

Looking at Specific Examples „Philip Morris“, „Eli Lilly“ and Other Cases: Which Safeguards Exist for Public Policy and TRIPS Flexibilities

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INTELLECTUAL PROPERTY RECHTSANWÄLTE

How have arbitral tribunals dealt
with public policy considerations
in IP-related investment disputes?

Overview

- Public Policy
- Intellectual Property Law
- WTO Law
- International Investment Law
- IP-related Investment Disputes
- Philip Morris vs. Uruguay
- Eli Lilly vs. Canada
- Conclusions

Public Policy

- Essential security interests
- Maintenance of public order and morality
- Taxation
- Elections
- Public services (schools, social security)
- Economic development
- Environmental protection
- Public health

Public Policy

Organisations that decide what topic should be a public policy:

- National level: Legislative, executive & judicial branches of government, interest groups
- International level: States, international organisations, international courts, interest groups

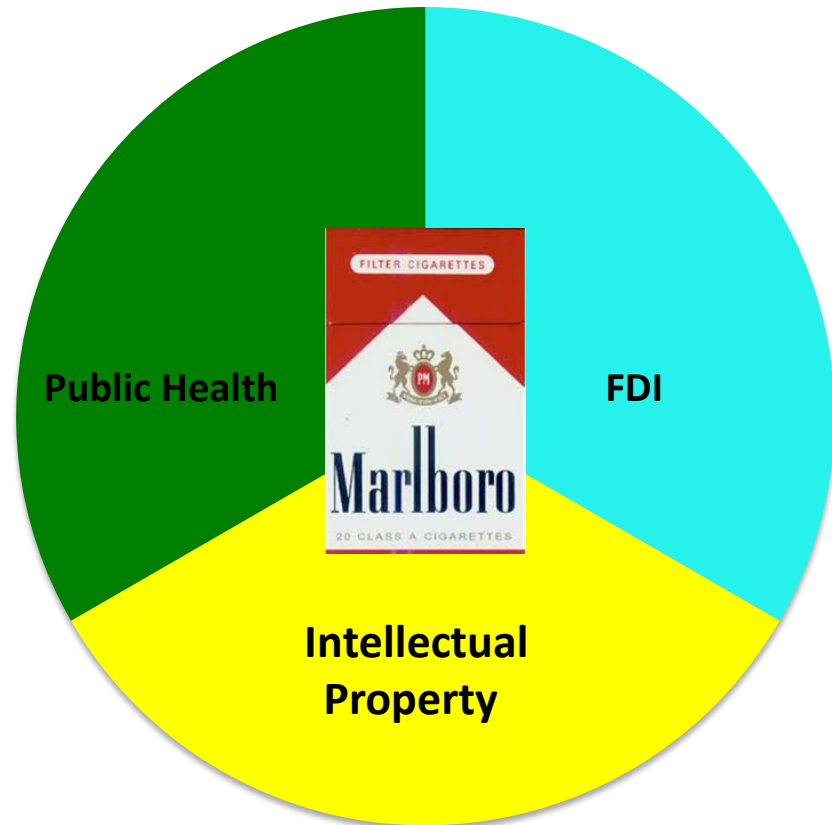
Public Policy

How to implement a public policy?

- National level: Acts of parliament, executive orders, adjudication, private initiatives
- International level: Treaties, international organisations, private initiatives
- Examples
 - FDI: investment guarantees; IIAs
 - Innovation: National & international IP law
 - Public health: Anti tobacco legislation; WHO FCTC

Public Policy

One topic can be the subject matter of various public policies:



How do intellectual property law,
WTO law, and international investment
law deal with different public policies?

Intellectual Property

The public policy of intellectual property law is

“[...]to encourage creative activity, [...]”

WIPO Convention 1967, Preamble

Intellectual Property



EUROPEAN PATENT SPECIFICATION

④ Date of publication of patent specification: 13.09.95 ④ Int. Cl.⁸ C07D 495/04, C07D 333/38, A61K 31/55, //(C07D495/04, 333:00,243:00)
④ Application number: 91303679.4
④ Date of filing: 24.04.91

The file contains technical information submitted after the application was filed and not included in this specification

④ Pharmaceutical compounds.

