VI. Legitimate Expectations, Intellectual Property Rights and International Intellectual Property Law Framework – Eli Lilly and Beyond

A. Eli Lilly and Legitimate Expectations

So far there has been no other award in NAFTA jurisprudence that has address the relationship of international IP sources and legitimate expectations.[289] However from the analyzed case law some general principles can be extracted and applied to the circumstances of the *Eli Lilly* case, despite the case already being decided without fully addressing the issues related to legitimate expectations claims. There are several ways that Eli Lilly could have theoretically relied on the NAFTA IP Chapter as grounds for its legitimate expectations.

1. Customary International Law

Eli Lilly held that the "promise utility doctrine" is contrary to the generally accepted utility standard contained in the NAFTA IP Chapter. This argument can be used to determine violations of FET and legitimate expectations directly if it can be proved that the definition proposed has become part of contemporary customary international law or that it has become part of the customary international law standard for the protection of aliens. In these cases the Tribunal would be obliged to apply the law to the facts of the case. This standard was set by the *Mondev v. USA* Tribunal.[290] Even though Eli Lilly had tried to establish a uniformity of the utility standard[291], the fact that countries apply the standard differently[292] leads to the

289 The *Apotex* case which could have been the first one was decided on jurisdiction grounds. See, Apotex Holdings Inc. & Co. v. USA, ICSID Award, Case No. ARB(AF)/12/1, (2014) available at: http://www.italaw.com/sites/default/files/case-documents/italaw3324.pdf (Visited last on Mar. 6, 2018).

290 *Mondev v. USA,* Supra note 230.

291 Claimant's Post-hearing Brief, Supra note 112, §§ 136-37 & § 158.

292 Erstling, Samela & Woo, Supra note 191, at 12 (2012).

conclusion there is no standardized state practice or *opinio juris*.[293] Without the existence of the two fundamental requirements there can be no customary international law rule on patent utility which the Tribunal would be obliged to apply. Consequently, there could have been no basis for the establishment and violation of legitimate expectations in customary international law as well for Eli Lilly in the case.

2. Representations of State

As in the *Waste Management, Glamis Gold, Thunderbird and Mobil* the Tribunals have consistently held that for legitimate expectations to arise there needs to be a representation or conduct by the state, possibly in "quasi-contractual" form, on which the investor relied on to make its investment.

a) Patents as Representations of State

Patents confer particular rights to its right holder, which are guaranteed by the state.[294] Therefore a patent can be viewed as a representation made by the state.[295] Therefore only what is contained in the representation can create the basis for legitimate expectations.[296] The text of a granted Canadian patent states the following: "The present patent right grants its owner and to the legal representatives of its owner, for a term which expires twenty years from the filing date of the application in Canada, the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used, subject to adjudication before any competent court of jurisdiction."[297]

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293 State practice and *Opinio Juris* (The belief that states are legally obliged to follow the rule) are needed to establish rules of customary international law. See, Miles, Supra note 48, at 225.

294 Canadian Patent Act, Supra note 165, § 27 & § 2.1.

295 Eli Lilly has proposed this argument. See, Claimant's Reply, Supra note 124, § 360.

296 See *Mobil v. Canada*, Supra note 268,§ 152(3).

297 The text can be found on every front page of an issued hard copy of a Canadian patent. For example see, http://2innovative.net/wp-content/uploads/2015/05/Canadian_patent.jpg (Visited last on Mar. 6, 2018).

Very clearly the patent, as a representation of the state guarantees, offers no stability in relation to possible changes in the applicable law. The patent does not create any kind of link to international treaty standards. Even if the NAFTA is observed in isolation the patent gives no guarantee to the patent holder that the conduct of the state will be in line the NAFTA. Quite the contrary, it clearly points to the jurisdiction of Canadian law and courts. Even if the Tribunal acknowledges that a patent is a "quasi-contractual" document there should be a causal link between the "quasi-contract" and the requirement to keep a stable legislative framework or for the state to strictly adhere to its international obligations. A Canadian patent offers no such thing. The patent does not provide obligations for the state to implement a particular interpretation of the utility requirement. Therefore, the patent as such provides no grounds for legitimate expectations in relation to Canada's international obligations. In fact, the only thing that Eli Lilly could have legitimately expected is to use the inventions in a way prescribed by the text of the patent. Anything else would amount to an *ultra vires* act of interpretation.

b) Patentability Requirement Standards as Representations

Eli Lilly proposed the argument that the patentability standards are representations made by the state. "Unlike a law of general applicability, Canada's patentability standards, including its utility requirement, were technical regulations aimed, and relied upon, by a discrete and identifiable group."[298] This argument is far-fetched from the beginning. The practice of the NAFTA Tribunals requires that the representation is individualized.[299] Even though the patentability standards are relied on by a small number of persons they are still a part of the legislation aimed at the general public. Furthermore, the patentability standards do not point to any sources of international law and therefore cannot be used to establish international IP standards as grounds for legitimate expectations.

