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Should India Adopt ISDS for IP Disputes? Re-Evaluating the Model BIT from IP and Public Health Perspective

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International investment agreements ("IIAs") are increasingly incorporating intellectual property ("IP") into the scope of 'investment', which has substantial implications for public health, particularly in developing economies such as India. In the budget speech of 2025, the Finance Minister of India, Smt. Nirmala Sitharaman stressed upon revising the Model Bilateral Investment Treaty of India to draw more foreign direct investment ("FDI"). Simultaneously, the government of India is also apprehensive over Investor-State Dispute Settlement ("ISDS") processes being utilised to contest legislations enacted for the public interest. In the past, pharmaceutical or biotech firms have challenged host-state regulations through the use of investment protections in ISDS cases, which are discussed in the paper in some detail. As a capital-importing nation, India needs to prioritise attracting FDI while simultaneously, safeguarding public health of its citizens. This article analyses the changing investment environment in India and investigates the potential effects of forthcoming Bilateral Investment Treaty ("BIT") reforms on the regulation of IP as an investment, while preserving the autonomy of public health policy laws. It concludes by proposing that India may adopt the ISDS mechanism in its BITs, as it cultivates investor confidence, attracts additional FDI, and bolsters India's credibility in the global investment arena.

Keywords: Intellectual Property, Bilateral Investment Treaty, International Investment Agreements, Investor-State Dispute Settlement, Public Health, Foreign Direct Investment

Rethinking India's Model BIT

In the budget speech on February 1st, 2025, the Indian Finance Minister Smt. Nirmala Sitharaman, announced that the current Model BIT will be updated and made more investor-friendly to draw more foreign investment, in keeping with the idea of *first develop India*.[1] She has also mentioned that the government has only signed two BITs in the year 2024.[1] Notably, with United Arab Emirates and Uzbekistan,[2] a figure considerably low for a country looking to enhance its FDI inflow. This is especially alarming because the net FDI falls to a twelve year low in April-October 2024.[3] As India works to address its economic issues and attracting more FDI, it must also successfully manage the complexities of investment protection. One significant issue in this context is the recourse taken by corporations and investors to use ISDS to contest government policies, including those related to public interest laws and environmental regulations.

The Finance Minister has appropriately observed that the foreign corporations have utilised ISDS mechanisms in order to challenge government policies, environmental regulations, and laws that safeguard the public interest.[4] This trend is especially noteworthy when it comes to IP-based investments, as foreign investors may use ISDS mechanism to challenge domestic laws pertaining to intellectual property, compulsory licensing, or public health initiatives that impact their exclusive rights. A growing number of foreign investors are filing claims against host states, asserting that State actions are impacting their IP-based protected investments, even though such state actions were enacted to safeguard public health or to serve the public interest, a problem that will be elaborated upon in subsequent portions of the paper.

Christophe Geiger (2023) advocates for exclusion of IP from investments from future BITs and other investment treaties, in order to make sure that the states continue to maintain their authority to regulate.[5] Dreyfuss and Frankel (2018) have proposed a narrow understanding of IP as an investment to make ISDS procedures only available under very strict conditions.[6] This is largely because stringent enforcement of IP protections through IIAs may attract FDI inflow, but it also poses a risk to

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the affordability and accessibility of important pharmaceuticals for India's population. While existing literature examines the risks of ISDS in IP-related disputes, there is little research on how India, as both a capital importer and exporter, can design a BIT framework that balances regulatory sovereignty with investor protection.

India is regarded as the foremost exporter of generic pharmaceuticals, possessing a substantial proportion of the worldwide generic medication industry by volume.[7] India is recognised as the "pharmacy of the world" for its capacity to offer affordable and accessible drugs to people across numerous countries.[8] The Indian pharmaceutical industry is a prominent participant in the global healthcare sector due to its innovative research and development ("R&D") and high-quality standards.[8] Nevertheless, it is important to acknowledge that mere export of generic drugs do not qualify as FDI, as FDI typically entails a long-term commercial commitment in the host country, such as the establishment of production facilities, the acquisition of assets, or the generation of employment.

India's reputation as a capital exporter is expected to continue to enhance while it persists in augmenting its footprint in the global market. Therefore, it is imperative that India acknowledges ISDS mechanism, as the country is in the process of negotiating its BIT framework. Although robust public health exceptions have the potential to maintain regulatory autonomy, they may simultaneously restrict protections for Indian investors investing outside of India. Indian companies investing abroad are less protected under a BIT model that prioritises the host state's regulatory authority over home state investors.[9] The most recent World Intellectual Property Indicators (WIPI) report, released in November 2024, indicates that India experienced a 15.7% increase in patent applications in 2023, marking its sixth consecutive year of double-digit growth.[10] India, with 64,487 patent applications, ranks sixth internationally, showcasing robust innovation, especially in the pharmaceutical and medical technology sectors, which constituted 15% of total filings and placed second only to computer technology in patent volume.[10] While strong public health exceptions preserve India's regulatory space, they may have unintended consequences, such as discouraging FDIs and an impact on Indian private investors looking to grow abroad, as these exceptions might limit their capacity to compete in international markets. Incorporating investor-friendly provisions in BITs would help Indian enterprises secure equitable conditions and foster a more favourable investment climate. The pharmaceutical industry, which is critical to global markets, stands to benefit the most from a well-balanced BIT that includes reciprocal protections.

