

# International Investment Agreements, Intellectual Property Rights and Public Health

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## I. Introduction

There are about 3,000 international investment agreements (IIAs), and most of them contain provisions for the investor-state dispute settlement (ISDS) mechanism. The number of ISDS arbitration is increasing, and disputes relating to intellectual property rights (IPRs) are starting to be handled in such arbitration. Because policy measures with objectives concerning public health often relate to IPRs, these measures may trigger disputes relating to IPRs of foreign investors, which may be dealt with in investor-state arbitration.

IPRs and public health are interrelated in several different ways. First, IPRs, patents in particular, function as a promoter of public health through innovation. Second, IPRs are sometimes considered to be an obstacle to public health. For example, pharmaceutical patents are often alleged to hinder access to medicines. Third, IPRs may be affected by public health policies. For example, tobacco control regulation can restrict exploitation of IPRs such as trademarks.

In IIAs, IPRs have been almost always explicitly counted as an “investment”

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to be protected.<sup>1)</sup> As for public health and investment, foreign direct investment (FDI) can promote public health directly (e.g., by investment on health related business or facilities), or indirectly through contributing to the development of the host country. However, in some cases, facilitation of FDI may conflict with state sovereignty in pursuit of public health.

Thus, the three pillars of the subject of this paper, i.e. IIAs, IPRs and public health, are closely related to each other. It is no wonder then that there are cases handled by investor-state arbitration that are more or less related to both IPRs and public health.<sup>2)</sup> In this paper, I would like to introduce three cases: a case concerning the Australian legislation for tobacco plain packaging (*Philip Morris v. Australia*), another case filed by a producer of generic medicine (*Apotex v. US*), and the third one concerning Canada's treatment of the patentability of medicines (*Eli Lilly v. Canada*).

In spite of active use of ISDS, there seem to remain many systemic issues about this type of dispute settlement. Here, issues from the perspective of the WTO agreements are taken up. Then, as a conclusion, I would like to discuss briefly how we should evaluate ISDS as well as the future work to be done as to IIAs.

## II. Overview of IIAs and ISDS

### 1. IIAs (International Investment Agreements)

#### (1) Purposes

Generally speaking, the purpose of IIAs is to protect investments and investors. Some IIAs also aim at liberalization of investment by incorporating, for example, obligations concerning performance requirements.

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1) Julian Davis Mortenson, *Intellectual Property As Transnational Investment: Some Preliminary Observations*, 6 TRANSNATIONAL DISPUTE MANAGEMENT (2009), at [www.transnational-dispute-management.com](http://www.transnational-dispute-management.com).

2) There are recent works which discuss the topic of this paper in a fairly comprehensive manner. See 6 TRANSNATIONAL DISPUTE MANAGEMENT, Issue 2 (2009), at [www.transnational-dispute-management.com](http://www.transnational-dispute-management.com); VALENTINA VADI, PUBLIC HEALTH IN INVESTMENT LAW AND ARBITRATION (2013).

## (2) Types

Roughly speaking, there are two types of IIAs. The first (hereinafter called “type-A”) is a type of stand-alone and investment-specific agreements. The second (hereinafter called “type-B”) is a type of agreements which are parts (e.g., a chapter on investment) of Regional Trade Agreements (RTAs) including Free Trade Agreements (FTAs) and Economic Partnership Agreements (EPAs). In short, type-B is an investment-related part of agreements with broader scope than type-A agreements.

Another way of grouping IIAs is to distinguish them by the numbers of participating parties. Namely, there are bilateral, plurilateral and multilateral IIAs. Bilateral IIAs include so-called BITs (bilateral investment treaties) and bilateral FTAs or EPAs. Examples of plurilateral IIAs are the Japan-China-Korea Investment Treaty and the Trans-Pacific Strategic Economic Partnership Agreement (TPP). As to multilateral IIAs, the Energy Charter Treaty is the only example currently existing.

The numbers of IIAs which some of the major countries concluded by 15 October 2014 are shown below.<sup>3)</sup>

	BITs	Other IIAs	Total
China	130	17	147
France	103	65	168
Germany	134	65	199
India	84	12	96
Japan	22	18	40
Republic of Korea	90	15	105
UK	104	65	169
US	46	65	111
EU	-	65	65

3) OECD & UNCTAD, *Twelfth Report on G20 Investment Measures* 7 (4 November 2014).

