

PATENTS, PROMISES AND DEFERENCE TO DOMESTIC COURT DECISIONS: THE ELI LILLY VS CANADA INVESTMENT DISPUTE UNDER THE NORTH AMERICAN FREE TRADE AGREEMENT (NAFTA)*

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Resumen

El documento analiza los argumentos presentados por la empresa Eli Lilly and Company (Estados Unidos) en la Solución de Controversias Inversionista-Estado iniciada contra el Gobierno de Canadá a la luz del Capítulo 11 (Inversión) del Tratado de Libre Comercio de América del Norte (TLCAN), debido a la revocación de dos patentes canadienses de dicha sociedad, sobre la base de la no conformidad con el requisito de utilidad. Hasta la fecha esta diferencia está pendiente de ser resuelta por el tribunal arbitral correspondiente.

En primer lugar, se explora el grado de escrutinio que un tribunal de arbitraje posee, en el cumplimiento del TLCAN, especialmente cuando se trata de la salvaguardia de la inversión. A continuación, se evalúa el nivel de armonización de los criterios de patentabilidad entre los miembros del TLCAN.

Por último, se analiza si los argumentos de la demandante son válidos y, por lo tanto, si el tribunal arbitral tiene competencia en este caso o si, por el contrario, es pertinente aplicar deferencia.

Palabras clave: Patentabilidad; Utilidad; Doctrina de la Promesa; TLCAN; Solución de Controversias Inversionista-Estado; Deferencia.

Abstract

The paper reviews the arguments made by the corporation Eli Lilly and Company (US) in the Investor-State Dispute Settlement initiated against the Government of Canada under the light of Chapter 11 (Investment) of the North American Free Trade Agreement (NAFTA), due to the revocation of two Canadian patents of such corporation, on the basis of the non-compliance with the utility requirement. Up to date, this dispute is pending to be solved by the corresponding arbitral tribunal.

* Las opiniones vertidas en este artículo representan la visión exclusiva del autor sobre las diferentes materias abordadas y no comprometen en modo alguno la posición de los órganos resolutores y otras áreas de la institución.

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In the first place, the degree of scrutiny that an arbitral court possesses is explored in compliance with the NAFTA, specially when it comes to the safeguard of investment. Then, the level of harmonization of the patentability criteria between the NAFTA Members is assessed.

Finally, we analyze if the plaintiff's arguments are valid and whether the arbitration court has competences in this case or if, otherwise, it is convenient to apply deference. Keywords: Patentability; Utility, Promise Doctrine; NAFTA; Investor-State Dispute Settlement; Deference.

I. INTRODUCTION

Under the light of international investment law, undertakings are opting to seek for the protection of their intellectual property rights with more frequency.² Nonetheless, it is also debated whether investment tribunals are proper forums to deal with governmental decisions or whether these decisions rely on the sovereignty of the States and that, therefore, scrutiny in this cases is not possible.

This paper has the purpose to study the *Eli Lilly vs Canada* case³, which has been initiated on the basis of a breach of the obligations acquired by Canada, as a Member of the North American Free Trade Agreement (NAFTA). Particularly it will be assessed whether regardless the arguments proposed by both parts of the process, there are foundations or not to consider that an investment tribunal has jurisdiction in this case.

This paper is structured in three parts. First, it will be given a general overview on the deference doctrine, which permits to assert if an investment tribunal has or doesn't have competence in a concrete case. In second place, there will be explained how aspects such as the safeguard of investment and patentability are treated in the NAFTA. Finally, it will be analyzed whether in the referred *Eli Lilly vs Canada* case the investment tribunal might have jurisdiction.

² For instance, nowadays there is an arbitration between Philip Morris Asia Limited and the Government of Australia because of the passing of the Tobacco Plain Packaging Bill 2011 (TPPB), prohibiting the use of trademarks and other marks on tobacco packaging (Philip Morris Asia Limited's Written Notification of Claim under the Agreement between the Government of Hong Kong and the Government of Australia for the Promotion and the Protection of Investments, 27 June 2011 at page 2, available at <http://italaw.com/sites/default/files/case-documents/ita0664.pdf>).

³ *Eli Lilly and Company v. The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2.

