CAPÍTULO 35

THE USE OF INVESTOR-STATE ARBITRATION TO RESOLVE CONFLICTS IN PATENT LAW

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INTRODUCTION

The development of innovative technologies demands hefty investments. In this sense, unlike investment in manufacturing and tangible means of production, the investment in research and development results in the production of new knowledge – information that is readily appropriable by third parties[262]. For this reason, the State assures incentives to the production of novel technical advancements through the issuance of temporary privileges over such contributions, guaranteeing the property of the asset – even if for a limited time – to their respective owners[263].

Some specific commercial fields, such as pharmaceuticals, are especially dependent upon patent protection. In empiric studies conducted by DiMasi, Grabowski, and Hansen (2016), the authors point to the fact that only one in every eight prospective medicines survive the clinical trial phase[264]. To this connection, under a qualitative analysis, Grabowski, DiMasi, and Long (2015) argue that the few medicines which reach the market must attain sufficient financial resources to cover the investments spent with the other candidates that could not obtain clinical success[265].

Furthermore, beyond representing a considerable investment made by innovators, the development of technologies also provides a broad possibility of technological refinement

[262] For a thorough analysis of the inherent traits of intellectual property as assets translatable into information, see: BARBOSA, C. R. **Propriedade Intelectual. Introdução à Propriedade Intelectual Como Informação**. 1. ed. Rio de Janeiro: Elsevier, 2009.

[263] A review of the main legal and philosophical theories that permeate the intervention of the State in the field of intellectual property may be seen in: DE AZEVEDO TINOCO, J. E. Reformulando Promessas: das Teorias e Objetivos dos Sistemas de Propriedade Intelectual. **Revista FIDES**, Natal, v. 12, n. 1, p. 908–926, 2021.

[264] DIMASI, J. A.; GRABOWSKI, H. G.; HANSEN, R. W. Innovation in the pharmaceutical industry: New estimates of R&D costs. **Journal of Health Economics**, Amsterdam, v. 47, p. 20–33, 2016. Available at: https://doi.org/10.1016/j.jhealeco.2016.01.012. Accessed on: 17 March 2024.

[265] GRABOWSKI, H. G.; DIMASI, J. A.; LONG, G. The Roles Of Patents And Research And Development Incentives In Biopharmaceutical Innovation. **Health Affairs**, Washington D.C., v. 34, n. 2, p. 302–310, 2015. Available at: https://doi.org/10.1377/hlthaff.2014.1047. Accessed on: 17 March 2024.

and absorption of know-how for the countries in which the innovators decide to practice their inventions – the so-called "receiving countries". For this reason, one may highlight the critiques to the Brazilian position developed in the second half of the 20th Century, such as the one posed by Magalhães (2017)[266], especially represented by the Normative Act no. 15 of the National Institute of Industrial Property (INPI), in which substantial scrutiny was placed on the transfer of foreign technologies into Brazil.

To this effect, it is also notable that the regulation of intellectual property assets is uncontroversially linked to the context of international commerce, which is only made more evident with the significant adherence of states to the World Trade Organisation's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (known by the English acronym: TRIPS Agreement)[267]. The insertion of intellectual property matters into the multilateral commercial negotiations, which is at times seen as an emphatic clash between the global North and South[268], caused some countries (e.g., Brazil, India) to review internal policies concerning the protection of certain technologies, such as those in the pharmaceutical field, for example[269].

Faced with this context, it is certain that patents represent a substantial investment of financial and human resources in the development of new knowledge applicable in the industry. It is equally known that countries, in the exercise of their sovereignty, may implement measures thought of as detrimental to the investment of foreign entities in intellectual property. Thus, to curb abuses in this sense, some Bilateral Investment Treaties (BIT) and Free Trade Agreements (FTA) tend to include rules regarding the resolution of disputes concerning foreign investments. An example of such is found on Chapter 11 of the

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[266] MAGALHÃES, J. C. de. **Direito Econômico Internacional - Tendências e Perspectivas**. 2. ed. Curitiba: Juruá Editora, 2017. p. 258. It is worth highlighting the following snippet of the alluded text: "*[t]his policy, if from an angle, stimulated the local preparation for learning a foreign technology, from another, impeded the transfer of technologies which, in one form or another, would end up being absorbed by local workers and technicians. The rigid State control exerted on the matter, allowed that a low number of technocrats, some ideologically motivated, decided which technologies were relevant to the country. It was taken away from the private company the decision on whether to import the [technologies] which were most convenient*" (free translation).