This present work is structured into five sections. The Paper's section II traces the evolution of IP into a protected investment, providing a brief background on how IP has been evolving through the centuries. Section III explores how the reconceptualization of IP as an investment subjects it to procedural safeguards typically granted to investments, thereby enabling IP holders access investor-state arbitration mechanism to resolve disputes. The section IV discusses the implications of such arrangement, highlighting both its challenges and benefits. Section V analyses India's approach to the BIT framework, assessing how the country has navigated the goal of attracting foreign investments and safeguarding public health priorities. Finally, the 'Conclusion' proposes critical reforms, underscoring the necessity for India to integrate ISDS into its BITs in order to effectively address emerging investment challenges.

Redefining IP: From Privileges to Protected Investments

Over the centuries, the concept of IP has undergone profound transformation. This transformation is critical for understanding how intellectual property became recognised as an investment in modern international law. IP was originally intended to be a state-granted economic instrument to promote the introduction of useful skills and techniques rather than an inherent right of inventors.[11] In the 14th century, patents and other forms of IP, used to be awarded to people who could bring a valuable art or technique to a particular area or who promised financial gain rather than incentivising the inventor or creator.[11] In Venice, payments were made from a special privilege fund to *Bartolomeo Verde*, in 1332, who had pledged to build a windmill in Venice.[11] The type of mill was not necessarily invented by Verde, he was, in all likelihood, the only one who knew how to construct them, and the government wanted to disseminate and advance this information.[11] In the fifteenth century, similar payments were frequently given to individuals who claimed to be knowledgeable about millwork systems, ship types etc. as a recognition; along with, rights or license to manufacture, market, or use the invention, referred to as privileges.[11] As these systems proved beneficial, they spread to other European states like France and England; and privileges were given to anyone who brought new technology or skills, like, *Etienne Turquetti*, in France was given a privilege in 1536 for producing silk and was considered as the "inventor" of the art, although, it's unclear if he created it himself or imported it from another country.[11] These privileges or initial monopoly patents were conferred by the state, and were far from being considered as the intrinsic rights of the 'creator'.[11] The idea that IP is an inherent right of the creator was influenced by the French Revolution and the political climate of the 18th century.[11] Numerous state copyright acts from the 1780s featured preambles underscoring that authors should be guaranteed the income derived from the sale of their creations, asserting that the result of one's labour belongs to oneself.[11]

This transition was institutionalised by international treaties such as the Paris Convention for the Protection of Industrial Property (1883) and the Berne Convention for the Protection of Literary and Artistic Works (1886), which established the foundation for current IP law.[12] The principal rationale for IP protection is to stimulate innovation and creativity while safeguarding creators against counterfeiters, who can negatively impact prices, impede cost recovery, and diminish profits.[13] In modern times, World Intellectual Property Organization ("WIPO") played a central role in international IP lawmaking. The Paris[14] and Berne[15] Conventions under the WIPO laid down minimal standards of protection, such as 'national treatment' obligating member states to extend protection under domestic IP law to foreigners but leaves the countries to define the scope of protection, restrictions and exceptions within domestic legislation.[16] The Paris Convention does not define what constitutes a patentable invention, does not specify the type of signs that are eligible for trademark registration or the duration of protection of various IP rights, leaving these matters largely at the discretion of member states.[16] It aimed to balance a level of exclusivity required to promote innovation while accommodating public access to knowledge and creativity.[16] The WIPO, however, lacked an efficient enforcement mechanism to guarantee compliance by member states which is identified as one of the causes for the transition of the forum from the WIPO to the World Trade Organisation ("WTO") during the Uruguay Round of Negotiations.[17]

IP gained increasing relevance after World War II as trade expanded, aided by the international regime established by the General Agreement on Tariffs and Trade ("GATT") in 1947.[16] Intellectual property acquired global economic significance, while the WIPO lagged behind in adapting to globalisation and the evolving dynamics of IP in international trade.[18] Consequently, IP started transforming into a "commodity" for the purpose of promoting trade, under the aegis of WTO.[16] The Trade-Related Aspects of Intellectual Property Rights ("TRIPS") Agreement,[19] adopted in 1995 under the WTO framework, marks a watershed moment in the development of IP. TRIPS developed a structured, standardised system, supported by the Dispute Settlement Understanding ("DSU") of the WTO, that facilitated resolution of disputes.[20] As a result of which, higher emphasis has been placed on the enforcement of IP rights, which were recast as "rights" that are legally enforceable rather than only being policy objectives.[16] This is in clear contrast to the earlier stand taken by the WIPO Agreements which had a more voluntary character.[16]