④ Priority: 25.04.90 GB 9009229
④ Date of publication of application: 30.10.91 Bulletin 91/44
④ Publication of the grant of the patent: 13.09.95 Bulletin 95/37
④ Designated Contracting States: AT BE CH DE DK ES FR GB GR IT LI LU NL SE
④ References cited:
GB-A- 1 533 235
GB-A- 1 533 236
GB-A- 1 577 743
US-A- 3 953 430

CHEMICAL ABSTRACTS, vol. 93, no. 17, 27 October 1990 Columbus, Ohio, USA J.K. CHAKRABARTI et al.: "Heteroarenebenzodiazepines. 3. 4-Piperazinyl-10 H-thieno[2,3-b][1,5]benzodiazepines as potential neuroleptics" page 21; ref. no. 160947N & J. Med. Chem. 1980, 23(8), 878-84

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Note: Within nine months from the publication of the mention of the grant of the European patent, any person may give notice to the European Patent Office of opposition to the European patent granted. Notice of opposition shall be filed in a written reasoned statement. It shall not be deemed to have been filed until the opposition fee has been paid (Art. 99(1) European patent convention).

Rank Xerox (UK) Business Services
0 1073 0933 3 3

Claims

Claims for the following Contracting States : AT, BE, CH, DE, DK, FR, GB, IT, LI, LU, NL, SE

1. 2-Methyl-10-(4-methyl-1-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine, or an acid addition salt thereof.
2. 2-Methyl-10-(4-methyl-1-piperazinyl)-4H-thieno[2,3-b][1,5]benzodiazepine, or a pharmaceutically acceptable acid addition salt thereof.
3. 2-Methyl-10-(4-methyl-1-piperazinyl)-4H-thieno-[2,3-b][1,5]benzodiazepine.
4. A compound according to claim 2 or 3 for use as a pharmaceutical.
5. The use of a compound according to claim 2 or 3 for the manufacture of a medicament for the treatment of a disorder of the central nervous system.
6. The use of a compound according to claim 2 or 3 for the manufacture of a medicament for the treatment of schizophrenia.
7. The use of a compound according to claim 2 or 3 for the manufacture of a medicament for the treatment of a schizophreniform disease.
8. The use of a compound according to claim 2 or 3 for the manufacture of a medicament for the treatment of acute mania.
9. The use of a compound according to claim 2 or 3 for the manufacture of a medicament for the treatment of mild anxiety states.

EP 0 454 436 B1

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INTELLECTUAL PROPERTY RECHTSANWÄLTE

Intellectual Property

International IP law
(e.g. Paris Convention, Berne Convention, TRIPs, PCT)

Regional IP law
(e.g. European Patent Convention, EU Trademark Regulation)

National IP law
(e.g. Patent Act, Trademark Act, Copyright Act, Design Act)

Intellectual Property

How does IP law deal with extrinsic public policies, e.g. morality/public health:

- Rule 28 (1) EPC – Exceptions to Patentability

“Under Article 53(a), European patents shall not be granted in respect of biotechnological inventions which, in particular, concern the following:

(a) processes for cloning human beings;

(b) processes for modifying the germ line genetic identity of human beings;

(c) uses of human embryos for industrial or commercial purposes;

(d) processes for modifying the genetic identity of animals which are likely to cause them suffering without any substantial medical benefit to man or animal, and also animals resulting from such processes.”

- EPO, G 2/06 – Use of embryos/WARF
- ECLI:EU:C:2011:669 - Oliver Brüstle v Greenpeace eV

Intellectual Property

- Section 11 (2b) German Patent Act – Bolar Exemption

„The effect of a patent shall not extend to studies, experiments and the practical requirements resulting therefrom which are necessary for obtaining authorisation to place medicinal products on the market in the European Union, or which are necessary for obtaining authorisation to place medicinal products on the market in the Member States of the European Union or in third countries;“

- Düsseldorf Higher Regional Court, order of December 5, 2013, I-2 U 68/12

Intellectual Property

- Section 24 (1) German Patent Act – Compulsory Licenses

„The non-exclusive authorisation to commercially use an invention shall be granted by the Federal Patent Court in an individual case in accordance with the following provisions (compulsory licence) where

- 1. a licence seeker has, within a reasonable period of time, unsuccessfully attempted to obtain permission from the proprietor of the patent to use the invention on reasonable commercial terms and conditions, and*
- 2. the public interest calls for the grant of a compulsory licence.“*

