* The tribunal dismissed the claims, stating that the claimant failed to set the prima facie claim of expropriation or the minimum standard of treatment under NAFTA.
* Nor did the tribunal find the subject measure to be arbitrary or discriminatory. The tribunal ordered Eli Lilly to bear all costs of arbitration and 75% of Canada’s legal fees.

##### Apotex Inc. v. USA (I&II), NAFTA, UNCITRAL: claims concerning regulation of generic drugs manufacturing and sale

***The measure***

* Apotex Inc. (Apotex), a Canadian generic drug manufacturer, initiated NAFTA Chapter 11 arbitration under the UNCITRAL Arbitration Rules on 10 December 2008 and 4 June 2009.
* After USA filed its preliminary objections, the parties agreed that until resolution of the preliminary objections, the two claims would be heard concurrently, but not consolidated.
* On 14 June 2014, the tribunal issued its award on preliminary matters.[[3]](#footnote-2)
* In its award on the preliminary matters, the tribunal agreed with Respondent that the purpose of NAFTA Chapter 11 was not to ‘support[] cross-border sales’. It likened Apotex’s ANDA and the associated expenses to an ‘export or import licence’, noting ANDA’s tentative and preliminary nature, and concluded that Apotex did not have an ‘investment’ in the United States, and that therefore both the sertraline and pravastatin claims were dismissed.
* Moreover, the tribunal upheld two U.S. jurisdictional objections to the pravastatin claim, holding that:
  + the claim concerning the actions of the U.S. courts required exhaustion of domestic remedies or a showing that judicial remedies were futile, either of which Apotex failed to demonstrate; and
  + the claim concerning the administrative actions of the FDA was time-barred under NAFTA procedural preconditions.

##### Apotex Holdings Inc., Apotex Inc. v. United States (III), NAFTA, ICSID Additional Facility: claims concerning regulation of generic drugs import

* On 29 February 2012, claimants submitted their request for arbitration against USA under NAFTA Chapter 11 and Jamaica-USA BIT.
* On 25 August 2014, the tribunal issued its final award,[[4]](#footnote-3) holding that:
  + patent applications were not investments under NAFTA Chapter 11, following the Apotex I and II award.
  + only investment in Apotex Corp., a U.S.-based pharmaceutical company, was a qualified investment under NAFTA Chapter 11.
  + the U.S. subjected national and foreign pharmaceutical companies to different *bona fide* regulatory regimes, the national comparators could never have been subject to any import alert—the only measure Apotex complained about—therefore, national companies could not be considered to be in like circumstance. The tribunal thus dismissed the national treatment claim.
  + the FDA treated the foreign comparators differently ‘influenced by the FDA’s genuine concerns over shortages of essential drugs’. The most-favoured-nation treatment claim was therefore also dismissed.
  + the FDA administered procedure was not unreasonable and provided ways to challenge the decision of the FDA.
  + Apotex failed to establish ‘specific procedural rights required by customary international law in the context of the FDA’s regulatory decision’ and dismissed Apotex’s claim for violation of the minimum standard of treatment.

1. [↑](#endnote-ref-1)
2. [↑](#footnote-ref-1)
3. [↑](#footnote-ref-2)
4. [↑](#footnote-ref-3)