The conceptualisation of IP in international law has undergone substantial evolution, transitioning from financial and economic advantage to an incentive-based framework, to one that regards IP as a tradeable commodity and, in more recent times, as an investment.[16] As intellectual property emerged as a pivotal element in the proliferation of global trade and economic development, legal status of IP transformed further as a form of investment and protection expanded beyond domestic laws into IIAs, particularly BITs.[16] BITs are treaties between two nations that intend to safeguard investments made by investors from both nations.[21] In 1959, for the first time, the definition of the term "investment" explicitly covered IP rights under Article 8(1)(a) of the BIT signed between Germany and Pakistan.[22] Additionally, it was the first contemporary BIT to be signed, marking a crucial juncture in the development of international investment law.[21] Since the conclusion of this BIT, a series of developments have taken place in the domain of international investment law and Intellectual Property. The definition clause of various Model BITs and IIAs have increasingly included IP rights within the definition of the term "investment", in various forms.[23] This inclusion indicates the growing acknowledgement of intellectual property as a valuable investment that must be protected.[23] As innovation and technology continue to power global economies, protecting intellectual property rights has become critical to attracting international investment.[23] Consequently, the expansion of international investment law to explicitly include IP rights has been a vital step in addressing the shifting contours of international investment law.[6]

While this advancement improves IP protection, accelerates technology-driven investments, and promotes global innovation, it also creates new obstacles.[16] The designation of IP as an investment exposes it to investor-state dispute settlement mechanisms, possibly reducing national regulatory autonomy, particularly in sectors like public health.[6] Furthermore, it raises questions concerning the extent to which private rights should be prioritised over public policy goals.[6] As nations want to attract FDI, they need to achieve a challenging equilibrium between augmenting intellectual property rights and preserving their sovereign capacity to regulate for the public good. The subsequent sections will investigate these implications, with a particular emphasis on regulatory flexibility, investment protection, and dispute resolution.

Investor Protection and IP Enforcement: Expanding role of Investment Arbitration

Expanding on the idea that IP is a protected investment under BITs, this section delves into the legal consequences of this categorisation, focussing on the substantive and procedural safeguards that IP owners enjoy. Incorporating IP into the definition of 'investment' subjects IP to the extensive substantive protections to foreign investors under BITs, including Most-Favoured Nation ("MFN") treatment, National Treatment ("NT"), and safeguards against expropriation, among others.[23] Also, the procedural safeguards give IP holders access to an investor-state arbitration mechanism to resolve disputes, a potent method of settling investment related disputes.[24] The host nation may incur international responsibility to the foreign investors if it fails to safeguard their intellectual property in violation of a relevant BIT-related international commitment.[29] Thus, the incorporation of IP within the scope of investments has opened gates for the foreign investors to enforce IP in an additional forum through investor-state arbitration tribunals.[29]

Traditional dispute resolution processes, such as diplomatic protection or the expiration of local remedies, frequently proved insufficient for investors.[21] Foreign investors were reliant on the diplomatic protection offered by their home states and lacked direct access to international remedies against host states.[21] The diplomatic protection heavily relied on the discretion of the government of the home state, leaving very little control in the hands of the investors, over the claims being pursued.[21] Additionally, other approaches like exhaustion of local remedies, obliged the investors to resolve disputes in the domestic courts of the host state, causing major worries among investors regarding the lack of impartiality that exists in the domestic courts of the host states.[21] These limitations highlighted the need for an alternative mechanism that could provide independent, enforceable, and investor-controlled avenues for dispute resolution, which led to the introduction of the ISDS mechanism.

The ISDS mechanism available in an investment treaty, granted foreign investors the ability to directly seek resolution of investment related issues through an international tribunal.[25] It enabled investors to pursue remedies against the host state if the substantive elements of the IIAs are not upheld by the host state.[21] Consequently, investors can protect their interests against the host state without resorting to diplomatic protection or local remedies.[24] The ISDS mechanism is the greatest advantage provided to the investors that has also been the most controversial aspect of IIAs.[26] As far as the intersection of IP and investment is concerned, there exists sufficient apprehension regarding ISDS as an additional forum of IP enforcement.[27] Prominent academicians have cautioned that this mechanism may be abused because investment arbitration may prioritise private interests over the general welfare.[24]

The ISDS mechanism is primarily designed to safeguard the interests of the investors.[21] Applying this mechanism to IP related disputes, creates an additional layer of judicial review, one in which investors rights take precedence.[27] The ISDS system may not adequately weigh IP related concerns, considering foreign investors use the forum to achieve outcomes that are likely to be more favourable to them.[27] Decisions of the Investor-State Arbitral Tribunals have the potential for creating new dynamics of lawmaking and enforcement which will invariably have an impact on the other forums where IP rights are traditionally protected and enforced; and, there is no way to establish hierarchy between them in order to avoid any conflict that may arise.[27] The potential impact of ISDS on traditional IP enforcement mechanisms is a cause for concern, as it allows IP holders to seek compensation for state regulatory actions, even when such actions are consistent with WTO/TRIPS provisions.[27] The following sections of the paper delves deeply into these tensions, particularly when ISDS mechanism is used to challenge public interest regulations.