[267] BASSO, M. A proteção da propriedade intelectual e o direito internacional atual. **Revista de Informação Legislativa**, Brasília, v. 41, n. 162, p. 287–309, 2004.

[268] OWADA, H. International Economic Law in an Age of Globalization. **Boletim da Sociedade Brasileira de Direito Internacional**, Rio de Janeiro, v. 103, p. 1083–1115, 2017.

[269] DE AZEVEDO TINOCO, J. E.; PRESGRAVE, A. B. A Construção da Jurisprudência do Superior Tribunal de Justiça sobre o Acordo TRIPS. *In*: MENEZES, W. (org.). **Direito Internacional em Expansão**. 1. ed. Belo Horizonte: Arraes Editores, 2023. v. XXIV, p. 302–323.

North America Free-Trade Agreement (NAFTA), and, later, on Chapter 14 of the United States-Mexico-Canada Agreement (USMCA).

Nevertheless, although existent, such means tend not to be used frequently. Even though some cases involving intellectual property have been submitted to Investor-State Arbitration (ISA) along the last few decades[270], in the field of patents, the most relevant disputes taken to the ISA framework were the cases *Apotex Inc v. United States of America* ("the Apotex case"), and *Eli Lilly v. Canada* ("the Eli Lilly case").

Being aware of this, the present study aims to delineate the conditions in which claims relating to patent protection may be brought to ISA, and, from analysing real cases, extrapolate possible tendencies regarding the use (or lack thereof) of this dispute-resolution mechanism for controversies between patent owners and States in the future. Considering the foregoing, this work relates to the Sustainable Development Goals (SDG), specifically SDG no. 8 (decent work and economic growth), and 9 (industry, innovation and infrastructure).

It is worth underscoring that there exists some literature, particularly from English-speaking backgrounds, relating to the matter in discussion: Gibson (2010)[271] broadly discusses the use of ISA to resolve intellectual property disputes; Vadi (2015)[272] examines matters relating to Patent Law that were submitted to ISA under the lens of public health and Public International Law; Gaspar and Aitelaj (2022)[273] offer an analysis that favours reflections on remedies available to patentees in the context of ISA. However, none of the alluded works proposes an analysis specifically relating to discussions involving patents in the scope of ISA, as a means of instigating the discussion of Portuguese-speaking legal scholars on the matter. It is in this niche that this work focuses.

With that said, it is important to emphasise that this work is stemming from a qualitative and exploratory analysis. The logical-deductive method is employed along with the procedures of bibliographic review from a plethora of sources (e.g., legislation, legal

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[270] *e.g.*, Philip Morris v. Australia (PCA, 2017); AHS v. Niger (ICSID, 2013).

[271] GIBSON, C. S. Latent Grounds in Investor-State Arbitration: Do International Investment Agreements Provide New Means to Enforce Intellectual Property Rights? *In*: SAUVANT, K. P. (ed.). **Yearbook on International Investment Law & Policy 2009-2010**. 1. ed. Oxford: Oxford University Press, 2010. p. 397–476.

[272] VADI, V. New Forms of Dialects between Intellectual Property and Public Health: Pharmaceutical Patent-Related Investment Disputes. **The International Lawyer**, Dallas, v. 49, n. 2, p. 149, 2015.

