

BIG PHARMA AND INVESTMENT ARBITRATION

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Abstract

Investment Arbitration in the pharmaceutical sector raises some specificities. Regarding jurisdiction of arbitral tribunals, it is questionable whether the registration of a patent abroad or a patent license granted to a foreign partner constitutes an investment. Similarly, as health products are not ordinary goods, arguments according to which marketing authorizations or monopolies granted constitute an investment are real issues. On the merits, the invalidation of a patent, the refusal or withdrawal of a marketing authorization or the decision of a state authority to end a monopoly can be analyzed as a violation of some of the commitments made by States in the treaties they conclude. The aim of this study is to address these questions thanks to the awards already rendered, making it a useful tool for countries -like Vietnam- that wish to develop their pharmaceutical sector by attracting foreign investors.

Keywords: foreign investors, investment arbitration, notion of investment, patent, marketing authorization, monopoly, international obligations, fair and equitable treatment, expropriation

Not all companies have the same relationship to arbitration as a means of resolving their disputes. Some of them have no reluctance to use it, while others avoid it as much as possible. Extractive sector companies (mining, oil and gas) do not hesitate to use it,¹ while companies in the banking sector are said to hardly use it.² Taken as a whole, because obviously the practice may differ from one company to another, companies in the pharmaceutical sector are occasional users of international arbitration.³ This has already been noted with regard to commercial arbitration; it is also true with regard to investment arbitration, which is a form of international arbitration between an investor and a State on the basis of the latter's

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¹ The UNCTAD investment arbitration database as of 15 April 2021 counted 172 cases registered by extractive companies (mining and hydrocarbons sector). Retrieved from <https://investmentpolicy.unctad.org/investment-dispute-settlement> [accessed on 15 April 2021].

² See for example, Affaki G. (2004), 'Le banquier et l'arbitre', *Banque & Droit*, No. 93.

³ Schwarz F. and Berajano S. (2014), 'Arbitration: Big Pharma, Big Player', www.cdr-news.com, Nov.-Dec..

consent to arbitration expressed in a treaty or, more rarely, in a law.⁴

To date, there have been at least 13 investment arbitration proceedings initiated by pharmaceutical companies against States on the basis of an investment treaty, but not all of them have resulted in an arbitral award.⁵ Five cases were terminated at an early stage of the proceedings, where the dispute was finally not registered,⁶ settled out of court⁷ or discontinued early.⁸ Two cases are at an early stage of the proceedings and currently pending.⁹ Finally, six cases have resulted in an award, four in favor of the defendant State and two in favor of the foreign investor.¹⁰

Involved in more than half of the cases¹¹ under Chapter XI of the North American Free Trade Agreement (NAFTA), these arbitration proceedings reveal some of the particularities of investment arbitration in pharmaceutical disputes due to the specificities of this activity.¹²

⁴ Ugarte R., Stirnimann F. et Bentolila D. (2013), 'Pharmaceuticals: a new frontier in investment treaty arbitration', *Global Arbitration Review*, 6 September 2013. Retrieved from www.globalarbitrationreview.com [accessed on 15 April 2021].

⁵ According to the UNCTAD website. Retrieved from <https://investmentpolicy.unctad.org/investment-dispute-settlement> [accessed on 15 April 2021]. See also in annex the list of cases identified. It should be noted, however, that three cases concern the same dispute, *Apotex Inc. v. USA* (I), (II) and (III).

⁶ In *Signa SA v. Canada*, the case was settled after the sending of a notice of intention to submit a request for arbitration. In *CEN Biotech v. Canada*, a notice to submit a request for arbitration (in relation to the proposed construction of two marijuana drug manufacturing plants facing denial of investment authorization by the Canadian authorities) was registered in September 2015 and has never been acted upon.

⁷ *Gilead Pharma Corp. C. Ukraine and Hourani v. Kazakhstan*.

⁸ *Kenex Ltd v. USA*, a case arising from the decision of the Food and Drug Administration (FDA) to refuse the marketing of a drug made from cannabis, pursuant to the *Controlled Substances Act* in that it would prohibit the sale of products whose intake results in the absorption of THC by the human body.

⁹ *Qatar Pharma v. Saudi Arabia* and *Santamarta v. Venezuela*.

¹⁰ In *Apotex Inc. v. USA* (I), (II) and (III), the proceedings ended through awards declining jurisdiction. An award on the merits dismissing all of the investor's claims was made in *Ely Lilly v. Canada*. Two awards on the merits upheld all or part of the investor's claims, in *Servier SAS v. Poland* and *Merck v. Ecuador* (partial award). All the awards cited in this article are available online on the above-mentioned UNCTAD website or at <https://www.italaw.com> or <https://icsid.worldbank.org>.

¹¹ In 7 cases out of the 12 identified (see Annex below).

¹² The meeting of investment law with industrial property law or intellectual property law has already given rise to a number of writings, including: Dubuisson F. (2017), 'Investissement étranger et droits de propriété intellectuelle', in *Le droit des investissements internationaux: perspectives croisées*, Sabrina Robert-Cuendet dir., Bruylant, pp. 359-387; Vadi V. S. (2015), 'Towards a new dialectics : pharmaceutical patents, public health and foreign direct investments', 5 *NYU Journal of Intellectual Property and Entertainment Law*, No. 1, pp. 113-195; Boie B. (2010), *The Protection of Intellectual Property Rights Through Bilateral Investment Treaties: Is There a TRIPS-Plus Dimension?*, 4 NCCR Trade Regulation, Working Paper No. 2010/19; Liberti L. (2010), *Intellectual Property Rights in International Investment Agreements: An Overview*, OECD Working Papers on Int'l Inv. 2010/01; Sell S. K. (2007), "TRIPS-Plus Free Trade Agreements and Access to Medicines", 28 *Liverpool L.R.*, 41.

Indeed, for investment arbitration to take place, the dispute must relate to an investment made on the territory of a host State. If we make an exception to the classical hypothesis of the development of a research and/or production activity abroad, some specificities of the pharmaceutical activity raise questions about the notion of investment. Patents and trademarks (and related contracts) are particularly important in the pharmaceutical sector. One may then wonder whether the registration of a patent abroad or a patent license granted to a foreign partner constitutes an investment. Similarly, as health products are not ordinary goods, it is questionable whether marketing authorizations (MA) or monopolies granted constitute an investment.

On the merits, the invalidation of a patent, the refusal or withdrawal of a marketing authorization or the decision of a State authority to end a monopoly can be analyzed as a violation of some of the commitments made by States in the treaties they conclude, in particular the obligation of fair and equitable treatment or the right to expropriate foreign investors subject certain conditions are met.

All this constitutes features to be taken into account for any country, such as Vietnam, that already welcomes foreign investments in the pharmaceutical sector¹³ and that wish to develop it further by attracting new foreign investors.¹⁴

In order to further explore these issues, this study will successively address certain specificities of the pharmaceutical business with regard to the notion of investment (I) and with regard to the protection of the pharmaceutical business by substantial norms of investment law (II).

