RETHINKING BILATERAL INVESTMENT TREATIES

CRITICAL ISSUES AND POLICY CHOICES

EDITED BY KAVALJIT SINGH AND BURGHARD ILGE

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First Published in 2016

This book is jointly published by:

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Cover photos: www.123rf.com

Designed by KS Designers, New Delhi.

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ISDS, Intellectual Property Rights and Public Health

Brook K. Baker and Katrina Geddes

Investor-state dispute settlement (ISDS) provisions in bilateral investment treaties and other trade or investment treaties allow foreign investors to challenge, in a secretive tribunal of highly paid lawyers, any government action that interferes with investors' 'legitimate' expectations of profit. The ISDS process, despite lacking the safeguards and transparency of domestic legal systems, has the potential to drastically affect the lives of millions of people, particularly when it affects national intellectual property policies or decisions concerning public health.

Investment treaties and provisions generally protect both investors and their investments, which are often broadly defined to include intellectual property rights. In the health context, three types of claims are generally asserted by investors:[1] (i) that government action has directly or indirectly expropriated the value of their investment; (ii) that the government by its policies or decisions has failed to accord the investor fair and equitable treatment and full protection and security; and (iii) that the government unfairly discriminates in favour of domestic investors compared to foreign investors.[2] The first two types of claims

1. See for example Dearden, R. "Arbitration of Expropriation Disputes between an Investor and the State under the North American Free Trade Agreement," *Journal of World Trade* 1995, Vol. 29, Issue 1, pp. 113-128.
2. Other types of claims include imposition of performance requirements, e.g., local content requirements, and restrictions on capital flows into and out of the country.

are frequently based on an investor's assertion that its legitimate expectations of future profits have been adversely affected. These types of claims can severely deter governments from protecting public health in their policies and practices.[3] Although all such possible claims have not yet been brought, the types of health-related claims that might be asserted are broad indeed: (i) tobacco and fast-food regulation; (ii) product safety, disclosure, and content requirements affecting food and other consumer products and industrial inputs; (iii) environmental and workplace safety rules and decisions; (iv) decisions affecting the registration status of medicines and other health technologies;[4] (v) health product price controls, reimbursement schemes, and placement on therapeutic formularies; and (vi) controls on the advertising of medicines.

A particularly pernicious feature of investment protections arises in the intellectual property arena where ISDS claims might be brought with respect to alleged diminution of expected profits arising from trade secrets, trademarks, patents, and data protections. In the trade secret arena, foreign pharmaceutical companies might oppose government requirements that they disclose 'secret' proprietary information on clinical trials, suspected counterfeiting, or the content of regulatory filings. They might also use trade secret law to argue that trademark protections require countries to adopt data exclusivity and to not rely on previously submitted data to register generic equivalents. In the trademark context, foreign companies might argue, as they already have, that certain packaging and disclosure requirements might dilute

3. See for example: Ethyl-Canada dispute over gasoline additive MMT; Pacific Rim-El Salvador dispute over the contamination of water supplies from a local mine; the Renco Group-Peru dispute over a metal smelter causing Peruvian children to suffer from lead poisoning; and the claim brought by Swedish energy company Vattenfall against Germany for closing its nuclear power plants.
4. One of the first such cases was *Apotex v. United States*, a case dismissed on jurisdictional grounds, which sought damages because the US Food and Drug Administration refused to grant regulatory approval on two imported medicines. *Apotex Inc. v. The Government of the United States of America* (UNCITRAL), Award on Jurisdiction and Admissibility, 14 June 2013. Although the applicant was deemed to be an 'exporter' rather than an investor, there is no guarantee that a similar complaint might not be brought with respect to denials of marketing approvals or regulatory labelling restrictions.

the value of their trademark investments. Finally, in the patent sphere, foreign pharmaceutical companies might raise ISDS challenges to (i) adverse patent decisions and revocations; (ii) granting of compulsory and government-use licenses; (iii) allowance of parallel importation; (iv) adoption of exemptions, limitations, and exceptions affecting medicines; and (v) inadequate enforcement of patents by governments through border measures, anti-counterfeiting rules, and even criminal enforcement.