- German Supreme Court GRUR 2017, 1017 - Raltegravir

WTO Law

The public policies of WTO law are:

- raising standards of living
- full employment
- growing volume of real income and effective demand
- expanding the production of and trade in goods and service
- optimal use of the world's resources
- sustainable development
- environment
- economic development

WTO Agreement 1994, Preamble

WTO Law

- Multilateral Agreements on Trade in Goods
- General Agreement on Trade in Services
- TRIPs
- Trade Policy Review Mechanism
- Plurilateral Trade Agreements

WTO Law

WTO Dispute Settlement



DSU



WTO Law

How does TRIPs deal with extrinsic public policies, e.g. public health:

- Objectives and Principles under Article 7 and 8 TRIPs
- Article 27 (2) TRIPs – Exceptions to patentability

„Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect ordre public or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by their law.“

WTO Law

- Exceptions to patent rights conferred, Article 30 TRIPs
„Members may provide limited exceptions to the exclusive rights conferred by a patent, provided that such exceptions do not unreasonably conflict with a normal exploitation of the patent and do not unreasonably prejudice the legitimate interests of the patent owner, taking account of the legitimate interests of third parties.“
- Compulsory licenses under Article 31 TRIPs
- Security exceptions under Article 73 TRIPs
- Doha Declaration on TRIPs and Public Health 2001

International Investment Law

The public policies of international investment law are:

- economic co-operation
- favourable conditions for investments
- to stimulate private business initiative
- to increase the prosperity of both nations

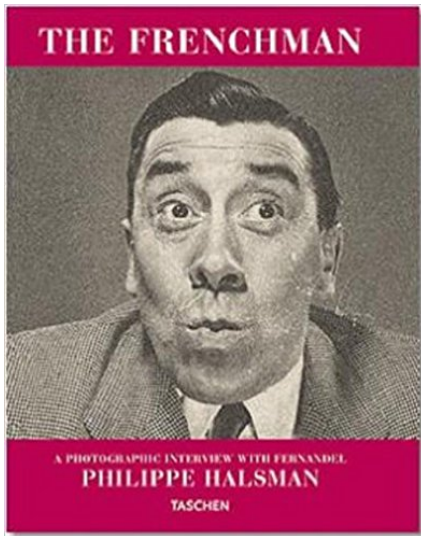
German Model BIT 2008

International Investment Law

- Standards of treatment
 - National treatment
 - Most favoured nation treatment
 - Fair and equitable treatment (FET)
 - Full protection and security
 - Umbrella clauses
 - Expropriation
- Remedies: Compensation

International Investment Law

Investor-state dispute settlement (ISDS)



**French-Spanish BIT
(fictitious)**



International Investment Law

How does international investment law deal with extrinsic public policies:

- Treaty exceptions, e.g. IP-specific exception: Article 8.12 (5) and (6) CETA

„5. This Article does not apply to the issuance of compulsory licences granted in relation to intellectual property rights, to the extent that such issuance is consistent with the TRIPS Agreement.

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

International Investment Law

- Police power doctrine

„A state is not responsible for loss of property or for other economic disadvantages resulting from bona fide general taxation, regulation, forfeiture for crime, or other action of the kind that is commonly accepted as within the police powers of states, if it is not discriminatory.“