IIAs may also list more than one dispute resolution forum for an investor to approach which raises the problem of Investors raising multiple claims in numerous forums causing the host states to bear massive litigation costs.[26] Investors may have access to domestic courts of the host state, arbitration governed by the rules of International Centre for Settlement of Investment Disputes ("ICSID"), ad hoc arbitration pursuant to UNCITRAL Arbitration Rules, or institutional arbitration through entities such as the International Chamber of Commerce ("ICC") or the Stockholm Chamber of Commerce ("SCC").[30] It is contended that enforcement of IP through ISDS marks a departure from the multilateral IP framework represented by TRIPS to a more fragmented bilateral system.[27] TRIPS Agreement is the sole international agreement that contains such thorough provisions on the enforcement of IP.[28] This departure can give rise to a variety of challenges. Any attempt to enforce IP through ISDS mechanism may have the potential to enforce stricter norms of IP, undermining the flexibilities established within the TRIPS Agreement.[29] To illustrate the point, foreign investors may see compulsory licensing, a major TRIPS flexibility for public health and access to pharmaceuticals, as "indirect expropriation" because it reduces the economic value of patent investments.[29] Additionally, the ISDS functions on a bilateral basis, while the TRIPS Agreement functions within a multilateral framework within the framework of WTO dispute settlement procedures, which may lead to disparities in the way intellectual property rights are enforced.[27] It is because of this that concerns have been raised regarding forum shopping and the possibility that investors could obtain more favourable rulings through investment arbitration than they would under the TRIPS Agreement.[30] Investor-State dispute settlements, especially those facilitated by the ICSID, are predominantly influenced by prominent, elite private attorneys or legal scholars from Europe and the United States.[27] They possess greater expertise in the private and commercial law-focused investor-state arbitration framework than the public law-centric WTO dispute resolution system.[27]

However, contrary to the apprehensions, the arbitral decisions in a majority of the decisions, except a few,[31] have been found to favour the host states' public interest initiatives, ruling against investors.[32] It is the exorbitant litigation costs that has the potential to deter states from enacting public interest policies related to IP, even if successfully defended by the respondent State.[6] This is especially concerning in sectors such as public health, where nations require the policy space to utilise the TRIPS compliant flexibilities to modify their IP standards to tackle emerging difficulties.[29] It may create a significant *"regulatory chill"* that discourages states from enacting legitimate measures in the public interest.[6] Thus, while ISDS gives a channel for IP holders to challenge state initiatives, its potential to dissuade states from pursuing vital public health and innovation policies highlights the need for a delicately balanced approach in drafting BITs.

ISDS and IP-Based Investments: Safeguarding Rights or Restricting Public Policy?

There have been a substantial number of ISDS disputes that have been initiated against both developed and developing countries that are directly tied to public health.[33] A growing number of foreign investors are filing claims against host states, asserting that State actions are impacting their IP-based protected investments, even though such state actions were enacted to safeguard public health or to serve the public interest.[27] IIAs can potentially impact fundamental public interest by restricting the regulatory autonomy of State, particularly in matters of public health.[24] To cite just one example, in 2012, Australia became the first nation to pass legislation that mandated the use of plain packaging for tobacco products.[32] Since then, a number of countries adopted similar legislations, in line with World Health Organization ("WHO") Framework Convention on Tobacco Control ("FCTC"), in order to promote public health.[34] The Convention encouraged standard packaging with limited brand and promotional images on tobacco products to trim down their appeal, eliminate tobacco packaging as advertising, and increase health warning visibility and efficacy.[35] These developments were not appreciated by the tobacco industry.[36] Philip Morris made the decision to initiate international arbitration proceedings against Australia and Uruguay, two nations that had placed tight restrictions on tobacco packaging.[37,38] Philip Morris Asia Limited, in the matter of *Philip Morris* v *Australia*, contended that the Plain Packaging Act, 2011, passed by Australia violated the IP rights of the investor leading to an indirect expropriation that significantly diminished the value of its investments in the host state, Australia.[37] The Tribunal decided that the investor modified its organisational structure with the explicit objective of initiating investment arbitration proceedings, hence the claim failed at the jurisdictional level.[37]