[273] GASPAR, C. J.; AITELAJ, K. When Intellectual Property Is the 'Investment': Arbitrating Against Sovereigns. *In*: PIERCE, J. V. H.; GUNTER, P. Y. (ed.). **The Guide to IP Arbitration**. 2. ed. London: Law Business Research Ltd, 2022. p. 205–220. *E-book*.

literature, jurisprudence), as well as the analysis of the Apotex (ICSID, caso nº ARB(AF)/12/1, 2014) and Eli Lilly (ICSID, caso nº UNCT/14/2, 2017) cases.

From the alluded procedures, it is our goal to: *(i)* establish, conceptually, how a patent may be understood as a "foreign investment"; *(ii)* analyse some of the situations in which frictions may arise between States and investors in the patent context; *(iii)* analyse how the International Centre for Settlement of Investment Disputes (ICSID) behaved when adjudicating patent disputes; *(iv)* extrapolate, from the conclusions set on the foregoing items, some common issues found in cases in which ISA is used to settle patent-related disputes.

ON THE RIGHT THAT MUST BE PROTECTED: HOW MAY PATENTS BE SEEN THROUGH THE LENS OF PROTECTION TO FOREIGN INVESTMENTS?

When offering an economic definition to what may be seen as an investment, Costa (2010, p. 30)[274] states that "*[...] any asset susceptible to be economically evaluated and which may not be destined to consumption for the immediate satisfaction of needs may be considered an investment*" (free translation). In this sense, considering that most States assures the property of their inventions to innovators, it is certain that the issuance of a patent represents an asset of significant economic value, and which is destined to the expansion of the patentee's capital. In other words, patents are, undoubtedly, an investment which, when owned by a foreign entity, may be defined as a "foreign investment".

Still, it should be noted that this investment may be classified, in a general sense, as a "direct investment", as: *(i)* it is held and administrated by a foreign entity; *(ii)* it relates directly to the exercise of a productive activity by the holder or a licensed third party; and *(iii)* seeks the development of an economic activity with long-term intentions[275]. For this reason, the text of BIT and FTA commonly includes, in an explicit manner, "intellectual property assets" in the scope of their definitions over what may constitute a foreign investment[276].

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[274] COSTA, J. A. F. **Direito Internacional do Investimento Estrangeiro**. 1. ed. Curitiba: Juruá Editora, 2010. p. 30.

[275] Ibid., p. 33–34. As noted by Costa (2010), one may understand that the dichotomy over "direct" or "indirect" foreign investments is clear in their extreme meanings, but there are nuances depending on the concrete case under analysis. However, for the alluded reasons, it is uncontroversial that the administration of a patent is more akin to the "direct" classification than to the "indirect" one.

[276] It is worth underlining, in this sense, the text contained in Chapter 14 of the USMCA, in which intellectual property is explicitly treated as a form of foreign investment: "*[...] investment means every asset that an investor owns or controls, directly or indirectly,*

Nevertheless, if, from one angle, the attainment of a patent by a foreigner implies issuing a market privilege to an alien entity, it is certain that this fact does not mean that the receiving State shall bear no advantage from providing the patentee with the alluded asset. As noted by Magalhães (2017)[277], the process of technology transfer implies a dissemination and absorption of knowledge produced by a foreign company in the receiving country. To this effect, the local legislation of some countries (e.g., Brazil) also advocates for local working as a determinant factor for the allowance of the privilege[278].

Being aware of this discussion, the goal of this section is to identify the main traits of patents which may approximate them to foreign investments and to analyse how the exploitation of the intangible asset in national soil affects the legitimate expectations of the investor and the receiving State.

ANNULMENT, REDUCTION OF SCOPE AND COMPULSORY LICENSING OF PATENTS AS POSSIBLE ACTS OF EXPROPRIATION OF A FOREIGN INVESTMENT

A fundamental matter in what pertains to the International Law of Foreign Investment concerns the expropriation of assets belonging to foreigners, the justification for such and the remedies available to the party whose property is expropriated. In the patent context, although there is no tangible asset that may be reclaimed from a private entity by the State, it is certain that the privilege held by the patentee may sustain broad effects stemming from the State's actions.

