GENERICS AND PATENT ECOSYSTEMS IN INTERNATIONAL INVESTMENT ARBITRATION: THE IMPORTANCE OF APOTEX INC. V USA

Abstract

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The *Apotex v USA* tribunal decisions regarding Sertraline and Pravastatin ANDAs have attracted scant indepth analysis, as to their ultimate effect on the treatment of intangible asset categories in investment arbitration. The Tribunal's decision in the final Apotex Inc. claim (2012) employed res judicata to preclude the company from claiming that its finally approved ANDA was indeed intangible property acquired for the purpose of economic benefit. This decision may prove problematic for future investment claims by foreign investors in generics manufacturing. Little known outside the specialist circles of patent law, Hatch-Waxman Amendment ANDAs, for which final FDA approval is attained, can create patent-related rights, that provide a shorter route to market entry for generic pharmaceuticals. Approved paragraph IV ANDAs provide 180 exclusivity for the first successful generic applicant, bestowing a narrow right to exclude other generic competitors, that can also be traded and valued in a similar manner to patents. The right to exclude is a defining feature of property, followed by a conditional right to use. ANDAs, fall into the category of a sui generis proprietary rights (somewhere between an intangible property right and a license). Indeed, US tax law categorises ANDAs as intangibles, a category of property. Res judicata and jurisdiction *rationae temporis* cannot change the proprietary nature of an intangible, nor should a Tribunal appear to decide on the content and scope of intellectual property regulatory norms. In light of this, this paper will discuss the issues that may arise for foreign investors in generics manufacturing, if they encounter FET violations in the preparation of their ANDAs.