(3) Obligations with regard to investment

Obligations with regard to investment provided in IIAs<sup>4)</sup> include those related to:

- National Treatment,
- Most-Favored-Nation Treatment,
- Fair and Equitable Treatment,
- Full Protection and Security,
- Expropriation, and
- Dispute Settlement.

Type-B IIAs contain also obligations regarding trade and other economic matters, often including IP protection.

In disputes involving IPRs, claimants often refer to expropriation clauses. Specifically, compulsory licenses<sup>5)</sup> and revocation or invalidation of IPRs<sup>6)</sup> may be alleged to be “indirect expropriation.” In this context, it is notable that some recent IIAs provide exemption from the obligation concerning expropriation for measures related to IPRs or with public welfare objectives.

For example, the EU-Canada Comprehensive Trade and Economic Agreement (CETA) contains the following provision.<sup>7)</sup>

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4) For an analysis of existing IIAs, see R.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 TRANSNATIONAL DISPUTE MANAGEMENT (2009), at [www.transnational-dispute-management.com](http://www.transnational-dispute-management.com).

5) Tsai-Yu Lin, *Compulsory Licenses for Access to Medicines, Expropriation and Investor-State Arbitration Under Bilateral Investment Agreements – Are There Issues Beyond the TRIPS Agreement?*, IIC 2009, 152; Christopher Gibson, *A Look at the Compulsory License in Investment Arbitration: The Case of Indirect Expropriation*, 25 AM. U. INTL L. REV. 357 (2010).

6) Marie Louise Seelig, *Can Patent Revocation or Invalidation Constitute a Form of Expropriation?*, 6 TRANSNATIONAL DISPUTE MANAGEMENT (2009), at [www.transnational-dispute-management.com](http://www.transnational-dispute-management.com).

7) The negotiation on the CETA was concluded just recently and its full outcomes were made public in September 2014. With respect to the article quoted in the text, there is “Declaration to Investment Chapter Article X.11 Paragraph 6” which confirms that each party maintains discretionary power over measures related to IPRs. The declaration

#### Article X.11: Expropriation

6. For greater certainty, the revocation, limitation or creation of intellectual property rights to the extent that these measures are consistent with TRIPS and Chapter X (Intellectual Property) of this Agreement, do not constitute expropriation. Moreover, a determination that these actions are inconsistent with the TRIPS Agreement or Chapter X (Intellectual Property) of this Agreement does not establish that there has been an expropriation.

Another example is Annex B (para. 4.(b)) of the 2012 U.S. Model BIT which states:

“Except in rare circumstances, non-discriminatory regulatory actions by a Party that are designed and applied to protect legitimate public welfare objectives, such as public health, safety, and the environment, do not constitute indirect expropriations.”

## 2. ISDS (Investor-State Dispute Settlement)

### (1) Procedures

The ISDS mechanism is provided in most IIAs.<sup>8)</sup> ISDS procedures usually start with consultation between investors and host states. When the dispute is not settled in consultation, investors may submit it to arbitration. As to arbitration institutions, the World Bank's International Centre for Settlement of Investment Disputes (ICSID) is most often used. Other institutions such as the United Nations Commission on International Trade Law (UNCITRAL) and the International Chamber of Commerce (ICC) are also used.<sup>9)</sup>

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also states that “[t]he Parties agree to review the relation between intellectual property rights and investment disciplines within 3 years after entry into force of the agreement or at the request of a Party.”

8) There are IIAs which lack provisions for ISDS, such as the US-Australia BIT, the Japan- Philippines EPA and the Japan-Australia EPA. Concerning Australia's recent policy not to include ISDS in IIAs, see Leon E. Trakman, *Australia's Rejection of Investor-State Arbitration: A Sign of Global Change*, in REGIONALISM IN INTERNATIONAL INVESTMENT LAW 344 (Leon E. Trakman & Nicola W. Ranieri eds., 2013).

