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# "INVESTMENT" NARROWLY CONSTRUED UNDER NAFTA IN *APOTEX v. UNITED STATES*

**A RECENT DECISION PROVIDES A NARROW INTERPRETATION OF "INVESTMENT" UNDER NAFTA CHAPTER ELEVEN**

In a recent NAFTA Investor-State claim brought against the United States by Apotex Inc., Canada's largest producer of generic drugs, the Tribunal upheld the United States' preliminary objections to jurisdiction on the grounds, *inter alia*, that the company's efforts to win approval for generic drugs in the United States market did not make it an "investor" under Article 1139 of NAFTA Chapter Eleven. In *Apotex Inc. v. The Government of the United States of America,* Award on Jurisdiction and Admissibility (14 June 2013), the Tribunal held that significant expenses incurred in: (i) seeking Food and Drug Administration ("FDA") approval; (ii) purchasing materials and ingredients in the United States intended for the manufacture of products abroad (in this case in Canada); and (iii) conducting litigation and establishing an agent in the United States for the purpose of corresponding with and making submissions to the FDA, were all insufficient to qualify as an "investment" under the treaty. This award sheds further light on the precise meaning of the term "investment" under NAFTA and confirms that, as with other provisions of NAFTA Chapter Eleven, investors must surmount a high jurisdictional threshold in order to bring claims before a NAFTA tribunal.

Apotex alleged in the arbitration that its rights were violated by the United States in breach of NAFTA Articles 1102 (obligation to accord national treatment to foreign investments), 1105 (obligation to accord fair and equitable treatment to foreign investments) and 1110 (obligation not to expropriate without payment of fair compensation). Apotex claimed that it was subject to mistreatment by the United States, its agencies (in particular the FDA) and its Federal Courts in the course of the company's efforts to bring generic versions of the anti-depressant drug Zoloft (to be marketed as Sertraline by Apotex) and the anti-cholesterol drug Pravachol (to be marketed as Pravastatin by Apotex) to market in that country. In particular, the Sertraline claim arose out of three United States Federal Court

decisions pertaining to Apotex's application for FDA approval of its generic drug. The Pravastatin claim arose out of a decision by the FDA and three decisions of the United States Federal Courts, pertaining to Apotex's application for FDA approval of its generic drug.

The United States objected to the jurisdiction of the NAFTA Tribunal on the grounds, *inter alia*, that Apotex did not qualify as an "investor" which had made an "investment" in the United States for the purposes of NAFTA Article 1139 (which Article contains the definitions of "investment" and "investor of a Party").

Apotex argued in response that: (i) it had invested millions of dollars in developing its products and preparing and filing its submissions to the United States' FDA; (ii) the sole purpose of Apotex's development and submission of the FDA application was to obtain FDA approval to commercialize its products in the United States; (iii) Apotex's FDA application was manifestly a U.S. investment (i.e. property, tangible or intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes); (iv) Apotex had made substantial commitments of capital and other resources towards economic activity in the United States, including the purchase of raw materials from United States suppliers for its Pravastatin manufacturing process; and (v) Apotex had designated its United States affiliate and distributor as its United States agent for FDA regulatory purposes, as well as designating an agent for service of process in the United States, thus consenting to jurisdiction and suit there.

The Tribunal addressed Apotex's defenses to the United States' main jurisdictional objection and found that, "*each of the specific activities and expenses relied upon by Apotex simply supported and facilitated its Canadian-based manufacturing and export operations*," meaning that such expenditures could not count as investments in the United States. Further, the Tribunal held that Apotex's activities with respect to the contemplated sales of its Sertraline and Pravastatin products in the United States were "*those of an exporter, not an investor*" and as such were not protected by NAFTA's provisions on national treatment. Similarly, the Tribunal held that the purchase of materials and ingredients in the United States could not count as an investment as they were intended for the manufacture of products abroad. Finally, the Tribunal found that conducting litigation in the United States and establishing an agent in the country to assist with FDA submissions, constituted an ordinary part of doing business and did not amount to an investment. Consequently the Tribunal held that no "investment" had been made by Apotex in the territory of the United States within the scope of NAFTA Chapter Eleven and that Apotex itself did not therefore qualify as an "investor" under the treaty. This finding was sufficient for the Tribunal to dismiss Apotex's claims in their entirety.

