WHAT DOES THE FUTURE HOLD FOR FOREIGN PHARMACEUTICAL COMPANIES IN INDIA? INVESTMENT ARBITRATION FOR PHARMACEUTICAL COMPANIES IN THE INDIAN CONTEXT

Boris Kasolowsky & Stuti Gadodia[*]

Abstract

Recently, India has witnessed a number of controversial measures affecting intellectual property rights. These measures have particularly impacted the pharmaceutical sector. In one high-profile instance, the Indian authorities granted a compulsory licence of a patented cancer drug to an Indian pharmaceutical company. In another instance, the Indian patent authorities, and subsequently the Indian courts, rejected an application for the grant of a patent in what appeared to be, at least to foreign investors, surprising circumstances. While these measures may well appear justified on grounds of Indian public policy, they may nevertheless run counter to India's international obligations under its international investment agreements. Against this backdrop, it is possible that investors in the pharmaceutical sector will, in the near future, commence investment treaty arbitration proceedings against India. This article examines some of the key issues that are likely to arise in investment arbitrations between investors in the Indian pharmaceutical sector and the Indian State, and considers some of the most relevant changes in the protection afforded to foreign investments in the sector.

I. Introduction

Over the past decade, at least nine international investment arbitration proceedings relating to intellectual property ["**IP**"] rights have been initiated.[1] Five of these cases arose in the pharmaceutical sector, two concerned alleged expropriation of trademarks, and the others concerned marketing limitations imposed by States on tobacco companies on grounds of public health.[2] None of these cases, however, concerned India.

Yet, India is the third-largest pharmaceutical market in the world in terms of volume, and thirteenth-largest in terms of value.[3] Low production costs and the availability of skilled labour make the country an important destination for foreign investment: between April 2014 and March 2016, India received foreign investment of over USD 2.25 billion into the pharmaceutical

---

[*] Boris Kasolowsky is a partner and Stuti Gadodia is an associate in the International Arbitration Group at Freshfields Bruckhaus Deringer LLP. They are both presently based in Frankfurt and can be reached by email on boris.kasolowsky@freshfields.com and stuti.gadodia@freshfields.com. The authors wish to thank their colleague Caroline Kittelmann for her valuable comments. Any views expressed in this article reflect only those of the authors, and any errors are the authors' own.

1 Philip Morris Brands Sàrl, Philip Morris Products S.A. and Abal Hermanos S.A. v. Oriental Republic of Uruguay, ICSID Case No. ARB/10/7 [*hereinafter* "Philip Morris v. Uruguay"]; Philip Morris Asia Limited v. The Commonwealth of Australia, PCA Case No. 2012-12 [*hereinafter* "Philip Morris v. Australia"]; Eli Lilly and Company v. The Government of Canada, ICSID Case No. UNCT/14/2; Apotex Inc. v. The Government of the United States of America, ICSID Case No. UNCT/10/2; Les Laboratoires Servier, S.A.A., Biofarma, S.A.S., Arts et Techniques du Progres S.A.S. v. Republic of Poland; Apotex Holdings Inc. and Apotex Inc. v. United States of America, ICSID Case No. ARB(AF)/12/1; AHS Niger and Menzies Middle East and Africa S.A. v. Republic of Niger, ICSID Case No. ARB/11/11; Signa S.A. de C.V v. Government of Canada; Shell Brands International AG and Shell Nicaragua S.A. v. Republic of Nicaragua, ICSID Case No ARB/06/14. Given the confidentiality protections available in international investment arbitration, it is entirely possible (if not likely) that there are more IP cases which have been initiated, but about which there is no information in the public domain.

2 For a detailed discussion on the cases, *see* PETER CHROCZIEL, BORIS KASOLOWSKY, ROBERT WHITENER & WOLRAD PRINZ ZU WALDECK UND PYRMONT, INTERNATIONAL ARBITRATION OF INTELLECTUAL PROPERTY DISPUTES, A PRACTITIONER'S GUIDE, 135–141, 159-168 (2017).

3 *Sector Survey: Pharmaceuticals*, MAKE IN INDIA (Mar. 25, 2017), http://www.makeinindia.com/article/-/v/sector-survey-pharmaceuticals (last accessed on July 31, 2017).

sector.[4] The Indian State and its authorities have taken a keen interest in the sector. Indian authorities and the courts have recently taken and upheld wide-ranging measures impacting individual pharmaceutical companies. It may therefore simply be a matter of time before such measures result in investors pursuing claims on the basis of international investment agreements ["**IIAs**"].

In this regard, it is also relevant that the Indian government is currently overhauling its existing investment treaty regime. India recently unveiled its new Model Bilateral Investment Treaty ["**Model BIT**"] with significantly trimmed down investor protections,[5] and is planning to renegotiate all of its existing bilateral investment treaties ["**BITs**"] on the basis of the Model BIT.[6] Notices of termination have already been sent, for example, to the German and Swiss governments; given the sunset clauses contained in the respective BITs, German and Swiss investors will, however, be able to benefit from the terminated BITs for another fifteen years.

Against the background of the Indian State taking measures affecting foreign investment in the pharmaceutical sector and its policy of limiting foreign investors' rights under the Model BIT, this article discusses two developments in the Indian pharmaceutical sector which could potentially give rise to IP related investment treaty arbitration claims (section **II**), and then examines a number of specific issues which may arise in that context; namely to what extent IP rights[7] may be considered to be "investments" covered by existing IIAs and the Model BIT, and when IP right holders may qualify as "investors" under the relevant IIAs (section **III**). Finally, the article considers issues that may arise in the Indian courts when enforcing investment arbitration awards relating to IP rights (section **IV**).