9) See RUDOLF DOLZER & CHRISTOPH SCHREUER, PRINCIPLES OF INTERNATIONAL INVESTMENT LAW 238-44 (2d ed. 2012).

(2) Grounds for claims by investors

A dispute which can be subject to ISDS is usually called an “investment dispute.” However, the scope of investment disputes can vary according to each IIA.

First, there are investment disputes based on claims of breach of obligations specifically provided with regard to investment in IIA. For example, Art. 11.15 of the U.S.-Korea FTA provides:

“an ‘investment dispute’ in which a claim is made (1) that the respondent has breached (a) an obligation in the investment chapter of the IIA, (b) an investment authorization, or (c) an investment agreement; and (2) that the claimant has incurred loss or damage from the breach”.

Second, the scope of investment disputes can be broader for Type-B IIAs. For example, Art. 96 of the Japan-India EPA provides:

“an ‘investment dispute’  
(1) that has incurred loss or damage on the investor  
(2) by an alleged breach of any obligation under the Chapter on investment and other provisions of this Agreement as applicable with respect to the investor and its investments”

In the second case, breach of obligations beyond those provided in the investment-related part of the IIA can be grounds for claims as long as the obligations are applicable with respect to investors and investments. There is a possibility that if the IIA at issue contains provisions on IP enforcement, investors can raise these provisions as grounds for claims against host states.<sup>10)</sup>

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10) For example, the Japan-India EPA contains Chapter 9 on intellectual property, and it seems that investors can resort to ISDS concerning breach of obligations under that chapter which affects their investments.

It may be worth noting here that the tribunal of ISDS might face the need to interpret other treaties including the TRIPS Agreement. For example, Art. 6.5 of the US-Uruguay BIT states as follows. In order to apply this article, the tribunal would have to interpret the TRIPS Agreement in judging the measures were consistent with the Agreement.

“This Article [on Expropriation and Compensation] does not apply to the issuance of compulsory licenses granted in relation to intellectual property rights in accordance with the TRIPS Agreement, or to the revocation, limitation, or creation of intellectual property rights, to the extent that such issuance, revocation, limitation, or creation is consistent with the TRIPS Agreement.”

### III. Cases

#### 1. Introduction

As of 2009, it was reported that at least six IPR-related disputes had been brought to ISDS arbitration.<sup>11)</sup> After that, one of the six came to conclusion in 2013, and some new disputes have been filed. Among them, the following three cases are more or less related to public health, and worth discussing here.

#### 2. Tobacco Plain Packaging Case

The Australian regulation of tobacco plain packaging, which has been implemented since 2012, is a very strict regulation of tobacco packaging. It has been arousing bitter controversy from both practical and theoretical viewpoints. Several countries brought cases against Australia under the WTO Dispute Settlement system, alleging violations of the WTO agreements.<sup>12)</sup> Tobacco

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11) James Hosking & Markus Perkams, *The Protection of Intellectual Property Rights Through International Investment Agreements: Only a Romance or True Love?*, 6 TRANSNATIONAL DISPUTE MANAGEMENT 1 n. 2 (2009), at [www.transnational-dispute-management.com](http://www.transnational-dispute-management.com).

12) For a detailed analysis of the consistency of the Australian measure with the WTO agreements, see Masabumi Suzuki, *Domestic Measures for Public Health Policy and International IP/Trade Law - The Case of the Australian Plain Packaging Act -*, 247

companies filed a suit at a domestic court alleging the unconstitutionality of the legislation, but the claims were rejected by the High Court of Australia.<sup>13)</sup>

In 2011, Philip Morris Asia Limited (PM Asia) started a dispute over the regulation against Australia under the Australia-Hong Kong BIT. PM Asia is domiciled in Honk Kong, owns all shares of Philip Morris Australia whose subsidiary, Phillip Morris Limited (PML), manufactures and sells tobacco products, and holds various intellectual property rights and goodwill in Australia. The dispute proceeded to arbitration.<sup>14)</sup>

PM Asia alleges that Australia, through the plain packaging legislation, breached its obligation under the BIT as to expropriation, fair and equitable treatment, unreasonable impairment, full protection and security, and the umbrella clause.<sup>15)</sup>

I do not delve into details of the legal arguments,<sup>16)</sup> but would like to give a couple of comments on this case.

