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The international journal of commercial and treaty arbitration
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Pharmaceuticals: a new frontier in investment treaty arbitration

6 September 2013

Ricardo Ugarte, **Franz Stirnimann** and **Dolores Bentolila** of Winston & Strawn in Geneva discuss the increasing willingness of pharmaceutical companies to invoke investment treaty arbitration to respond to adverse foreign government measures.

Until recently, pharmaceutical companies had not sought to advance or protect their interests through investment treaty arbitration. However, the potential for pharmaceutical companies that invest abroad to use this form of arbitration against foreign governments to help overcome unfair regulatory obstacles and political risks is evidenced through a number of arbitrations recently brought by major US, Canadian and French companies. For example, Apotex, Eli Lilly, Servier, Signa, and Merck each have brought investment treaty claims against a wide range of foreign governmental measures, including the mishandling of marketing approvals, the undue delay in lifting an import alert, measures allegedly contrary to intellectual property (IP) treaty standards and the allegedly gross mishandling of IP disputes by foreign courts. This article briefly examines certain of these arbitrations, focusing on the types of "investments" that pharmaceutical companies make abroad that may qualify for protection under investment treaties, and the types of claims such companies may bring against adverse governmental measures.

Pharma "investors" and their "investments" under treaties

To bring a claim under an investment treaty, the claimant will need to satisfy the various jurisdictional elements set forth in the treaty, that is, it will need to demonstrate that it satisfies the conditions upon which the foreign state consented to arbitration under the treaty at issue. Two conditions commonly found in such treaties are that the claims be brought by an "investor" in relation to an "investment" as these terms are defined under the relevant investment treaty.

This article was first published in the Global Arbitration Review online news, 6 September 2013
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The term "investor" is most often defined by reference to the claimant's nationality or state of incorporation. Thus for example corporations, by simply being incorporated in the US, often fall within the definition of an "investor" under many of the investment treaties entered into by the US with foreign governments.

Most investment treaties define the term "investment" broadly. An "investment" often includes "every kind of asset having an economic value"; and investment treaties frequently provide an illustrative list of assets that qualify as investments, including shares in a local company, tangible property, intangible property, IP rights, and any rights given by law or contract or by a decision of a public authority. Depending on the treaty, pharmaceutical companies may also file claims arising out of investments that are based purely upon their IP rights, marketing approvals, import permits, and contracts in the foreign jurisdiction at issue.

IP rights and IP rights applications

IP rights and IP rights applications include not only patents, but also trademarks and knowhow. Registration, when the IP right is subject to it, has to be completed because the right is generally only conferred once the application is processed and approved. Further, IP rights are territorial in nature and most investment treaties provide that the investment must be made in the territory of the host state. Therefore, IP rights generally have to be registered in the host state to qualify as an investment.

Naturally, whether IP rights applications are covered investments will depend on the treaty wording. Some investment treaties define investments as including "rights with respect to copyrights, patents…" or "patentable inventions". Even in the absence of such provisions, pharmaceutical companies could argue that such applications are intangible property if they have the characteristics of property such as the capability of being "owned" and assignable to third parties. Although there are no investment arbitration awards deciding this issue, the European Court of Human Rights held in Anheuser-Busch v Portugal that applications to register trademarks are property rights and possessions within the meaning of article 1, protocol 1 of the European Convention on Human Rights.

Marketing approvals and import permits

Marketing approvals and import permits are also important assets of pharmaceutical companies, whether they refer to patented or generic drugs. Although pharmaceutical companies increasingly invest in research and development abroad, they still distribute and import drugs in other countries, particularly in those with low IP protection regimes. In principle, drug approvals and import permits are covered by the definitions of "investment" found in many investment treaties, which include "rights given by the decision of a public authority" or "any asset having an economic value".

Nevertheless, some investment treaties have definitions that are more restrictive. For instance, NAFTA provides an exhaustive list of covered investments that does not refer to rights granted by a decision of a public authority. The scope of NAFTA's definition of "investment" was examined when Apotex, a Canadian generic drug

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manufacturer that imports and sells drugs in the US, brought two international arbitrations against the US claiming that drug approvals and applications to obtain such approvals were "investments" covered by NAFTA.

