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Investment Agreements: A New Threat to Health and TRIPS Flexibilities?

By Carlos M. Correa

The bilateral investment treaties (BITs) may be a threat to access to medicines as shown by a recent legal suit by a drug multinational against Canada for invalidating a patent.

Recent complaints based on bilateral investment treaties (BITs) demanding a compensation for the alleged damage caused by anti-tobacco policies adopted in Uruguay and Australia, have illustrated the pervasive implications that such treaties may have on public policies. If successful, those complaints will undermine the States' right to adopt measures to protect public health.

The North American Free Trade Agreement (NAFTA), like other free trade agreements (FTAs) signed in the last twenty years, includes a detailed chapter on investment protection with a scope and obligations similar to those found in BITs. The notification of a complaint against Canada under such chapter in connection with the invalidation of a patent raises new concerns about the power given to investors under investment agreements (IAs).

Eli Lilly, a major US pharmaceutical company, has notified an investment complaint as the result of a 2010 Federal Canadian court decision to invalidate, five years before its expiry, a patent it had obtained in Canada. In accordance with generally accepted principles of international law, the courts of the country of grant of a patent enjoy *exclusive* jurisdiction to address issues of invalidation. Eli Lilly, however, wants an arbitral tribunal that will operate outside the Canadian jurisdiction and whose decision would not be appellable before Canadian courts, to award it an economic compensation for the alleged losses caused by the patent invalidation. Eli Lilly claims it has suffered damages of at least 100 million Canadian Dollars.

Patents as an investment

The broad definition of 'investment' typically contained in IAs is the starting point of Eli Lilly's complaint.

NAFTA, as well as BITs and the investment chapters in FTAs, incorporate an all-encompassing concept of "investment" that includes any kind of tangible or intangible asset. All assets of an enterprise, such as movable and immovable property, equity in companies, claims to money, contractual rights, intellectual property rights (IPRs), mining concessions, licenses and similar rights are generally included.

Some IAs generally refer to IPRs, while others explicitly indicate the types of IPR covered, such as copyrights and related rights, patents, rights in plant varieties, industrial designs, rights in semiconductor layout designs, trade secrets, trade and service marks, and trade names. In some IAs reference is also made to "technical process" or "know how" and "goodwill".

NAFTA does not mention explicitly IPRs. However, in accordance with article 1139(g), 'investment' includes 'real estate or other property, tangible or intangible, acquired in the expectation or used for the purpose of

economic benefit or other business purposes'. A patent and other IPRs would fall under the category of 'intangible' property.

In addition to the broad definition of 'investment', a particular feature of IAs is that, unlike in the case of WTO disputes, IAs grant 'investors' the right to directly sue the State where the investment was made. Eli Lilly's decision to sue the Canadian government, thus, follows its own assessment of the pros and cons of engaging in litigation. It would be interesting to know whether the US government would have shared the company's opinion.

The US government was sued under chapter 11 of NAFTA by APOTEX, a Canadian company, which claims that wrong decisions by US courts in applying federal law violate NAFTA Article 1102 (national treatment) and Article 1105 (minimum standard of treatment under international law), and that the decisions amounted to an expropriation of the company's investments under NAFTA Article 1110. The US Department of State has indicated its intention to defend against this claim 'vigorously'.

Data on patent invalidation in the USA show a growing court's tendency to invalidate patent claims. US District courts invalidated patent claims in 86% of the cases they decided in 2007-2011; between 2002 and 2012 the Federal Circuit confirmed 70% of the invalidation decisions by lower courts.

This means that, if Eli Lilly were successful, the USA (as well as other countries parties to IAs) may face an increasing risk of being sued and eventually obligated to pay compensations when their courts invalidate wrongly granted patents. This may be particularly troublesome in the light of the large number of sub-standard patents granted as a result of lax patentability requirements, or the poor quality of the examination conducted by patent offices.

Patent invalidation

Patents are granted by States to achieve certain objectives including, in the case of WTO members, to comply with the obligation imposed by the TRIPS Agreement. They are granted as result of a deliberate policy decision, and not because inventors enjoy a 'natural' right over the invention. Thomas Jefferson, fervent advocate of the patent system, observed, in a famous letter to an inventor in 1813, that inventions 'cannot, in nature, be a subject of property. Society may give an exclusive right to the profits arising from them, as an encouragement to men to pursue ideas which may produce utility, but this may or may not be done, according to the will and convenience of the society, without claim or complaint from anybody'.

A patent is generally granted after an examination by the patent office to establish whether the claimed invention meets the patentability standards (novelty, inventive step and industrial applicability or utility). The decisions to grant a patent are often based on incomplete information, or on incorrect judgments. For instance, a publication that anticipated the invention and, hence, destroys its novelty, may be found after the patent was granted, particularly when competitors affected by the patent undertake detailed patent searches with tools more sophisticated than those available to the patent office.

Given the limitations inherent to examination, a patent only provides a precarious title to the invention. Although patents are generally presumed to be valid, some patent laws clarify that patents are issued without any guarantee by the State. Even the US Federal Trade Commission has alerted against a strong presumption of validity. It noted that "[O]nce an application is filed, the claimed invention is effectively presumed to warrant a patent unless the [US Patent and Trademark Office] PTO can prove otherwise...The PTO's procedures to evaluate patent applications seem inadequate to handle this burden". The report concluded that "[T]hese circumstances suggest that an overly strong presumption of a patent's validity is inappropriate...It does not seem sensible to treat an issued patent as though it had met some higher standard of patentability".