Likewise, Uruguay had passed an Ordinance mandating ‘single presentation’ for each cigarette brand and prohibited use of ‘variants’ for cigarette packaging sold under a specific brand; and also enacted a Decree to enlarge the statutory health warnings on tobacco packaging from fifty percent to eighty percent, thereby allocating only a miniscule twenty percent of the package for branding purposes.[36] Philip Morris Brand Sàrl argued in the *Philip Morris* v *Uruguay* dispute that the host State’s actions breached the expropriation and Fair and Equitable Treatment (“FET”) standards regarding the use of trademarks.[38] The claims were rejected by the tribunal, which determined that expropriation is not the result of a partial loss and that indirect expropriation does not occur if there is enough value left after the contested measures are put into place.[38] Regarding the FET issue, a majority of the Tribunal determined that the claimant’s reasonable expectations were not violated.[38] The tribunal further declared that the measures in question were a permissible application of the State’s police power and Uruguay’s commitments under the FCTC to safeguard human rights and health.[38] These battles demonstrate that government regulations pertaining to health are subject to challenge, in arbitral proceedings and this trend is expected to continue.

In the past, IIAs didn’t explicitly include provisions for public interest regulatory measures, especially those that protect public health.[33] There are over three thousand IIAs that are currently in effect, and the majority of these are older IIAs that lack provisions regarding public health, contrasting subsequent IIAs, executed after 2012, which feature public health provisions.[33] Such public health provisions in BITs serve two main purposes: first, to protect states’ authority to regulate public health; and second, to guarantee that investment agendas do not undermine public health; only miniscule percentage of IIAs incorporate health provisions in pursuit of advancing public health.[39] On the one hand, the reference to health-related provisions are gradually increasing in IIAs and on the other hand, disputes involving Trademarks and Patents are also appearing before investment tribunals.

States possess an intrinsic authority to regulate, especially public health and from a pragmatic standpoint, states are more adept at understanding the demands of local populations.[24] Consequently, international treaties safeguarding diverse facets of intellectual property recognise the state’s authority and commitment to uphold public health, as specified in Article 8 of the TRIPS Agreement.[40] Patent holders are progressively utilising investor-state arbitration to contest regulatory actions enacted by host nations, and such arbitrations substantially affect state regulatory independence.[24] Given the recent increase in the number of arbitrations, it is imperative to consider the potential implications of this emerging jurisprudence on the regulatory autonomy of the host nations, implementing public health policies, as envisaged by the Finance Minister of India.

While ISDS has frequently been criticised for favouring multinational firms, it has also been used by generic manufacturers to ensure fair market access and to challenge protectionist policies. Cases involving generic manufacturers illustrate that ISDS mechanism can be used to secure fair market access and oppose protectionist practices in host countries. ISDS provides investors with a robust mechanism to uphold their rights under investment treaties, guaranteeing the fulfilment of obligations by host states. ISDS enables private investors to initiate claims against state actions that breaches investment treaties, ensuring that their rights are upheld under international law. It reduces the risks associated with political instability, abrupt policy changes, and discriminatory state actions that could harm foreign investments. Several cases have demonstrated how ISDS has successfully compensated investors for losses caused by state actions, highlighting the importance of protecting private investments and ensuring legal predictability.

For instance, in the matter of *Les Laboratoires Servier* v *Poland*, Poland updated its pharmaceutical laws to conform to EU standards as part of its EU accession process and as part of one of these EU harmonisation measures it made marketing authorisation renewal necessary for medicines intended for sale in Poland.[41] For unexplained reasons, the Polish health officials denied renewal of marketing authorisation for two of the generics manufactured by the claimants, French pharmaceutical firms, but Polish businesses were given permission to manufacture commercial substitutes for these medications.[41] The claimants initiated arbitration under the France-Poland BIT, arguing that rejection of authorisations constituted a substantial deprivation of value, thereby amounting to expropriation, and asserting that the state's actions were irrational, disproportionate, and discriminatory in nature.[41] Poland maintained that the arbitrators should respect the state's regulatory decisions and that the country's decision to deny marketing authorisations to specific medicines was made in good faith and in proportion to the public interest in promoting public health.[41] The tribunal found Poland liable for violating the France-Poland BIT and concluded that a State's significant intrusion with the rights of the foreign investors was involved in the turning down of marketing authorisations, resulting in an indirect expropriation.[41]

India is a leading global exporter of generic medications, significantly contributing to the availability of affordable pharmaceuticals worldwide.[7] Indian pharmaceutical firms have broadened their international activities, making substantial investments in overseas markets.[7] These investments may encounter obstacles like rigorous regulatory frameworks, market entry barriers, and discriminatory behaviours by host nations, just like the other generic companies discussed in this section.