II. SCRUTINY OF STATES' DECISIONS UNDER INVESTMENT LAW: DEFERENCE OR INTERVENTION

Deference within Investment Treaty Arbitration (ITA) is associated with the degree of review that an investment tribunal applies when assessing an accused State's conduct, so depending of such standard the intervention of the tribunal could be seen as a harm to the sovereignty with which the States count. In this context, the degree of review may oscillate between an entire deference, characterized by the absolute absence of the arbitral intervention, to the application of an indiscriminate reconsideration of any accused State's conduct, so what is relevant is the level of scrutiny of the investment tribunal.⁴

It has to be said that there is not any clarity regarding the application of deference within an ITA. Thereon, one recognized approach asserts that investment tribunals are not higher courts of appeals and, hence, should not be used by foreign investors against what they might consider as an unfair decision, but, nonetheless, the scrutiny proceeds before the breach of a minimum standard of accessing to justice.⁵

III. INVESTMENT PROTECTION AND PATENTABILITY UNDER NAFTA

3.1. Safeguard of investment: the Minimum Standard of Treatment

Chapter Eleven (Investment) of the NAFTA provides in Article 1105(1) (Minimum Standard of Treatment - MST) that its Members must treat investments from investors of another Member in connection with international law, which comprehends standards such as the fair and equitable treatment (FET).

Due to consistent practice, it is out of discussion that FET should be applied to administration of justice.⁶

⁴ Stephan W. Schill, 'Deference in Investment Treaty Arbitration: Re-conceptualizing the Standard of Review through Comparative Public Law' (2012) Society of International Economic Law Working Paper 2012/33 <<http://www.ssrn.com/link/SIEL-2012Singapore-Conference.html>> accessed 13 May 2016.

⁵ In this line it is important to allude to what has been determined in *Chevron Corporation (USA) and Texaco Petroleum Company (USA) v. The Republic of Ecuador* UNCITRAL, PCA Case No. 34877, 180 (2010): "Furthermore, the uncertainty involved in the litigation process that is noted by the Respondent is taken into account in determining the standard of review. As noted above, if the alleged breach were based on a manifestly unjust judgment rendered by the Ecuadorian court, the Tribunal might apply deference to the court's decision and evaluate it in terms of what is 'juridically possible' in the Ecuadorian legal system. However, in the context of other standards such as undue delay under Article II(7), no such deference is owed."

⁶ As referred in Martins Paporinskis, *The International Minimum Standard and Fair and Equitable Treatment* (OXFORD 2014) 181.

On this regard, some NAFTA dispute settlement cases have contributed to understand the reach of FET and, hence, the MST. In *Mondev*⁷ it has been stated that which is relevant to this purpose is to determine if the accused decision is evidently improper and discreditable under the light of the international generally accepted standards as to the administration of justice, resulting in an unfair and inequitable treatment of the investment.

Later on, in *Loewen*⁸, it has been referred that the corresponding assessment involves, in the first place, the examination of the entire judicial proceeding of the accused Member, in order to realize what possible legal resources the foreign investor has to defend its interests. In the second place, and according to *Mondev*, it is crucial to determine the existence of a deficiency in the administration of justice, related to the lack of a due process, which, at the end, implies an unfair decision.

Then the denial of justice becomes a relevant aspect when there is an analysis regarding the MST. Particularly, a denial of justice may occur before a situation that involves the failure as to the safeguard of the minimum procedural guarantees, which covers, among others, the right to be heard and the right to produce evidence.⁹

3.2. Harmonization on the scope of the patentability requirements

Chapter Seventeen (Intellectual Property) of the NAFTA provides in Article 1709(1) -Patents- that its Members have the obligation to make patents available for any inventions, whether products or processes, in all fields of technology, provided that these are new, result from an inventive step and are capable of industrial application, being valid for the purposes of the Article to consider the terms “inventive step” and “capable of industrial application” as synonymous of the terms “non-obvious” and “useful”, respectively.

Nonetheless, even when there exists standardization as to these requirements, there is not any formal harmonization regarding the understanding of each of them.¹⁰ Thus, each

⁷ On this regard *Mondev International LTD v. United States of America* ICSID, Case No. ARB (AF)/99/2, 45 (2002) states “In the end the question is whether, at an international level and having regard to generally accepted standards of the administration of justice, a tribunal can conclude in the light of all the available facts that the impugned decision was clearly improper and discreditable, with the result that the investment has been subjected to unfair and inequitable treatment.”

⁸ In this context, *The Loewen Group, Inc. and Raymond L. Loewen v. United States of America* ICSID, case No. ARB (AF)/98/3, 38 (2003) states “Neither State practice, the decisions of international tribunals nor the opinion of commentators support the view that bad faith or malicious intention is an essential element of unfair and inequitable treatment or denial of justice amounting to a breach of international justice. Manifest injustice in the sense of a lack of due process leading to an outcome which offends a sense of judicial propriety is enough, even if one applies the Interpretation according to its terms.”

