

### III. Eli Lilly v. Canada – Facts and Proceedings

The case central to the analysis of this thesis is the investment arbitration case between Eli Lilly, a US pharmaceutical company and the government of Canada. Eli Lilly was the proprietor of two pharmaceutical patents for commercially successful drugs called Strattera and Zyprexa. Both of the patents were revoked in court proceedings after being challenged by competing generic producers. Having lost both cases in the final court instance Eli Lilly started the investment arbitration proceedings under NAFTA Investment Chapter in 2012. The proceedings were conducted according to the UNCITRAL Rules.<sup>95</sup>

#### A. *Eli Lilly's Patents in Canadian Courts*

##### 1. Strattera Patent

The Strattera patent was a patent for a new use of an already known substance called atomoxetine, a drug used to treat manifestation of ADHD.<sup>96</sup> The patent was challenged on the grounds for the lack of utility by Novopharm, now Teva Canada, a generic pharmaceutical producer.

The trial judge found that, at the time of the filing of the patent, the evidence provided by Eli Lilly did not suffice to show that atomoxetine would fulfill the promise disclosed in the patent.<sup>97</sup> The judge determined that the clinical study used as evidence of the utility of the patent was not enough to establish a promise of utility at the time of the filing.<sup>98</sup> The decision was latter appealed to the Supreme Court of Canada, which refused to hear it. With that Eli Lilly exhausted all recourse to domestic courts.<sup>99</sup>

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<sup>95</sup> UNCITRAL Rules, Supra note 65.

<sup>96</sup> *Eli Lilly & Co. v. Teva Canada Ltd.*, § 2, [2011] FCA 220, [herein after: *Eli Lilly v. Teva*].

<sup>97</sup> *Id.*, § 5.

<sup>98</sup> *Id.*, §§ 34-40.

<sup>99</sup> *Eli Lilly & Co v. Teva Canada Ltd.*, [2011] Supreme Court No. 34396, (Can.), available at: <https://scc-csc.lexum.com/scc-csc/scc-l-csc-a/en/item/8970/index.do> (Visited last on Mar. 6, 2018).

## 2. Zyprexa Patent

The Zyprexa patent was a selection patent for a previously patented substance called olanzapine. Olanzapine is used for the treatment of schizophrenia.<sup>100</sup> The patent holders claimed: “[w]e have now discovered a compound which possesses surprising and unexpected properties by comparison with flumezapine and other related compounds”. Such a disclosure pointed to the advantages of the previously known substance.<sup>101</sup> The patent itself was attacked on two grounds - the lack of utility and insufficient disclosure. While the insufficiency of disclosure claim was rejected, the utility claim was nevertheless successful.<sup>102</sup> The court found that the evidence presented did not prove the marked advantages of olanzapine over the rest of the patent genus.<sup>103</sup> Moreover the court found that the evidence submitted did not establish a prediction needed to fulfill the promise of utility.<sup>104</sup>

The decision was appealed and eventually dismissed by the Supreme Court of Canada.<sup>105</sup>

The reasoning for the revocation of both patents is very similar. The courts found that the utility of the patent could not have been demonstrated at the moment of filing, nor that any indication of utility was demonstrated at the same time. Based on pure speculation, the patents were revoked for their lack of utility.<sup>106</sup>

Dissatisfied with the outcome of the court proceedings Eli Lilly decided to start an investment arbitration against Canada according to the NAFTA Investment Chapter. The case would become the first, publicly available investor-state arbitration dealing with patent rights as investment. Eli Lilly caught on with the trend of large companies trying to challenge domestic

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100 *Eli Lilly & Co. v. Novopharm Ltd.*, § 1, [2011] FC 1288 (Can.) [herein after: *Eli Lilly v. Novopharm*].

101 *Id.*, §§ 32 – 36.

102 *Id.*, § 7.

103 *Id.*, § 73.

104 *Id.*, §§ 74-78.

105 *Eli Lilly & Co. v. Novopharm Ltd.*, Supreme Court No. 35067 (Can.) available at: <https://scc-csc.lexum.com/scc-csc/scc-l-csc-a/en/item/13052/index.do> (Visited last on Mar. 6, 2018).

106 James Billingsley, *ELI LILLY AND COMPANY V. THE GOVERNMENT OF CANADA AND THE PERILS OF INVESTOR-STATE ARBITRATION*, 20 Appeal 27, 30 (2015).