§ 712 Restatement of the Law Third, the Foreign Relations of the United States

- Necessity under Article 25 ILC Draft Articles on State Responsibility

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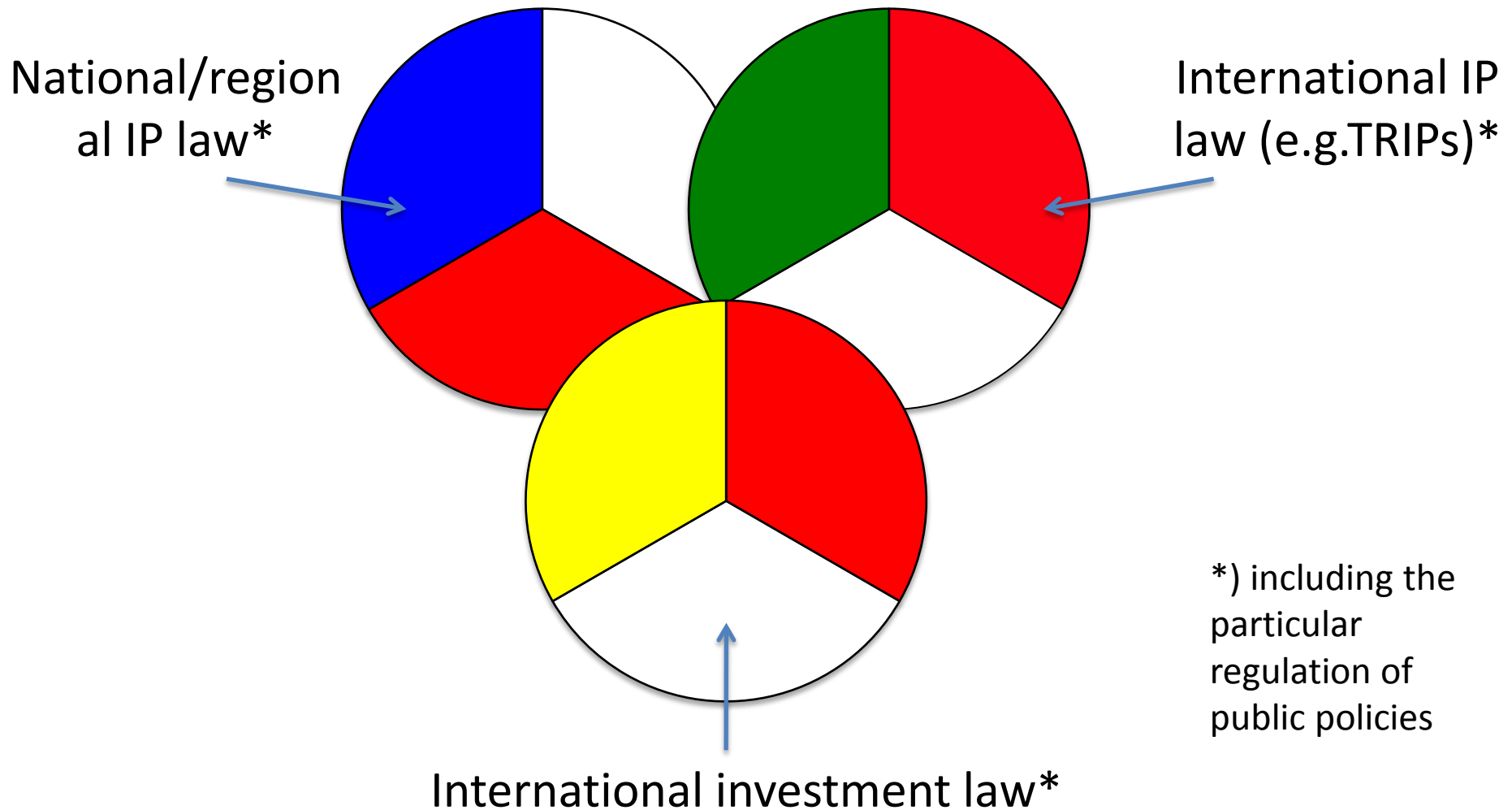
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IP-related Investment Disputes

	IP disputes	BITs disputes	WTO disputes
Parties	Private vs. private	Private vs. state	State vs. state
Subject matter	Infringement, validity, contract	State conduct	State conduct
Applicable law	National, regional and international IP law*	BITs*	WTO law*

