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THE CHALLENGED STATE SOVEREIGNTY: A REVIEW OF ELI CASE

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Abstract

Normally the intellectual property is defined as “asset” (Frankel, 2016, p. 21) in FTAs that allows the investors to protect their rights and interests when disputes arise. In 2010 and 2011, the Canadian courts made decisions that invalidated two patents protection on Strattera and Zyprexa, respectively. To protect its interests, Eli Lilly and Company brought a patent right dispute to ICSID in the late of 2012. According to the claims of Eli, the decisions of the Canadian courts can be deemed as the violation of Article 1110 (Expropriation) and Article 1105 (Minimum Standard of Treatment) of North American Free Trade Agreement (NAFTA). Although the Tribunal dismissed the claims of Eli in March 2017 eventually, the actions of Eli de facto challenged state sovereignty and decreased the discretion of Canada to define and regulate its internal intellectual property system (Billingsley, 2015, p. 27). This essay will first present a brief introduction of the Eli Lilly and Company v. Canada and will discuss the evaluation of the Tribunal’s decision in Part 2.

Keywords

Denial of Justice; Fair and Equitable Treatment; Expropriation; NAFTA

1. Brief Introduction of the Eli Lilly and Company v. Canada

This part will introduce the case of Eli Lilly and Company v. Canada, the first individual-state investment dispute arbitration involving the invalidation of patent rights.

1.1 The Background

The Canadian courts invalidated two second patents on Strattera and Zyprexa which were originally held by Eli Lilly and Company in 2010 and 2011 respectively. According to the Final Award, these two patents are supposed to protect the Eli's drug Market in Canada, and the ground of the Canadian courts is that these two patents on drugs cannot satisfy the requirement of Canadian patent law, which is the judicial interpretation announced by the Canadian Federal Court—the invention must be “useful,” aka “Promise Utility Doctrine (*Eli Lilly and Company v. Government of Canada*, 2017, pp. 4-5).” Lentner (2017) noted that the “Promise Utility Doctrine” can be interpreted as the following: first, the authorities such as patent examiners and judges normally try to identify a “promise” in the patent disclosure and such “promise” shall be considered as the standard for measuring the “utility”; second, the evidence used to prove the “promise” shall be strictly scrutinized when it is submitted with the patent application, and the evidence submitted after patent application (“post-filing evidence”), such as commercial use, may not be relied on; third, the evidence which existed before the patent application (“pre-filing evidence”) may not be allowed to support a reliable prediction unless such evidence has been mentioned in the patent application (p. 815).

Correspondingly, Eli Lilly and Company claimed that the “Promise Utility Doctrine” can be deemed as a new and discriminatory policy which actually damaged its profit of two second patents on Strattera and Zyprexa, and brought the investment arbitration to the Tribunal by referring NAFTA Article 1110 and Article 1105.

1.2 The Statement of the Claimant

According to the Notice of Intent to Submit a Claim to Arbitration under NAFTA Chapter Eleven (2013), the Eli Lilly and Company claimed that the Canadian Government's actions, which caused the invalidation of Eli's patents on Strattera and Zyprexa, violated the obligations under NAFTA Article 1110 and Article 1105 (pp. 99).

The notice (2013) noted that the Eli Lilly and Company submitted that its patents on Strattera and Zyprexa have been directly expropriated by reviewing the actions Canada has conducted: (a) the Canadian courts invalidated the patents on Strattera and Zyprexa by referring

the “Promise Utility Doctrine;” (b) the Canadian Government did nothing to refine this decision or action; (c) the judge-made law on the “Promise Utility Doctrine” has been incorporated to Canadian legal system. Because of these measures, the exclusive rights to prohibit the third parties from producing, using, or selling the products already be patented have been indirectly expropriated from Eli Lilly and Company (pp. 99 - 102).

Furthermore, according to this notice, the Eli Lilly and Company pointed out that Canada breached obligations under Article 1110 Expropriation on the following grounds: (a) considering the fact that Canada has invalidated abundant of effective patents on drugs by referring the “Promise Utility Doctrine” in the past decade (since 2005), Eli has a reasonable belief that the discriminations de facto exist in the Canadian judicial decisions relating to the type of biopharmaceutical patents; (b) the requirement of “Promise Utility Doctrine” actually enhances the burden that the patent applicators should take under the requirement of TRIPS Agreement and the NAFTA obligations (2013, pp. 104).