II. Developments in the Indian pharmaceutical sector and the protection of IP rights

In May 2016, the Indian government issued its National Intellectual Property Rights Policy ["**National IPR Policy**"].[8] The policy reiterates India's commitment to the Agreement on Trade-Related Aspects of Intellectual Property Rights ["**TRIPS Agreement**"] and the Doha Declaration on the TRIPS Agreement and Public Health, adopted by the WTO in 2001.[9]

While the National IPR Policy contemplates the protection of IP rights, it also expressly stipulates the need to balance the interests of the owners of IP rights with the wider public

---

4 *Pharmaceuticals Section: Achievements Report*, DEPARTMENT OF INDUSTRIAL POLICY AND PROMOTION (Jan. 18, 2017), http://www.makeinindia.com/sector/pharmaceuticals (last accessed on July 31, 2017).

5 India's Model Bilateral Investment Treaty Text (Dec. 28, 2015), http://dea.gov.in/sites/default/files/ModelBIT_Annex_0.pdf (last accessed on July 31, 2017) [*hereinafter* "Model BIT"]; *See also* Grant Hannesian & Kabir Duggal, *Final 2015 Indian Model BIT: Is This the Change the World Wishes to See?*, 32(1) ICSID REV. 216 (2017).

6 India has accordingly already issued termination notices to 58 out of the 83 countries with which it has entered into a BIT, *see* ANSWERS TO UNSTARRED QUESTION NO 1290 (Department of Industrial Policy and Promotion, Ministry of Commerce & Industry), http://www.dipp.gov.in/sites/default/files/lu1290.pdf (last accessed on July 31, 2017). With respect to the remaining 25 BITs, India has circulated a joint interpretative note seeking to align those BITs with the provisions of the Model BIT, *see* Memorandum, Ministry of Finance, Department of Economic Affairs, Investment Division Office, Issuing Joint Interpretative Statements for Indian Bilateral Investment Treaties, Feb. 8, 2016, http://indiainbusiness.nic.in/newdesign/upload/Consolidated_Interpretive-Statement.pdf (last accessed on July 31, 2017).

7 For purposes of this article, "IP rights" shall include registered as well as unregistered IP rights.

8 Press Release, Cabinet approves National Intellectual Property Rights Policy, Press Information Bureau (May 13, 2016), http://pib.nic.in/newsite/PrintRelease.aspx?relid=145338 (last accessed on July 31, 2017).

9 *Id.*

interest. Indeed, over the last few years India has adopted various measures signalling that public health and welfare concerns are of paramount importance to the State.[10] However, it is these measures which are justified by reference to public health and welfare that may impact IP rights and give rise to claims under IIAs. The following considers instances of actual measures taken by the Indian State which shall serve as illustrations for our analysis in section III below:

A. Compulsory licensing of patented medicines

Compulsory licensing of pharmaceuticals is an especially sensitive issue for countries like India, which have growing pharmaceutical production capacities alongside significant public demand for access to essential medicines.

Compulsory licensing is not per se contrary to international law. Article 31 of the TRIPS Agreement actually permits the grant of compulsory licences by WTO member States, provided certain conditions are met.[11] The Doha Declaration further confirms that under Article 31, member States have the right to grant compulsory licences to protect public health.[12] In the context of investment treaty arbitrations, the issue of a treaty breach will, in practice, often turn on whether or not the compulsory licence was granted in accordance with the requirements of the TRIPS Agreement. This has been recognised by the authors of the Model BIT which expressly provides that its protection shall not extend to the issuance of compulsory licences, to the extent that such issuance is "consistent with the international obligations of Parties under the WTO Agreement".[13]

India's regime for the grant of compulsory licences provides that Indian generic pharmaceutical companies can apply for such licences to the Indian State's patent authorities. Section 84 of the Indian Patents Act, 1970 authorises the grant of compulsory licences on any of the following grounds: (a) the requirements of the public with respect to the patented invention have not been

---

[10] In a recently released report, the United States of America has, in fact, placed India on its intellectual property priority watchlist "*for lack of sufficient measurable improvements to its IP framework on long-standing challenges and new issues that have negatively affected US right holders over the past year, particularly with respect to patents, copyrights, trade secrets, and enforcement.*" *See* Press Release, USTR Releases Special 301 Report On Intellectual Property Rights, Office of the United States Trade Representative, (April, 2017), https://ustr.gov/about-us/policy-offices/press-office/press-releases/2017/april/ustr-releases-2017-special-301-report (last accessed on July 31, 2017).

[11] According to the TRIPS Agreement: (i) Each compulsory licence "shall be considered on its individual merits" (art. 31(a)); (ii) except in cases of national emergency, the compulsory licence can be authorised only after efforts have been made to obtain authorisation from the right holder "on reasonable commercial terms and conditions" (art. 31(b)); (iii) the scope and duration of the compulsory licence "shall be limited to the purpose for which it was authorized" (art. 31(c)); (iv) the compulsory licence must be "non-exclusive" and "non-assignable" (art. 31(d) & (e)); (v) the compulsory licence must be used "predominantly for the supply of the domestic market" of the authorising State (art. 31(f)); and (vi) the right holder must be "paid adequate remuneration in the circumstances of each case, taking into account the economic value of the authorisation" (art. 31(h)).

[12] World Trade Organisation, Declaration on the TRIPS Agreement and Public Health, adopted on November 14, 2001, WTO Doc. WT/MIN(01)/DEC/2, art. 4. There are also relevant regional rules, such as an EU procedure, allowing compulsory licences to be issued for pharmaceutical patents in order to address public health emergencies, *see* Regulation (EC) No. 816/2006 of the European Parliament and of the Council of 17 May 2006 on compulsory licensing of patents relating to the manufacture of pharmaceutical products for export to countries with public health problems, 2006 O.J. (L157/1).