The threat of legal action has a powerful deterrent effect on governments considering the introduction of pro-public health measures,[5] particularly in low- and middle-income countries that can least afford expensive and protracted litigation.[6] The deterrent effect is significant given the readiness with which investors launch such disputes, their relatively high success rate, and the costs involved in defending the dispute. In 2012 alone, 58 new cases were initiated, representing the highest number of known treaty-based disputes ever filed in one year.[7] In 70% of the public decisions addressing the merits of the dispute, investors' claims were accepted, at least in part.[8] The costs associated with defending these disputes can reach astronomical heights as arbitrators are paid $600-700 per hour, with little incentive to expedite matters.[9] The highest known award of damages in the history of investment treaty arbitration featured in the 2012 case of *Occidental v. Ecuador II* where the investor was awarded US$1.77 billion plus pre- and post-award compound interest.[10] The *Occidental* award demonstrates

5. Gleeson, D. & Friel, S. "Emerging threats to public health from regional trade agreements," *The Lancet* 2013, available at http://www.nzcphm.org.nz/media/61306/emerging_threats_to_public_health_from_regional_trade_agreements_-_gleeson_friel_-_lancet_2013__2_.pdf.
6. Ibid.
7. UNCTAD, "Recent developments in investor-state dispute settlement," IIA Issues Note, May 2013, available at http://unctad.org/en/PublicationsLibrary/webdiaepcb2013d3_en.pdf.
8. Ibid.
9. *The Economist*, "The arbitration game," 11 October 2014, from the print edition, available online at http://www.economist.com/news/finance-and-economics/21623756-governments-are-souring-treaties-protect-foreign-investors-arbitration.
10. Above, n 3.

the power of arbitration tribunals to radically alter the wealth of shareholders as well as the well-being of respondent citizens.

What has developed into a lucrative business of raiding government treasuries has had a chilling effect on the introduction and implementation of pro-public health measures worldwide. In Australia, for instance, the introduction of plain packaging laws to reduce the use of tobacco products triggered a trademark-related legal action by a multinational tobacco corporation. In 2011, Philip Morris Asia (PMA), a subsidiary of Philip Morris International (PMI), launched an investor-state dispute against the Australian government through an ISDS clause in a bilateral investment treaty signed between Australia and Hong Kong in the early 1990s. This is the second investor-state dispute to arise over tobacco labelling; PMI is bringing a similar case against Uruguay through a Swiss subsidiary.[11]

PMA argues that Australia's plain packaging measure: (a) constitutes an expropriation of its Australian trademark-related investments in breach of Article 6 of the Hong Kong Agreement (HKA); (b) is in breach of its commitment under Article 2(2) of the HKA to accord fair and equitable treatment to PMA's investments; and (c) constitutes an unreasonable and discriminatory measure, depriving PMA's investments of full protection and security in breach of Article 2(2) of the HKA.[12]

Australia rejects these claims. It argues that "plain packaging legislation forms part of a comprehensive government strategy to reduce smoking rates in Australia. This strategy is designed to address one of the leading causes of preventable death and disease in Australia, which kills around 15,000 Australians each year, causes chronic disease for many others and is a significant burden both on productivity and on Australia's health care system. The implementation of these measures is a legitimate exercise of the Australian Government's regulatory powers to protect

11. Gleeson, D. et al. "Challenges to Australia's national health policy from trade and investment agreements," *MJA Online*, 29 February 2012.
12. Attorney-General's Department, Australian government, "Tobacco plain packaging – investor-state arbitration," Summary of arbitration, available at: http://www.ag.gov.au/tobaccoplainpackaging.

the health of its citizens."[13] PMI's blanket disregard for Australia's public health prerogative raises concerns that other corporations could bring similar investor-state disputes against national governments for food nutrition or GM food labelling laws that prioritise public health over corporate profits.