In other words, based on the claimant’s position recorded by the Final Award, Eli alleged that the behaviors of Canadian courts can be defined as indirect expropriation due to the violation of the rule of international law (*Eli Lilly and Company v. Government of Canada*, 2017, pp. 181). Thus, as the notice recorded, Eli Lilly and Company claimed that the judicial decisions made by the Canadian courts can be deemed as illegal (2013, pp. 103).

Another clause the Eli Lilly and Company used to sue against Canada is the Article 1105(1) of NAFTA. According to the notice (2013), Eli holds the view that the actions mentioned above are discriminatory and opinionated, which exerted a devastating influence on the framework of Eli’s investment in Canada and destroyed Eli’s reasonable expectation of Canadian commercial and legal environment (pp. 109 - 117).

Thus, Eli brought the suit into the Tribunal in 2013 and required 500 million US Dollars as the compensation under Chapter Eleven of NAFTA.

1.3 The Tribunal’s Analysis

The Tribunal mainly focused on the following points to examine the dispute between Eli Lilly and Company and Canada and make the final decisions (Based on the Final Award noted).

1.3.1 Denial of Justice

The core and initial argument in this dispute is whether a denial of justice is required for forming a claim under Articles 1105 and 1110 of NAFTA.

According to the Final Award (2017), The Claimant Eli Lilly and Company disagreed that the denial of justice forms the only basis (pp. 211-213) while the Respondent Canada insisted that the denial of justice is the only basis to examine whether the judicial decisions of the Canadian courts, which invalidated Eli's two patents, can be deemed as the "Expropriation" under Article 1110 (2017, pp. 188).

The Tribunal noted that it depends on how to define the "Denial of Justice" (2017, pp. 218). According to the Tribunal's analysis, the actions that may not establish a denial of justice still should be considered to see if they violate Articles 1105 or 1110 of NAFTA (2017, pp. 219). As the Final Award (2017) noted, the Tribunal held a view that "[a] violation of ... Article 1105 of the NAFTA requires an act that is sufficiently egregious and shocking—a gross denial of justice, manifest arbitrariness, blatant unfairness, a complete lack of due process, evident discrimination, or a manifest lack of reasons—so as to fall below accepted international standards... (pp. 222)" In addition, the Tribunal admitted that the Tribunal cannot be an "appellate tier" to review the judicial decisions of Canadian courts and the Tribunal should respect such judicial decisions, unless in rare situation which stated above (pp. 224). In *Eli Lilly and Company v. Canada*, the Tribunal believed that there does not exist any specific and rare circumstance mentioned above to meet the requirement of bringing the case to the Tribunal (pp. 226).

1.3.2 The "Promise Utility Doctrine" under the Canadian Patent Law

To determinate whether the Canadian patent law changed dramatically—more specifically, the new utility requirement, aka the "Promise Utility Doctrine," which resulted in the invalidation of two patents on Eli's drug (2017, pp. 261), the Tribunal examined three elements of the new "Promise Utility Doctrine" with the evidences that Eli exhibited by combining these three elements as a whole. After the analysis, the Tribunal concluded that Eli failed

Promise Standard is the new law" created by Canadian courts (2017, pp. 316). After reviewing Canadian judicial decisions in the past decade, the Tribunal found that although the "Promise Standard" might not showed a significant impact on Canadian judicial decisions in the past decade, and the disclosure of promise had been considered in limited cases, the rule de facto was existing. Furthermore, the Canadian courts still cite *Consolboard* for the standard of

“promise” nowadays. Thus, the “Promise Standard” could not be deemed as new law (2017, pp. 324 - 325).