[13] Model BIT, art. 2.4(iii). Similar provisions with respect to the exclusion of compulsory licenses from expropriation claims can be found in the India-Japan Comprehensive Economic Partnership Agreement (art. 92.5), India-ASEAN Agreement on Investment under the Framework Agreement on Comprehensive Economic Cooperation (art. 8.7) and the India-Singapore Comprehensive Economic Cooperation Agreement (art. 6.5.6).

satisfied, or (b) the patented invention is not available to the public at a reasonably affordable price, or (c) the patented invention is not "worked" in the territory of India.[14]

In 2012, the Indian patent authorities issued one of the first ever compulsory licences to an Indian pharmaceutical company. The Indian company had applied for a compulsory licence in respect of the anti-cancer drug "Nexavar", the Indian patent to which was held by the German pharmaceutical company, Bayer AG. The patent authorities found that all three conditions of Section 84 of the Indian Patents Act, 1970 were fulfilled and accordingly issued the compulsory licence.[15] Bayer appealed against the decision all the way up to the Supreme Court of India. But the Supreme Court upheld the grant of the compulsory licence.[16]

This decision was applauded in India for ensuring access to affordable medicines. However, the international business community was concerned that this approach would "*open the door to a flood of other compulsory licences in India and possibly in other developing countries*".[17] In order to assuage such concerns, in early 2016, the Indian government reportedly extended "private assurances" to the US Trade Representative that the patent authorities would not grant compulsory licences for commercial purposes.[18] The Indian government, however, subsequently dismissed these reports as "factually incorrect"[19] and issued an official statement reiterating its right to grant such licences in accordance with the Doha Declaration and the TRIPS Agreement.[20] Notwithstanding the government's clarification of its stand on compulsory licences, two Indian companies, BDR Pharma and Lee Pharma, subsequently abandoned their challenges to the rejection of their applications for compulsory licences of drugs manufactured by Bristol-Myers Squibb and AstraZeneca respectively. While reports suggest that these decisions were taken in light of the Indian government's "private assurances" against the granting of compulsory licences,[21] it

---

14 *See* Cipla Limited v. Novartis AG, 239 (2017) DLT 41 (India). Novartis brought a patent infringement case against an Indian drug manufacturer, Cipla. In its judgment, the Delhi High Court commented on this requirement and found that, "*It is not necessary that for a patent to be worked in India, the product in question must be manufactured in India. It can be worked in India even through imports and all that is to be seen is that the imports are of sufficient quantity so as to meet the demands for the product, especially in the case of pharmaceutical products.*" (*Id.* ¶ 25).

15 In the matter of Natco Pharma Limited and Bayer Corporation, Decision of the Controller of Patents, Mumbai, Compulsory Licence Application No. 1 of 2011 (Mar. 9, 2012).

16 Bayer Corporation v. Union of India & Ors, SLP no. 30145/2014, Supreme Court of India, Dec. 12, 2014 (India); *See also* Apoorva Mandhani, *Apex Court dismisses Bayer's SLP against compulsory license for anti-cancer drug*, LIVE LAW (Dec. 12, 2014), http://www.livelaw.in/apex-court-dismisses-bayers-slp-compulsory-license-anti-cancer-drug/ (last accessed on July 31, 2017).

17 Vikas Bajaj & Andrew Pollack, *India orders Bayer to license a patented drug,* THE N.Y. TIMES, Mar. 12, 2012, http://www.nytimes.com/2012/03/13/business/global/india-overrules-bayer-allowing-generic-drug.html (last accessed on July 31, 2017).

18 *See* Amit Sengupta, *India Assures the US it Will Not Issue Compulsory Licenses on Medicines*, THE WIRE (March 12, 2016), https://thewire.in/24621/india-assures-the-us-it-will-not-issue-compulsory-licences-on-medicines/ (last accessed on July 31, 2017) referring to US India BusinessCouncil, U.S.-India Business Council Hearing Statement to the Office of the United States Trade Representative, 5 (Feb. 5, 2016); US CHAMBER OF COMMERCE'S GLOBAL INTELLECTUAL PROPERTY CENTER, 2016 SPECIAL 301 SUBMISSION, USTR-2014-0025, at 94 (Feb. 5, 2016); *See also* Patralekha Chatterjee, *Special Report: India Rocked By Report Of Secret Assurance To US Industry On IP,* IP WATCH (Mar. 22, 2016), https://www.ip-watch.org/2016/03/22/india-rocked-by-report-of-secret-assurance-to-us-industry-on-ip/ (last accessed on July 31, 2017).

19 Press Release, Clarification on media reports regarding compulsory license, Ministry of Commerce and Industry, (Mar. 22, 2016), http://pib.nic.in/newsite/PrintRelease.aspx?relid=138271 (last accessed on July 31, 2017).

20 *Id.*

21 *See* Zeba Siddiqui, *Two Indian generics makers end battle to copy drugs amid patent debate*, REUTERS, Apr. 12, 2016, http://in.reuters.com/article/us-india-medicine-patents-idINKCN0X918Z (last accessed on July 31, 2017).

appears that the applications made by BDR Pharma and Lee Pharma were in fact ultimately rejected by the Indian patent authorities due to procedural shortcomings.[22]

In any event, it is not clear how Bayer will proceed in light of the Supreme Court decision upholding the compulsory licensing of Nexavar. For the time being, Bayer has not initiated any claim under the Germany-India IIA for example, for violation of the fair and equitable treatment standard or for expropriation or otherwise.

Bayer's woes, however, look set to continue. The Delhi High Court recently allowed the export by a local manufacturer of the generic version of Nexavar.[23] Bayer had unsuccessfully tried to contest the export on the basis that it is contrary to the terms of the compulsory licence.[24] Bayer has now appealed the Delhi High Court's decision and it remains to be seen whether it will ultimately be successful in reversing the court's decision on appeal. In any event, the violations of the terms of the compulsory licence may well give rise to a separate breach of the applicable IIA. Bayer may therefore consider a separate treaty claim against India.

B. Rejection of patent applications

The Swiss pharmaceutical company, Novartis AG, developed the anti-cancer drug "Glivec" and applied to the Indian patent authorities to have it registered. Novartis claimed that Glivec transformed the nature of a known compound in a novel way, resulting in a new treatment for cancer.[25] The Indian patent authorities rejected Novartis's application on the basis that the drug did not meet the standard of inventiveness required under Indian patent law,[26] as its active ingredient was already known.