298 Claimant's Memorial, Supra note 126, § 284.

299 *Glamis Gold v. USA,* Supra note 260, § 766 & See *Mobil v. Canada*, Supra note 268, § 152(3).

3. Direct Application of International Intellectual Property Norms

The possibility of directly applying international IP norms is not allowed under the NAFTA jurisprudence. As set out by the FTC's Note and later confirmed by the *Grand River* Tribunal the breach of an external treaty, in this case the NAFTA IP Chapter, even though contained in the same wider agreement cannot automatically be a breach of the FET standard. Consequently, legitimate expectations cannot be established in such a way. The fact that there is no language in article 1105 that points to any kind of link with NAFTA IP Chapter, supports this reasoning.

Through the three situations mentioned it is clear that there can be no direct application of the NAFTA IP Chapter. There is no representation by the state that would let Eli Lilly rely on the NAFTA IP Chapter. Neither is the same Chapter and its standards part of customary international law. Nevertheless, the role of the NAFTA IP Chapter should not be entirely excluded.

The NAFTA IP Chapter can be used for interpretative guidance, with a prudently limited application scope. Such limitations could be inferred from the *S.D. Myers v. Canada* case where the Tribunal held that the breaches of article 1105 should be treated as a matter of international law but that the Tribunal should also show deference to domestic law and the state's right to regulate.[300]

4. "Arbitrary", "Grossly Unfair", "Unjust" or "Idiosyncratic" Changes in Law

In *Waste Management* and *Mobil* the Tribunals referred to the severity of change in the law that could frustrate legitimate expectations of the investor. [301] The change needed to justify the legitimate expectations claim needs to be "arbitrary", "grossly unfair", "unjust" or "idiosyncratic". However, the Tribunals have not offered a concrete definition of those terms. This is understandable as the standards set out by each of Tribunals were applied to the facts of the respective cases. Moreover, in the *Grand*

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300 *S.D. Myers v. Canada*, Supra note 222, § 262.

301 *Waste Management v. Mexico*, Supra note 233, § 98. Likewise the Tribunal in *Mobile v. Canada* uses the term "grossly unfair". See, *Mobile v. Canada*, Supra note 268, § 153.

River case the Tribunal, even though rejecting the direct application of external treaties, went on to analyze them as possible grounds for legitimate expectations. It concluded that they do not form part of legitimate expectations.[302] This approach then leaves some room for the following possibility – the use of the NAFTA IP Chapter as a benchmark for determining "arbitrary", "grossly unfair", "unjust" or "idiosyncratic" changes in the law. The proposed analysis would function in the following way: The Tribunal needs a reference point to determine the "acceptable margin of change."[303] This reference point can be the NAFTA IP Chapter. The Tribunal should nevertheless limit its analysis exclusively to the text of the NAFTA IP Chapter. A Tribunal could therefore find a factor in determining the breach of article 1105 if the damage suffered by the investor resulted from a complete exclusion of the utility standard in national law or if the meaning of the utility requirement given in domestic law is blatantly contradictory or utterly irrational to the ordinary meaning of the word 'utility'. Any argument that provides a minimum of legal sense and rationality, which justifies the currently applicable law on the utility requirement, should be interpreted in favor of the respondent, keeping in mind the state's right to regulate. This can only be negated if the appropriate bodies, as set out in the NAFTA Institutional Arrangements and Dispute Settlement Procedures Chapter, would create a binding interpretation of the NAFTA IP Chapter, to which the domestic law is contrary. No such interpretation exists, and the benefit of the doubt should be given, for the previous reasons provided,[304] to the respondent state of Canada. Applying this formula, the Tribunal would have to conclude that the utility requirement, seen through the promise utility doctrine, does not create grounds for legitimate expectations based on (in)consistency with the NAFTA IP Chapter.

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302 *Grand River v. USA*, Supra note 263, § 141.

303 Eli Lilly claims that the changes in Canadian patent law were outside of the "acceptable margin of change." See, Claimant's Memorial, Supra note 126, § 279.

304 See Chapter III for Canada's argumentation on the legitimacy and compliance of the utility requirement to international IP sources.

B. Eli Lilly outside of NAFTA – International Investment Agreements and TRIPS as a Source of Legitimate Expectations

Outside of the specific context of NAFTA there is a sea of different IIAs that protect IPRs as investments. Investors have the power to start investment arbitration proceedings and challenge their revoked patents, much like Eli Lilly has done. The TRIPS being the world's most important international IP treaty offers itself as a possible source of legitimate expectations. The relevance of the TRIPS for investors is not small as the share of assets in multinational companies consisting of intangible assets is on the rise.[305] However its role should, much like the role of the NAFTA IP Chapter in *Eli Lilly*, be limited.