For instance, Eli Lilly, an American pharmaceutical company, in the matter of *Eli Lilly* v *Canada*, submitted a Notice of Intent against the Government of Canada, asserting that Canadian courts had invalidated the patents due to their failure to satisfy the 'usefulness' criterion as stipulated by the 'promise utility doctrine', constituting unlawful expropriation.[42] Eli Lilly argued that the promise doctrine would overly hamper R&D while contravening Canada's obligations under multiple intellectual property treaties by imposing arduous and supplementary utility requirements, thereby resulting in the denial of patent rights for inventions that meet the criteria for patentability and causing the invalidation of numerous patents in recent years.[42] The tribunal, though dismissed Eli Lilly's claims, it, nevertheless, provided a forum for foreign investors like Eli Lilly to challenge the controversial 'promise utility' doctrine, adopted by the host state as a pre-condition to Patent protection, which was prejudicial towards pharmaceutical corporations and their products. The said doctrine had severe and unjust consequences for pharmaceutical companies that disclosed promises in good faith that were not fulfilled, despite reasonable expectations.[43] Thereafter, in the year 2017, the Supreme Court of Canada abolished the concerned doctrine in the case of *AstraZeneca Canada Inc* v *Apotex Inc*.[44] and the argument raised by the pharmaceutical company Eli Lilly is also referred to in the concerned Supreme Court judgment.

In another dispute, *Signa S.A.* v *Government of Canada*, a Mexican generic drug manufacturer, Signa was prevented from entering the market for three years as Signa required authorisation for the drug to be sold in Canada and the Patent regulations of Canada stipulated that the Patent holder could prevent a generic competitor for three years from entering the market.[45] Signa, thus, challenged Canada's patent regulations and argued that the authorisation regulations violated NAFTA's FET standard as it suffered loss of revenue and market share after the patent holder, Bayer, prevented the generic manufacturers from manufacturing the drug.[45] No document in the public domain exists regarding the dispute, aside from the notice of intent filed by the Claimant, however there are reports that the matter was subsequently withdrawn[46] and no official arbitration was held. Nevertheless, the matter is noteworthy as it illustrates that private investors can contest domestic patent regulations of the host state concerning the extent of patent protection and the authorisation procedures.[24]

In another dispute, *Apotex Holdings Inc.* v *United States*, Apotex Inc. contended that it had been subjected to less favourable treatment, asserting that the competitor's facilities in Israel when examined by FDA identified numerous violations, but opted not to penalise the Israeli manufacturer with an import notice.[47] However, the United States Food and Drug Administration ("FDA") issued an 'Import Alert' on generic medicines manufactured by Apotex Inc. in Canada, following a failed inspection where FDA found adulterated drugs in major violations of U.S. laws.[47] Consequently, Apotex's US business took a major hit, suffering losses.[48] The Import Alert on the foreign investor was allegedly the most severe measure that has ever been applied to any US investor, the claimants thus, argued that the U.S. had violated the FET standard, as well as the MFN and NT requirements.[47] Although, the tribunal ultimately dismissed Apotex's claims on jurisdictional grounds concluding that the claimant lacked a qualified investment in the host state,[47] the dispute highlights broader concerns for Indian pharmaceutical companies, aspiring to access global markets mostly through exports, which may find it challenging to compete fairly in international markets with other generic companies without adequate investment protection. The Tribunal underscores the idea that mere incurring of expenses to gain market access does not mean creation of a protected "investment" under treaty definitions.[48]

A complicated terrain emerges when IP and ISDS interact. ISDS enables generic drug manufacturers to challenge restrictive patent policies that impede market access, an outcome that has the potential to improve public health, while also giving foreign investors the opportunity to contest state regulations that affect their IP rights, even at the expense of public health. This dual function of ISDS raises serious concerns about its ability to balance investment protection with broader societal interests. Given these complications, India's investment policies may be carefully crafted to protect both regulatory authority and investor confidence. The subsequent section delves into the primary policy considerations that India needs to address when developing its investment strategy in the health sector.

India's shifting Policy Perspective: From Enthusiasm to Caution

India did not sign any BIT until 1994, despite the fact that the contemporary BIT movement began in 1959, indicating that India was hesitant to depend on international law for dispute settlement and investment protection.[49] The year 1991 was a watershed moment for the Indian economy, as the country began to open up to foreign investment.[49] The first BIT that India signed, was on March 14, 1994, with the UK.[50] India embarked on a BIT signing wave from 1994 to 2010 and a majority of these treaties negotiated by India during this period mostly concentrated on safeguarding foreign investment and did not include clauses that would have given the host country the ability to prioritise public health, or any other strong public policy goal.[49]