Novartis unsuccessfully challenged the patent authorities' rejection in the Indian courts. In that context, it was also suggested that Novartis was engaging in the practice of "evergreening", whereby pharmaceutical companies introduce new drugs that are incrementally modified formulations of older drugs in order to maintain or extend patent protection.[27] In 2013, the Supreme Court of India finally rejected Novartis's application to patent Glivec in India for lack

---

22 The patent office held in the case of BDR Pharma that the company failed to make a sincere effort to procure a voluntary licence prior to making an application for compulsory licence, while in Lee Pharma's case it held that it failed to provide evidence regarding the existence of any of the grounds mentioned in Section 84 for the grant of a compulsory licence, *see Patent Office refuses Lee Pharma's application for Astrazeneca's diabetes drug,* BUSINESS STANDARD, Jan. 21, 2016, http://www.business-standard.com/article/companies/patent-office-refuses-lee-pharma-s-application-for-astrazeneca-s-diabetes-drug-116012100191_1.html (last accessed on July 31, 2017); *see* C.H. Unnikrishnan, *BDR Pharma's compulsory licensing application for blood cancer drug rejected*, LIVE MINT (Oct. 31, 2013), http://www.livemint.com/Companies/lR6TQA2EY5gejvMl63zHOM/Patent-office-rejects-BDR-Pharmas-application-for-blood-can.html (last accessed on July 31, 2017).

23 Bayer Corporation v. Union of India & Ors, 238 (2017) DLT 701 (India).

24 *Id.*

25 R. Jai Krishna & Jeanne Whalen, *Novartis Loses Glivec Patent Battle in India*, WALL ST. J., Apr. 1, 2013, http://www.wsj.com/articles/SB10001424127887323296504578395672582230106 (last accessed on July 31, 2017).

26 Under the Patents Act, No. 39 of 1970 (India) [*hereinafter* "Patent Act"], § 2(1)(j), "invention" means a new product or process involving an inventive step and capable of industrial application. Further, under § 2(1)(ja), "inventive step" means a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art.

27 Section 3(d) of the Patents Act, 1970 seeks to prevent the practice of evergreening by providing that "the mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least one new reactant [is not an invention within the meaning of this Act]".

of a relevant "invention" within the meaning of the Indian Patents Act, 1970.[28] Novartis has publicly criticised and protested against the final rejection of its patent application.[29] Other pharmaceutical companies have also expressed "*concern about the environment for innovation and investment in India*".[30]

Against this background it is conceivable that Novartis may resort to a claim under an applicable IIA, here, for instance, the Switzerland-India IIA. If Novartis (or a foreign company in a similar situation)[31] brought a claim against India under an IIA relating to the rejection of its patent application for Glivec, it would raise the interesting question of whether Novartis was ever vested with an IP right and thus whether it held an investment, given that its application for patenting Glivec was rejected. This question is considered in detail in section III.A.ii. below.

III. Analysis of legal issues under IIAs: "investment" and "investor"

In this section, we will examine in more detail the conduct of investment claims relating to IP rights with a focus on the jurisdictional requirements that a claim must fulfil before it can be heard by a tribunal, i.e. the existence of an "investment" (sub-section A) and an "investor" (sub-section B). When appropriate, we will refer to the scenarios described in section II above.

A. IP rights as an "investment"[32]

The question of whether IP rights constitute an "investment" must always be examined with reference to the relevant IIA and where applicable, also with reference to the requirements of the ICSID Convention. We will concentrate in part (i) on IP rights as traditionally understood, before looking in part (ii) at the special situation of an application for the registration of an IP right. We will then in part (iii) briefly discuss arguments on the basis of which host States may try to resist the conclusion that IP rights are covered investments. The requirements under the ICSID Convention are discussed in part (iv) because although India is not a party to the ICSID Convention, the requirements have been invoked by India for the purposes of defining covered investments under the Model BIT.

i. Traditional treatment of IP rights under IIAs

Many IIAs make explicit reference to IP rights in their definition of covered investments,[33] with most specifying in detail the types of covered rights,[34] and a few others providing little or no detail about the scope.[35] While IIAs belonging to the latter category may require interpretation as

---

28 Novartis AG v. Union of India & Ors, (2013) 6 SCC 1 (India).

29 Krishna & Whalen, *supra* note 25.

30 *Id.*

31 For example, the American pharmaceutical company Genentech, now a subsidiary of the Swiss company Roche. In September 2015, the Indian patent authorities refused an application for the grant of a patent in respect of Genentech's cancer drug on similar grounds. However, it appears that Genentech has informed the authorities that it is not interested in pursuing the case, *see Patent Office refuses application for Genentech's cancer drug,* BUSINESS STANDARD, Sept. 25, 2015, http://www.business-standard.com/article/companies/patent-office-refuses-application-for-genentech-s-cancer-drug-115092500552_1.html (last accessed on July 31, 2017).

32 For a more detailed analysis, *see* CHROCZIEL ET AL., *supra* note 2, at 141-148.

33 *See Id.* at 141 & 142.

34 Rachel A. Lavery, *Coverage of Intellectual Property Rights in International Investment Agreements: An Empirical Analysis of Definitions in a Sample of Bilateral Investment Treaties and Free Trade Agreements*, 6(2) TRANSNAT'L. DISP. MGMT. 1, 1 (2009).

35 *Id.* at 1-5 (2009). *See, e.g.,* the BITs of UK-Antigua and Barbuda, UK-Korea, UK-Papua New Guinea, UK-Yemen, and UK-Thailand; Netherlands-Egypt, Netherlands-El Salvador, Netherlands-Moldova, Netherlands-Mexico, Netherlands-Venezuela, and Netherlands-Tanzania.

to the scope of coverage of IP rights, patents, trademarks and copyrights are generally accepted as IP rights covered by the definition of "investment".[36] However, even if IP rights are not expressly mentioned in an IIA's definition of "investment", they are likely to enjoy treaty protection by virtue of falling into the broad catch-all category of "assets".[37]

In the Model BIT, India has adopted a broad definition of IP rights as part of its definition of protected investments. "Copyrights, know-how and intellectual property rights such as patents, trademarks, industrial designs and trade names, to the extent they are recognized under the law of a Party"[38] are included in the definition of investment, as are "licences, permits, authorisations or similar rights".[39]

Registered IP rights such as Bayer's patent for Nexavar would fall plainly within the definition of "investment" under any IIA and the Model BIT. The extension of IIA protection to unregistered or not yet registered IP rights can give rise to complex arguments and will be discussed in the following part.

ii. Is an application for the grant of IP rights an "investment"?