Second, Eli argued that the prior law had been changed on that “Post-filing Evidence” is prohibited to prove utility in the 2002 AZT decision. According to the Tribunal’s opinion, the main point to figure out this second element should determine one problem: whether the AZT decision changed the prior law that the patent right holders could submit the “Post-filing Evidence” to prove utility of their products (2107, pp. 326). And the Tribunal found the observations which noted in the paragraph 331 and 336 of the Award (2017) as the following: “

- The fact that the AZT decision made by the Supreme Court dismissed the previous decision made by the lower court could not be deemed as a change in the law.
- The AZT decision was clearly and satisfactorily made on the basis of the Canadian patent law, jurisprudence and relevant policies.
- The role of the Tribunal was to determine whether the Canadian patent law changed dramatically in the AZT decision, instead of judging the persuasiveness of the court’s analysis of Ciba- Geigy in AZT.
- After the AZT decision was made, it appeared that some commercially successful products were found to lack utility. But Eli failed to prove that it is caused by the change of Canadian patent law.”

Therefore, the Tribunal believed that there was no evidence showing that the AZT decision made by the Supreme Court gave rise to a dramatic change of Canadian patent law (2017, pp. 337).

For the third element of the “Promise Utility Doctrine”, according to the Claimant, the 2008 Raloxifene decision changed the law by requiring the disclosure of the basis of sound prediction in the patent application (2017, pp. 338). After analyzing, the Tribunal found that such change only could be deemed as “incremental and evolutionary” rather than dramatic (2017, pp. 350).

1.3.3 Fair and Equitable Treatment

Finally, the Tribunal examined whether the Canadian courts have conducted any arbitrary and discriminatory measure which could lead to the breach of FET standard under Article 1105(1) and Article 1110(1) of NAFTA without the circumstance that the Canadian patent law had changed dramatically (2017, pp. 416). The Tribunal recognized that Articles 1105 and 1110

are highly related. A breach of minimum standard of fair and equitable treatment under Article 1105(1) could also induce the violation of Article 1110(1)(c) when it comes to the issue of expropriation (2017, pp. 417).

Eli argued that the “Promise Utility Doctrine” should be deemed as “arbitrary.” The reason is, as they pointed out, that this doctrine “is unpredictable and incoherent and lacks a legitimate public purpose (2017, pp. 419).” Besides, the Claimant argued that the discrimination against patents on drugs actually exists in the “Promise Utility Doctrine,” which is prohibited by Article 1709(7) of NAFTA (2017, pp. 397). Furthermore, Eli claimed that the “Promise Utility Doctrine” only negatively affected the patents belonged to foreign corporations, and aimed to benefit the local drug industry (2017, pp. 401). This implied that Canada violated the FET standard. Personally, it might be a “weird” and “smart” excuse that allows the Article 1110 (Expropriation Clause) to be reviewed by the Tribunal, since the Article 1110(7) of NAFTA regulated that the Expropriation Clause can be applied to intellectual property rights only if the issuance, annulment, limitation, or creation of particular intellectual property rights is not consistent with Chapter 17 of NAFTA (The more specific details and discussion will be presented in Part II).

Responding to Eli’s claims, according to the Final Award (2017), Canada pointed out that: (1) first, the “Promise Utility Doctrine” is a “longstanding principle” rather than an “arbitrary interpretation (pp. 403);” (2) second, the prohibition of “Post-filing Evidence” can be justified with the reasonable goal of “preventing patenting too far upstream (pp. 406);” (3) third, requiring the disclosure of the basis of sound predictions in the patent application is “an essential part of the patent bargain (pp. 407);” (4) finally, there was no discrimination against foreign drug companies because the same rule applies to local corporations (pp. 415).

From the Tribunal’s perspective, the Final Award (2017) noted that the judicial measures of Canadian courts are not arbitrary or discriminatory and the decision of revoking two patents on Strattera and Zyprexa could not be deemed as the violation of Article 1105 or Article 1110 of NAFTA (pp. 418).

In terms of “arbitrariness,” the Tribunal found that: (1) each element of the “Promise Utility Doctrine” is not arbitrary, for such doctrine is neither “unpredictable” nor “incoherent,” nor lack “a legitimate purpose;” (2) the judicial decisions which invalidated two patents on

Strattera and Zyprexa are not arbitrary, for such decisions have “a foundation in Canadian law” and are “coherent and consistent with the policy justifications stated by Respondent.”