⁹ Paparinskis (n 3) 193-194.

¹⁰ On this regard Umakant Mishra, ‘Patentability Criteria in Different Countries’ (2014) <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2430768> accessed 13 May 2016: “These standard requirements are given different shapes by the legislative and judicial systems of different countries.”

country gives the three basic requirements an interpretation and scope that is in accordance with its concrete patent system. It has to be said that the determination on the content of each requirement is carried on primarily through national legislation or guidelines, but then this task is performed by the patent administrative authorities or by courts through their decisions. It implies a constant and dynamic evolution of the patentability criteria.¹¹

With the purpose of focusing in the mentioned dissimilarity and according to its pertinence to this study, it is relevant to say that the “utility” requirement has particular nuances in each of the NAFTA Members, which are revealed in the following table I.

TABLE N.º I

COMPARISON BETWEEN THE REACH OF ANALYSIS OF THE UTILITY REQUIREMENT EXISTING IN THE NAFTA MEMBERS

	CANADA	MEXICO	UNITED STATES
“Utility/ Industrial application” requirement	Utility must be specific, practical and credible. ¹² An applicant must be in a position to establish the utility of their invention, by demonstration or sound prediction, no later than at the filing date of their application. ¹³ Consequently, the factual basis upon which either the demonstration or sound prediction are based on, must necessarily exist as of the filing date. Similarly, if a sound prediction is to be relied upon, the articulable and sound line of reasoning must also exist as of the filing date. ¹⁴	Inventions must be industrially applicable. ¹⁵ In order to meet the “industrial application” requirement, there must exist a possibility for being produced or used in any branch of economic activity. ¹⁶ The applicant may be called to submit additional or complementary information or documentation. It may also be necessary to make such clarifications as a result of the substantive examination. ¹⁷	An invention has a well-established utility if it is specific, substantial, and credible. If the examiner makes a <i>prima facie</i> rejection and the applicant responds it, the Office personnel should review any new reasoning or evidence provided by the applicant, in support of an asserted specific and substantial credible utility. ¹⁸

Source: Own elaboration

¹¹ For instance, in the United States the concept of novelty has changed at a legislative level through the enactment of the Public Law 112 – 29 – Leahy-Smith America Invents Act, in force since September 16, 2012, swifting from a first to invent system to a first to file system. At a judicially level, the determination of the non-obviousness requirement has been redefined after *KSR International Co. v. Teleflex, Inc.* 550 U.S. 398 (2007), by which the test for teaching, suggestion, or the patentee’s motivation loses its degree of relevance in the assessment of such requirement.

¹² Manual of Patent Office Practice (MPOP) (2016) 12-22.

¹³ According to *Apotex Inc. v. Wellcome Foundation Ltd.* [2002] 4 S.C.R. 153, 2002 SCC 77: “Utility is an essential part of the definition of an invention (Patent Act, s. 2). A policy of patent first and litigate later unfairly puts the onus of proof on the attackers to prove invalidity, without the patent owner’s ever being put in a position to establish validity. Unless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner ‘by law’ is required to refuse the patent (Patent Act, s. 40).”

¹⁴ MPOP, 12-26.

¹⁵ Ley de Propiedad Industrial (LPI) (2006) art 16.

¹⁶ *ibid.* art 12.IV.

IV. ANALYSIS OF THE ELI LILLY VS CANADA INVESTMENT DISPUTE

4.1. Facts in discussion: The promise doctrine

During the late 90s and the early 2000s, Eli Lilly (hereinafter Lilly) obtained, in Canada, the patent No. 2,209,735 (the '735 Patent), that claims the use of tomoxetine for treating attention deficit/hyperactivity disorder (ADHD), and the patent No. 2,041,113 (the '113 Patent), which claims the active principle olanzapine.

In 2008, a request for the revocation of the '735 Patent was filed by Novopharm Limited, before the Canadian Federal Court, having alleged that the invention lacks utility as of the time of the corresponding filing. As a result, the trial judge determined that since there was not enough evidence in the Canadian patent application as to the utility of the atomoxetine in the effective treatment of patients with ADHD, or at least a soundly prediction basis to establish the existence of such efficacy, Lilly failed to opportunely demonstrate or reasonably set the basis to predict that what was promised was, indeed, true and, therefore, the "utility" requirement was not met.¹⁷

On the other hand and before an intent of the company Novopharm Limited to obtain a Notice of Compliance from the Minister of Health to introduce into the market a pharmaceutical product which included olanzapine, Lilly filed an action to request the Federal Court the prohibition on the issuance of such Notice, on the basis of an infringement to the '113 Patent. As a response, the defendant asserted that the '113 Patent did not comply with disclosing sufficiently the invention and neither it had the degree of utility that was promised when the corresponding application was filed. The Court established a lack in the sufficiency of disclosure.