1. Pharmaceutical activity and existence of an investment

The obtaining and protection of patents embodying industrial property rights on a new molecule is a particularly important issue

¹³ Abbott (USA), Bayer HealthCare Pharmaceuticals (Germany), Nipro Pharma Corporation (Japan), Sanofi (France), Taisho Group (Japan) and B. Braun (Germany) are among the large-scale pharmaceutical firms already established in Vietnam Vietnam Investment Review (2018), "Vietnam's six large-scale foreign pharmaceutical firms", 1 March 2018. Retrieved from <https://vir.com.vn/vietnams-six-large-scale-foreign-pharmaceutical-firms-56624.html> [accessed on 15 April 2021].

¹⁴ Tran J., "Vietnam 2020: A Pharmaceutical Industry with Major Opportunities for Multi-National Companies". Retrieved from <https://www.linkedin.com/pulse/vietnam-2020-pharmaceutical-industry-major-companies-james-tran/> [accessed on 15 April 2021].

in the pharmaceutical business, as are the marketing authorizations and sales monopolies obtained. But do these rights conferred by state authorities (A), or even the steps taken to obtain them (B), constitute investments?

1.1. Is a patent or a marketing authorization an investment?

In order for the holder of a patent or marketing authorization to be protected by a treaty concluded in relation to investment, the right conferred must be covered by that treaty, i.e. fall within its scope because it is considered to be an investment within the meaning of that treaty. The answers provided by these texts in this respect require that patent and marketing authorization be dealt with separately.

Investment treaties do not specifically address the pharmaceutical sector but often include industrial and intellectual property rights as examples in a non-exhaustive list of what can be considered an investment. Such is the case for instance in the BIT concluded between Viet Nam and Sweden which entered into force on 2nd August 1994:

“Article 1 Definitions

For the purposes of this Agreement:

1. The term “investment” shall comprise every kind of asset, invested by an investor of one Contracting Party in the territory of the other Contracting Party, provided that the investment has been made in accordance with the laws and regulations of the other Contracting Party, and shall include in particular, though not exclusively:

a) movable and immovable property as well as any other property rights, such as mortgage, lien, pledge, usufruct and similar rights;

(b) shares and other kinds of interest in companies;

(c) title to money or any performance having an economic value;

(d) patents, other industrial property rights, technical processes, trade names, know-how, and other intellectual property rights as well as goodwill; and

(e) business concessions conferred by law, administrative decisions or contracts, including concessions to search for, cultivate, extract or exploit natural resources;

A change in the form in which assets are invested does not affect their character as investment.”

Industrial property rights, and among them patents, are more specifically referred to in Article 1.1.d. as an example of what is considered an investment. The patent for invention certainly also falls within the broader categories of “*every kind of asset*” in Article 1.1, or “*title to money or any performance having an economic value*” in Article 1.1.c. Widely used in the context of pharmaceutical arbitration, Chapter XI of the NAFTA Treaty, which contains its rules relating to investments, also adopts the model of the exhaustive illustrative list, which includes in particular “*other property, tangible and intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes*”.¹⁵ Under this approach, too, a patent is an investment. However, it should be noted that patents are granted on a territorial basis. In order for there to be an investment in a

¹⁵ The concept of investment is approached this way in Chapter XI of the NAFTA Treaty: Article 1139: Definitions

(...)

investment means :

an enterprise ;

an equity security of an enterprise shareholding in a company

a debt security of an enterprise

(i) where the enterprise is an affiliate of the investor, or

(ii) where the original maturity of the debt security is at least three years,

but does not include a debt security, regardless of the original maturity, of a state enterprise;

a loan to an enterprise

(i) where the enterprise is an affiliate of the investor, or

(ii) where the original maturity of the loan is at least three years,

but does not include a loan, regardless of the original maturity, to a state enterprise;

an interest in an enterprise that entitles the owner to share in income or profits of the enterprise;

an interest in an enterprise that entitles the owner to share in the assets of that enterprise on dissolution, other than a debt security or a loan excluded from subparagraph (c) or (d) ;

real estate or other property, tangible and intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes; and

interest arising from the commitment of capital or other resources in the territory of a Party to economic activity in such territory, as under:

(i) contracts involving the presence of an investor's property in the territory of the Party, including turnkey or construction contracts, or concessions, or

(ii) contracts where remuneration depends substantially on the production, revenues or profits of an enterprise;

but investment does not mean

claims to money that arise solely from

(i) commercial contracts for the sale of goods or services by a national or enterprise in the territory of a Party to an enterprise in the territory of another Party; or

(ii) the extension of credit in connection with a commercial transaction, such as trade financing, other than a loan covered by subparagraph (d); or

any other claims to money,

that do not involve the kind of interest set out in subparagraphs a) to h);

given State, the patent must therefore be registered there or at least a license to use the patent must be used in that territory, for example as a contribution to a joint venture company responsible for producing the drug derived from the molecule protected by the patent.

The case of marketing authorization for a medicinal product is more complex. It is undeniable that once this authorization is granted, it has a patrimonial value; it can be transferred to a third party (in particular to the purchaser of the patent) and is sometimes a very important asset for a pharmaceutical company. With regard to the above-mentioned “definitions”, marketing authorization is certainly part of “every kind of asset”, or “*other property, tangible and intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes*”. The concept of “*title to money or any performance having an economic value*” seems so broad that it also justifies the qualification of investment for a marketing authorization. Regarding a marketing authorization granted by virtue of a law or a marketing monopoly granted by *virtue of a contract*, can it not be argued that they can be analysed as “*business concessions conferred by law, administrative decisions or contracts*” “?

The problem with the marketing authorization is not so much its nature as its function, to allow its holder to proceed with the sale of a medicinal product. Indeed, some investment treaties exclude sales from the “investment” category, followed by some arbitration awards. Can the right to sell be qualified as an investment when a sale is not an investment?

This qualification was rejected by the arbitral tribunal in the *Apotex I and II* cases. The dispute arose out of applications in the USA by the Canadian company Apotex for approval of two generic drugs, Sertraline (a generic of a well-known anti-depressant marketed by Pfizer) and Pravastatin (a generic drug for certain heart conditions). Specifically, Apotex had filed two Abbreviated New Drug Applications (ANDAs) with the US Food and Drug Administration (FDA), which are reserved for generic drugs that are bioequivalent to the originator drug. Apotex’s ANDAs were ultimately rejected by the US courts, in part as a result of proceedings brought by its competitors. For Apotex, these decisions constituted violations by the USA of its obligations under NAFTA. Since no authorization – and therefore no rights – had yet been granted to the Canadian company, the United States objected to

the jurisdiction of the tribunal, contesting, in particular, that the requests for authorization could be considered as investments.