IP law through shifting the forum to investor-state arbitration.<sup>107</sup> A view exists which posits that investment arbitration Tribunals have an investment-centered approach and have a different perspective when it comes to observing property rights.<sup>108</sup> The idea behind Lilly's actions was that through forum shifting it would be possible to mitigate the negative consequences of domestic law or judicial decisions. Although Lilly lost the case and the battle<sup>109</sup>, one could say that they still won the war, as the Supreme Court of Canada eventually struck out the promise utility doctrine.<sup>110</sup>

## B. Investment Arbitration Proceedings

### 1. Eli Lilly's Position

Eli Lilly's claims were based on the general premise that the "promise utility doctrine", as such, applied to their two patents constituted the breach of the obligations imposed on Canada by the NAFTA Investment Chapter.

First of all, Eli Lilly tried to show that the "promise utility doctrine" was a "radically new, additional requirement for patentability."<sup>111</sup> According to Eli Lilly the "promise utility doctrine" required a heightened evidentiary and disclosure standard.<sup>112</sup> Eli Lilly claimed that the doctrine was a novel occurrence in Canadian patent law and that such requirements had not existed at the time the patents at issue were filed.<sup>113</sup>

The doctrine was impermissible both at a domestic law level as well as under international standards, according to Lilly. They went on to explain

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107 Philip Morris Asia Ltd. v. Australia, PCA Case No. 2012-12 (2011) [herein after: *Philip Morris v. Australia*] available at <http://www.italaw.com/cases/851> and Philip Morris Brands Sàrl et al. v. Uruguay, ICSID Case No. ARB/10/7 (2009) (Visited last on Mar. 6, 2018) [herein after: *Philip Morris v. Uruguay*].

108 Vadi, Supra note 51, at 30.

109 Final Award, Supra note 3.

110 See AstraZeneca Canada Inc. v. Apotex Inc., [2017] Supreme Court No. 36654, (Can.), available at: <https://scc-csc.lexum.com/scc-csc/scc-csc/en/item/16713/index.do> (Visited last on Mar. 6, 2018).

111 *Eli Lilly v. Canada*, Supra note 1, Claimant's Post-hearing Memorial, § 18, available at: <http://www.italaw.com/sites/default/files/case-documents/italaw7465.pdf> (Visited last on Sept. 14, 2016) [herein after: Claimant's Post-hearing Brief].

112 *Id.*, §§ 18-19.

113 *Id.*, § 45, § 71.

this claim by taking a comparative approach and contrasting the patent laws of Canada on one side and Mexico and US on the other.<sup>114</sup> The attempt at showing dissonance of Canadian law on utility with the rest of the NAFTA partners, which structure their IP laws according to the same international agreement, was evident. This line of argumentation led to the conclusion that there seems to be a generally accepted standard for utility in jurisdictions across the world. Canada's law was thus portrayed as idiosyncratic.<sup>115</sup>

Having given a characterization of the promise utility doctrine, Lilly used it as a basis to prove breaches of NAFTA IP Chapter provisions. They claimed that the measures undertaken by the Canadian courts amounted to both direct and indirect expropriation pursuant to article 1110 as well as the minimum standard of treatment guaranteed by article 1105.<sup>116</sup>

## 2. Canada's Position

Canada's first defensive arguments suggested that Eli Lilly had failed to construct a proper investment arbitration claim according to NAFTA rules. According to Canada's position, it was manifest that there was no denial of justice. The denial of justice was the only type of action a successful claim can be based on. Without it there could be no breaches of NAFTA articles 1105 and 1110.<sup>117</sup>

The Canadian position then turned to explaining the legitimacy of the standards of utility in their legal system, thus countering Eli Lilly's claims of the "radical new changes" pertaining to the utility requirement.

Canada purported that promises, derived from the patent claims, have been part of Canadian patent before 2005, using the landmark *Consol-board* and *Wellcome* cases as examples of the doctrine's long standing presence in Canadian patent law.<sup>118</sup> The promise doctrine was not only

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114 *Id.*, §§ 136-137.

115 *Id.*, § 158.

116 *Id.*, §§ 200-1.

117 *Eli Lilly v. Canada*, Supra note 1, Government of Canada Post-hearing Submission, §§ 19-20 available at: <http://www.italaw.com/sites/default/files/case-documents/italaw7464.pdf> (Visited last on Sept. 14, 2016) [herein after: Respondent's Post-hearing Brief].