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NAGOYA UNIVERSITY JOURNAL OF LAW AND POLITICS 374 (2012), at [http://ir.nul.nagoya-u.ac.jp/jspui/bitstream/2237/17433/1/11\\_%e9%88%b4%e6%9c%a8%e5%b0%86%e6%96%87%e6%a7%98.pdf](http://ir.nul.nagoya-u.ac.jp/jspui/bitstream/2237/17433/1/11_%e9%88%b4%e6%9c%a8%e5%b0%86%e6%96%87%e6%a7%98.pdf).

13) JT International SA v Commonwealth of Australia; British American Tobacco Australasia Limited v The Commonwealth, [2012] HCA 43 (Aug. 15, 2012).

The plaintiffs' argument was that the plain packaging legislation was contrary to section 51 (xxxi) of the Australian Constitution which provides for "the acquisition of property on just terms from any State or person."

14) Philip Morris Asia Limited v. The Commonwealth of Australia, UNCITRAL, PCA Case No. 2012-12.

15) Notice of Arbitration by PM Asia, paras. 7.1 ff. (21 November 2011).

16) See, e.g., Mark Davison, *The Bilateral Investment Treaty Dispute between Australia and Philip Morris Asia: What Rights Are Relevant and How Have They Been Affected?*, 9 TRANSNATIONAL DISPUTE MANAGEMENT (2012), at [www.transnational-dispute-management.com](http://www.transnational-dispute-management.com); Valentina S. Vadi, *Global Health Governance at a Crossroads: Trademark Protection v. Tobacco Control in International Investment Law*, 48 STAN. J. INTL L. 93 (2012); Luke Nottage, *Consumer Product Safety Regulation and Investor-State Arbitration Policy and Practice after Philip Morris Asia v Australia*, in REGIONALISM IN INTERNATIONAL INVESTMENT LAW 344 (Leon E. Trakman & Nicola W. Ranieri eds., 2013).



First, this is a typical case in which the question is asked, to what extent and how the tribunal should take into account the nature of the measure at issue as a public policy. Given that the case has attracted so much attention worldwide, its result can become a very important precedent for future disputes under IIAs that involve public health and other public policy matters.

Second, this is also a case involving the question of how other international law should be taken into account during the interpretation of IIAs. Namely, the Australian law has been introduced in order to “give effect to certain obligation that Australia has as a party” to the WHO Framework Convention on Tobacco Control (WHO FCTC),<sup>17)</sup> and a plain packaging measure is explicitly mentioned in the “Guidelines for implementation of Article 11 of the WHO Framework Convention on Tobacco Control.” Although the WHO FCTC is just a framework treaty which gives much discretion to signatory countries, the relation between the international law and the Australian law should be taken into consideration by the arbitration tribunal in the application of requirements under the BIT to the Australian law (e.g., interpretation of “expropriation” and “fair and equitable treatment”).

Third, much of the strength of the claim would depend on the nature of PML’s rights/interests, particularly trademark rights. Specifically, trademark rights are arguably just negative rights, i.e. rights to prohibit other persons’ use of the mark, and not rights to use it exclusively.<sup>18)</sup> Actually, this point was discussed by the High Court of Australia in the domestic case on the constitutionality of the law. Most judges took the view described above and rejected the allegation that the law amounted to an “acquisition” of proprietary interests. Such an understanding of the nature of trademark rights, if shared by the arbitration tribunal, will affect the tribunal’s judgment.

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17) Section 3(1)(b) of the Tobacco Plain Packaging Act 2011.

18) Suzuki, *supra* note 12, at 356.

### 3. Generic Medicine case

Apotex, a Canadian generic pharmaceutical company, filed a so-called Abbreviated New Drug Application (ANDA) at the United States Food and Drug Administration (FDA). It also filed an action against Pfizer for a declaratory judgment of patent non-infringement and invalidity. But the U.S. courts dismissed Apotex's action for lack of subject-matter jurisdiction. Then, in 2008, Apotex filed a claim against the U.S. under the NAFTA, alleging that the U.S., through the judgments of the courts, acted in breach of its obligations under the NAFTA by failing to give fair and equitable treatment, failing to meet the minimum standard of treatment under international law, and by expropriating Apotex's property right.