The two requests for arbitration were joined and, in an award dated June 14, 2013, the arbitral tribunal decided that it did not have jurisdiction to hear the dispute. In answering the question whether a marketing authorization application could be considered as an investment,¹⁶ the arbitral tribunal also analysed the marketing authorization itself, its nature and purpose. The arbitral tribunal noted that the ANDA was only a “clearance” application and did not fall within any of the categories of the exhaustive list of Article 1139 of the NAFTA Treaty, which expressly excludes claims arising solely from commercial contracts for the sale of goods or services.¹⁷ The arbitral tribunal added that the request for clearance was not intended to change the nature of the activity for which the clearance was sought,¹⁸ a commercial sale, not covered by Chapter XI of the NAFTA Treaty on Investment. Relying on the precedent set by the NAFTA *Grand River* Award,¹⁹ the tribunal added that any finding to the contrary would run counter to the fundamental objectives of NAFTA.²⁰

The distinction between sale and investment is not unique to NAFTA since, in *Global Trading Resource Corp. et al. v. Ukraine*, it was on the basis of the ICSID Treaty that the arbitrators declined jurisdiction, noting that pure commercial transactions could not be considered an investment within the meaning of that treaty, which does not contain a definition of or an approach to the concept of investment.²¹ Most investment treaties differ from NAFTA in that their illustrative list is not exhaustive. However, if the chosen arbitration institution is ICSID, distinguishing a sale from an investment may be the policy followed by the arbitral tribunal. It would therefore seem that it would be difficult to avoid a case-by-case analysis and, as long

¹⁶ See *infra* I.B.

¹⁷ See *supra* note 13.

¹⁸ Award of incompetence of 14 June 2013, § 193.

¹⁹ *Grand River Enterprises Six Nations Ltd. v. United States*, Incompetence Award of 12 January 2011. The refusal of an application for authorization to sell cigarettes is at the origin of this case submitted to an *ad hoc* arbitral tribunal on the basis of the NAFTA Treaty.

²⁰ Award of incompetence of 14 June 2013, § 194–195.

²¹ *Global Trading Resource Corp. and Others v. Ukraine* (ARB/09/11), Incompetence Award of 1 December 2010, § 56. It should also be noted that in the inter-State dispute between Italy and Cuba concerning the interpretation of the BIT concluded between the two States, the *ad hoc* arbitral tribunal decided that a contract for the sale of pharmaceutical products was not an investment within the meaning of that treaty (§ 215 of the award of 15 January 2008).

as the diversity of the treaties prevails on this issue, there is no point in expecting a constant and clear jurisprudence.

The other decisions currently handed down in pharmaceutical arbitration do not provide any additional elements of analysis. Most of the cases identified does not directly concern the granting of a patent or the obtaining of a marketing authorization and the only two cases that could have given rise to developments in this area are disappointing. In *Eli Lilly v. Canada* (arbitration arising from the annulment by the Canadian courts of two patents previously granted to the US company), the respondent State did not challenge the existence of an investment and the arbitral tribunal therefore did not have to rule on it. As for the reasoning of the arbitral tribunal on the existence of an investment in the award in *Servier et al. v. Poland* (dispute arising from the refusal to renew authorizations to import several medicines marketed by the French company on the Polish market), it is one of the – many – passages of this decision which have not been made public. However, it is clear from the table of contents that the arbitral tribunal took into account the clientele (in Poland) of the claimants, as the applicable BIT is expressly aimed at client group as a form of investment.²² It would therefore seem that the clientele as an intangible asset – rather than the import permit – was used to characterize the existence of an investment.²³

Awards that have already answered the question of whether the steps taken to obtain a patent or a marketing authorization constitute an investment are not more numerous, but they also shed some interesting light on this other question.

²² BIT Article 1(1) defines “investment” as follows:

The term “investment” shall mean assets such as property, rights and interests of any kind related to an economic activity in any sector whatsoever, in accordance with the laws of the Contracting Party in whose territory or maritime areas the investment has been made, including inter alia, but not limited to:

(a) ...

(d) Copyrights, industrial property rights (such as patents for inventions, licenses, registered trademarks, industrial models and designs), technical processes, registered names and clientele, ...

provided that the said assets related to an economic activity must be or must have been invested in accordance with the laws of the Contracting Party in whose territory or maritime areas the investment is made, before or after the entry into force of this Agreement.

²³ It should be noted that in an approach aimed at differentiating a sale from an investment, considering the clientele as an investment is also not without problems if clients only mean those who have concluded sales contracts with the exporter. How can the result (building up a clientele) of an activity that is not an investment be an investment?

1.2. Are the steps taken to obtain a patent or MA an investment?

This question is obviously more delicate because in this case the pharmaceutical company is not yet, by definition, the owner of the rights conferred by a patent or a marketing authorization. This being the case, the steps taken to this end require companies to devote time, work and money to it in the hope of obtaining the coveted right, which is itself the prerequisite for an economic activity that is hoped to be lucrative. In this respect, one might think that it is fairly close to the definition of what an investment is, i.e. a contribution to a project with a view to obtaining a²⁴ future return. However, it should be added that it is not the coveted authorization that will generate future rights by itself but the sale of the medicines it makes possible, and that simple sales are most of the time excluded from the “investment” category.

Here again, the relevant treaties offer a variety of solutions.²⁵

Some treaties seem to exclude that patent applications can be considered as covered investments. This is the case of the ASEAN Comprehensive Investment Agreement, Article 4.c.iii. of which considers as investment only “(...) *intellectual property rights which are conferred pursuant to the laws and regulations of each Member State*”. As the property rights attached to a patent arise with the grant of the patent, before the patent is granted – and therefore during the period of filing and examination of the application – there are no rights and therefore no investment yet.

Other treaties protect “rights with respect to copyrights”²⁶ or “patentable inventions”,²⁷ which may allow for the inclusion of patent applications.

Finally, other treaties protect “intangible rights”, a notion broad enough to include patent or marketing authorization applications.

²⁴ On this issue, see for instance Manciaux S. (2010), ‘Actualité de la notion d’investissement international’, in *La procédure arbitrale relative aux investissements internationaux : aspects récents*, C. Leben dir., Anthémis/LGDJ, pp. 145-173.

²⁵ On this question, see notably Vadi V. S. (2015), ‘Towards a new dialectics: pharmaceutical patents, public health and foreign direct investments’, 5 *NYU Journal of Intellectual Property and Entertainment Law*, No. 1, pp. 113-195, whose study inspires much of this development.

²⁶ For example, the BIT concluded on 15 September 1993 between Hong Kong and Australia (Article 1.(e).(iv)) or the BIT concluded on 11 May 1991 between Argentina and Canada (Article 1.(a).(iv)).

²⁷ For example, the BIT concluded on 2 February 1994 between the USA and Jamaica, (Article I.1.(a).(iv)).

Once again, this means that a textual analysis on a case-by-case basis is necessary and may lead to various conclusions.²⁸

The place of proceedings is also important because the protection of the treaties with regard to investment is only granted to foreign investments, i.e. investments made by nationals of a State party to this treaty on the territory of another State party. Can a dematerialized approach carried out essentially from the home State of the pharmaceutical entrepreneur then enable him to claim that he has invested abroad?