*) including the particular regulation of public policies

IP-related Investment Disputes

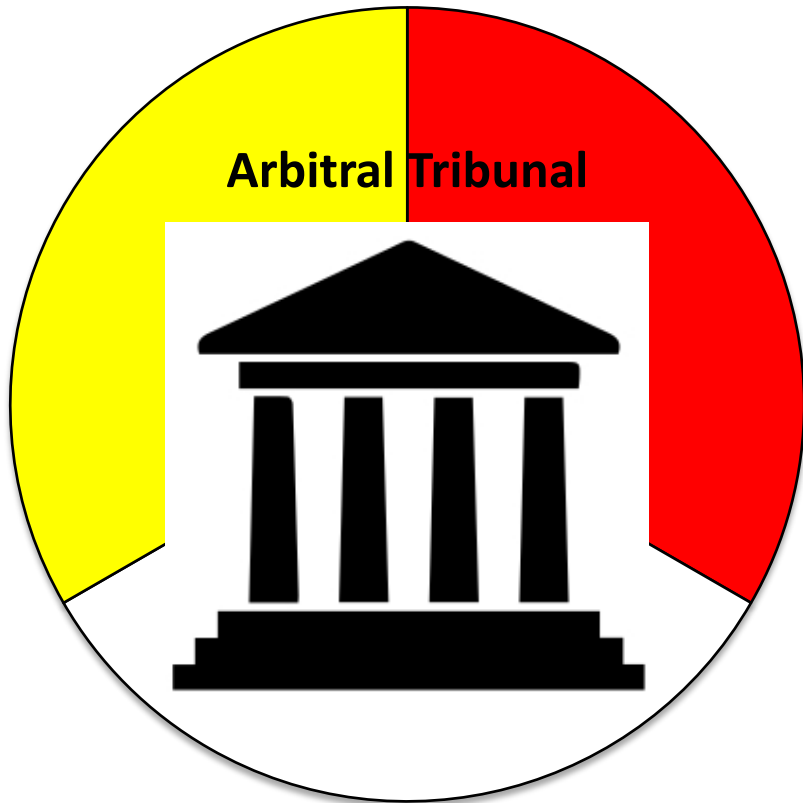


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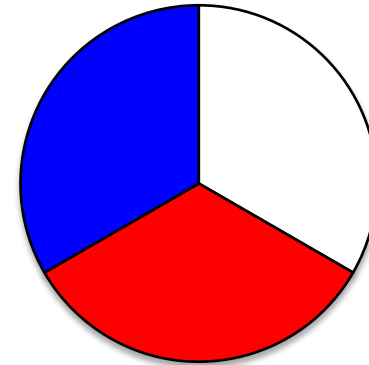
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IP-related Investment Disputes

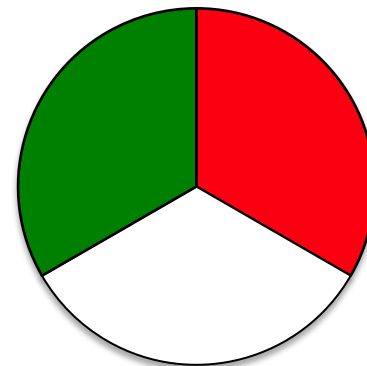


International investment law*

*) including the particular regulation of public policies



National/regional IP law*



International IP law (e.g. TRIPs)*

IP-related Investment Disputes

Extrinsic public policy considerations in international adjudication

„The task of interpreting and applying the chapeau is, hence, essentially the delicate one of locating and marking out a line of equilibrium between the right of a Member to invoke an exception under Article XX and the rights of the other Members under varying substantive provisions (e.g., Article XI) of the GATT 1994, so that neither of the competing rights will cancel out the other and thereby distort and nullify or impair the balance of rights and obligations constructed by the Members themselves in that Agreement. The location of the line of equilibrium, as expressed in the chapeau, is not fixed and unchanging; the line moves as the kind and the shape of the measures at stake vary and as the facts making up specific cases differ.“

US – Shrimps (AB 1998)

➔ WTO AB subjected „extrinsic public policies“ to a strict scrutiny.

IP-related Investment Disputes

Extrinsic public policy considerations in international adjudication

„In the Tribunal’s view, the present case concerns a legislative policy decision taken against the background of a strong scientific consensus as to the lethal effects of tobacco. Substantial deference is due in that regard to national authorities’ decisions as to the measures which should be taken to address an acknowledged and major public health problem. The fair and equitable treatment standard is not a justiciable standard of good government, and the tribunal is not a court of appeal. Article 3(2) does not dictate, for example, that a 50% health warning requirement is fair whereas an 80% requirement is not. In one sense an 80% requirement is arbitrary in that it could have been 60% or 75% or for that matter 85% or 90%. Some limit had to be set, and the balance to be struck between conflicting considerations was very largely a matter for the government.“

Philip Morris v. Uruguay (Award 2016)

➔ Arbitral tribunal applied a more lenient standard to „extrinsic public policies“.