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that has the characteristics of an investment, including such characteristics as the commitment of capital or other resources, the expectation of gain or profit, or the assumption of risk. An investment may include: […] (f) intellectual property rights". UNITED STATES OF AMERICA; MEXICO; CANADA. **Chapter 14: Investment (United States-Mexico-Canada Agreement, USMCA)**. Mexico City: 2018. Available at: https://ustr.gov/sites/default/files/files/agreements/FTA/USMCA/Text/14-Investment.pdf. Accessed on: 19 January 2024. p. 1.

277 Magalhães, 2017, p. 256–257.

278 To this effect, one may recall the norm contained in article 68, §1º, I, of Public Law no. 9,279/96 (Brazilian Industrial Property Statute), in which it is states: "*Art. 68. The owner will be subject to having the patent compulsorily licensed if they exercise the rights deriving from it in an abusive manner, or by means of it practice abuse of economic power, proven under the terms of the law, by administrative or judicial decision. § 1º A compulsory license is also warranted due to: I - Failure to exploit the object of the patent in the Brazilian territory due to lack of manufacture or incomplete manufacture of the product, or lack of full use of the patented process, with the exception of cases of economic unfeasibility, when imports will be permitted.*" (free translation). BRAZIL. **Lei nº 9.279, de 14 de maio de 1996**. Regulates rights and obligations related to industrial property. Brasília: Presidency of the Republic, 14 May 1996. Available at: http://www.planalto.gov.br/ccivil_03/leis/l9279.htm. Accessed on: 19 January 2024. One should not forget that this very same rule had its compatibility with the TRIPS Agreement (articles 27 and 28) questioned by the United States of America through the DS-199 in the Dispute Settlement Body of the World Trade Organisation (DSB/WTO).

This nuance makes it clear that, while the act of "taking" a patent privilege by the State is not common, the devaluation of said asset by the actions of a State may be interpreted as an equivalent form of expropriation (i.e., a measure "tantamount to expropriation"), as it interferes, indirectly and negatively, with the interests of foreign investors[279].

As is known, patents represent, by their nature, a distortion of the ideal market conditions of competitive parity. Consequently, the patent privilege is an exception to the rule of free availability of information – that is why one may often hear about the "irrevocability of the public domain"[280].

Aware of this scenario, it is possible to conclude that the annulment and/or the adoption of restrictive measures to the exercise of patent rights (e.g., reduction of scope, compulsory license) by a foreign entity in the national territory creates effects that are equivalent to (or at least approximate to) the nationalization of the asset. This owes to the fact that the invention covered by the patent, which was formerly subjected to the exclusionary rights of the foreign patentee, may now be appropriated by anyone within the national territory.

With that said, such act of expropriation does not stem, commonly, from a deliberate and intentional act carried out by the Execute – something more commonly observed in the "classic" forms of expropriation[281]. To the contrary, in what pertains to patents, the Judiciary is the most common stage for State interference in the rights of previously granted patents to occur.

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[279] SCHREUER, C. H. The Concept of Expropriation under the ETC and other Investment Protection Treaties. **Transnational Dispute Management (TDM)**, Nootdorp, v. 2, n. 5, 2005. Available at: https://www.transnational-dispute-management.com/article.asp?key=596. Accessed on: 20 January 2024.

[280] Regarding this theme, one may highlight the opinion of Prof. Denis Borges Barbosa, prepared in the context of Direct Action of Unconstitutionality no. 4,234, in which the scholar calls attention to the notion of irrevocability of the public domain as one of the causes through which the "pipeline patents", a special kind of "revalidation patent" instituted by the Brazilian legislature to comply with article 70.8 of TRIPS, would be incompatible with the Brazilian legal order. BARBOSA, D. B. **Inconstitucionalidade das Patentes Pipeline**. Rio de Janeiro, 2009. Available at: https://ip-iurisdictio.org/wp-content/uploads/2020/09/Parecer-Prof.-Denis-Barbosa.pdf. Accessed on: 21 January 2024.p. 57–58.