These two issues are not specifically addressed by the investment treaties but have already given rise to an interesting decision already cited, the one rendered in relation to the first two proceedings brought by Apotex against the USA on the basis of NAFTA.

Specifically with respect to its ANDAs, Apotex claimed that its applications and all matters relating to their development and submission constituted an investment within the broad approach to the concept adopted by NAFTA and, more specifically, within the meaning of Article 1139 (g) of NAFTA, which refers to “*other property, tangible and intangible, acquired in the expectation or used for the purpose of economic benefit or other business purposes*”.²⁹ To this end, the plaintiff insisted in particular on the efforts made to meet the requirements of the ANDA, in the hope of being able to market its generics on the United States territory.³⁰

The arbitral tribunal first considered that, like the development and production of generics, the preparation of the ANDA application had been done in Canada and not in the US, and thus the claimant did not establish that it had made an investment in the US.³¹ The Court then rejected the argument that the ANDA itself constituted “*property, (...), acquired in the expectation or used for the purpose of economic benefit or other business purposes*”. First, it held that, as an application for authorization (“application”), the ANDA did not fall within the NAFTA concept of property, even though the ANDA procedure could be assigned.³² It then decided that even if the ANDA applications were provisional approval for the drug in question, they

²⁸ See *above* for developments already devoted to this subject.

²⁹ Award of incompetence of 14 June 2013, § 148.

³⁰ *Ibid.*, § 181.

³¹ *Ibid.*, § 187 à 192.

³² *Ibid.*, § 207.

could not be considered as “*property*” precisely because they were provisional and revocable until final approval was granted by the FDA.³³

Not all of the arbitral tribunal’s reasoning achieves the same degree of persuasion. Taking into account the place where the activity is carried out seems very relevant with regard to the application of a treaty which makes it a condition for its application. Distinguishing an authorization to sell from an investment in the case of a treaty that opposes sales and investments seems logical. However, it is not self-evident to refuse to classify an application to obtain a right as an intangible asset, even though the application itself generates rights for its holder and has the characteristics of an asset (i.e. the possibility of transferring ownership).

This solution is all the more necessary since, faced with a similar question, a high international court has ruled differently. The European Court of Human Rights (ECHR) has in fact had to answer the question of whether the application for registration of a trade mark was constitutive of a possession within the meaning of Article 1 of Protocol No. 1 to the European Convention on Human Rights. Although it was an application for registration of a trade mark (and not a patent or an application for marketing authorization) in respect of an alcoholic beverage (and not a medicinal product), the parallel between the two cases is nevertheless interesting. In *Anheuser-Busch v. Portugal*, the American company which owned the *Budweiser* trade mark challenged the decision of the Portuguese courts which had refused to register the trade mark in Portugal following an action brought by a Czech company which also marketed beer and which invoked a protected designation of origin. At first instance, a chamber of the ECHR had concluded that an application for registration of a trade mark did not fall within the category of “*existing possessions*”, the only one considered by Article 1 of Protocol No. 1.³⁴ Although the court found that the application for registration already produced certain legal effects (including a right of priority over possible subsequent applications and the possibility of assigning that right), it held that “*In the instant case, the applicant company could not be sure of being the owner of the trade mark in question until after final registration and then only on condition that no objection was raised by a third party. In other*

³³ *Ibid.*, § 209.

³⁴ ECHR (2nd section), *Anheuser-Busch v. Portugal*, judgment of 11 October 2005, Application No. 73049/01, § 49.

*words, the applicant company had a conditional right, which was extinguished retrospectively for failure to satisfy the condition, namely that it did not infringe third-party rights.”*³⁵

After an appeal was lodged against this decision, the Grand Chamber of the Court issued a more nuanced decision in which it accepted that a trade mark application may fall within the concept of property and as such enjoys minimum protection:

“(...) the Court takes due note of the bundle of financial rights and interests that arise upon an application for the registration of a trade mark. It agrees with the Chamber that such applications may give rise to a variety of legal transactions, such as a sale or licence agreement for consideration, and possess – or are capable of possessing – a substantial financial value (...).

*These elements taken as a whole suggest that the applicant company’s legal position as an applicant for the registration of a trade mark came within Article 1 of Protocol No. 1, as it gave rise to interests of a proprietary nature. It is true that the registration of the mark – and the greater protection it afforded – would only become final if the mark did not infringe legitimate third-party rights, so that, in that sense, the rights attached to an application for registration were conditional. Nevertheless, when it filed its application for registration, the applicant company was entitled to expect that it would be examined under the applicable legislation if it satisfied the other relevant substantive and procedural conditions. The applicant company therefore owned a set of proprietary rights – linked to its application for the registration of a trade mark – that were recognised under Portuguese law, even though they could be revoked under certain conditions.”*³⁶

The ECHR therefore decided that an application for recognition of intellectual property gives rise to an economic value sufficiently substantial to constitute a possession. However, it would be excessive to overly oppose this solution to the one enshrined in the *Apotex I* and *II* awards. Admittedly, apart from the difference in products and the nature of the applications (marketing authorization or trademark registration), the question raised was whether the steps taken for such a purpose constitute a possession that could benefit from the protection of the treaty invoked. The two courts did not reach the same conclusion as to the revocable nature of the rights conferred on

³⁵ *Ibid.*, § 50.

³⁶ ECHR (Grande ch.), *Anheuser-Busch v. Portugal* judgment, 11 January 2007, Application No. 73049/01, § 76 and 78.

the holder of an application for recognition of industrial or intellectual property or marketing authorization.

The difference in solution seems essentially linked to the objectives pursued by each of the two texts: Article 1 of Protocol No. 1 of the European Convention on Human Rights protects possessions while Chapter 11 of NAFTA protects investments. This being the extensive approach of the latter notion – leading, for example, to consider as investment a large number of tangible or intangible assets – erases this first difference. But there is another one: Article 1 of Protocol No. 1 of the European Convention on Human Rights protects all “existing” possessions without distinction when Chapter 11 of NAFTA limits this protection to certain goods or operations from which marketing authorizations should be excluded. Is this the reason why the *Anheuser-Busch* decision of the ECHR is not referred to in the *Apotex* (I) and (II) award, even though it was handed down more than six years later?

It is not certain that the solutions will be much more assertive and certain when we look at the protection of pharmaceutical activity by the material norms of investment law.

2. The protection of the pharmaceutical activity by the material norms of investment law

Although it has its own particularities, the pharmaceutical activity also has points in common with those developed in other sectors. For example, like other sectors, pharmaceutical companies set up operations abroad to develop and produce all or part of their ranges of drugs. The subsidiaries, branches and production units of pharmaceutical companies established abroad may then suffer damage as a result of the intervention (or lack of intervention) of the local authorities. The dispute between Merck and Ecuador is a good illustration of this.