118 *Id.*, §§ 117-23.

tied to the utility of the patent but also to the over-breadth of protection.<sup>119</sup> Canada went on to explain why the “promise utility doctrine” did not impose a heightened patentability standard. Establishing utility at the moment of filing had always been a requirement of Canadian patent law.<sup>120</sup> Canada likewise claimed that the utility standard offered to pharmaceutical patents was a less stringent requirement than usual, as there was a possibility to claim utility even before it was established.<sup>121</sup> Canada further stated that the interpretation of the utility requirement had not been altered by a new disclosure requirement for claiming utility based on the promise doctrine.<sup>122</sup> Eli Lilly’s claims of discrimination of pharmaceutical patents were likewise opposed by Canada.<sup>123</sup> Moreover, Canada pointed that since the alleged changes took place in the mid-2000s, from an international perspective, it had received no complaint regarding the law. This was put into the perspective of the international agreements which Eli Lilly claimed Canada had breached.<sup>124</sup>

Having given its own interpretation of the facts and qualification of the utility requirement in Canadian patent law, Canada rejected both the article 1110 expropriation claim, as well as the 1105, minimum standard of treatment claim.<sup>125</sup>

### *C. Legitimate Expectations in Relation to International Intellectual Property Standards*

#### 1. Eli Lilly’s Position

Eli Lilly’s legitimate expectation claim relied on a number of factors. However, the focus of this thesis is on the relationship of legitimate expectations and international IP treaties, therefore only the arguments related to this relationship will be discussed in detail.

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<sup>119</sup> *Id.*, § 131.

<sup>120</sup> *Id.*, § 139.

<sup>121</sup> *Id.*, § 148.

<sup>122</sup> *Id.*, § 151.

<sup>123</sup> *Id.*, § 222-223.

<sup>124</sup> *Id.*, § 172.

<sup>125</sup> *Id.*, § 175.

Eli Lilly claimed that their legitimate violations had been violated, as they had expected that the “promise utility doctrine” would not be inconsistent with Canada’s obligations in the NAFTA IP chapter, which in the NAFTA context is the relevant international IP treaty. Eli Lilly claimed that the doctrine was wrong both from a national and an international perspective and that the changes were allegedly, so drastic, that their legitimate expectations had been violated.<sup>126</sup> In order to prove frustration of its legitimate expectations Lilly stated 4 points as to why Canada’s utility standard was inconsistent with the NAFTA IP Chapter.

The first point tried to show that the two patents were revoked despite having utility, thus breaching article 1709(1).<sup>127</sup> In order to support its argument Eli Lilly invoked the rules of the VCLT,<sup>128</sup> in particular articles 31 and 32. Eli Lilly held that the promise utility doctrine did not conform to the interpretation rules under article 31 of the VCLT in light of the “text, context, object and purpose, subsequent practice, and relevant rules of international law to interpret the ordinary meaning of the terms ‘capable of industrial application’ and ‘useful.’” Likewise, Eli Lilly claimed that nothing in the interpretative sources<sup>129</sup> pointed to the interpretation that would sustain the “promise utility doctrine”.<sup>130</sup>

The second point alleged that the promise utility doctrine discriminates against a field of technology contrary to 1709(7).<sup>131</sup> Eli Lilly stated that there existed a *de facto* discrimination and that their statistical analysis offered as proof, had demonstrated it.<sup>132</sup>

The third point addressed the retrospective application of the doctrine, thus breaching article 1709(8).<sup>133</sup> According to Eli Lilly the doctrine had

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126 *Eli Lilly v. Canada*, Supra note 1, Claimant’s Memorial Index, § 279, available at: <http://www.italaw.com/sites/default/files/case-documents/italaw4046.pdf> (Visited last on Mar. 6, 2018) [herein after: Claimant’s Memorial]; *Eli Lilly v. Canada* Claimant’s Reply Memorial, § 364, available at: <http://www.italaw.com/sites/default/files/case-documents/italaw4384.pdf> (Visited last on Mar. 6, 2018) [herein after: Claimant’s Reply], Claimant’s Post-hearing Brief, § 280.

127 Claimant’s Memorial, Supra note 126, § 186.

128 Vienna Convention on the Law of Treaties, *opened for signature* May 23, 1969, 1155 U.N.T.S. 331.

129 Claimant’s Reply, Supra note 126, §§ 283–89.

130 *Id.*, § 290.