The tribunal dismissed Apotex's claims, stating that because the claimant did not qualify as an "investor" who had made an "investment," the tribunal lacked jurisdiction.<sup>19)</sup> It added that even if Apotex had been qualified as an "investor," its claims would have to be dismissed on the basis that it had failed to exhaust all local remedies.

This case is related to the unique system of the U.S. under the Hatch-Waxman Act. Still, the award by the tribunal is instructive as to the issue of when a foreign generic pharmaceutical company is regarded as an investor in the context of IIAs.

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19) Apotex Inc. v. The Government of the United States of America, UNCITRAL, Award on Jurisdiction and Admissibility (June 14, 2013). Apotex initiated another separate dispute (which does not involve IP-related issues) against the U.S. under the NAFTA, which proceeded to ICSID arbitration. The tribunal rejected all claims on August 25, 2014. The award in this case, Apotex Holdings Inc. and Apotex Inc. v. United States of America (ICSID Case No. ARB(AF)/12/1), is available at [https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC5075\\_En&caseId=C2080](https://icsid.worldbank.org/ICSID/FrontServlet?requestType=CasesRH&actionVal=showDoc&docId=DC5075_En&caseId=C2080). See also U.S. Department of State, *Media Note: NAFTA Tribunal Dismisses Apotex Claims* (August 27, 2014), at <http://www.state.gov/r/pa/prs/ps/2014/230995.htm>.

#### 4. Case concerning Patentability of Medicine

Eli Lilly, a large American pharmaceutical company, was granted patents in Canada for pharmaceutical use of chemical compounds. However, the patents were determined as invalid by the Canadian Federal Court. Since 2005, the judiciary of Canada created a new doctrine (the “promise doctrine”) to assess the utility requirement for patentability. The Court applied this doctrine to Eli Lilly’s patents and invalidated them. Eli Lilly filed a claim against Canada under the NAFTA, alleging that Canada breached its obligations under the NAFTA as to expropriation and minimum standard of treatment.<sup>20)</sup> The claimant is demanding as much as C \$500 million in compensation.

This case is seen by some commentators as a test case for large pharmaceutical companies to check the possibility of using ISDS to their benefits. For example, an American NGO “Public Citizen” states that “if the NAFTA tribunal allows this claim, it would open the door for corporations to privately enforce any international intellectual property treaty in investor-state tribunals.”<sup>21)</sup>

Because Eli Lilly’s claims relate directly to the substantive standards of IP protection, the result of this case may possibly have a great impact on international IP law. The Canadian measure, the promise doctrine, may appear to be exceptional in that it was introduced and implemented by the judiciary rather than through legislation. However, it often occurs even in civil law countries like Japan that the judiciary introduces revolutionary doctrines in the area of IP law. In that sense, the Canadian measure is not so exceptional. The tribunal will probably examine whether the measure infringed legitimate expectations of the claimant in the context of determination about fair and equitable treatment. In that judgment, the fact that the measure is judge-made law should not be overestimated.

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20) Eli Lilly and Company v. The Government of Canada, UNCITRAL, UNCT/14/2.

21) Public Citizen, *U.S. Pharmaceutical Corporation Uses NAFTA Foreign Investor Privileges Regime to Attack Canada’s Patent Policy, Demand \$100 Million for Invalidation of a Patent* (March 2013), at <http://citizen.org/eli-lilly-investor-state-factsheet>.

## IV. SYSTEMIC ISSUES

### 1. Introduction

Concerning ISDS, many commentators point out its systemic problems such as a lack of legitimacy, consistency and predictability, and offer proposals to improve the system.<sup>22)</sup> Because I am not ready to give comprehensive opinions on ISDS in general, I would like to just touch on some points which I am concerned about as an intellectual property law scholar with experience of handling disputes at the WTO Dispute Settlement (DS) system.

### 2. Relation to the WTO DS system

As to the WTO DS system, the Understanding on Rules and Procedures Governing the Settlement of Disputes (DSU)<sup>23)</sup> provides as follows.