The way an international treaty can be brought into investment arbitration is through one of the standards of protection provided in an IIA. Creating a link just by referencing the treaty to general rules of international law would not suffice.[306] Secondly a direct reference to an international IP treaty like the TRIPS in an IIA is problematic as well. Not only does article 23 of the DSU[307] confer the sole jurisdiction of WTO law to the WTO dispute settlement mechanism but the capability of the arbitrators to address a legal issue stemming from another body of law is also unsettling.[308] Albeit this approach is with all of the hurdles conceivable,[309] it is undesirable as it might lead to a paradoxical application of the law.[310]

However, there is little to prevent arbitration Tribunals looking at the TRIPS, even in instances where there is no express link between the ap-

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305 The Oxford Handbook of International Investment Law, Supra note 246, at 380.

306 Henning Grosse Ruse-Khan, Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation, (Uni. Of Cambridge Faculty of Law Legal Studies Research Paper Ser., Paper No. 52/2014, 2014), 1, 22 http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711 (Visited last on Mar. 6, 2018).

307 See DSU, Supra note 62, art. 23.

308 Bryan Mercurio, Safeguarding Public Welfare?—Intellectual Property Rights, Health and the Evolution of Treaty Drafting in International Investment Agreements, 6 J. Int'l Econ. L., 252, 261 (2015).

309 Fola Adeleke, Investor – State Arbitration and the Public Interest Theory, Online Proceedings, Working Paper No. 2014/12, Soc. Int'l Econ. L., 1, 39-40 available at: http://www.ssrn.com/link/SIEL-2014-BernConference.html (Visited last on Mar. 6, 2018).

310 An investment Tribunal could determine a violation of a IIA treaty standard even if WTO would proclaim the measure legal.

propriate IIA and the TRIPS. The application of the TRIPS would therefore depend on the qualification of the FET clause. A narrow definition and a link to customary international law would thus render the TRIPS out of the scope of the clause.[311] In a case where the FET clause is broadly worded there might be some room for the TRIPS to play a role. It seems that there would be no objection for an investment Tribunal to consider the TRIPS as a rule of applicable law.[312] A limited jurisdiction does not mean a limited scope of applicable law.[313] Accordingly one way that an investor could use the TRIPS as a basis for legitimate expectations is if the host state has provided for a direct application of the treaty in its domestic legal system.[314] This can be done through legislation or through representations given to the investor. The other way TRIPS can be used in FET and legitimate expectation claims is if the Tribunal uses the TRIPS directly for the interpretation of the facts of the case or as an interpretative guidance for certain provisions of the IIA. This approach is based on the VCLT 31(3)(c) by using TRIPS as "relevant context" for the interpretation of IIA clauses.[315] However article 31(3)(c) VCLT prevents direct application of other international treaty norms to the facts of the case.[316] Since the only proper interpretation of WTO law rests in the hands of the dispute settlement mechanism the maneuver space is very small. So, what could the Tribunals do when looking at the TRIPS? When determining violations of legitimate expectations according to TRIPS they can see whether the measure is in compliance with TRIPS by checking the decisions of the WTO panels. If the panel has ruled that the particular measure had violated the TRIPS, and in a case where the Tribunal is persuaded or obliged to use the TRIPS, the Tribunal may determine there has been a breach of legitimate expectations. However, until there is uncertainty whether the measure is

311 Vanhonnaeker, Supra note 204, at 110-12.

312 An approach not applicable under NAFTA investment Tribunals. See, Simon Klopschinski, The WTOs DSU Article 23 as Guiding Principle for the Systemic Interpretation of International Investment Agreements in the Light of TRIPs, J. Int'l Econ. L., 211, 222 (2016).

313 *Fragmentation of International Law: Difficulties Arising from the Diversification and Expansion of International Law*, Report by the Study Group of the International Law Commission, § 45 (2006) available at: http://legal.un.org/ilc/documentation/english/a_cn4_l682.pdf (Visited last on Mar. 6, 2018).

314 Klopschinski, Supra note 312, at 234.

315 *Id,* at 236.

316 Adeleke, Supra note 309, at 26.

contrary to the TRIPS, the Tribunal should give the benefit of the doubt to the respondent state and show deference to domestic law. This approach is more acceptable as not only does it allows clarity of the law stemming from the appropriate body, but that it reinvigorates and reinforces the legitimacy of the TRIPS. However even this approach should be carefully considered. Besides the situation mentioned earlier, where the state expressly creates a link to an international source of IP law, the states by not mentioning the TRIPS in IIAs have never actually agreed for it to be a part of that particular IIA. This approach would essentially impose on the states obligations to which it never adhered to in the first place.[317]

317 Vadi, Supra note 46, at 174.