[281] An analogous situation is found, for an example, in the case of expropriation of property related to the Mexican petroleum – a situation in which the Mexican State expropriated assets from American oil companies operating in the Country and which gave rise to the doctrine of "prompt, effective and adequate" compensation to expropriation. For more information on this historic event and its implications, see: MAURER, N. The Empire Struck Back: Sanctions and Compensation in the Mexican Oil Expropriation of 1938. **The Journal of Economic History**, Cambridge, v. 71, n. 3, p. 590–615, 2011. Available at: https://doi.org/10.1017/S0022050711001859. Accessed on: 18 March 2024.

Taking Brazil as an example, the rationale of judicial decisions which are permissive of a notion of a "*in dubio contra patentem*" principle[282] – a postulate of doubtful legality[283] – to nullify patents, may be considered a violation to the legitimate expectation of investors. Alternatively, in the Legislature, questions may also arise regarding the eventual use of permissive norms relating to compulsory licensing that may surpass the limits and conditions place on international treaties[284].

Faced with this context, this section shall aim at investigating the imposition of limitations to the full enjoyment of patent privileges in a situation of (or analogous to) expropriation of a foreign investment by the receiving country. We also seek to delineate which remedies may be available to the expropriated parties in such scenarios.

THE INACTIVITY OF A STATE BEFORE AN ACT OF INFRINGEMENT AS DENIAL OF PROTECTION TO A FOREIGN INVESTMENT

Beyond the limitations to the exercise of the patent privilege, as alluded in the previous section, another matter that may be brought in the context of an ISA relates to situations in which the State fails in its obligations to protect foreign investments substantiated in the intellectual property asset.

For illustrative purposes, one may envision that the failure of a State to provide patent protection to foreigners may mean a failure in assuring parity and non-discriminatory

[282] For illustrative purposes, it is worth mentioning the opinion of Federal Appellate Judge André Fontes in some judgments of the Federal Court of Appeals for the 2nd Circuit (TRF-2) in patent matters. Repeatedly, the magistrate cites a principle of "*in dubio contra patentem*" to justify nullifying or suspending the effects of a patent throughout proceedings. BRASIL. TRIBUNAL REGIONAL FEDERAL DA 2ª REGIÃO. **Apelação nº 0807776-97.2010.4.02.5101**. Appellant: Indústria Machina Zaccaria S.A. Appellees: Instituto Nacional da Propriedade Industrial - INPI and Máquinas Suzuki S.A. Rapporteur: Federal Appellate Judge Marcelo Pereira da Silva, 12 December 2013; as well as **Apelação nº 0103886-26.2012.4.02.5101**. Appellant: Kuhn do Brasil S.A. Appellees: Instituto Nacional da Propriedade Industrial - INPI and Semeato S.A. Indústria e Comércio. Rapporteur: Federal Appellate Judge Simone Schreiber, 9 May 2016; and furthermore, **Agravo de Instrumento nº 0007334-34.2016.4.02.0000**. Appellant: Companhia Siderúrgica Nacional - CSN. Appellees: Instituto Nacional da Propriedade Industrial - INPI e Fábio Jorge Botelho Baptista. Rapporteur: Federal Appellate Judge Simone Schreiber, 3 February 2017.

[283] CHALOUPKA, P. In Dubio Contra Patentem? **Derechos Intelectuales**, Buenos Aires, v. 2, n. 1, p. 34–71, 1987.

[284] For an analysis regarding the compatibility of some legislative bills presented during the COVID-19 pandemic to the compulsory licensing parameters brought by TRIPS, see: COSTA, J. A. F.; BERCOVICI, G. Licenciamento Compulsório de Patentes: os Projetos de Lei Brasileiros no Contexto da Crise da Covid-19. **Revista de Direito Intelectual**, Lisbon, v. 2020, n. 2, p. 159–175, 2020.

treatment[285]. Likewise, it is also possible to ascertain that such failure may constitute a violation of the "full protection and security clauses" (FPS)[286].