The slow creep of corporate tentacles into the intellectual property policy sphere has even reached a nation's sovereign right to set and enforce its own patent policy. US-based Eli Lilly is suing the Canadian government for invalidating its patents for two drugs, Strattera and Zyprexa, for want of utility. It brings the suit under Chapter 11 of the North American Free Trade Agreement (NAFTA), claiming that Canadian patent law contravenes both the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and NAFTA by imposing "onerous and additional utility requirements that have had the effect of denying patent rights for inventions which meet the conditions precedent to patentability" embodied in international agreements.[14] Eli Lilly claims that Canadian patent law not only contravenes its treaty obligations but also is "discriminatory, arbitrary, unpredictable and remarkably subjective." It claims, inter alia, that the invalidation of both patents constitutes an "expropriation" of "intangible property acquired in the expectation or used for the purposes of economic benefit."[15]

Canada has defended its position by arguing, *inter alia*, that court decisions invalidating a patent do not amount to the expropriation of property but to the determination of whether property rights exist at all.[16] It argues that judicial decisions concerning the existence of rights under domestic law are not subject to review by international investment tribunals save in the extraordinary circumstance of gross procedural

13. Australia's Response to the Notice of Arbitration, 21 December 2011, available at: http://www.ag.gov.au/Internationalrelations/InternationalLaw/Documents/Australias%20Response%20to%20the%20Notice%20of%20Arbitration%2021%20December%202011.pdf.
14. *Eli Lilly and Company v. The Government of Canada*, Notice of Intent to Submit a Claim to Arbitration Under NAFTA Chapter Eleven, 7 November 7, 2012, available at: http://italaw.com/sites/default/files/case-documents/italaw1172.pdf.
15. Ibid.
16. *Eli Lilly and Company v. Government of Canada*, Statement of Defence, 30 June 30, 2014, available at: http://italaw.com/sites/default/files/case-documents/italaw3253.pdf.

misconduct amounting to a denial of justice or the bad faith exercise of decision-making power to mask a violation of international law – neither of which is alleged here. In defence of its particular system of patent examination, Canada argues that, given the high social and economic costs associated with granting patent-owners a monopoly on their invention, "a patent cannot be granted or its validity confirmed lightly."[17] Canada denies any breach of its international treaty obligations.

Eli Lilly's investor-state dispute marks the first attempt by a pharmaceutical company to use investor-state privileges to appeal against unsuccessful outcomes at the domestic judicial level.[18] It also represents an unprecedented attack on national sovereignty over public health policy – a reserved power of sovereignty on which the US has consistently relied. Professor Reichman summarizes the situation in the following words:

> "The hard truth that Big Pharma cannot swallow is that U.S. patent law did not become global law under TRIPS, and that the United States cannot prescribe universal patent standards for the rest of the world any more than France could prescribe uniform patent law in 1883, when the Paris Convention was first adopted ... Instead, under both TRIPS and NAFTA there is built-in flexibility to implement patent eligibility standards in each WTO member's domestic laws so as to advance states' own technological and economic development needs. No huffing and puffing about investment treaties will change these facts of life under international law as currently adopted."[19]

17. Ibid.
18. Brook K. Baker, Threat of Pharmaceutical-Related IP Investment Rights in the Trans-Pacific Partnership Agreement: An Eli-Lilly v. Canada Case Study, *Investment Treaty News*, 30 September 30, 2013, available at http://www.iisd.org/itn/2013/09/20/threat-of-pharmaceutical-related-ip-investment-rights-in-the-trans-pacific-partnership-agreement-an-eli-lilly-v-canada-case-study/.
19. Reichman, J. "Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection," 2014, Proceedings of the 108th Annual Meeting of the American Society of International Law, available at: http://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=6067&context=faculty_scholarship&sei-redir=1&referer=https%3A%2F%2Fscholar.google.com%2Fscholar%3Fq%3D%2522eli%2Blilly%2522%2Bcanada%2Bstrattera%2Bpatent%26btnG%3D%26hl%3Den%26as_sdt%3D0%252C22#search=%22eli%20lilly%20canada%20strattera%20patent%22