131 Claimant’s Memorial, Supra note 126, § 186.

132 Claimant’s Reply, Supra note 126, § 292.

133 Claimant’s Memorial, Supra note 126, § 186.

not existed at the moment the patents were filed and they could not have been revoked should the same law still be applicable.<sup>134</sup>

The final point stated that there was a failure to provide adequate protection and enforcement of rights violating article 1701(1).<sup>135</sup> Eli Lilly claimed that by changing the law and retroactively applying it to the two patents, which resulted in their revocation, Canada had essentially denied protection to the two patents.<sup>136</sup>

## 2. Canada's Position

The basis of Eli Lilly's argument was that the "promise utility doctrine" is inconsistent with the NAFTA Investment Chapter. Canada addresses this first point in the following way:

Canada claimed that it did not breach article 1709(1) as it challenged the way Lilly applied the VCLT, qualifying it "specific" and "extremely restrictive". They accused Eli Lilly of using a "self-serving" interpretation.<sup>137</sup> Canada argued that the proper source for the evaluation of patent law should be domestic law. Patent law is territorial and there are no international definitions for concepts such as utility.<sup>138</sup> Furthermore Canada contended that had the parties wanted to establish a precise meaning of "useful" or "capable of industrial application" they would have provided a definition.<sup>139</sup> Turning to the application of VCLT article 31(1)(c), Canada denied the relevance of the PCT as the relevant rule of law and highlighted the TRIPS which likewise did not provide a precise meaning for the patentability requirements.<sup>140</sup> Lastly, Canada rejected the article 32 argument by claiming that the failure of the SPLT and the SPC survey did not

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134 Claimant's Reply, Supra note 126, §§ 301-2.

135 Claimant's Memorial, Supra note 126, § 186.

136 Claimant's Reply, Supra note 126, § 306.

137 *Eli Lilly v. Canada*, Government of Canada Rejoinder Memorial, § 139, available at: <http://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207014.pdf> (Visited last on Mar. 6, 2018) [herein after: Respondent's Rejoinder Memorial].

138 *Id.*, § 151.

139 *Id.*, § 169.

140 *Id.*, §§ 178-81.

provide any kind of restrictive standardization of the utility requirement.<sup>141</sup>

Canada rejected Eli Lilly's violation claim of 1709(7) by stating that Eli Lilly's argument was based on a flawed interpretation of statistics. Canada thus held that there was no *de facto* discrimination against pharmaceutical patents.<sup>142</sup>

Canada further rejected Lilly's claims in relation to article 1709(8). It states that the law had not been applied retroactively, rather jurisprudence had developed over time. Canada stated that evolving legal standards applied to the patent during the whole patent term.<sup>143</sup>

Canada likewise rejected the claim related to article 1701(1). It stated that its law offered a comprehensive system of IP protection by giving substantive protection to IPRs and providing an enforcement mechanism as well. This was contrary to Lilly's arguments of the system being ineffective. Canada supported the defense with statistical proof.<sup>144</sup>

With this line of argumentation Canada rejected the inconsistency of its law with the NAFTA IP Chapter. However, Canada likewise held that even if there had been inconsistencies, they could not have amounted to a breach of article 1105. This view was based on the FTC's Note<sup>145</sup> which stated that a breach of another international treaty does not amount to a breach of article 1105.<sup>146</sup>

However finally, the complex exchange of argumentation was never really addressed by the Tribunal. The Tribunal ruled that the law as applied to the promise utility doctrine did not constitute a violation of either article 1105 and 1110 of the NAFTA. Moreover, it stated that there was no arbitrary or discriminatory measure that can infringe either of the articles.<sup>147</sup> In that regard the Tribunal was satisfied with its findings, seeing no need to address further arguments, including the ones regarding legitimate expectations and the NAFTA IP Chapter. However, the arguments

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141 *Id.*, §§ 183-84.

142 *Id.*, §§ 190-203.

143 *Id.*, § 207.

144 *Id.*, § 134-137.

145 Notes of Interpretation of Certain Chapter Eleven Provisions (Free Trade Commission, July 31, 2001), available at <http://www.international.gc.ca> (Visited last on Mar. 6, 2018) [herein after: FTC's Note].

146 Respondent's Rejoinder Memorial, Supra note 137, § 295.

147 Final Award, Supra note 3, § 442.



still have value as it is possible that similar arguments might be proposed in future investment arbitration cases.