With that said, it is certain that a State would seldom outright deny protection to a foreign investment. As one may observe in measures "tantamount to expropriation", practical situations may often befall over an intermediary point, in which protection is late, insufficient or unduly burdensome to a foreign investor.

Hence, this section seeks to identify some of the situations in which a State may, through deliberate act or omission, deny protection to a foreign investment, and, consequently, violate obligations relating to non-discrimination and/or full protection and security.

PRACTICAL CASES: CHALLENGES TO BE OVERCOME

After discussing and presenting the theoretical bases in which the problem under examination is inserted, it is important to assess two real cases in which States were accused in the context of an ISA: the Apotex case and the Eli Lilly case. Through this topic, we aim to: *(i)* investigate the arguments brought forth to justify the admissibility of the arbitral proceedings, *(ii)* how the merit of the case was assessed (if applicable), and, from such analysis, *(iii)* extract conclusions over the use of ISA in analogous situations and to identify which challenges must be overcome in the utilisation of this mechanism in future disputes.

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[285] In this sense, it is worth to remind oneself, as an example, of some snippets found in article 5 (non-discrimination) of the BIT established between Mexico and Brazil: "*1. Without prejudice to the exceptions established by the legislation at the date in which this Agreement enters into force, one Party shall grant to the investors of the other Party and to their investments, treatment that is no less favourable than the one granted to their own investors and their investments. […] 2. Without prejudice to the exceptions established by the legislation in the date in which this Agreement enters into force, one Party shall grant to investors of the other Party and to their investments treatment that is not less favourable than the one granted to investors of a Non-Party State and their investments […]*" (free translation). BRAZIL. **Decreto nº 9.495, de 6 de setembro de 2018**. Promulgates the Agreement of Cooperation and Facilitation of Investments between the Federative Republic of Brazil and the United States of Mexico, struck in Mexico City, on 26 May 2015. Brasília: Presidency of the Republic, 6 September 2018. Available at: https://www.planalto.gov.br/ccivil_03/_ato2015-2018/2018/decreto/d9495.htm. Accessed on: 24 January 2024.

[286] On this possibility, it is worth bringing attention to the comments of Gaspar and Aitelaj (2022) regarding specifically the violations by States of the FPS clauses: "*This sort of clause may find more subtle applications, however, in the context of IP rights. Indeed, to the extent that a patent is intended to provide a monopoly to its holder, state-sanctioned infringement could be argued to violate the obligation to ensure full protection and security to the investment*". Gaspar; Aitelaj, 2022, p. 214.

THE APOTEX INC. V. UNITED STATES OF AMERICA CASE: THE CHARACTERISATION OF AN INTELLECTUAL PROPERTY ASSET AS A "FOREIGN INVESTMENT"

The Apotex case relates to ISA proceedings initiated by the Canadian pharmaceutical company Apotex Holdings Inc. against an act by the United States Food and Drug Administration (FDA) in which, according to the Claimant, created barriers for the importation into the United States of a generic drug manufactured by the Canadian headquarters of Apotex. Claimant contends that this act violates the obligations of the United States in complying with articles 1102 (national treatment), 1103 (most favoured nation treatment) and 1105 (minimal standard of treatment) of NAFTA.

In a decision discussed worldwide, the arbitral court (ICSID) rejected Apotex's claims based on a formal analysis (i.e., lack of jurisdiction), without getting into the merits of the discussion raised by the Claimant. This decision may be interpreted, as already stated by some authors[287], as a barrier to the use of ISA to the adjudication of claims relating to intellectual property. However, it is equally important to stress that this case presents many particularities that were relevant to the court's decision, and which make this a heavily "fact-dependent" case[288].