India's stance on international law pertaining to foreign investment began to shift in 2011, when the ISDS tribunal determined that India had violated the terms of the India-Australia BIT in the matter of *White Industries Australia Limited* v *The Republic of India*.[49, 51] Subsequent to the White Industries ruling, India was confronted with a plethora of additional ISDS claims brought by foreign investors.[49] This led to several internal discussions and deliberations by the Indian government, highlighting several concerns in the BITs signed by India.[9] Concerns about public health were high on the list of priorities as the Ministry of Commerce acknowledged that the granting of compulsory licenses for patented pharmaceuticals was not exempted from the scope of expropriation, which would provide an opportunity for foreign investors-patent holders to potentially initiate a BIT claim against India.[9] Consequently, India started terminating its contemporary BITs and adopted the Model BIT of 2015.[9]

The Model BIT of 2015 introduced several provisions that sought to protect India's sovereign power to pass legislation for safeguarding public health. Among the several modifications introduced by, Article 5.5 of the Model BIT stands out, as it stipulates that non-discriminatory measures implemented by a Party, or decisions rendered by its judicial bodies, intended to safeguarding public interests or purposes such as public health, safety, and environmental protection, will not be construed as an expropriation, thus protecting India's sovereign authority to take such measures.[49] Also, the general exception clause, found in Article 32 of the Indian Model BIT, 2015 acknowledges that states have the right to diverge from treaty obligations when it is necessary to safeguard public health, or preserve public order, or protect the environment.[49] Furthermore, the 2015 Model BIT incorporates the ISDS provision with numerous restrictions, comprising the prerequisite that the foreign investor must pursue domestic remedies in the Indian courts and tribunals for no less than five years before turning to international arbitration; the foreign investor is subject to an overall limitation period of six years before resorting to international arbitration; and the investor must give up the right to commence or maintain proceedings in the host state's domestic courts or tribunals.[49] In contrast to South Africa and other Latin American nations, India continues to permit private investors to contest the regulatory measures of the state in ISDS under the latest Model BIT.[52] In fact, South Africa enacted the Protection of Investments Act, 2015, which superseded the BITs as the primary tool for regulating foreign investment.[49]

Several countries have praised the decision made by India to implement the Model BIT of 2015, particularly in the context on how to strike a compromise with the duty of the host state to regulate public health with investor rights.[9] However, Indian BIT practice may further evolve because of the government's push to draw in additional international investments, especially through initiatives like 'Make in India'.[9] The relevance of BITs for international investors is particularly pronounced in India, given the country's lack of an image as a business-friendly environment.[9] Furthermore, India isn't solely a capital-importer, but is also acknowledged as a capital-exporter, being the foremost exporter of generic pharmaceuticals globally, possessing a substantial portion of the international generic medication industry by volume.[7] India is also a major supplier of low-cost vaccinations to the world and primarily exports medication formulations and biologicals, which account for approximately seventy five percent of overall pharmaceutical exports from India.[53] Thus, Indian companies investing overseas will have less protection under a BIT model that prioritises the host state's regulatory authority.[9] This could limit the success and growth of Indian businesses that operate internationally, as they may face stricter regulations and less support from their host countries.[49] In order to preserve domestic interests and foster international competitiveness, it is crucial for policymakers to meticulously evaluate the potential effects of regulations on Indian businesses that operate internationally. As India customises its strategy for investment treaties while protecting public health concerns, it is critical to consider potential modifications to its Model BIT.

Conclusion

In response to several ISDS claims, India's 2015 Model BIT sought to protect regulatory sovereignty. Thus, it has become challenging for India to negotiate BITs with other nations and draw in foreign investment, because the treaty is generally viewed as being unfriendly to investors. To address these challenges, India may revise its Model BIT and draft a new one that effectively balances its regulatory authority with investment protection. An optimal BIT may be able to adeptly balance two opposing goals: safeguarding foreign investments while maintaining the regulatory authority of the state in its pursuit of public good. A meticulously crafted BIT can foster economic advancement and regulatory consistency.

One of the most discouraging aspects of the current Model BIT is the prerequisite to exhaust all available local remedies for a minimum of five years prior to initiating claims with the ISDS.[54] The inability to address disputes immediately through the ISDS system renders Indian BITs less attractive in comparison to treaties provided by rival economies.[54] Thus, it is comprehensible why Professor Prabhas Ranjan advocated for the elimination of the obligatory five-year waiting period, permitting foreign investors the choice to litigate issues in local courts or to engage in international treaty-based arbitration.[54]

Additionally, considering the pressure on India's court, it seems improbable that issues will be settled within this five-year period, perhaps resulting in considerable delays for foreign investors.[54] Foreign investors prefer unbiased and enforceable conflict resolution systems over domestic courts, which they may view as sluggish or prejudiced.[30] The majority of India's main trading partners have opposed the 2015 Model BIT, which has been the foundation for BIT negotiations, because of the limited protection and recourse it offers foreign investors.[55] Therefore, an effectively organised ISDS framework can streamline BIT discussions, ensuring India's competitiveness in international investment treaties. Opting ISDS mechanism would also protect Indian companies doing business overseas by guaranteeing reciprocal protections, especially in the pharmaceutical industry where regulatory ambiguities can present significant risks. While there is a global debate over the legitimacy of ISDS, including concerns about transparency, consistency, and regulatory chill, India's growing profile as a capital exporter necessitates cautious engagement rather than outright rejection of ISDS mechanisms. Thus, rather than simply benefiting foreign investors investing in India, a well-structured ISDS framework will empower Indian investors abroad, enhancing India's position as a vital player in international investment while retaining its appeal as an FDI destination.