In some cases, the treatment by a host State of an application for a grant of IP rights (i.e. prior to registration) arguably violates treaty protections. The authority dealing with the application may, for example, have violated the fair and equitable treatment standard (for instance, by creating and then defeating legitimate expectations), or the investor may have been given a non-transparent and arbitrary decision rejecting its application, or the process for challenging the patent authorities' decision may amount to a denial of justice. In all these instances, the investor will, however, need to convince the tribunal that the application for a grant of IP rights amounts to an investment.

In such cases, the express language of some IIAs may help to extend the scope of the protection of IP rights to applications for the grant of such rights.[40] For example, the US-Jamaica IIA specifically includes "patent*able* inventions" in its definition of "investment",[41] and the Canada-Argentina IIA refers to "*rights with respect to* copyrights, patents..." in its definition of "investment".[42] Next, the existence of provisions in an IIA relating to the pre-establishment activities of an investor (i.e. the admission phase of the investment) could also be interpreted to bring applications for grant of IP rights within the scope of a protected investment.[43] A number of recent Canadian and American IIAs protect pre-establishment investment activity by defining "investor" as encompassing "a national or enterprise of a Party, that *attempts to make*, is making or has made an investment[…]".[44] Finally, an inclusive definition of "investment" covering "every

36 CHROCZIEL ET AL., *supra* note 2, at 142 referring to Lavery, *supra* note 34, at 12.

37 *Id.* 141, referring to Marie Louise Seelig, *Can Patent Revocation or Invalidation Constitute a Form of Expropriation?* 6(2) TRANSNAT'L. DISP. MGMT. 2 (2009).

38 Model BIT, art. 1.4(f).

39 *Id.* art. 1.4(d).

40 *See* CHROCZIEL ET AL., *supra* note 2, at 143 & 144.

41 Treaty between the United States of America and Jamaica Concerning the Reciprocal Encouragement and Protection of Investment, Jam.–U.S., Feb. 4, 1994, S. TREATY DOC. No. 103-35 (1994), art. I(1)(a)(iv).

42 Agreement Between The Government of Canada And The Government Of The Republic Of Argentina For The Promotion And Protection Of Investment, Arg.-Can., Nov. 5, 1991, art. 1(a)(iv).

43 *See* CHROCZIEL ET AL., *supra* note 2, at 144.

44 *Id.*; 2012 US Model BIT, art. 1.

kind of asset"[45] may also be relied on by an investor where it can show that an application for a grant of IP rights possesses value and can, for example, be sold or traded.

There are, however, no published awards in which applications for IP rights have been considered to be covered investments. Thus, particularly in circumstances where the investor cannot demonstrate the economic value of its invention prior to the registration of the relevant IP rights, it may struggle to establish the jurisdictional requirement of the existence of a protected "investment". The fact that some IIAs require IP rights to be registered before affording the owner any protection may, moreover, be used to argue that mere applications for registration of IP rights were not intended to be protected as investments under those IIAs.[46]

The Model BIT seems to limit its protective scope to registered IP rights. Firstly, "pre investment activity"[47] has been excluded from the scope of application of the Model BIT. Secondly, the Model BIT stipulates an exclusion with respect to "creation of intellectual property rights"[48] to the extent "such creation is consistent with the international obligations of Parties under the WTO Agreement."[49] In other words, so long as the rejection of an application for grant of IP rights does not result in a violation of the TRIPS Agreement, the protections under the Model BIT may not extend to any such application. These requirements might make it more difficult for an investor to argue that an application for the grant of an IP right should be considered a covered investment.

If Novartis were to commence arbitration proceedings against India (for instance, regarding Glivec), it may be able to base its claim on the Switzerland-India IIA, relying upon its broad definition of "every kind of asset".[50] It may be able to argue that its application to patent Glivec is a covered investment by showing that the application is a tradeable asset and therefore caught by the definition of "investment". In such a case, Novartis would not have to rely on the list of IP rights in the IIA's definition of investment which requires that such rights should be "in accordance with the relevant laws of the respective Contracting Party"[51] and which India may argue requires that the IP rights – insofar as registrable – be registered in accordance with Indian law. Further, the Switzerland-India IIA is also more investor friendly than the Model BIT in another respect. Unlike the Model BIT, it does not contain an express exclusion of claims relating to "pre-investment activities" or claims regarding "the creation of intellectual property rights".

iii. Other issues with respect to "covered investments"

In some cases, even though the IP right in question prima facie qualifies as a covered "investment" under the provisions of the governing IIA, the respondent State may seek to contest the extent (or existence) of the protection offered to such investment by reference to

45 For example in the Agreement between the Swiss Confederation and the Republic of India for the Promotion and Protection of Investments, India-Switz., Apr. 4, 1997, IC-BT 332 (1997) [*hereinafter* "India-Switz. IIA"], art. 1(2)(a) states that "investment shall include every kind of asset and particularly[…]".

46 *See* CHROCZIEL ET AL., *supra* note 2, at 143.

47 Model BIT, art. 2.2.

48 *Id.* art. 2.4(iii).