This long-running case arose from legal proceedings initiated by Nueva Industria Farmaceutica Asociada SA (Nifa), an Ecuadorian company, following Merck’s refusal to sell it a pharmaceutical unit operating in Ecuador. After the local courts ruled in Nifa’s favor, Merck initiated arbitration proceedings against the host State, claiming that the legal proceedings against it and their outcome constituted a denial of justice. A partial award rendered on 25 January 2018 ruled in favour of the claimant but the case is still

pending an award on the amount of compensation awarded.³⁷ However, this case does not reveal any particularities related to the activity carried out and is therefore of limited interest from the point of view of our approach.

Here again, it is the particularities of disputes in the pharmaceutical sector that will be the focus of attention. These peculiarities stem from the specificities of the pharmaceutical business, the development and production of medicines, i.e. goods containing active substances that make them both potentially dangerous and so necessary to fight diseases. Their availability and the possibility for all to have access to them constitute additional specificities which cannot be without consequences on its production and marketing.

These specificities explain the importance of state regulations governing the production and marketing of pharmaceutical products. The decisions of state authorities to patent – or not – a molecule, to grant, refuse or withdraw a marketing authorization, to confer or withdraw a marketing monopoly for a drug are fraught with consequences for pharmaceutical companies. It is therefore understandable that, faced with a State decision prejudicial to their activities, some pharmaceutical companies do not hesitate to challenge their decision on the grounds that it constitutes a violation of States' treaty commitments in the area of investment. Two of the substantive rules contained in these Treaties seem more particularly relevant in this respect, the standard of fair and equitable treatment (A) and the conditional right for States to expropriate (B).

2.1. The standard of fair and equitable treatment

Host States' obligation to treat foreign investments and foreign investors fairly and equitably is a classic standard of customary international law transposed in Investment Treaties.³⁸ Fair and equitable treatment has the characteristic features of any standard,

³⁷ For more information on this case. Retrieved from <https://investmentpolicy.unctad.org/investment-dispute-settlement/cases/437/merck-v-ecuador> [accessed on 15 April 2021].

³⁸ On this subject and among numerous references, see Nanteuil A. De (2017), *Droit international de l'investissement*, Pedone éd. 2^e éd., p. 334 et seq. and Manciaux S. (2019), 'The Full Protection and Security Standard in Investment Law: A Specific Obligation?', in *International Investment Law and the Law of Armed Conflict*, Katia Fach Gomez, Anastasios Gourgourinis and Catharine Titi eds, *European Yearbook of International Economic Law*, Springer ed., pp. 217-228.

a framework but flexible concept with indeterminate content. Personal understanding, which differs from one person to another, of what is fair and equitable does not help to clarify the content of the concept.

The Comprehensive Economic and Trade Agreement (CETA) concluded between the European Union and Canada, which crystallises the case law on the subject, provides the following delimitation to the standard of fair and equitable treatment:

Article 8.10: Treatment of investors and of covered investments

1. Each Party shall accord in its territory to covered investments of the other Party and to investors with respect to their covered investments fair and equitable treatment and full protection and security in accordance with paragraphs 2 through 7.

2. A Party breaches the obligation of fair and equitable treatment referenced in paragraph 1 if a measure or series of measures constitutes:

- (a) denial of justice in criminal, civil or administrative proceedings;
- (b) fundamental breach of due process, including a fundamental breach of transparency, in judicial and administrative proceedings;
- (c) manifest arbitrariness;
- (d) targeted discrimination on manifestly wrongful grounds, such as gender, race or religious belief;
- e) abusive treatment of investors, such as coercion, duress and harassment; or
- (f) a breach of any further elements of the fair and equitable treatment obligation adopted by the Parties in accordance with paragraph 3 of this Article.

It follows from this article that a State will not accord fair and equitable treatment to a foreign investor if it treats its administrative applications for a patent or marketing authorization in an arbitrary and/or discriminatory manner, or if the processing of such an application discloses “a *fundamental breach of due process, including a fundamental breach of transparency, in a judicial and administrative proceeding*”. In other words, when faced with an application for the grant of a patent or MA, local authorities retain the right to refuse the application, but the refusal must be the result of an analysis of the application that is neither arbitrary nor discriminatory and carried out in accordance

with the legal procedures in force in that State, which must meet certain criteria.³⁹

It is then interesting to note that pharmaceutical companies in known investment arbitration proceedings regularly complain that their patent or marketing authorization applications have been refused following arbitrary and/or discriminatory instructions. Unfortunately, for a variety of reasons, few decisions have been rendered on this issue.

In *Servier*, the applicable French-Polish BIT only provided for recourse to arbitration in the event of expropriation:⁴⁰ the plaintiff could not therefore argue before the arbitral tribunal that the refusal to renew the marketing authorization of its originator drug coupled with the agreement given for two generic drugs constituted an infringement of the obligation of fair and equitable treatment. This peculiarity of the BIT, which is specific to investment treaties concluded with (then) communist countries, probably also explains why the investor's goodwill was used to establish the jurisdiction of the arbitral tribunal. Indeed, it makes more sense to claim that one has been dispossessed of one's clientele than to claim that one has been expropriated of one's marketing renewal application. In light of

³⁹ The ECHR follows the same logic in such circumstances, and thus decided in the *Anheuser-Busch v. Portugal* case cited above that the refusal to register the Budweiser trade mark in that country was not wrongful because it resulted from the proper application of "clear, precise and reasonable" legislation, ECHR (2nd section), *Anheuser-Busch v. Portugal*, judgment of 11 October 2005, req. no. 73049/01, § 50.

⁴⁰ Article 8 of the Franco-Polish BIT reads as follows (Article 5.2 being the provision devoted to direct or indirect expropriation):

1. Any dispute relating to investments between one Contracting Parties and an investor of the other Contracting Party shall, as far as possible, be settled amicably between the two parties concerned or, failing that, through internal means of recourse.

2. However, disputes relating to the divestment measures referred to in Article 5.2, particularly those relating to possible compensation, its amount and terms of payment and the interest payable in the event of a delay in payment, shall be settled according to the following conditions:

-if any such dispute has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute, it shall, at the request of either party, be submitted to arbitration. It shall be settled definitively in accordance with the Arbitration Rules of the United Nations Commission on International Trade Law, as adopted by the General Assembly of the United Nations in resolution 31/98 of 15 December 1976.

-when both Contracting Parties have become parties to the Convention on the settlement of investment disputes between States and nationals of other States, signed at Washington on 18 March 1965, any such dispute which has not been settled amicably within six months from the time when the matter was raised by one of the parties to the dispute shall be submitted for arbitration to the International Centre for Settlement of Investment Disputes.

this claim, it makes more sense to reason in terms of treatment, which may not have been fair and equitable. Moreover, it is interesting to note that certain circumstances – such as the discriminatory nature of the measure or its disproportionate nature – which contribute to the unlawfulness of the expropriation but also characterize a violation of the obligation of fair and equitable treatment were noted in the award by the arbitral tribunal.⁴¹

The case of *Gilead Sciences, Inc. v. Ukraine* could also have given rise to the application of the fair and equitable treatment obligation.

