

Eli Lilly v. Canada – The First Final Award Ever on Patents and International Investment Law

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In the international investment arbitration of [Eli Lilly v. Canada](#) the arbitral tribunal rendered on March 16, 2017 the first [final award](#) ever on patents and international investment law, thereby creating a completely new forum for litigating patents (ICSID Case No.: UNCT/14/2). The arbitral tribunal had to decide whether Canadian courts complied with standards of treatment under international investment law when they revoked Eli Lilly's Canadian patents concerning the compound olanzapine (Zyprexa Patent) and the use of the compound atomoxetine for treating attention-deficit/hyperactivity (Strattera Patent). Even though the award dismisses all claims, which the US pharmaceutical company Eli Lilly had asserted against Canada, these arbitral proceedings set the standards for litigating patents under [international investment law](#) in the future.

In 2010 and 2011 the Federal Court of Canada revoked the Zyprexa and Strattera patents for lack of utility on the basis of the so-called 'promise utility doctrine' under Canadian patent law. This doctrine comprises three elements: (i) the identification of a 'promise' in the patent disclosure, against which utility is measured; (ii) the prohibition on the use of post-filing evidence to prove utility; and (iii) the requirement that pre-filing evidence to support a sound prediction of utility must be included in the patent. In view of the Federal Court, both patents of Eli Lilly did not meet this standard, since the patent specifications did not contain the factual basis of the inventor's sound prediction of utility. The Federal Court of Appeal and the Supreme Court of Canada confirmed these decisions.

In response to the invalidation of its Canadian patents, Eli Lilly commenced international investment arbitration against Canada under Chapter 11 (Investment) of the [North American Free Trade Agreement \(NAFTA\)](#) of 1994 between Canada, the United States, and Mexico. NAFTA Chapter 11 is one of more than 3,300 international investment agreements (IIAs), which currently exist worldwide. Germany is for instance party to approx. 140 IIAs. Under IIAs, the contracting states are obliged to accord certain standards of treatment to investors and investments of the other contracting state, e.g. the fair and equitable treatment standard or the expropriation standard. IIAs regularly define patents, trademarks, and other intellectual property rights (IP) as protected investments. If a host state denies the investor of the other contracting state treatment in accordance with standards set forth in the IIA, most modern IIAs provide for a dispute settlement mechanism which allows the foreign investor to sue the host state before an international arbitral tribunal established under the IIA, without being dependent on the consent or assistance of its home state. In 2016 the total count of international investment arbitrations was nearly 700. The majority of investment disputes is heard by the [International Centre for the Settlement of Investment Disputes \(ICSID\)](#), which was established by the ICSID Convention of 1965 and is located at the World Bank in Washington DC. Even though IP rights have been mentioned in IIAs as protected investments for decades, Eli Lilly v. Canada is the first case on the protection of patents under international investment law where an arbitral tribunal rendered a final award.

In the arbitral proceedings Eli Lilly alleged that the revocation of its Zyprexa and Strattera patents (which were filed in 1991 and 1996, respectively) was an unfair and inequitable treatment contrary to NAFTA Article 1105 as well as an expropriation under NAFTA Article 1110. Eli Lilly argued in this respect that the 'promise utility doctrine' was a radical departure from Canada's traditional utility standard and the utility standards applied by Canada's NAFTA partners, the US and Mexico. It claimed that for decades Canada had applied the traditional utility test for which a 'mere scintilla' of utility applied, and under that test, pharmaceutical patents were never found to lack utility until the advent of the 'promise utility doctrine' in the mid-2000s.

In response Canada rejected Eli Lilly's allegations of a recent sea-change in the Canadian law on utility. According to Canada, the term 'useful' was not defined in the Canadian Patent Act, and its meaning had therefore necessarily evolved through jurisprudence. Canada argued that what Eli Lilly presented as a unitary 'promise utility doctrine' was in reality three distinct long-standing patent law rules.

In its reasoning the arbitral tribunal made clear that state courts are not exempt from NAFTA Chapter 11 and that consequently Canada could be held liable, in principle, for the conduct of its courts if they did not comply with the standards of treatment established under NAFTA Chapter 11. On the other hand, the arbitral tribunal also noted that it was not an appellate tier in respect of the decisions of the national judiciary. It was not the task of an investment tribunal to review the findings of national courts and considerable deference should be accorded to the decisions and conduct of such courts.

The tribunal rejected Eli Lilly's allegations, as it did not find a fundamental or dramatic change in Canadian patent law. The evidence before the tribunal only showed that Canada's utility requirement underwent incremental and evolutionary change between the time that the Zyprexa and Strattera patents were granted and then invalidated. Therefore, the arbitral tribunal dismissed Eli Lilly's claim and ordered the pharmaceutical company to bear the costs of the arbitration (US 749,697.97 in total) and to pay 75% of Canada's costs of representation (CAD 4,448,625.32).

Even though a violation of the standards of treatment of international investment law requires more than a simple violation of national law and arbitral tribunals do not act as mere appellate courts in respect of national courts, one can imagine circumstances where international investment law could be a real option for the patentee to defend its patent. Such a scenario could be for instance the grant of a compulsory license, radical revisions of court practice in respect of patentability, novelty, inventive step or utility, legislative measures impacting on patents, as well as procedural deficits in patent proceedings. One example for the latter case is the decision [G 1/97](#) of the Enlarged Board of Appeal of the EPO, which preceded the introduction of [EPC Article 112a](#). There the Enlarged Board of Appeal found that the EPC 1973 did not provide for a remedy against final decisions of a Board of Appeal if there was a violation of a fundamental principle of procedural law. It is arguable that such a situation would amount to a breach of the fair and equitable treatment standard under international investment law.

Further reading on the protection of IP under IIAs:

1) Simon Klopschinski, [Der Schutz geistigen Eigentums durch völkerrechtliche Investitionsverträge \(The Protection of Intellectual Property under International Investment Agreements\)](#), 579 pages, 1st ed. (Köln: Carl Heymanns Verlag, 2011). ISBN: 978-3-452-27553-0 (English version in co-authorship with Professor Christopher Gibson, Suffolk University Boston, forthcoming [publisher: Oxford University Press])

2) Simon Klopschinski, [The WTO's DSU Article 23 as Guiding Principle for the Systemic Interpretation of International Investment Agreements in the Light of TRIPs](#), 19 *Journal of International Economic Law* 211-239 (2016)

3) Simon Klopschinski, [Philip Morris loses investment arbitration against Uruguay's anti-tobacco legislation](#), *The IPKat Blog*, September 13, 2016