In Apotex I, the company claimed, among other things, that abbreviated new drug applications (ANDAs) filed with the US Food and Drug Administration (FDA) to obtain approval for its generics were property acquired in the expectation of economic benefit or other business purposes, thus qualifying as an "investment" under NAFTA article 1139(g). In particular, it argued that ANDAs can be bought and sold like other property and that ANDA applicants have the exclusive right to possess, use and enjoy the ANDA and the products approved under it by the FDA, which made it tantamount to an investment under article 1139(g). Further, Apotex Inc claimed that it had committed significant capital and resources towards the preparation, filing, and maintenance of its ANDAs and the products approved under it to sell its drugs in the US as well as towards US patent litigation arising from these ANDAs, which qualified as an investment under article 1139(h).

In an award rendered in June this year, however, the tribunal dismissed the arbitration for lack of jurisdiction, reasoning that the claimant did not have an investment in the US. The tribunal declared that the claimant's expenditures in ANDAs were not made in the US, and, even if they were, the expenditures were intended to comply with security clearance requirements for importing the products rather than investments. Further, the tribunal considered that the ANDAs themselves were mere applications for revocable permission to export products to sell in the US, and that property was not an "investment" if it merely supported cross-border sales of goods. Finally, the ANDAs were only "tentatively" approved. Thus, they could not be considered as property in the sense of Article 1139 (g) of NAFTA.

In Apotex II, Apotex relies upon a different argument, claiming that its marketing authorisations and capital commitments in regards to these authorisations are the investments under articles 1139(g) and (h). A decision in that matter is still pending.

Contracts

Investment treaties usually cover investments associated with claims to money. Such claims to money include those arising from voluntary licenses for the use of patents and trademarks, compulsory licenses, and contracts between pharmaceutical companies and state companies or agencies for developing or selling drugs.

Some investment treaties limit claims to money to those arising from investment contracts as opposed to purely commercial contracts. Similarly, in arbitrations under the ICSID Convention, the contract at issue must constitute an investment under article 25 of the convention. Although article 25 does not define what an investment is, many arbitral awards apply an objective test to distinguish between commercial and investment transactions. Known as the Salini test, it is based on the existence of certain elements that characterise an investment, namely duration of the economic activity; profit; risk; and, for some tribunals, contribution to the economic development of the host state. In non-ICSID arbitrations, and in the absence of restrictive definitions of "investments" in investment treaties, pure sale of goods contracts may be covered. This was decided in 2005 in a case brought under the Energy Char-

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ter Treaty regarding an oil sale contract between Gibraltar entity Petrobart and a Kyrgyz state-owned company. Nevertheless, there are tribunals that have held to the contrary. For example, in Italy v Cuba, an inter-state tribunal established under the Cuba-Italy BIT considered that a contract to sell pharmaceutical products to a Cuban state-owned company was not an investment covered by the BIT because there was neither an economic contribution to the host state, nor a non-commercial risk undertaken by the investor.

Pharma claims against host states

Pharmaceutical companies may bring claims for the violation of the substantive obligations of investment treaties, and, in some cases, for the breach of contracts that they have with states or agencies thereof. Investment treaties provide investment protection standards, such as the duty of the foreign state to provide fair and equitable treatment, national treatment, most favoured nation treatment, and non-arbitrary or non-discriminatory treatment towards the investment of the investor. In addition, such treaties limit the right of the foreign state to expropriate the investment of the investor (including direct takings and indirect takings that are effected through abusive regulations). Such treaties provide that such expropriations may only occur under certain conditions; that is, for a public purpose, in accordance with due process of law, in a non-discriminatory manner and upon payment of prompt, adequate and effective compensation to the investor. Some investment treaties permit the investor to bring an investment arbitration when the foreign state has breached a contract entered into with the investor through provisions contained in certain treaties, often referred to as the "umbrella clause."

Fair and equitable treatment (FET)

This standard has acquired particular prominence with investors as they have successfully invoked it in many cases, and it is perhaps the most commonly invoked standard by pharmaceutical companies. The substantive content of FET is hotly contested in investment arbitrations but has been held by some tribunals to include protecting the legitimate expectations of the investor to the extent these were formed at the time the investment was made. The FET provision also has been held to protect against manifest arbitrariness, denial of justice and due process, discrimination and abusive treatment.

A frustration of the investor's legitimate expectations was successfully claimed in relation to the cancellation of marketing approvals in the UNCITRAL case, Servier v Poland. Servier claimed that the withdrawal by Polish authorities of Servier's marketing authorisations for certain medicines in Poland's legal harmonisation process, after Poland's accession to the EU, was contrary to the France-Poland BIT. In this process, regulatory authorities reviewed thousands of medicines, and Servier's patented medicines were arbitrarily screened out because they were not more effective than generic alternatives.