#### Article 23 (Strengthening of the Multilateral System)

1. When Members seek the redress of a violation of obligations [...], they shall have recourse to, and abide by, the rules and procedures of this Understanding.

2. In such cases, Members shall:

(a) not make a determination to the effect that a violation has occurred [...], except through recourse to dispute settlement in accordance with the rules and procedures of this Understanding, and shall make any such determination consistent with the findings contained in the panel or Appellate Body report adopted by the DSB or an arbitration award rendered under this Understanding [...].

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22) See, e.g., THE FOUNDATIONS OF INVESTMENT LAW: BRINGING THEORY INTO PRACTICE (Zachary Douglas et al. eds., 2014); 11 TRANSNATIONAL DISPUTE MANAGEMENT, Issue 1 (2014), at [www.transnational-dispute-management.com](http://www.transnational-dispute-management.com), which features "Reform of Investor-State Dispute Settlement: In Search of a Roadmap"; Policy Department of European Parliament, *Investor-State Dispute Settlement (ISDS) Provisions in the EU's International Investment Agreements* (2014), at <http://www.jura.fu-berlin.de/fachbereich/einrichtungen/oeffentliches-recht/lehrende/hindelang/Studie-fuer-Europaeisches-Parlament/index.html>.

23) Annex 2 of the Marrakesh Agreement Establishing the World Trade Organization.

On the other hand, in ISDS arbitration, the tribunal may face the need to interpret the WTO Agreements and decide on the violation thereof. For example, as we saw before, with respect to Art. 6.5 of the US-Uruguay BIT, the tribunal would have to determine the measure at issue (compulsory licenses, or revocation, limitation, or creation of IPR) is consistent with the TRIPS Agreement or not. The question is whether individual WTO Members may give an authority to “make a determination to the effect that a violation [of the WTO agreements] has occurred” to the arbitration tribunal.

The answer can be in the affirmative,<sup>24)</sup> if we may distinguish cases where Members themselves make a determination of WTO violation from cases where Members just empower ISDS to make such decisions, and if we then, through a narrow interpretation of Article 23(2) of DSU, apply the article only to the former cases. In addition, from a policy perspective, we may be able to regard ISDS as an alternative mechanism for the WTO DS system, because ISDS is expected to achieve de-politicization of dispute resolution, one of the main aims of the WTO DS system, through neutral and objective decision making.

However, some uneasiness remains. The WTO DS system is transparent, as well as watched and controlled by the multilateral body consisting of WTO Members. On the other hand, ISDS is not always transparent, and after all, it is based on a bilateral or plurilateral agreement. In short, ISDS is a fragmented system, and not a coherent system shared by the international community.

### 3. Consistency with the MFN treatment principle under the TRIPS Agreement

There is another question related to the principle of Most-Favoured-Nation

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24) Some commentators argue that disputes involving WTO-related issues can be handled by ISDS, without discussing the possible problem under the DSU. *See, e.g.,* Gaetan Verhoosel, *The Use of Investor-State Arbitration Under Bilateral Investment Treaties to Seek Relief for Breaches of WTO Law*, 6 J. INTL ECON. L. 495 (2003); Michael Ewing-Chow, *Thesis, Antithesis and Synthesis: Investor Protection in BITs, WTO and FTAs*, 30 U. NEW S. WALES L.J. 548, 551 (2007); Gibson, *supra* note 5, at 404.

treatment provided in Article 4 of the TRIPS Agreement. The article states that “[w]ith regard to the protection of intellectual property, any advantage, favour, privilege or immunity granted by a [WTO] Member to the nationals of any other country shall be accorded immediately and unconditionally to the nationals of all other Members”. Under IIAs with ISDS, nationals (investors) of the parties of the agreements are given the possibility of resolution of disputes related to IP protection in ISDS. Is such a status not an “advantage, favour, privilege or immunity” with respect to IP protection? If so, must the same treatment be accorded to the nationals of all other WTO Members?

It is well understood among practitioners and scholars that obligations concerning IP protection under IP-related provisions (mostly TRIPS-plus provisions) in Regional Trade Agreements (RTAs: FTAs, EPAs, etc.) must be abided by toward the nationals of all WTO Members including non-parties of the agreements.<sup>25)</sup> In the context of interpreting the term “advantage, favour, privilege or immunity,” distinguishing procedural aspects from substantive aspects of IP protection does not seem to make much sense.<sup>26)</sup> In addition, we should recall that Article 4 demands “unconditional[ ]” MFN treatment.