49 *Id.*

50 India-Switz. IIA, art. 1(2)(a).

51 *Id.* art. 1(2)(d).

general public policy considerations.[52] Arguments to this effect were made by Uruguay in the *Philip Morris* case.[53]

Uruguay relied on a provision in the Uruguay-Switzerland IIA recognising the host State's right "not to allow economic activities for reasons of public security and order, public health or morality."[54] On that basis, Uruguay argued that it was entitled to "not allow" Philip Morris to engage in its "economic activity" by passing its disputed anti-smoking measures. The crux of Uruguay's argument was that even if Philip Morris's trademark was a prima facie "investment", it was not a "covered" investment for the purposes of the IIA.[55] This argument was rejected by the tribunal on the ground that the provision allows a party to refuse admission of an investment for public health reasons but it does not operate to prevent application of the IIA to investments that have already been admitted in accordance with Uruguayan law.[56]

India's existing IIAs with Germany and Switzerland, which might be relevant to Bayer and Novartis respectively, contain provisions regarding the host State's right to take steps for the protection of essential security interests and in situations of extreme emergency.[57] However, there is no express mention of public health, as in the Uruguay-Switzerland IIA. Still, India may conceivably argue that steps taken to ensure the availability of medicines at an affordable price fall within the ambit of protection of essential security interests, and are therefore not covered by the IIA.[58] The language in these IIAs is, however, not clear in that regard and it may very well prove difficult for India to convince a tribunal that it was permitted to issue a compulsory licence or to refuse to register a patent on account of its "essential security interests" or because of an "extreme emergency."

By comparison, the corresponding provision in the Model BIT is unambiguous. It states that the provisions of the treaty shall not be "construed to prevent the adoption or enforcement by a Party of measures of general applicability applied on a non-discriminatory basis that are necessary to…(ii) protect human, animal or plant life or health."[59] Going forward, it may therefore become harder for investors relying on IIAs based on the Model BIT to make successful claims against India with regard to compulsory licences and other regulatory measures regarding pharmaceuticals.

iv. ICSID Convention

A claim brought before ICSID will generally have to satisfy the requirements of an "investment" under the ICSID Convention. Since India is not a signatory to the ICSID Convention, investment claims against India have usually proceeded under the UNCITRAL Rules, and the

52 CHROCZIEL ET AL., *supra* note 2, at 144.

53 Philip Morris v. Uruguay, ICSID Case No ARB/10/7.

54 Agreement between the Swiss Confederation and the Oriental Republic of Uruguay on the Reciprocal Promotion and Protection of Investments, Switz.-Uru., Oct. 7, 1998, art. 2(1).

55 CHROCZIEL ET AL., *supra* note 2, at 144; *See* Philip Morris v. Uruguay, ICSID Case No. ARB/10/7, Decision on Jurisdiction (July 2, 2013), ¶¶ 151-162.

56 Philip Morris v. Uruguay, ICSID Case No ARB/10/7, Decision on Jurisdiction (July 2, 2013) ¶ 174; *See also* CHROCZIEL ET AL., *supra* note 2, at 144 & 145.

57 India-Switz. IIA, art. 11(2); Agreement between the Federal Republic of Germany and the Republic of India for the Promotion and Protection of Investment, Ger.-India, July 10, 1995, art. 12.

58 In fact, the mission statement of the National IPR Policy, lists as one of its objectives, enhancing access to healthcare.

59 Model BIT, art. 32.1(ii).

ICSID requirements were therefore not in issue. Nevertheless, we will briefly analyse whether IP rights constitute an "investment" under the ICSID Convention, because this approach and analysis occasionally apprises how non-ICSID tribunals interpret the meaning of "investment". Moreover, the ICSID requirements have been used in defining the requirements for an "investment" under the Model BIT.[60]

The term "investment" is not defined under the ICSID Convention. However, the Tribunal in *Salini* v. *Morocco,*[61] laid down the following criteria which characterise an "investment" for the purposes of the ICSID Convention: (1) a contribution of money or assets (2) for a certain duration (3) containing an element of risk and (4) contributing to the economic development of the host State.[62] These criteria are referred to as the *Salini* test or the *Salini* criteria.[63]

While most common types of IP investments (trademarks, patents, and copyrights) will generally fulfil the *Salini* criteria,[64] there may be some cases in which the contribution of the IP right holder's activities to the host State's economic development is in issue.[65] For example, in the *Philip Morris* case, Uruguay argued that Philip Morris' interests do not constitute "investments" under the ICSID Convention because the public health effects of smoking promoted by Philip Morris' activities have harmed and continue to harm Uruguay's economic development.[66] The tribunal, however, rejected this argument, holding that the negative effects of smoking do not provide *"[a] basis for concluding that the Claimants' long-term, substantial activities in Uruguay do not qualify as 'investments' under the IIA and the ICSID Convention.*"[67] In the context of pharmaceuticals, host States may try to argue that high prices charged by foreign pharmaceutical companies prevent the population from having access to essential medicines, and that such activities therefore do not constitute a contribution to the host State's economic development. Given the decision in *Philip Morris* v. *Uruguay*, it seems unlikely that host States would prevail with such an argument.

Insofar as applications for the grant of IP rights are concerned, the situation may be more complex. First, the investor will have to prove that the invention and the application for an invention amount to an asset. In the event an investor convinces a tribunal that its application does qualify as an asset, the tribunal will have to examine whether such an application also fulfils the final *Salini* criterion i.e. a contribution to the economic development of the host State. In that regard, the investor may argue that the host State benefits from the investor's invention whether or not it is patented, and that the non-issuance of a patent would not diminish its contribution to such development.

---

60 *Id.* art. 1.4.

61 Salini Costruttori S.p.A. and Italstrade S.p.A. v. Kingdom of Morocco ICSID Case No. ARB/00/4.

62 *Id.* Decision on Jurisdiction (July 23, 2001), ¶ 52.

63 Some tribunals have suggested that these requirements must be met in order for jurisdiction under ICSID to be satisfied, *see e.g.,* Quiborax S.A., et al. v. Plurinational State of Bolivia, ICSID Case No. ARB/06/2, Decision on Jurisdiction (Sept. 27, 2012), ¶ 219. Others have held that they are typical features of investments which "*may assist in identifying or excluding in extreme cases the presence of an investment but cannot defeat the broad and flexible concept of investment under the ICSID Convention[…]*", *see* Philip Morris v. Uruguay, Decision on Jurisdiction, (July 2, 2013), ¶ 206.