THE ELI LILLY V. CANADA CASE: SITUATIONS IN WHICH THE DEVELOPMENT OF NATIONAL LAW MAY AFFECT THE PROTECTION OF FOREIGN INVESTMENTS

The Eli Lilly case, in its turn, initiated when the pharmaceutical company Eli Lilly & Co. initiated arbitration proceedings against the Canadian government due to the denial in granting patents covering medicines marketed towards the Canadian market. The reason for such would be Eli Lilly's perceived failure in complying with the Canadian legal doctrine (built by Case Law) known as the "promise doctrine". According to Claimant, the promise doctrine imposed an undue restriction to Eli Lilly's right of seeking patent protection, diverging from standards used internationally for the patentability examination. In this

[287] KOTUBY, C. T., Jr; EGERTON-VERNON, J. Apotex Inc v The Government of the United States of America1: Will Barriers to Jurisdiction Inhibit an Emerging Trend? **ICSID Review - Foreign Investment Law Journal**, Oxford, v. 30, n. 1, p. 21–29, 2015. Available at: https://doi.org/10.1093/icsidreview/siu031. Accessed on: 21 March 2024.

[288] GASPAR; AITELAJ, 2022.

sense, the company argued that Canada was non-compliant with articles 1105 (minimum standards of treatment) and 1110 (expropriation) of NAFTA, which led to the initiation of arbitral proceedings.

Contrary to the Apotex case, the arbitral court (ICSID) issued a ruling on the merits of the Eli Lilly case through which the court established, in general, that the jurisprudential evolution in Canadian Patent Law does not constitute, *per se*, a violation to the legitimate expectations of foreign investors. It is noted, however, that the judgment represents the first time in which an ISA on Patent Law came to a decision on the merits, something that may serve to encourage potential claimants in what pertains to the use of this mechanism[289]. Furthermore, it is worth noting that shortly after the ICSID judgment, the Canadian Supreme Court issued a ruling through which the application of the promise doctrine for the patentability evaluation was outright rejected[290].

A PROSPECTIVE OUTLOOK: WHAT CAN ONE EXPECT FROM THE USE OF INVESTOR-STATE ARBITRATION MOVING FORWARD?

After analysing the Apotex and Eli Lilly cases, this section aims at realising prospective reflexions towards the use of ISA in the adjudication of claims between patentees and the countries in which the investment is received. This analysis shall occupy itself with some aspects of larger importance, such as the challenges pertaining to: (i) the admissibility of ISA proceedings in analogous matters, and (ii) the burden of the Claimants in demonstrating the State's violations of its obligations.

CONCLUSION

We seek, through the methodology discussed in the preceding sections, including the bibliographic review and the study of the two highlighted cases, to construct essential and commonly observable notions in ISA cases involving Patent Law. This seeks especially to build a solid understanding on what are the main challenges that oppose the broad utilisation of ISA in the field of patent disputes.

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[289] LENTNER, G. M. Litigating patents in investment arbitration: Eli Lilly v Canada. **Journal of Intellectual Property Law & Practice**, Oxford, v. 12, n. 10, p. 815–816, 2017. Available at: https://doi.org/10.1093/jiplp/jpx153

[290] CROWNE, E. Promises not kept: Supreme Court of Canada abandons promise doctrine. **Journal of Intellectual Property Law & Practice**, Oxford, v. 12, n. 10, p. 816–817, 2017. Available at: https://doi.org/10.1093/jiplp/jpx154

In this sense, the hypothesis guiding this work may be formulated and presented as the following question: "*is it possible to identify possible trends on the use (or lack thereof) of ISA in the adjudication of patent disputes between investors and States moving forward?*".

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BRAZIL. TRIBUNAL REGIONAL FEDERAL DA 2ª REGIÃO. **Apelação nº 0807776-97.2010.4.02.5101**. Appellant: Indústria Machina Zaccaria S.A. Appellees: Instituto Nacional da Propriedade Industrial - INPI and Máquinas Suzuki S.A. Rapporteur: Des. Fed. Marcelo Pereira da Silva, 12 December 2013.

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