In terms of “discrimination,” the Final Award (2017) noted that Claimant failed to prove the “Promise Utility Doctrine” has created the factual basis of the discrimination against foreign patent holders (pp. 439 - 441).

In addition, as the Final Award (2017) noted, Eli insisted that the “Promise Utility Doctrine” represents a dramatic and unacceptable change of the law, which harmed the reasonable expectation of Eli. Eli also complained that Canada failed to provide the stable legal circumstance and damaged the interests of its investment. However, the Tribunal noted that, the increasing disputes of pharmaceutical patents would inevitably prompt the change of relevant rules (pp. 386). The normal development of law cannot be deemed as the breach of the legitimate expectation (pp. 387).

Thus, the Tribunal decided that the Claimant’s compensation requirement could not be supported since there was no violation of Article 1105(1) and/or Article 1110(1) (2017, pp. 387).

2. Extended Discussion

This part will provide a critical evaluation of the Tribunal’s decision in *Eli Lilly and Company v. Canada*, focusing on: (1) whether the invalidation of patents on Strattera and Zyprexa should be deemed as the expropriation when the Article 1110 (7) of NAFTA is considered; (2) how to interpret the FET standard under Article 1105 of NAFTA.

2.1 Determination of the “Expropriation” under the Article 1110 and Chapter 17 of NAFTA

According to the Final Award (2017), the ground of Tribunal to avoid the examination of Article 1110 (7) of NAFTA is that “the Tribunal does not have a right to determine whether the Canadian judicial actions of invalidating Eli’s patents violate the regulations of Chapter 17 of NAFTA (pp. 224).” However, the interesting point is that, on the one hand the Tribunal refused to interpret and examine the NAFTA Clauses because the state sovereignty cannot be intervened by the Tribunal; on the other hand, the Tribunal ignored that the TRIPS and NAFTA actually allow Canada to set up the reasonable utility standard in patentability. Instead, Baker and Geddes (2017) noted that the Tribunal seriously considered Eli’s and United States’ criticism of Canadian patent law (p. 502). It indicates that the opinions from relevant parties can show

significant influence on the decisions made by the Tribunal to some extent. As Baker and Geddes criticized (2017), “the Tribunal seemed to forget the discretion afforded to sovereign nations by TRIPS (p. 502).”

In brief, to show respect for the state sovereignty of Canada cannot form the ground that [t]he Tribunal refused to examine the Article 1110 (7) of NAFTA, which is the exception of intellectual property right of expropriation. A further discussion about whether the invalidation of patents on Strattera and Zyprexa should be considered as the expropriation in the situation that Article 1110 (7) of NAFTA is considered will be presented below.

2.1.1 Two types of Expropriation

As Dolzer and Schreuer (2014) have noted, to determine whether an expropriation is legal, most of treaties consider the following four requirements at the first time:

- The public purpose should be obeyed;
- “Arbitrary” and “discriminatory” are extremely prohibited;
- The due process must be followed (In NAFTA, the “due process” can be explained as the requirement of “the Minimum Standard” and “FET”);
- The reasonable and effective compensation should be paid to the investor whose right has been transferred by the host nation.

If the requirements mentioned above cannot be met, the behavior of expropriation should be prohibited.

Most of theories separate the expropriation as two types: “direct expropriation” and “indirect expropriation.” According to Rudolf, Dolzer and Christoph Schreuer (2014), “direct expropriation” means the “legal title” of investor’s right is taken or transfer by the host state (but this type of expropriation is rare in current times); “indirect expropriation” is that the “legal title” is not transfer but the right under this “legal title” de facto is taken by the host state (p. 139).

In the dispute between Eli Lilly and Company and Canada, these two types of expropriation both happened, according to the claims of Eli. Specifically, the patents on Strattera and Zyprexa have been directly expropriated by the Canadian courts; meanwhile, the notice (*Eli Lilly and Company v Government of Canada*, 2013) pointed out that the measures of the Canadian courts damaged the value of Eli’s investment in Canada, which constitute the indirect expropriation of Eli’s exclusive patent rights on its two drugs (pp. 102).