Later Lilly raised an action for infringement of the '113 Patent against Novopharma Limited. Again, the defendant made observations to the sufficiency of disclosure and the utility of the invention. The Court established in this context that, in order to confirm the validity of a selection patent, it is necessary to assess whether the invention had a substantial advantage over the state of the art. In this sense, it was considered that the invention did not comply with the referred aspect, reason why the patent was revoked.

¹⁷ Ibid. art 55.

¹⁸ Manual of Patent Examining Procedure (2015) Section 2107.

¹⁹ *Novopharm Ltd. v. Eli Lilly and Co.*, 2010 FC 915, para. 112 (R-027).

The decision from the Federal Court was appealed by Lilly and later the Federal Court of Appeal allowed the appeal, arguing that it was mistaken to consider that a selection invention has independent requirements for being patented.

Then the trial judge assessed the case again. This time, a construction was conducted to determine what the promise of the application was, which, in view of the judge, was related to the enhanced fashion that olanzapine has in the treatment of schizophrenia, but at most Lilly showed early signals of safety and efficacy on patients in some small research, which was not sufficient to demonstrate the compliance with the “utility” requirement.

According to the stated facts, Lilly filed a Notice of Arbitration against the Government of Canada on September 12, 2013, seeking investment protection under the light of Chapter Eleven of the NAFTA.

Lilly asserts that, by being arbitrary and discriminatory, the so-called “promise utility doctrine”, applied by the Canadian judiciary to revoke its patents, implies a breach to the obligations adopted by Canada under the Article 1105. Moreover, Lilly adduces that the application of the referred patentability criteria also signifies a breach of the obligation contained in Article 1110, as far as it is inconsistent with Chapter Seventeen of the NAFTA and the Patent Cooperation Treaty (PCT).

On June 30, 2014, Canada filed its corresponding Statement of Defence referring that the competence of the investment tribunal would only arise in front of a denial of justice, nevertheless Lilly was not deprived of its right to justice. Furthermore, Canada argued that its interpretation of the “utility” requirement was consistent with Chapter Seventeen of the NAFTA and the PCT.

4.2. Denial of justice: Curtailment of the right to submit evidence

Lilly has argued that the “promise doctrine” applied by the Canadian Courts to revoke its patents is totally arbitrary and discriminatory and therefore constitutes a breach to the MST.

In this context it is necessary to understand in the first place the nuances on the criteria applied in Canada to interpret the extent of the “utility” requirement. As noted by Lilly in its Notice of Arbitration²⁰ and the government of Canada in its Statement of Defence²¹

²⁰ Notice of Arbitration filed on 12 September, 2013 para. 36 <<http://www.italaw.com/sites/default/files/case-documents/italaw1582.pdf>> accessed 13 May 2016.

²¹ Statement of Defence filed on 30 June, 2014.

the “promise doctrine”, used to assess the compliance of the “utility” requirement, is established on the basis of three relevant steps:

1. The determination of the effect that is achieved by the invention and that constitutes the promise made by the applicant within the patent specification. It is done in accordance with what has been expressly asserted by the applicant in the specification or, in its absence, through the construction of the intended effect by the authority.
2. The assessment on whether at the time of filing the applicant has demonstrated that the referred promise is really achieved or, at least, that there is an objective basis that permits a skilled in the art to predict that such promise is achievable (sound prediction).
3. When the utility is based on a sound prediction, the applicant should have been disclosed enough evidence to support the objective basis of the prediction and the line of reasoning which will help the skilled in the art to make the pertinent inference.

Having said it, it is necessary to recall that even when the NAFTA establishes the basic requirements that an invention has to meet in order to be patented (novelty, non-obviousness, utility), there is not any commitment as to the interpretation on the scope of each of them. Therefore, every member has the prerogative to delineate the content of each requirement provided by Article 1709(1), attending to its particular technological development and general public policies.

Additionally, Lilly has said that this criteria was not in force when the patentability of the respective applications was subject of evaluation by the Canadian patent authority and, hence, there is a contravention to the reasonable expectations that this Company had when it decided to protect the discussed inventions in Canadian territory. On this regard, it is relevant to say that the interpretation of the content of the basic requirements has an evolutive profile, and this is a fact that is seen commonly in the patentability practice of the NAFTA Members²².