There is concern that the Eli Lilly case will encourage other pharmaceutical companies to resort to investor-state arbitration to remedy lost expectations of profit arising out of government measures to improve public health, such as issuing compulsory licences, controlling the price of medicines, and requiring disclosure of clinical trial data. The pharmaceutical industry has strong economic interests in expanding its intellectual property (IP) protections in so-called 'pharmerging' countries where the bulk of its earnings growth is likely to occur.[20]

Despite the rhetorical support of the 2001 Doha Declaration, developing countries may be reluctant to issue compulsory licences for much-needed medication due to the threat of investor-state arbitration. The issuance of a compulsory licence, while TRIPS-compliant, may be viewed as an indirect expropriation of intellectual property in violation of an international investment treaty.[21] In 2007, for example, Brazil's decision to issue a compulsory licence on the patented anti-HIV drug Efavirenz prompted a hostile statement from Merck & Co. characterizing the Brazilian government's move as an expropriation of its property.[22] Christopher Gibson argues, however, that if a national government is able to demonstrate elements such as the non-exclusive nature of the licence, its limited scope and duration, limited use by any third parties for domestic market purposes only, and adequate remuneration, it may be able to present a solid defence against the investor's claims.[23] In the Philippines case of *Smith Kline and French Laboratories Ltd*, for instance, the issue of a compulsory licence to manufacture GlaxoSmithKline's medicine Cimetidine was successfully defended as a valid exercise of state power with just compensation (a royalty of 2.5% of the net wholesale price).[24]

20. IMS Institute for Health Informatics, Global Outlook for Medicines Through 2018, November 2014.
21. Gibson, C. "A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation," *American University International Law Review*, 2010, Vol. 25, Issue 3.
22. Ibid.
23. Ibid.
24. Vadi, V. "Access to Essential Medicines & International Investment Law – The Road Ahead," *The Journal of World Investment & Trade*, 2007, Vol. 8, pp. 505-531.

Like compulsory licensing, the disclosure of clinical trial data may also be deterred by the threat of investor-state disputes launched by foreign pharmaceutical companies. In November 2010, the European Medicines Agency (EMA) adopted a policy of greater transparency in clinical trial data, triggering the release of nearly two million pages of data. In 2013, however, two US drug companies, AbbVie and InterMune, obtained an interim injunction against EMA preventing the release of "commercially sensitive" information and EMA stopped releasing trial data for fear of further legal action from other pharmaceutical companies.[25] Jerome Reichman argues that clinical trial data, as a guarantor of public safety, should be regarded as a public good instead of a second revenue stream for pharmaceutical companies with a *sui generis* data exclusivity right.[26]

Plain packaging legislation, patent invalidations, compulsory licensing and the disclosure of clinical trial data represent only a few of the infinite means by which governments attempting to improve public health may be stymied by pharmaceutical litigation. As long as intellectual property continues to fall within the definition of 'investment' in international investment treaties, any pro-public health measure implemented by national governments may be viewed as an interference with foreign pharmaceutical investments, spurring expensive and protracted arbitration.

Henning Grosse Ruse-Khan believes that IP right holders who pursue this path are unlikely to be successful. He argues that IP rights such as patents cannot reasonably be regarded as absolute rights, untouchable by the state that issued them in the first place. On the contrary, states are entitled and expected to impose reasonable limitations on the use of those rights within the host state.[27] Measures supported by the pub-

25. Dyer, C. "European drug agency's attempts to improve transparency stalled by legal action from two US drug companies," *BMJ* 2013, 346: f3588.
26. Reichman, J. "Rethinking the role of clinical trial data in international intellectual property law: The case for a public goods approach," *Marquette Intellectual Property Law Review*, 2009; 13(1).
27. Ruse-Khan, H.G. "Litigating Intellectual Property Rights in Investor-State Arbitration: From Plain Packaging to Patent Revocation," Fourth Biennial Global Conference of the Society of International Economic Law (SIEL) Working Paper No. 2014-21, July 2014, available at : http://papers.ssrn.com/sol3/Papers.cfm?abstract_id=2463711.