Gilead is the company that produces the Sofosbuvir molecule (marketed by Gilead under the name Sovaldi), which is highly effective in the fight against chronic hepatitis C, but sold at over \$1,000 per pill, for a full treatment cost of between \$60,000 and \$80,000. Gilead has granted seven patent licenses to Indian pharmaceutical companies for the production and marketing of the drug in 91 states considered to be developing countries, a category in which Ukraine does not appear. By mid-2015 Gilead had obtained a patent in the Ukraine for Sovaldi giving it the exclusive right to market the molecule in the Ukraine. But as early as November 2015, a much cheaper competitor appeared on the official Ukrainian registers, the Grateziano drug produced by the Egyptian state company Europharma International. Gilead decided to bring an action before the Ukrainian courts in May 2016 to have the registration of Grateziano withdrawn, a request that was rejected by the Kiev District Administrative Court in October 2016. At the same time, in early 2016, Gilead notified Ukraine that it was initiating arbitration proceedings against it on the basis of the BIT between the USA and Ukraine. An amicable settlement finalized in January 2017 brought the dispute to an end under the following conditions: Gilead dropped all its lawsuits against Ukraine, agreed to market Sovaldi in Ukraine at a more affordable price in exchange for deregistering Grateziano from the list of medicines authorised in Ukraine. This agreement, which demonstrates the leverage of the threat of investment arbitration against a State, relieved Gilead from developing its legal arguments, among which the violation of fair and equitable treatment was to figure prominently.

⁴¹ Sentence du 14 février 2012, § 576 : “Moreover, the divestment violates the mandates of the first subparagraph. Not only was the refusal of authorization discriminatory, but the regulatory measure were disproportionate in nature and thus not a matter of public policy”.

In *Apotex*, the Canadian company complained that it had not received fair and equitable treatment from the American authorities and courts, whether with respect to the dispute generated by its applications for simplified authorizations (*Apotex I* and *II*) or with respect to the alert procedure triggered by the FDA following a visit to one of its production sites in Canada (*Apotex III*). Although the two differently constituted arbitral tribunals decided that they did not have jurisdiction to decide these disputes⁴², in the *Apotex III* award the arbitral tribunal – in an *obiter dictum* – held that it had the power to determine what would have been the fate of the claims on the merits. It concluded that should it had jurisdiction to decide the dispute, it would have rejected the investor's argument of breach of fair and equitable treatment because it had not exhausted administrative and judicial remedies to challenge the FDA's warning measure.⁴³

The requirement that domestic remedies must be exhausted in order to hold a State liable for a breach of the obligation of fair and equitable treatment is a classic one and is based on the idea that, while the State is responsible for the functioning of its judicial system, the latter must still be given the chance to remedy a mistake made by a court by using all the resources offered by that system.⁴⁴ There is, however, considerable room for interpretation regarding the need to exercise a remedy that is doomed to failure and therefore futile. This discussion took place before the arbitral tribunal and the tribunal found that the remedies available against the FDA's decision in the US courts could not be characterized as futile.⁴⁵

⁴² See Part I *above*.

⁴³ Award of 25 August 2014, § 9.65 :

"Given the overall record, including the Claimants' decisions not to pursue either administrative or judicial remedies to contest the FDA's allegedly improper action in imposing the Import Alert, the Tribunal decides that the Claimants have failed to establish that the Respondent's conduct rose to the threshold of severity and gravity required to establish a violation of NAFTA Article 1105, even assuming that such protection extends beyond an investment to the treatment of an investor."

⁴⁴ On the question see e.g. Nanteuil A. De (2017), *supra* note 38, p. 315.

⁴⁵ Award of 25 August 2014, § 9.64. The same discussion was conducted in the *Apotex I* and *II* cases with the same result regarding the application concerning Pravastatin. However, in so far as Chapter XI of NAFTA applies only to measures adopted or maintained by the host State (Article 1101), the United States argued in this instance that, as it concerns a judicial decision, this provision implies the exhaustion of domestic remedies in order to establish its finality (Award on jurisdiction and admissibility of 14 June 2013, § 251-252). The arbitral tribunal agreed with the defendant on this issue and held that, in the absence of exhaustion of domestic remedies in the USA, the claim concerning Pravastatin was either inadmissible or outside the jurisdiction *ratione materiae* of the tribunal (*ibid.*, § 298-299).

In *Eli Lilly v. Canada*, the US investor claimed, among other things, that the invalidation by Canadian courts of two of its patents – a few years before their expiry – in application of a new and stricter approach based on the ineffectiveness of the patent with respect to what the patent holder promised (doctrine of promise), was contrary to the Industrial Property Treaties concluded by Canada and incorporated into its legislation, and therefore contrary to the legitimate expectations of the investor protected by the standard of fair and equitable treatment.⁴⁶ The arbitral tribunal, after considering numerous arguments, finally decided that if there had been an evolution in the jurisprudence of the Canadian courts in this respect, it was neither spectacular nor fundamental but, on the contrary, had been progressive and was based on long-standing considerations, so that it could not claim that its legitimate expectations had not been respected by the host State.⁴⁷ The court therefore rejected the claim based on the breach of fair and equitable treatment just as it rejected the claim based on the existence of an expropriation.⁴⁸

2.2. *The conditional right to expropriate*

The rules on expropriation are interesting in that they contain the Gordian knot of investment law: protecting the interests of foreign investors while allowing States to regulate in the general interest

⁴⁶ On the question see e.g. Nanteuil A. De (2017), *supra* note 38, p. 352 et seq.

⁴⁷ Award of 16 March 2017, § 386 et seq:

“386. Taken as a whole, the evidence before the Tribunal shows that Canada’s utility requirement underwent incremental and evolutionary changes between the time that the Zyprexa and Strattera Patents were granted and then invalidated, in particular during the six-year period that Claimant highlights (2002–2008). Over those years, there was an increase in the number of utility-based challenges of pharmaceutical patents, which appears to have increased the pace of the development of the law most relevant to that sector. The Tribunal also sees that each of the three rules that Claimant considers part of the promise utility doctrine has a reasonably solid foundation in prior authority, even if there is a question about the extent to which that prior authority was applied in practice. 387. For all of the reasons in subsections (1) to (5) above, the Tribunal finds that, on the record in this arbitration, Claimant has not demonstrated a fundamental or dramatic change in Canadian patent law. For the interrelated reasons in subsection (6) above, the Tribunal finds that Claimant has not demonstrated, as a factual matter, that its legitimate expectations were violated by the application of Canadian patent law to the Zyprexa and Strattera Patents.”

⁴⁸ Note that the abandonment – at least on the surface – of the doctrine of promise on June 30, 2017 by the Supreme Court of Canada in its *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36 [*AstraZeneca*] gives, *a posteriori*, additional arguments to the unsuccessful plaintiff in 2016.

of their population.⁴⁹ States can therefore expropriate, including assets owned by foreign investors, but not in any way or under any conditions.

Investment treaties often include in the same article –or even in the same sentence– the hypothesis of direct expropriation and that of indirect expropriation (or measure equivalent to expropriation). This gives a false impression of similarities.