As a result, revocation (by the same patent office) or invalidation of a patent by a court is not something exceptional or that would be unexpected to patent owners. Claiming that invalidation implies a loss of an 'investment' suggests a gross misconception on the fundamentals and operation of the patent system. An invalid patent only has an appearance of validity; a finding of invalidity means that a legitimate right over the invention never existed.

Significantly, article 32 (*Revocation/Forfeiture*) of the TRIPS Agreement left a wide room for Member countries to determine the grounds and conditions for the revocation or forfeiture of a patent, including situations of invalidity. During the negotiations that led to the Agreement, India proposed to establish that a patent could be revoked when 'used in a manner prejudicial to the public interest'. The USA, on its side, wanted to permit revocation only where the invention were found to be non patentable. The adopted text

simply stipulates: 'An opportunity for judicial review of any decision to revoke or forfeit a patent shall be available'.

In the Eli Lilly's case, the Canadian court held that the patented invention had failed to deliver the benefits promised when the application was made. Eli Lilly questions the so-called 'promise doctrine' developed by the Canadian courts, and argues that this new, more stringent approach to patent invalidation applied after 2005, is contrary to the company's expectations "at the time of its investment". The company also argues that the 'promise-doctrine' has become a national standard as a result, for instance, of its recognition in the guidelines issued by the Canadian Intellectual Property Office and, therefore, questions Canada's right to determine how "utility" is defined for the purpose of granting or not a patent. Eli Lilly contends that the questioned judicial practice is not only inconsistent with various obligations provided for in Chapter 11 of NAFTA, but also with the TRIPS Agreement.

However, as noted, the only obligation the TRIPS Agreement imposes in relation to revocation relates to the availability of a judicial review. No substantive conditions are provided for. Further, Members can determine how they define and apply the patentability standards set out in article 27.1 of the Agreement. This is, in fact, one of the most important flexibilities in the TRIPS Agreement: it determines which standards need to be applied to establish patentability, but *does not define* them. Hence, WTO Members can adopt the criteria they consider adequate to implement such standards, including rigorous requirements to prevent the proliferation of patents on minor developments that, as it is the case in pharmaceuticals, may unduly block legitimate competition and increase prices for consumers. Section 3(d) of the Indian Patent Act is one example of how this flexibility can be used. Another one is the set of guidelines for the examination of pharmaceutical patents adopted by the Argentine government in 2012.

The admissibility of Eli Lilly's claims under NAFTA is also doubtful. In accordance with NAFTA article 1110.7, the provision mandating compensation in cases of direct or indirect nationalization or expropriation 'does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights, or to the revocation, limitation or creation of intellectual property rights, to the extent that such issuance, revocation, limitation or creation is consistent with Chapter Seventeen (Intellectual Property)'. This means that, in principle, an investor's compensation cannot be claimed in cases of invalidation of a patent. This is, as noted above, a logical consequence of the nature of the rights conferred. Such a claim could only be made in case of inconsistency with the rules contained in NAFTA Chapter 17.

NAFTA's article 1709.8 stipulates, in this respect, that a Party 'may revoke a patent only when : (a) grounds exist that would have justified a refusal to grant the patent; or (b) the grant of a compulsory license has not remedied the lack of exploitation of the patent'.

The Canadian Federal Court decision regarding the patent for Strattera is based on one of the grounds that would have justified the rejection of the patent application (lack of utility); hence, it seems consistent with paragraph (a) of article 1709.8. It would be difficult for an arbitral tribunal to ignore this provision, even in the light of Eli Lilly's argument that the 'promise doctrine' was not applied prior to 2005 when its alleged 'investment' took place.

Interestingly, the USA Model BIT contains a provision that carves out an exception for compulsory licenses - reflecting the US government interest in protecting its extensive use of these measures - as well as for revocation. Article 6.5. on 'Expropriation and Compensation' stipulates that this provision 'does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the TRIPS Agreement'. The TRIPS Agreement, as noted, does not provide for any substantial standard for revocation; inconsistency could only be found if an opportunity for judicial review were not offered.

Unrealized promises

A large number of developing countries entered into IAs with the promise that the protections conferred to investors will increase FDI and boost their economies. There is no evidence, however, suggesting that such promise has been realized. The Sixth Annual Forum of Developing Country Investment Negotiators concluded, for instance, that 'there was no clear correlation between the number of BITs and FDI, and that there was a need to shift towards a more balanced investment treaty regime that would take into account developing countries' sustainable development objectives'. FDI has primarily flown to countries with large markets and attractive growth prospects. Brazil has opted not to sign any BIT; it has been, however, one of the main recipients of FDI amongst developing countries.

While IAs have not been critical in attracting FDI, they have become platforms for multi-billion compensation complaints. The investors' right to directly sue the host States, in particular, has allowed unprecedented challenges to governmental action. In the view of the implications of BITs and other IAs, Ecuador has decided to denounce all BITs it had entered into. South Africa decided not to sign any new BIT and will attempt to exit from or re-negotiate existing ones. Australia announced that it would not agree on investor-state dispute settlement provisions in new IAs, and India is reviewing its BITS, especially their dispute resolution component.

One of the worrying dimensions of the Eli Lilly's complaint is that it involves matters that the TRIPS Agreement has left to the discretion of the WTO Members. Deciding on which grounds a patent can be invalidated and how the patentability requirements are applied are among the important flexibilities allowed by that Agreement. If Eli Lilly prevailed in this case, investor-state litigation could become a new, possibly more friendly, venue than the WTO dispute settlement mechanism for right-holders to question the interpretation and implementation of the TRIPS Agreement. Although the commented complaint may ultimately fail, its systemic implications may be very significant and would just add one more reason to seriously review the benefits and costs of being a party to or signing new IAs.

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