64 Julian Davis Mortenson, *Intellectual Property as Transnational Investment: Some Preliminary Observations,* 2 TRANSNAT'L DISP. MGMT. 7-9 (2009).

65 CHROCZIEL ET AL., *supra* note 2, at 146.

66 *Id.*; *See* Philip Morris v. Uruguay, ICSID Case No ARB/10/7, Decision on Jurisdiction, (July 2, 2013), ¶¶ 180-182.

67 CHROCZIEL ET AL., *supra* note 2, at 146; *See* Philip Morris v. Uruguay, ICSID Case No ARB/10/7, Decision on Jurisdiction (July 2, 2013), ¶ 209.

B. The IP rights holder as an "investor"[68]

The second jurisdictional requirement is that of a protected "investor". This issue has not been a point of contention in most IP-related investment arbitration proceedings, with the notable exception of *Philip Morris* v. *Australia*.[69] In this case, the issue was more nuanced, as the specific question before the tribunal was whether the investment treaty structuring[70] between Philip Morris entities for the purposes of pursuing a claim under a specific IIA constituted an abuse of rights.

The decision of the tribunal in *Philip Morris* v. *Australia* serves as a useful reminder that the timing of investment treaty structuring is of crucial importance. The key question before the tribunal was whether the restructuring of Philip Morris' investment had taken place before or after the dispute had arisen. The tribunal concluded that the restructuring activity occurred at a time "*when there was a reasonable prospect that the dispute would materialise*"[71] and "*it was carried out for the principal, if not sole, purpose of gaining treaty protection.*"[72] The tribunal held on the facts that the initiation of the arbitration constituted an abuse of rights by the Philip Morris entity benefitting from the treaty structuring and thus declined jurisdiction over the dispute.[73]

These considerations are likely to be particularly relevant for any investor not presently benefitting from any IIA protection.[74] Should an investor consider structuring its investment so as to be able to benefit from a particular IIA's protection, it should seek to do so before any dispute arises. In fact, investors would do well to engage in treaty dispute planning as part of their original investment decision rather than to wait until a dispute arises.

---

68 For a more detailed analysis, *see* CHROCZIEL ET AL., *supra* note 2, at 149-152.

69 *See generally Id.*; Philip Morris v. Australia, PCA Case No. 2012-12.

70 Investment treaty structuring is a device often used by foreign investors seeking to obtain the protection of an IIA in circumstances where their home State does not have an IIA with the potential host State, or to optimise their protection by taking advantage of a more favourable IIA between the potential host State and a third country, *see* CHROCZIEL ET AL., *supra* note 2 at 150.

71 Philip Morris v. Australia, PCA Case No. 2012-12, Award on Jurisdiction and Admissibility (Dec. 17, 2015), ¶ 588.

72 *Id.*

73 *Id.*

74 This issue may be of concern for the American seeds manufacturer Monsanto, which is currently involved in a dispute with the Indian government over price control measures relating to a specific type of genetically modified cotton seed. Currently, there is no IIA in place between India and the United States. Monsanto has termed these measures "*arbitrary and innovation stifling government interventions [which] make it impossible to recoup research and development investments*", *see* Mayank Bhardwaj, *Monsanto threatens to exit India over GM royalty row,* REUTERS, Mar. 4, 2016, http://in.reuters.com/article/india-monsanto-cotton-seeds-gm-idINKCN0W61F8 (last accessed on July 31, 2017). In July 2016, Monsanto withdrew its application to launch its latest generation of genetically modified cotton seeds in India, blaming uncertainty in the business and regulatory environment, *see* A Kazmin, *Monsanto steps up India cotton seed dispute*, FINANCIAL TIMES, Aug. 25, 2016, https://www.ft.com/content/a5ffb0c2-6a80-11e6-a0b1-d87a9fea034f (last accessed on July 31, 2017). Insofar as Monsanto made its investment as a US investor, as opposed to through one of its non-US subsidiaries, it will not be able to take advantage of investment treaty protection for a lack of an applicable treaty. If Monsanto's investment, however, benefitted from favourable investment treaty structuring in advance of any dispute, a claim against India might be possible.

IV. Analysis of legal enforcement of awards: Issues that may come up before Indian courts at the stage of enforcement

As India is not a party to the ICSID Convention, investment claims against India have been arbitrated under the UNCITRAL Rules, administered (in some cases) by the Permanent Court of Arbitration.[75]

In the event that an award is rendered against India in an investment arbitration proceeding, the investor may seek to enforce such award either abroad or in India. Insofar as the investor seeks enforcement in India, where it will be easier to locate assets against which an award can be enforced, the award will be subject to the grounds of review as set out in Article V of the New York Convention.[76] The scope for judicial control of an award, coupled with the interventionist approach of the Indian courts,[77] gives rise to a number of risks for an award-holder seeking to enforce the award through the Indian courts.

First, there may be some threshold issues as to the applicability of the New York Convention to the enforcement application presented by an award-holder. While India is a signatory to the New York Convention, it has made two reservations. These reservations relate to the definition of a "foreign award" under the Indian Arbitration and Conciliation Act, 1996:

- An Indian court will enforce an award as per the New York Convention only if it was made in the territory of another Contracting State, and the Central Government of India, being satisfied that reciprocal provisions have been made, declares by notification in the Official Gazette that such State is a territory to which the New York Convention applies.[78]
- India will apply the New York Convention only to differences arising out of the legal relationships, whether contractual or not, which are considered as commercial under the law of India.[79]

An award made in a country which is not the subject of a notification in the Official Gazette of India will not be eligible for enforcement in accordance with the provisions of the New York Convention (as reproduced in India's arbitration legislation).[80]

---

75 *See India – as respondent State,* INVESTMENT POLICY HUB, UNCTAD, http://investmentpolicyhub.unctad.org/ISDS/CountryCases/96?partyRole=2 (last accessed on July 31, 2017).

76 The grounds enumerated in Article V of the New York Convention are reproduced in Section 48 of the Arbitration and Conciliation Act, No. 26 of 1996 (India) [*hereinafter* "Arbitration Act, 1996"], as amended by the Arbitration and Conciliation (Amendment) Act 2015, No. 3 of 2016 (India).