2.1.2 Article 1110(7) of NAFTA & Chapter 17 (Intellectual Property) of NAFTA

Billingsley (2015) had words that, according to Article 1110(7) of NAFTA, Article 1110 cannot be applied to the circumstances that “the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter 17 [of NAFTA] (p. 37).” And this author also noted, if the Tribunal failed to critic or interpret this clause, it would be difficult to determine the violation of the rules of international law because there is no convincing ground can be used (p. 38). This indicates that the Tribunal should determine whether the disputed behavior is consistent with the regulations under Chapter 17 before reviewing the Article 1110(1) of NAFTA. The reasons are: (1) to avoid the abuse of intellectual property right and (2) to protect the “domestic regulatory autonomy” of the host state (Billingsley, 2015, p. 38).

In accordance with the above, a determination of “Expropriation” under Article 1110(7) of NAFTA should be briefly expressed as the following. Firstly, pursuant to the Article 1709(8) of NAFTA, the party “may revoke” a patent when “(a) the reasonable grounds that the issuance of patent right can be rejected exist; (b) the compulsory license granted cannot be a remedy to fix the lack of implement.” Second, the utility of patents on Strattera and Zyprexa cannot meet the requirements of “Promise Utility Doctrine,” decided by the Canadian courts. Third, as analyzed by the Tribunal, there is no evidence showing that the measures taken by the Canadian courts constitute the “Denial of Justice”, violate due process of law, or are discriminatory.

Therefore, there is no violation of Chapter 17 of NAFTA, and the regulation of “Expropriation” under Article 1110 of NAFTA cannot be applied to these two patents in dispute. The measures taken by the Canadian courts and its judicial decisions to invalidate Eli’s two patents do not constitute the violation of expropriation clause.

In fact, *Eli Lilly and Company v. Canada* is not the first case that the Tribunal has to interpret the international treaties relating to the determination of expropriation in intellectual property right disputes. Similarly, in *Philip Morris v. Uruguay*, the Tribunal dauntlessly referred to Article 31(3) of VCLT (Vienna Convention on the Law of Treaty) and used this clause to interpret the “Exception of the Expropriation” and then noted that there was no jurisdiction on this dispute. According to the award of *Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay* (2016), the Claimant referred the violation of Article 5 of BIT between the Switzerland and Uruguay to claim that its trademark

right and further the investment profits have been damaged by the measures of “Tobacco Plain Package” policy conducted by the Government of Uruguay (pp. 2 - 9). Although the Tribunal did not apply the Exception of Intellectual Property clause, the Tribunal de facto translated the “public power” as the “Exception” of Expropriation by referring and interpreting the Article 31(3) of VCLT. In particular, the Tribunal deemed the “Tobacco Plain Package” policy as the implementation of “public power”, meaning that protecting the public health was exercising sovereign power. Therefore, the “Tobacco Plain Package” cannot be deemed as the violation of BIT between Switzerland and Uruguay (*Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay*, 2016, pp. 287 - 307).

To sum up, although the Tribunal cannot be the “appellate tier” of domestic authority, the necessary interpretation of international treaties should be considered. And the decisions of invalidating Eli’s two patents made by the Canadian courts cannot be deemed as the expropriation either under the analysis of the Tribunal or under the Article 1110(7) & Chapter 17 of NAFTA.

2.2 The Interpretation of FET Standard

Personally, the purpose of Eli referring the Article 1105 of NAFTA to claim the breach of the FET standard maybe avoiding the Article 1110(7) of NAFTA, since the flexibility of FET standard may be an important supporting viewpoint to protect the profits of investors when the dispute arises. Personally, the purpose of Eli referring the Article 1105 of NAFTA to claim the breach of the FET standard maybe avoiding the Article 1110(7) of NAFTA, since the flexibility of FET standard may be an important supporting viewpoint to protect the profits of investors when the dispute arises. As provided in Part I, the Tribunal mainly focused on two aspects—arbitrariness and discrimination, and reasonable expectation—to determine whether the judicial measure of Canadian courts meet the FET standard. However, the interpretation of FET standard made by the Tribunal of *Eli Lilly and Company v. Canada* is barely satisfactory. To prevent the abuse of FET standard in future international investment disputes, it is necessary to narrow down the meaning of FET. The following cases and academic views may shed some light on this matter.