Direct expropriation consists of the open and claimed dispossession of the property of another person, who may be a foreign investor. Direct expropriation must comply with certain conditions, including the payment of compensation, failing which it is unlawful and will result in the injured owner obtaining damages of a different nature and possibly of a different amount than the compensation.

Indirect expropriation results from a measure (or a series of measures) which, without dispossessing the contractor of its assets, renders them so useless that the measure is tantamount to dispossession. A typical example is the classification as an ecological zone of a piece of land on which an activity (e.g. industrial or hotel) incompatible with the new status of the land is carried out. The investor retains ownership of a property that it can no longer exploit. Measures having an effect equivalent to expropriation are often not taken with this in mind and never announced as such. It is therefore necessary to first check that a measure has a sufficiently substantial effect to be considered equivalent to an expropriation. However, the effect of the measure, which has been the only feature considered in certain sentences at the beginning of this century,⁵⁰ is not enough any longer. In order to preserve the right for States to regulate and not to see each measure taken by them being considered as an expropriation, a series of hypotheses are reserved which remove the expropriatory nature of the State measure. These hypotheses have been set out for decades, first in 1950 by Article 1 of Protocol No. 1 to the

⁴⁹ On this question, see for example Titi C. (2014), *The Right to Regulate in International Investment Law*, Nomos Verlagsgesellschaft ed.

⁵⁰ In an award rendered in *Metalclad v. Mexico* (ARB(AF)/97/1), concerning the classification as an ecological zone of the land on which a waste storage and reprocessing plant had just been completed, the arbitrators held that “*The Tribunal need not decide or consider the motivation or intent of the adoption of the Ecological Decree*” before holding that “*the implementation of the Ecological Decree would, in and of itself, constitute an act tantamount to expropriation*” (Award of 30 August 2000, § 111).

European Convention on Human Rights,⁵¹ then in 1987 by the third *Restatement of Foreign Relations Law of the United States*.⁵² If one of these hypotheses applies, then there is no expropriation and therefore no compensation to be paid to the investor who suffers damages.⁵³ Most investment arbitral tribunals now rule to this effect.⁵⁴

The risk of confusion is illustrated by the award in *Servier*, in which the arbitral tribunal had jurisdiction only if an expropriation occurred. In this regard, the arbitral tribunal, appearing to consider the hypothesis of direct expropriation, began by pointing out that a State measure could only be taken under certain conditions, in particular in the public interest, in a manner proportionate to that public interest and in a non-discriminatory manner.⁵⁵ However, the arbitral tribunal then considered on the one hand that Article 5.2 of the applicable BIT did not distinguish the amount of compensation or indemnification to be paid according to the lawfulness or otherwise of the measure⁵⁶ and that on the other hand and in this case it was an indirect expropriation resulting from a measure substantially affecting

⁵¹ Article 1 of Protocol No. 1 to the European Convention on Human Rights
Right to property

“1. Every natural or legal person is entitled to the peaceful enjoyment of his possessions. No one shall be deprived of his possessions except in the public interest and subject to the conditions provided for by law and by the general principles of international law.

2. The preceding provisions shall not, however, in any way impair the right of a State to enforce such laws as it deems necessary to control the use of property in accordance with the general interest or to secure the payment of taxes or other contributions or penalties”.

⁵² American Law Institute, *Restatement of the Law third, the Foreign Relations Law of the United States*, American Law Institute Publishers, Vol. 1, § 712, Comment g, 1987, p. 8 :

“A State is responsible as for an expropriation of property when it subjects alien property to taxation, regulation or other action that is confiscatory, or that prevents, unreasonably interferes with or unduly delays, effective enjoyment of an alien’s property or its removal from the state’s territory...

A State is not responsible for loss of property or for other economic disadvantage resulting from bona fide general taxation, regulation, forfeiture for crime, or other action of the kind that is commonly accepted as within the police power of states, if it is not discriminatory...”

⁵³ In this sense it can be said that any measure tantamount to an expropriation is lawful by nature.

⁵⁴ Thus, in the case *Saluka Investments BV v. Czech Republic*, in which the investor complained, inter alia, that he had been the victim of indirect expropriation, the arbitral tribunal did not adopt its analysis, deciding that: “It is now established in international law that States are not liable to pay compensation to a foreign investor when, in the normal exercise of their regulatory powers, they adopt in a non-discriminatory manner bona fide regulations that are aimed at the general welfare.” (Partial Award of 17 March 2006, § 255).

⁵⁵ Award of 14 February 2012, § 569.

⁵⁶ *Ibid*, § 572.

the rights of the investor.⁵⁷ The line of reasoning is not crystal clear.

In *Eli Lilly v. Canada*, the investor claimed that the decisions of the Canadian courts not only violated the duty of fair and equitable treatment but also constituted unlawful expropriation. The respondent State noted that in the United States, the home State of the investor, the concept of judicial expropriation was not recognized and that in the international sphere there was no precedent for it.⁵⁸ The arbitral tribunal issued a convoluted decision in which it held that, to the extent that acts of the judiciary engaged the international responsibility of the State, it was conceivable that acts of the judiciary “*may engage question of expropriation*”.⁵⁹ Taking note of the reference made by Article 1110 of the NAFTA Treaty – relating to expropriation – to Article 1105 of the same treaty – relating to fair and equitable treatment – the Tribunal recalled that it was not an appeal body for decisions taken by the judiciary of a State.⁶⁰ The tribunal finally decided to reject the application, as the investor had failed to provide evidence that the decision rendered by the Canadian courts constituted expropriation or a violation of fair and equitable treatment within the meaning of the applicable treaty.⁶¹

This is the content of the only two arbitration awards issued to date in the investment field and dealing with the issue of expropriation in the pharmaceutical sector.⁶² It should be noted that one well-identified circumstance, which has its place in the field of pharmaceutical activities, has not yet been submitted to the wisdom of an arbitral tribunal: the hypothesis of compulsory licensing.

⁵⁷ *Ibid.* at § 576.

⁵⁸ Award of 16 March 2017, § 215.

⁵⁹ *Ibid.*, § 221.

⁶⁰ *Ibid.*, § 225.

⁶¹ *Ibid.*, § 469

“As a consequence of the findings set forth in Sections VIII and IX above, the Tribunal concludes that Claimant has failed to establish the factual premise of its claims. Specifically, the Tribunal holds that, based on the record of this case, the challenged measures – the invalidation of the Zyprexa and Strattera Patents through application of the legal rules that Claimant refers to as the promise utility doctrine – cannot form the basis of an expropriation claim under NAFTA Article 1110 or a claim for a violation of the minimum standard of treatment under NAFTA Article 1105. The Tribunal also finds that there was not an arbitrary or discriminatory measure in violation of NAFTA Article 1110 or NAFTA Article 1105. (...)”

⁶² It should be noted that the alleged expropriation of a pharmaceutical company was the cause of the arbitration proceedings registered in 2015 in the case *Devinci Salah Hourani and Issam Salah Hourani v. Republic of Kazakhstan*, ICSID Arbitration, No. ARB/15/13, but the case is pending.