77 *See, e.g.,* Harisankar K. Sathyapalan, *Indian judiciary and international arbitration: a BIT of a control,* ARB. INT'L, aiv074, https://doi.org/10.1093/arbint/aiv074 (last accessed on July 31, 2017).

78 Arbitration Act, 1996, § 44(b).

79 *Id.* § 44.

80 As of 2013, India has notified the following countries as reciprocating territories: Australia, Austria, Belgium, Botswana, Bulgaria, Canada, Central African Republic, Chile, Cuba, Czechoslovakia Socialist Republic, Denmark, Ecuador, The Arab Republic of Egypt, Finland, France, Germany, Ghana, Greece, Hungary, Italy, Republic of Ireland, Japan, Republic of Korea, Kuwait, Malagasy Republic (Republic of Madagascar), Malaysia, Mexico, Morocco, The Netherlands, Nigeria, Norway, People's Republic of China (including the Special Administrative Regions of Hong Kong and Macao), Philippines, Poland, Romania, San Marino, Singapore, Spain, Sweden, Switzerland, Syrian Arab Republic, United Republic of Tanzania, Thailand, Trinidad and Tobago, Tunisia, United Kingdom, United States of America and USSR, *see* Dharmendra Rautray, *Enforcement of Foreign Awards in India* 9(2) ASIAN J. INT'L ARB., 79, 85 (2013). In 2015, Mauritius was included in the list of reciprocating territories by a notification dated 13 July 2015, *see* Ministry of Law and Justice, Department of Legal Affairs, Notification, 2015, The

With regard to the second reservation, it will be interesting to see if the Indian courts would be inclined to consider disputes arising out of breaches of IIAs as "commercial" under the laws of India. While the Model BIT clarifies that a claim submitted to arbitration under its dispute settlement provisions "shall be considered to arise out of a commercial relationship or transaction for purposes of Article I of the New York Convention",[81] most of the existing Indian IIAs, including India's IIAs with Germany and Switzerland, do not contain such a clarification. More often than not investment arbitration claims relate to sovereign legislative and/or regulatory activities, giving rise to doubts regarding the qualification of such disputes as "commercial disputes". However, courts in many other jurisdictions called upon to enforce investment awards have held that a reservation limiting the application of the New York Convention to "commercial disputes" does not impede the actual enforcement of investment awards.[82] It is likely, though not certain, that the Indian courts will adopt the same approach.

Secondly, in the context of investment awards concerning IP rights, India may seek to resist the application for enforcement on the basis that the award is contrary to the public policy of India.[83] It is important to note that in the scenarios discussed above in section III, the rationale of the Indian authorities in adopting the measures in question seems to be premised on the interests of the Indian population. Specifically, the Indian government has sought to justify the compulsory licensing of Bayer's anti-cancer drug, and the rejection of Novartis' application for grant of a patent, *inter alia*, on the ground that these measures would ensure the availability of essential medicines at an affordable price. It is therefore not improbable that an Indian court might hold that public health and access to affordable medicines form part of the public policy of India. Indian courts may thus reject the recognition and enforcement of an international arbitration award rendered in favour of an investor where the Indian State's disputed measure was taken in the interests of public health and welfare.

V. Conclusion

The Model BIT, the bold measures taken by the State's authorities (and particularly the patent authorities) and the likely attitude of the Indian courts all seem to suggest that India can regulate the pharmaceutical sector more freely and pay less attention to the interests of foreign investors presently active in India while running a smaller risk of investors successfully pursuing

Gazette of India, pt. II, sec. 3, sub-sec. (ii) (July 13, 2015), http://egazette.nic.in/WriteReadData/2015/164985.pdf (last accessed on July 31, 2017).

81 Model BIT, art. 27.5.

82 August Reinisch, *Will the EU's Proposal Concerning an Investment Court System for CETA and TTIP Lead to Enforceable Awards? The Limits of Modifying the ICSID Convention and the Nature of Investment Arbitration*, 19(4) J. INT'L ECON. L. 761, § V.C (2016). "*A number of investment treaties expressly qualify claims that may be brought on the basis of their provisions as 'commercial' in nature. Also, the 1985 UNCITRAL Model Law on International Commercial Arbitration contains a broad definition of the notion 'commercial arbitration' which expressly includes a reference to 'investment'*". Further, the author gives examples including United Mexican States v. Metalclad Corporation, [2001] BCSC 664, 5 ICSID Reports 236, 247, ¶ 44 (Can. B.C.S.C.); United Mexican States v. Feldman Karpa, [2005] 9 ICSID Reports 508, 516, ¶ 41 (Can. O.A.C.); Czech Republic v. CME Czech Republic BV, Svea hovrätt [HovR] [Svea Court of Appeal] May 15, 2003, 9 ICSID Reports 439 (Swed.).

83 Recent amendments to the Indian Arbitration Act have clarified that an award is only in conflict with the public policy of India if (i) the making of the award was induced or affected by fraud or corruption or was in violation of section 75 (Confidentiality) or section 81 (Admissibility of evidence); or (ii) it is in contravention of the fundamental policy of Indian law; or (iii) it is in conflict with the most basic notions of morality or justice. Further, the test as to whether there is a contravention of the fundamental policy of Indian law does not entail a review on the merits of the dispute (§ 48(2)(b) of the Arbitration Act, 1996 which is identical to art. V(2)(b) of the New York Convention).

investment treaty arbitrations against India. This is, however, a risky policy and approach which must be managed very carefully by India. Unless the interests of holders of IP rights and the wider public interest are carefully balanced, foreign investors may be less willing to invest in India, whether it is in the distribution of certain products or in setting up local research and development facilities. If the interests of IP right holders and specifically pharmaceutical companies are not adequately taken into account, India risks less innovation in the pharmaceutical sector for lack of foreign investors willing to invest, and perhaps even fewer pharmaceutical products reaching fewer people.