lic health flexibilities in TRIPS are internationally accepted elements of the IP system. Compulsory licences, for example, were recognised in the Doha Declaration as a legitimate policy tool to improve access to medicines. Other forms of limitations to IP rights – such as parallel imports or higher standards of patentability – are equally legitimate exercises of the flexibility inherent within TRIPS. Ruse-Khan summarises his position as follows:

> "In all cases, the grant of the patent certainly does not and cannot create any legitimate expectation that the exclusivity it confers is absolute and will remain without interference from accepted checks and balances inherent in the IP system. Instead, the expectations of the patent holding investor are a priori limited by the regulatory tools the domestic IP law of the host state foresees. Even in case a host state newly introduces such tools, or changes its policy of using existing ones after the investor has obtained his patent, the general acceptance and widespread state practice vis-à-vis these measures would strongly side against findings of interference with legitimate expectations. In Eli Lilly v.. Canada, the investor hence cannot legitimately expect from the grant of patents by the Canadian Patent Office (CPO) that those remain free from any validity challenges in the courts. Also a change in how the Canadian courts apply patentability standards such as utility or the disclosure obligation as such does not affect legitimate investor expectations: No expectation for a stable and predictable business environment can go so far that the circumstances prevailing at the time the investment is made must remain unchanged. Any resort to familiar and commonly used mechanisms to limit IP exclusivity ... should never be considered as a breach of [fair and equitable treatment standards]."[28]

Furthermore, Ruse-Khan argues that the negative, rather than positive, character of IP rights – which allow the right holder to prevent others from utilizing the protected subject matter but do not confer a positive right to exploit – naturally means that the government may impose further limitations on the use of the protected subject matter, in the form of regulatory controls.[29] The World Trade Organiza-

28. Ibid.

tion (WTO) Panel in EC-Geographical Indications confirmed, "The TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement."[30] As Ruse-Khan concludes:

> "The negative right to exclude others from exploiting IP-protected subject matter does not entail a guarantee against state intervention which imposes conditions upon the production or limits the use and sale of the patented product. For example, the introduction of price controls for a certain patented medication does not interfere with the patent for that medicine. Since such a measure is outside the protection IP rights confer, these rights cannot create legitimate expectations as to the (continued) absence of such measures."[31]

Ruse-Khan's analysis offers a hopeful outlook on potential future disputes over patent invalidations, price controls or other government measures that may thwart pharmaceutical expectations of profit. The negative nature of IP rights should enable a sovereign state to introduce reasonable limits on the exercise or scope of those rights in the interests of public health. The outcome of ongoing disputes such as Eli Lilly-Canada and PMA-Australia will determine whether these arguments are accepted.

29. Ibid.
30. *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R, Report of the Panel, 15 March 2005, at para 7.210, available at : https://www.wto.org/english/tratop_e/dispu_e/174r_e.pdf.
31. Ruse-Khan, op.cit.

The ability of ISDS provisions to distort national intellectual property policy away from the public interest and users' rights in favour of transnational corporate interests intensifies the urgency of campaigns for ISDS provisions to be removed from the Trans-Pacific Partnership Agreement (TTP) and the Transatlantic Trade and Investment Partnership (TTIP). A private, unelected tribunal of three lawyers should not have the power to sanction a sovereign state for introducing democratically enacted pro-public health policies. Equally, foreign investors should not enjoy greater legal rights than citizens of a state by virtue of their ability to bring treaty claims against government measures, which domestic citizens cannot challenge. There must be recognition that not all areas of social life should be open to the market, and these must be defined with a clear rationale.[32]

32. Crouch, C. "Democracy at a TTIP'ing point," *Juncture*, 2014, Vol. 21, Issue 3, available at: http://onlinelibrary.wiley.com.ezp-prod1.hul.harvard.edu/doi/10.1111/j.2050-5876.2014.00802.x/epdf.