According to Partial Award of *Saluka Investment BV (The Netherlands) v. The Czech Republic* (2006), the Tribunal adopted the ordinary meaning of “fair” and “equitable,” which is “even-handed,” “unbiased,” and “legitimate,” and admitted that the breach of FET standard

“requires treatment in such an unjust or arbitrary manner that the treatment rises to the level that is unacceptable from the international perspective (pp. 297).”

According to the Award of *Técnicas Medioambientales Tecmed v. United Mexican States* (2003), the Tribunal defined the “FET”:

“[T]he host state is required to provide the investment treatment which would not affect the fundamental expectations the foreign investors normally expect that the behaviours of the host state can be in good faith, consistent, transparent, and they also expect the action or decisions made by the host state without arbitrary. Meanwhile, the foreign investors also expect that the host state treated them as similar as the local investors (pp. 154).”

To sum up, there are three requirements of the FET standard: (1) good faith; (2) no arbitrariness or discrimination; (3) reasonable expectation.

2.2.1 Arbitrariness & Discrimination

According to Dolzer and Schreuer (2014), the existence of arbitrariness and discrimination should be deemed as the violation of FET (p. 168).

In particular, “arbitrariness” mainly depends on whether the disputed policy or measure is reasonable, consistence, and transparent, as stated in *Saluka Investment BV (The Netherlands) v. The Czech Republic* (2006, pp. 309).

In terms of “discrimination,” the Tribunal in *Waste Management v. Mexico* explained it as “expos[ing] the claimant to sectional or racial prejudice, or involve[ing] a lack of due process leading to an outcome which offends judicial propriety (*Waste Management v. United Mexican States (II)*, 2004, pp. 98).”

2.2.2 Reasonable Expectation (Legitimate Expectation)

Zhang Sheng (2016) stated, the legitimate expectation can be simply interpreted in words that “the expectation of investors who hold good faith could not be violated (p. 71).” In international investment legal system, the reversal of legitimate expectation normally can be deemed as the breach of the FET standard (Dolzer& Schreuer, 2014, p. 169). In *National Grid v. Argentina*, the Tribunal noted that “the investors’ legitimate expectations should not be affected by the treatment the host state conducted (*National Grid PLC v. The Argentine Republic*, 2008, pp. 173).” In addition, the Arbitral Award of *International Thunderbird Gaming Corporation v. The United Mexican States* (2006) specified that “[t]he legitimate expectation is that the host state (one contracting party) creates a reasonable expectation for investment purpose to the

investors or investments (the other contracting party), and then the investors or investments conduct their activities based on this basic expectation. If the basic expectation cannot be satisfied, the profits of investors would be damaged (pp. 45).”

However, it is worth noting that the requirement that legitimate expectation could not be violated does not mean that the domestic law cannot change. In other words, as analysed by the Tribunal in *Eli Lilly and Company v. Canada*, the reasonable development of law cannot be deemed as the failure of basic expectation.

3. Conclusion

This essay simply reviews the *Eli v. Canada* case by discussing the decision of Tribunal on two disputed articles: NAFTA Article 1110 and Article 1105. Unfortunately, although Canada seems to have defended its right successfully in *Eli v. Canada* case, the “unduly cautious” decision made by the Tribunal negatively impacted on the following similar intellectual property right disputes in Canada, as Lentner commented (2107). In fact, after the final decision made by the Tribunal, the Supreme Court of Canada rejected the “Promise Utility Doctrine” as the standard to define the “utility” of patent right under the Patent Act of Canada (Lentner, 2017, p. 816).

As criticized above, the Tribunal’s analysis is far from satisfactory. First, the exception of intellectual property right under Article 1110(7) should be considered properly by Tribunal, and to respect the state sovereignty could not be an excuse for the Tribunal to ignore the Article 1110(7). Second, the Tribunal should have interpreted the FET standard in more detail. Otherwise, the state sovereignty may be likely to be infringed and the foreign investors can easily abuse the FET standard in individual-state investment disputes.

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