Similarly, Eli Lilly has sent two notices of intent to arbitrate disputes against Canada under NAFTA concerning the Canadian courts' invalidation of two patents a few years before the patents' scheduled expiration. Eli Lilly claims that the sudden adoption by Canadian courts of a new, more stringent approach to patent invalida-

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tion based on their ineffectiveness in relation to what was promised by the patent holder (the promise doctrine) is contrary to IP treaties incorporated in Canadian law, and, thus, to the company's legitimate expectations at the time of its investments. This case remains pending.

FET also may cover administrative due process and the denial of justice by domestic courts. A violation of administrative due process is linked to the lack of transparency, arbitrariness, inadequate right to participate, or excessive delays in the administrative proceedings. This element of FET is crucial for pharmaceutical companies as they are subject to numerous administrative decisions in order to register their IP rights successfully and have their products approved for sale and distribution.

Administrative procedural unfairness has been invoked in Apotex II. In this case, the FDA found that Apotex had violated certain standards of manufacturing practices and issued an import alert preventing Apotex from selling drugs and obtaining new marketing approvals. In a new inspection, the FDA found that there was no violation of the manufacturing practice standards, but the import alert was lifted only many months after that finding. A mere existence of a delay may not be sufficient to find a breach of administrative due process, but when the economic impact of the delay is important, as argued by Apotex, the delay may amount to a breach of FET.

Denial of justice also protects the handling of judicial proceedings. Although the state cannot be held directly liable for the conduct of private parties that infringe patent protections and other IP rights, it can potentially be responsible if "domestic courts refuse to entertain a suit, if they subject it to undue delay, or if they administer justice in a seriously inadequate way" (Azinan v Mexico). Denial of justice may also be pleaded by pharmaceutical companies in cases relating to a wide range of proceedings, such as the enforcement of arbitral awards and breach of contracts, product liability, and health-care cases and judicial challenges against administrative decisions. When considering the state's responsibility for denial of justice, tribunals often require that judicial decisions be final products of the state's judicial system. This was recently stated by the tribunal in Apotex I. Apotex claimed unjust and discriminatory handling of its ANDA by US courts in judicial challenges against an FDA ruling. The tribunal dismissed these claims because the claimant had elected not to exhaust all available remedies provided under the US judicial system, and such remedies were not "obviously" futile.

Expropriation

Investment treaties define expropriation in broad terms including both direct and indirect expropriation. Expropriation is direct when there is a formal transfer of title to the state. Direct expropriation of pharmaceutical companies may arise where the property (for example, a factory or machinery) is formally taken. In such a case, the Permanent Court of International Justice (the precursor to the International Court of Justice) considered in Certain German Interests in Polish Upper Silesia in 1925 that such an expropriation also encompasses contractual rights and IP rights, even though the state did not purport to expropriate intangible property.

Expropriation may also arise from indirect measures where the legal title to the property is not disturbed; instead, the economic value of the use, enjoyment or

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disposition of the assets is substantially diminished by acts attributable to the host state. Indirect expropriation may take two forms. It may be targeted (that is, when the measures tantamount to expropriation are individual and specific, such as the repudiation of a governmental authorisation or permit). They also may be regulatory (that is, when they result from the adoption of measures of general application). This second type of expropriation may result from environmental, health or other regulations banning the use of certain substances or medications, depriving the investor of the use or enjoyment of its investment. For instance, Mexican generics producer Signa sent a notice of arbitration to Canada in 1996, arguing that Canadian drug regulations permitting anyone claiming to hold a patent of the drug to obtain an injunction of up to 30 months against generic manufacturers of the drug, was an expropriation. In its arbitration against Canada, Eli Lilly also claims that the Canadian government expropriated its patents when its courts invalidated them based on the promise doctrine mentioned above.

The way forward

Investment treaties have the potential to serve as effective legal instruments for pharmaceutical companies because they permit such companies to bring arbitration claims to protect their investments against adverse foreign governmental measures that violate international law. The fate of the above-referenced cases has been mixed thus far and some cases have yet to be determined, but each should provide meaningful guidance for pharmaceutical companies that are considering filing similar arbitrations.

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