The United States had, in addition to the above jurisdictional objection, argued that: (i) Apotex had failed to pursue available remedies within the United States Court system with respect to its Pravastatin claim, such that the judicial acts complained of lacked sufficient finality to form the basis of claims under NAFTA Chapter Eleven; and (ii) the time bar in NAFTA Article 1116(2) precluded Apotex's allegation in its Pravastatin claim that the FDA's letter decision of 11 April 2006 (determining that a 180-day exclusivity period had not been triggered) itself constituted a violation of Articles 1102, 1105 and 1110 of NAFTA. Despite having already dismissed Apotex's claims in their entirety, the Tribunal went on to address these additional jurisdictional objections, finding in favor of the United States in both instances. Particularly noteworthy is the Tribunal's rejection of Apotex's argument that it had satisfied the requirement to exhaust local legal remedies because appealing to the United States Supreme Court would have been "obviously futile," based primarily on the small number of cases that this Court entertains each year. The Tribunal held that to accept such an argument would be, "*to write the US Supreme Court out of the exhaustion of remedies rule in almost all cases*." The tribunal, having rejected Apotex's jurisdictional defenses, ordered the company to pay the United States' legal costs as well as the costs of the arbitration.

It is noteworthy that Apotex chose, for unknown reasons, not to advance three arguments that could conceivably have resulted in it overcoming the jurisdictional objections of the United States. First, the award focused on investments the company claimed it *had* made in the U.S., as opposed to investments that it *intended* to make in the country. Apotex's apparent failure to focus on the investments it *intended* to make is surprising given that the company's attempts to bring new drugs to market in the United States could arguably be interpreted as Apotex "*establishing*, *acquiring*" and

"*expanding*" its investments in the country. A "pre-establishment" argument with respect to Apotex's national treatment claim under NAFTA Article 1102(2) (which states that, "*Each Party shall accord to investments of investors of another Party treatment no less favorable than that it accords, in like circumstances, to investments of its own investors with respect to the establishment, acquisition, expansion, management, conduct, operation and sale or other disposition of investments*") might arguably have stood a greater chance of success than the more straight-forward investment argument advanced by Apotex. Second, the Claimant could also have argued that its activities in the U.S. were covered by NAFTA Article 1139 (which states that, "*investor of a Party means a Party or state enterprise thereof, or a national or an enterprise of such Party, that seeks to make, is making or has made an investment*.") As both NAFTA Articles 1102(1) and 1103(1) explicitly extend treaty protection to "investors" as well as "investments", Apotex could well successfully have argued that its attempts to sell generic drugs in the U.S. were those of an investor "*seeking to make*" an investment in the United States. A final, albeit controversial, argument that could have been advanced was that the U.S. is obliged to extend NAFTA protection to the wider category of "*investments*" defined in that country's bilateral investment treaties with non-NAFTA states, as a consequence of the "*most favored nation*" clause contained in NAFTA Article 1103 (which states that, "*each Party shall accord to investors of another Party treatment no less favorable than it accords, in like circumstances, to investors of any other Party or of a non-Party with respect to the establishment, acquisition, expansion, management, conduct, operation, and sale or other disposition of investments*.") This wider category of investments would, based on the definitions of "*investment*" contained in a number of older U.S. BITs that remain in force (such as, for example, the U.S.-Congo BIT), likely be deemed to have included the "*investment*" made by Apotex in the United States.

## CONCLUSIONS

In light of the Apotex award, U.S., Mexico and Canada-based companies with investments in other NAFTA signatory countries should be aware that the barriers to jurisdiction in NAFTA Investor-State proceedings are continuing to grow higher—particularly when compared to those in other treaty-based Investor-State arbitrations—though they are by no means insurmountable. Whilst host countries continue aggressively to fight NAFTA claims brought against them, successful outcomes for investors remain possible if the system is navigated wisely, for instance by ensuring that claims are brought under the most appropriate provisions of the treaty. The tribunal's finding that Apotex's failure to exhaust local legal remedies in the U.S. would, in any event, have been fatal to its claim should also not be overlooked. It is a cautionary tale which demonstrates that investors in the U.S., if a NAFTA claim is on the horizon, should be sure to file a pro forma certiorari appeal to the Supreme Court to ensure that all local U.S. legal remedies have been exhausted. Jones Day has significant experience representing claimants in NAFTA proceedings and will continue closely to monitor developments in NAFTA jurisprudence. We would be happy to discuss any questions or concerns you may have regarding the protection of investments in the United States, Canada or Mexico, including through the arbitration of investment disputes under NAFTA's Chapter Eleven.

## LAWYER CONTACTS

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