Compulsory license – or forced license – is the technique by which a public authority may authorize a third party to use the patented process or manufacture the patented product without the consent of the patent holder and subject to the fixing of a royalty, often less than the one the holder could have obtained by contract.⁶³

As a mechanism for the safeguard of public interest when industrial and intellectual property rights protect private interests, compulsory licensing is provided for in many national legislations and at the international level by Article 31 of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). Article 31 of the TRIPS Agreement (which is one of the agreements administered by the WTO along with the GATT or GATS), under the heading of “*Other Use Without Authorization of the Right Holder*”, provides in particular for the possibility of a compulsory license in cases of urgency without the need for a prior request for a voluntary license.

It is easy to imagine that, faced with a virulent epidemic –such as the Covid 19– and without the necessary medicines to deal with it, public authorities could grant a compulsory license to a company to produce the remedy or the vaccine that its population urgently needs. There are, however, conditions to such a compulsory license, including its limitation in time (until the emergency circumstance disappears), in space (the needs of the internal market alone), and the payment of “adequate” remuneration to the right holder. But it is easy to understand that a compulsory license granted without the authorization of the right holder can be analysed for the latter as an expropriation and more specifically as an indirect expropriation.

An example of this was given some 20 years ago when South Africa passed the *Medicines and Related Substances Control Amendment Act* (1997) giving the Minister of Health the power to issue compulsory licenses in the interest of public health to produce locally produced generic medicines. Despite South Africa’s promise to pay reasonable compensation to patent holders to comply with Article

⁶³ On this issue, see in particular Kahn A.-E. (2007), ‘Les licences obligatoires’, in *Le médicament et la personne, aspects de droit international*, I. Moine-Dupuis dir. LexisNexis, travaux du CREDIMI Vol. 28, pp. 219 et seq. The following developments are largely based on this article.

31 of TRIPS, 39 international laboratories and the Pharmaceutical Industry Association of South Africa have launched legal proceedings to have the law invalidated. Against the backdrop of an expanding AIDS epidemic that was affecting a large number of South Africans who were economically unable to afford the original drugs to fight the disease, the mobilisation of world public opinion led the multinational pharmaceutical companies to withdraw their action in 2001. Nevertheless, the stage was set and it is more than likely that a similar case will occur again.

In such a hypothesis, it can already be argued that the compulsory license could be considered as a measure taken in the regular framework of the general interest defence of the population of that State, thus preventing the State measure from being qualified as a measure tantamount to an expropriation. It should also be noted that this is typically a conflict of international standards, that of the investment treaty protecting foreign investors and Article 31 of the TRIPS Agreement ratified by the 160 member States of the WTO. In this difficult balance – which is too often claimed to have been broken in favour of foreign investors⁶⁴ – it is highly likely that the rule protecting the general interest will prevail over that protecting private interests, provided that the legal framework of compulsory licensing is respected.⁶⁵

The use of investment arbitration by companies in the pharmaceutical sector has therefore not yet made it possible to explore all the specific issues raised (or likely to be raised) by this sector of activity, nor to clearly establish the first limits. But this last observation is not very surprising if one considers that investment arbitration considered globally is a still recent phenomenon which, like any complex legal construction, will take time to build and stabilize. However, the lessons that can already be drawn from the few cases analyzed in this article should certainly be taken into consideration by any government wishing to know the framework in which it can act to attract foreign investment in the pharmaceutical sector while retaining its right to regulate and to act. ●

⁶⁴ Statistics published regularly by ICSID or UNCTAD –and freely available online– on the outcome of investment arbitrations show that the situation is much more contrasted than it is said in many criticisms against this method of dispute settlement. See also the Annex.

⁶⁵ It is also possible to consider the rule on compulsory licensing as a special rule with regard to the general rule of protection of the property of foreigners.

Appendix: List of known investment arbitration proceedings concerning the pharmaceutical sector

Case (and year of initiation)	Applicable IIA	Facts	Issue
1) Signa SA v. Canada (1996)	NAFTA	Formation of a JV in Canada between Signa SA (Mexico) and Apotex Inc. (Canada) for the manufacture of a generic. The Canadian authorities, at the request of Bayer, the patent holder, banned the production of the generic for 3 years.	Case settled after the sending of a notice of intention to submit a request for arbitration (no decision published).
2) Kenex Ltd c. USA (2002)	NAFTA	FDA ban on the sale of a drug containing a cannabis derivative (THC).	Case discontinued, no decision published.
3) Apotex Inc. v. USA (I) (2008)	NAFTA	Refusal to issue a marketing authorization for a generic drug in the USA.	Award declining jurisdiction, 14/6/2013 (published), in favor of USA.
4) Servier SAS v. Poland (2009)	BIT France- Poland	Refusal to renew a marketing authorization to the patent holder when authorizations are granted to generic companies.	Award, 14/2/2012 (partly published), in favor of Servier.
5) Apotex Inc v. USA (II) (2009)	NAFTA	Refusal to grant a marketing authorization for a (other) generic drug in the US.	Award declining jurisdiction, 14/6/2013 (published), in favor of USA.
6) Merck v. Ecuador (2011)	BIT Ecuador/ USA	Refusal by the investor to sell a factory to a local company.	Case discontinued after a partial award (on liability) of 25/1/2018 in favor of Merck.

7) Apotex Inc v. USA (III) (2012)	NAFTA	Challenge to an “import alert” issued by the FDA concerning products manufactured by the applicant.	Award declining jurisdiction, 25/8/2014 (published), in favor of USA, <i>res judicata</i> .
8) Eli Lilly v. Canada (2013)	NAFTA	Invalidation of a patent previously granted to the investor for two of his molecules.	Award, 16/3/2017 (published), rejecting all investor’s claims.
9) Hourani v. Kazakhstan (2015)	BIT UK/ Kazakhstan and USA/ Kazakhstan	Expropriation of a pharmaceutical plant.	Concluded, discontinuance of the proceeding pursuant to ICSID Arbitration Rule 43(1), 15/7/2020
10) CEN Biotech c. Canada (2015)	NAFTA	Refusal of authorization for a marijuana drug manufacturing plant.	Notice to submit a request for arbitration in Sept. 2015; nothing since.
11) Gilead Pharma Corp v Ukraine (2016)	BIT USA/ Ukraine	Action in Ukraine by the patent holder against the marketing authorization given to a competitor offering a cheaper drug.	Amicable settlement of the dispute in January 2017.
12) Qatar Pharma v. Saudi Arabia (2019)	Investment Agreement of the Organization of the Islamic Conference (OIC)	Resolution of a sales contract leading to the closure of the local Qatari owned factory following the breakdown of diplomatic relations between Saudi Arabia and Qatar.	Pending case
13) Santamarta v. Venezuela (2020)	BIT Spain/ Venezuela	Claims arising out of Government’s alleged seizure of SM Pharma’s manufacturing facilities in Maracaibo	Pending case

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