On the other hand, it may be also possible to resort to the exemption from the MFN treatment principle, which is provided in Article 4 (a) of the TRIPS Agreement concerning treatment “deriving from international agreements on judicial assistance or law enforcement of a general nature.” However, it is

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25) Regarding the legal effects of TRIPS-plus provisions in RTAs, see Masabumi Suzuki, *Assessment and Prospects of Intellectual Property Rights Provisions in RTAs*, RIETI Discussion Paper 08-J-005 (2008) (in Japanese), at <http://www.rieti.go.jp/jp/publications/dp/08j005.pdf>.

26) Footnote 3 to Article 3.1 of the TRIPs Agreement provides “[f]or the purposes of Articles 3 and 4, ‘protection’ shall include matters affecting the availability, acquisition, scope, maintenance and enforcement of intellectual property rights as well as those matters affecting the use of intellectual property rights specifically addressed in this Agreement”. It is worth noting that the Panel report on U.S. – Section 337 of the Tariff Act of 1930 (L/6439 – 36S/345) found a violation of the national treatment principle under the GATT based on the procedural difference between the border measures and federal district court proceedings in the United States concerning patent infringing goods.

debatable whether IIAs can be regarded as “international agreements on judicial assistance or law enforcement of a general nature.”

Another possible interpretation may be to understand that the MFN principle in the TRIPS Agreement does not extend the consent of a WTO Member to submit a dispute to investor-state arbitration under a certain investment agreement to other WTO-Members who are not the parties of the agreement. Such an interpretation was taken concerning the MFN clause in a BIT by a tribunal,<sup>27)</sup> but it is not clear whether we can take a similar view for Article 4 of the TRIPS Agreement.

## V. Conclusion

Based on what we saw, how should we evaluate ISDS as a mechanism to resolve disputes related to IPRs and public health? In addition, what should be done in the future?

As to the evaluation, I can only say that it remains to be seen, because there are simply too few examples (in fact, only one) of investor-state arbitration which has reached conclusion with regard to disputes related to IPRs and public health. Actually, as we can sense from the cases filed by such large corporations as PM Asia and Eli Lilly, it would be better any way for investors to have as many options as possible for dispute resolution. On the other hand, States are responsible for ISDS, as it is they who establish the ISDS mechanism. States should be watchful over the effectiveness of ISDS as a system to strike a balance between the protection of investment and the realization of public policy objectives.

What should be done in the future? Needless to say, we should keep evaluating and trying to improve the ISDS mechanism. In addition, I would like to suggest to start (more precisely, resume) thinking about the multilateralization

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27) *Salini v Jordan*, Decision on Jurisdiction, 29 November 2004, 14ICSID Reports 306. See DOLZER & SCHREUER, *supra* note 9, at 272-73.

of international investment law.

So far, efforts to make multilateral rules on investment, for example, the negotiation for a Multilateral Agreement on Investment (MAI) at the OECD and putting investment on the agenda of the WTO Doha Round, failed. Given the proliferation of IIAs and the accumulation of investment disputes, however, we are in a better position than before to embark on the task to prepare multilateral investment rules or disciplines.<sup>28)</sup> It would be also more effective to tackle systemic issues concerning ISDS in the process of multilateralization than to deal with the issues on a piecemeal basis. Of course, past experience predicts strong opposition to such efforts. More flexible approaches, for example, use of soft law, adopting rules with an opt-out option, or using large-scale regional agreements (such as TPP, TTIP (Transatlantic Trade and Investment Partnership) and the Japan-EU EPA) as stepping stones, might be more realistic.

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28) On multilateralization of international investment law, see Stephen W. Schill, *Ordering Paradigms in International Investment Law: Bilateralism – Multilateralism – Multilateralization*, in *THE FOUNDATIONS OF INVESTMENT LAW: BRINGING THEORY INTO PRACTICE* 109 (Zachary Douglas et al. eds., 2014).