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Litigating patents in investment arbitration: *Eli Lilly v Canada*

Eli Lilly and Company v Government of Canada, Final Award, UNCITRAL, ICSID Case No. UNCT/14/2, 16 March 2017

For the first time in investment arbitration, a tribunal has ruled in a case involving the invalidation of a pharmaceutical company's patents by Canadian courts in an investment-based claim.

Legal context and facts

This patent dispute was litigated in international investment arbitration against Canada under Chapter 11 (Investment) of the North American Free Trade Agreement (NAFTA). The Investment Chapter of NAFTA is one of more than 3,000 international investment agreements (IIAs) that provide certain standards of treatment to foreign investors and their investments, such as non-discrimination, fair and equitable treatment and the prohibition against uncompensated expropriation. Most of these agreements provide for investor–state dispute settlement (ISDS) in which an arbitral tribunal may award compensation to the investor in case a state has violated these protection standards.

The US pharmaceutical company Eli Lilly claimed that Canadian courts had violated standards of treatment under international investment law by revoking two of Eli Lilly's Canadian patents (the Zyprexa Patent and the Strattera Patent). These were invalidated by the Canadian federal courts based on judicial interpretations of the utility requirements contained in the Canadian patent statute, referred to as the 'promise utility doctrine'. Under this doctrine:

1. patent examiners and judges seek to identify a 'promise' in the patent disclosure, and this promise becomes the measuring stick for utility;
2. evidence submitted with the patent application to show fulfilment of any promise in the patent description is subject to heightened scrutiny, and post-filing evidence such as commercial use may not be relied upon;
3. pre-filing evidence may not be considered to support a sound prediction unless that pre-filing evidence was referenced in the patent application itself.

Eli Lilly alleged that the Canadian courts' adoption of the promise utility doctrine is 'radically new, arbitrary and discriminatory against pharmaceutical companies and products' and that Eli Lilly had 'legitimate expectations that its Zyprexa and Strattera patents would not be invalidated on the basis of a radically new utility requirement.' Eli Lilly claimed that the court's action in 2010 and 2011, when the Federal Court of Canada revoked the patents for lack of utility, amounted to unlawful expropriation of its intellectual property and a violation of the Minimum Standard of Treatment under Articles 1110 and 1105 of the North Atlantic Free Trade Agreement (NAFTA).

Analysis

On 16 March 2017, an international investment tribunal rendered its final award in this case. It is the first award litigating patents in the history of ISDS. The arbitral tribunal made several important principal observations. First, it clarified that as organs of the state, courts and their judicial acts (or omissions) may engage questions of expropriation and fair and equitable treatment under the applicable investment agreement (paras 218–23). However, the tribunal noted that it is not an appellate tier and that it is not for an investment tribunal to review the findings of national courts, only in 'very exceptional circumstances, in which there is clear evidence of egregious and shocking conduct' (para 224).

On the merits, the tribunal dismissed the alleged breaches stating that the claimant had not met the required burden of proof. However, it noted inter alia that, contrary to what Canada argued, not only may a denial of justice serve as a basis of liability for judicial measures, but also other conduct which 'may also be sufficiently egregious and shocking, such as manifest arbitrariness or blatant unfairness' (para 232). It held that invalidation under naturally evolving patent laws is not a breach of legitimate expectations but also suggested that a violation could take place when 'a fundamental or dramatic change in Canadian patent law' occurs (para 389).

Finally, the Tribunal noted that the evolution of the Canadian legal framework, in relation to claimant's patents, could not sustain a claim of arbitrariness or discrimination amounting to a violation of NAFTA Articles 1105 or 1110.

Practical significance

The award comes at a time of heightened interest (and criticism) surrounding the use of ISDS for litigating IP-related disputes. While most IIAs explicitly refer to intellectual property rights (IPRs) as covered investments, the issue of litigating IP-related disputes via investment arbitration has largely remained an academic exercise. A growing body of literature has suggested that IPRs should be considered protected investments and that interference with IPRs of an investor in a host state may violate protection standards under IIAs. But only recently has this issue been brought before arbitral tribunals: Philip Morris challenged 'plain packaging', restrictions on branding, and compulsory health warnings on cigarette packaging in two separate cases against and Uruguay in 2010 and Australia in 2012. In both cases, the claimant was not successful.

The case at issue is the first to involve patents. It is interesting to note that the tribunal was careful not to dismiss out of hand IP-based ISDS claims. Rather, it provided several principal arguments for the general viability of litigating IP-related disputes through investment agreements. At the same time the tribunal did not provide any further clarification regarding such cases and the applicable legal standards for IP protection. Thus, this case will not necessarily serve to reduce the uncertainties in this area of law (it did not, for example, address how investor protection affect the flexibilities included in the Agreement on Trade-Related Aspects of Intellectual Property Rights, TRIPS), but it might encourage further such litigation in this forum.

This case might serve as a precedent for future IP-based claims against states' interference with IPRs of foreign investors. In particular, the reliance on international investment law might be a viable avenue for a patentee to defend its patent. The most obvious example would be the issuance of a compulsory license, which could be challenged before such investment tribunal having jurisdiction. But also legislative measures, significant revisions of court practice or procedural issues relating and impacting on patent holders could end up before an investment tribunal.

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