According to the Canadian government, both the free ground for interpretation and the evolutive profile of the patentability requirements involve a fair balance between the exclusive rights derived from a patent and an effective contribution to society. So basically, the investment protection sought by Lilly in this arbitration proceeding might be seen as an intent to reverse the adoption of this criteria on the basis of its unfairness. Nonetheless, as stated before the judgement of a likely unfair decision is

²² For instance, *KSR International Co. v. Teleflex, Inc.* 550 U.S. 398 (2007) regarding the non-obviousness requirement.

not of competence of an investment tribunal, and so, under the referred conditions, deference should apply.

Without prejudice of what has been stated in the prior paragraphs, it is considered necessary to give special attention to another specific matter of the “promise doctrine”. Particularly, it has to be noted that, according to the Canadian criteria, the applicant has only one opportunity to establish the utility of his invention, whether by demonstration or sound prediction: The filing date of the application. In other words, it is not possible for the applicant to provide supporting evidence after the filing date, nor during the patent examination nor in an action for patent revocation.

Thereon, it is relevant to mention that during the patent examination the Canadian Patent Office, as the rest of countries that conduct an exam before the granting of a patent,²³ provides at minimum one chance to the applicant to overcome the observations made by the examiner. This right might involve the presentation of arguments in the defense of the discussed patentability and also the filing of evidence to demonstrate the compliance of the legal requirements.

It should be taken into due account that just as the utility requirement, the non-obviousness requirement has to be met just at the filing date and yet the applicant may prove the existence of this condition by providing affidavit of support or new studies during the examination process or even while facing a patent revocation proceeding.

Thus, it might be validly considered that by limiting the right of the applicant to produce and present evidence to support the fulfilling of the promise asserted in the application or constructed by the authority, there is a curtailment of the right to produce evidence and, therefore, a denial of justice that may be scrutinized by an investment tribunal under the light of the Article 1105 of the NAFTA.

4.3. Expropriation on the basis of a patent revocation: To be or not to be

Regarding the accusation made under the light of Article 1110 of the NAFTA, it is pertinent to say that according to its subsection 7, an expropriation may occur when the

²³ According to Article 45 of the Decision 486 of the Andean Community if the competent national office finds that the invention is not patentable or does not comply with one of the requirements laid down in this Decision for the grant of a patent, it shall notify the applicant accordingly. Under the Article 94 of the European Patent Convention, if the examination reveals that the application or the invention related, does not meet the requirements of the Convention, the Examining Division shall invite the applicant, as often as necessary, to file his observations and to amend the application. Furthermore, according to the information provided by the Canadian Intellectual Property Office, if the application is not acceptable, the examiner will explain the corresponding reasons and the applicant will have a chance to make changes to the application or, in writing, argue against what the examiner said <<https://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03002.html#request> > accessed 13 May 2016.

revocation of an intellectual property right is not consistent with Chapter Seventeen (Intellectual Property). So it has to be noticed that Article 1709 (Patents) provides that, in order to be patented, an invention shall be new, non-obvious and useful.

As specified by Article 1709 patentable inventions have to be useful, so the granting of the exclusive right has to be founded in the prior identification of such requirement, which by merit of the proceeding must be done through information presented by the applicant, nonetheless the “promise doctrine” applied in Canada to revoke Lilly’s patents limits this search-of-being solely to the moment of filing. It is relevant to say that Article 1709 does not establish any restriction as to the finding of the fulfillment of the three basic requirements and, hence, there should not be any limitation related to such finding, which may be achieved with evidence submitted by the applicant during the examination stage of a patent administrative proceeding, or even during a revocation process.

Then, it may be noted that on regard the utility requirement, Canadian courts have reduced the demonstrating of the “being-standard” provided by Article 1709 to a solely moment (the filing date), which has not consistency with any other provision of the NAFTA.

Therefore, it might be held also that the revocation of Lilly’s patents in Canada implies an inconsistency with Chapter 17 of the NAFTA, so under the scope of its Article 1110(7), an expropriation could have taken place and, then, a violation of Chapter 11.

V. CONCLUSION

The “promise doctrine” represents a valid interpretation of the “utility” requirement provided by Chapter 17 of the NAFTA, considering that there is not any binding harmonization regarding the content of this requirement and that patentability involves an evolutive understanding not only within the NAFTA but, in general, all over the world.

Notwithstanding, linking the “promise doctrine” with the filing date may constitute a breach of the customary right of persons to provide evidence to support their allegations.

Thus, there might exist enough ground to enable an investment tribunal to review the Canadian Courts’ decisions and not apply deference.

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