Some authors are also of the view that if IP is not considered as an investment, it would prevent foreign companies from suing India over legitimate regulatory measures. The global trend of IP-related ISDS claims is increasing, as investors are utilising BITs to challenge domestic IP regulations. Christophe Geiger (2020) argues that it is "misleading" to equate intellectual property with an investment.[56] The author contends that the principal rationale behind IP is to encourage creativity and innovation.[56] Treating IP as if it were an investment goes against this fundamental premise, because investments do not inherently guarantee creative production or advantages for society.[56] The authors Dreyfuss and Frankel (2018) are also of the view that IP does not fit neatly into investment law, since there is no actual investment implied by the mere existence of an IP right, additional factors such as goodwill, local employment, cultural advancement are also necessary.[6]

Authors James Gathii and Cynthia Ho (2017) have expressed apprehension about the application of ISDS for disputes pertaining to intellectual property. They have used the term "regime shift" to refer the strategic and systematic move of the IP lawmaking and enforcement from TRIPS and WTO to ISDS.[27] The authors are especially concerned about this shift due to the investor-centric approach of the ISDS mechanism, that may have detrimental impact on the crafted TRIPS flexibilities, claiming that ISDS could lead to a "regime shift" that tilts the scales in favour of robust IP protection.[27] Rochelle Cooper Dreyfuss and Susy Frankel (2018) also suggested for limiting the definition of IP as an investment to limit accessibility to the ISDS mechanism, under specific situations.[6]

Contrary to the position taken by Christophe Geiger, Rochelle Cooper Dreyfuss, Susy Frankel, James Gathii and Cynthia Ho, we find Peter K. Yu's (2017) approach more compelling, as he argues that the interplay between IP and investment is inevitable, despite the strong opposition from policymakers, scholars and civil society groups.[57] It won't be long before investment aspects of IP rights are emphasised as much as their trade aspects.[57] It is therefore, crucial to study investment aspects of IP, as policymakers and civil society groups concentrate on keeping IP outside the realm of ISDS and they are unlikely to improve the present mechanism.[57] It will be too late to study intellectual property rights as investments, when it is realised that it is impossible to keep the mechanism out of the field.[57]

Robert J. Shapiro and Aparna Mathur (2014) also contend that enhanced IPR protection will draw increased FDI into the pharmaceutical industry, thereby augmenting R&D and improving access to novel medications, thus highlighting the positive implications of recognising IP as an investment.[58] Also, harmonising intellectual property rights norms with those of China or the United States would markedly enhance India's economic advancement and public health outcomes.[58] Consequently, the authors of this paper believe that it is imperative to incorporate IP into the definition of investment. Instead, public health exceptions in IIAs should be strengthened in order to safeguard the regulatory actions undertaken by host states in the event of public health crises.[59] The 2021 UNCTAD IIA Issue Note found that thirty-three ISDS cases pertaining to public health have been commenced against both developing and developed nations.[33] Christophe Geiger (2023) argues that the ISDS may impair nations' ability to safeguard human rights and public interests by constraining their power to impose restrictions on IP and this is especially concerning in areas such as public health, where states require the flexibility to implement actions that may jeopardise intellectual property rights.[5] Contrary to such apprehensions of ISDS obstructing public health control, Freya Baetens (2022) challenges the dominant belief that investment tribunals overlook public health issues and argues that an extensive review of the decisions of the Investment tribunals indicate that tribunals have taken public health into account, acknowledging that the host states' paramount objective is to prioritise health, contrary to the widely held perception that they neglect health concerns of the host states.[32] This suggests that the ISDS system, especially regarding IP-related investment disputes, may not be as restrictive as frequently apprehended.

India ought to re-evaluate the strict five-year waiting period in its Model BIT prior to granting ISDS claims. A reformed ISDS mechanism could be a strategic tool to attract FDI while ensuring that public health and other regulatory interests are adequately protected, rather than unduly limiting state sovereignty. In this context, Emmanuel Oke (2018) makes a valid point when he says that the ISDS system needs a broad interpretation that takes into account more general public interests and recognises the legitimate policy decisions of the host states, which will greatly improve the standing of investment tribunals as trustworthy and reliable to settle disputes.[60] Instead of viewing ISDS as a threat, India can use it to promote investment growth while remaining balanced and protecting public interests. As Shakespeare insightfully cautions in Measure for Measure, *"Our doubts are traitors, and make us lose the good we oft might win, by fearing to attempt"*.[61]

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