Philip Morris vs. Uruguay

Single presentation requirement: Prohibition of more than 1 variant of cigarette per brand family



Philip Morris vs. Uruguay

80/80 regulation: Increase of the size of health warnings from 50% to 80%

Health Warning Evolution in Uruguay



PHILIP MORRIS INTERNATIONAL

URUGUAY

Before

May 2005

Jun 2006

Nov 2008

Mar 2009

Dec 2009



Text warning 100%
of one side panel

Health warning 50%
both faces
Text warning 100%
of one side panel

Graphic health warning 50%
both faces
Text warning 100%
of one side panel

Graphic health warning 50%
both faces
Text warning 100%
of one side panel

Graphic health warning 50%
both faces
Text warning 100%
of one side panel

Graphic health warning 80%
both faces
Text warning 100%
of one side panel



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Philip Morris vs. Uruguay

- In 2010 Philip Morris commenced ISDS against Uruguay under Uruguay-Switzerland BIT.
- Philip Morris claimed that
 - the SPR had a negative impact on its brands and the underlying trademarks, as well as the investment in its Uruguayan subsidiary;
 - the 80/80 regulation limited the subsidiary's right to use its trademarks and to display them in their proper form, which in turn limited the value of the subsidiary.

Philip Morris vs. Uruguay

- Philip Morris' claims:
 - Expropriation
 - Denial of fair and equitable treatment
 - Unreasonable impairment
 - Umbrella clause
 - Denial of justice
- The arbitral tribunal rejected jurisdictional objections raised by Uruguay

Philip Morris vs. Uruguay

- The arbitral tribunal held that Uruguayan law is relevant for establishing the rights that the state recognizes as belonging to the claimant, e.g. trademarks. The reason is that trademarks are created under national/regional IP law.
 - ➔ This is a gateway for national/regional intellectual property law (including its regulation of intrinsic/extrinsic public policy considerations, e.g. promotion of creativity, Rule 28 (1) EPC, Section 11 (2b) German Patent Act)
- Uruguayan law is not relevant for determining whether the modification/cancellation of the claimant's rights constitutes a violation of the BIT.
 - ➔ This is a gateway for international investment law (including its regulation of intrinsic/extrinsic public policy considerations, e.g. promotion of FDI, police powers doctrine)

Philip Morris vs. Uruguay

The tribunal denied indirect expropriation caused by

- the 80/80 Regulation because the Marlboro brand continued to appear on cigarette packs. A 20% limitation constituted only a limitation on the use of the trademarks.
 - SPR because the tribunal focused on Philip Morris' investment in Uruguay as a whole and not on individual trademarks. SPR did not result in a „substantial deprivation“ of the value of Philip Morris' investment.
- ➔ The arbitral tribunal applied a lenient standard of treatment to Uruguay's public policy decision.
- ➔ A similar standard of treatment could be applied to compulsory licenses under section 24 (1) German Patent Act.

Philip Morris vs. Uruguay

International investment law as a gateway for considering public policy issues in IP-related investment disputes:

- The tribunal also rejected Philip Morris' expropriation claim on the basis that Uruguay's measures were a legitimate exercise of its police powers for the protection of public health.
 - The tribunal rejected denial of FET concerning Philip Morris' legitimate expectations, inter alia, because manufacturers of harmful products, such as cigarettes, can have no expectations that new and more onerous regulations will not be imposed.
- ➔ Arbitral tribunal deferred to Uruguay's public policy decision.

Eli Lilly vs. Canada

- In 1991 and 1996 Eli Lilly filed the Zyprexa and Strattera patent applications, respectively.
- In 2010 and 2011 Canadian courts invalidated the Zyprexa and Strattera patents for lack of utility on the basis of the so-called „promise utility doctrine“, which was developed in the mid-2000s by Canadian courts.



Eli Lilly vs. Canada

- In 2013 Eli Lilly commenced ISDS against Canada under NAFTA Investment Chapter 11.
- Eli Lilly claimed
 - that the promise utility doctrine was a radical departure from Canada's traditional utility standard (violating the NAFTA IP Chapter 17), and
 - that the retroactive application of the doctrine to invalidate the Zyprexa and Strattera patents resulted in an unlawful expropriation and denial of justice.

Eli Lilly vs. Canada

Eli Lilly's claims:

- Expropriation
- Denial of FET

Eli Lilly vs. Canada

- State courts are not exempt from NAFTA Chapter 11 so that Canada can be held liable if its courts do not comply with the standards of treatment under NAFTA Chapter 11.
 - However, the arbitral tribunal is not an appellate body as regards decisions of the national judiciary; therefore considerable deference should be accorded to the decisions and conduct of state courts.
- ➔ Arbitral tribunal exercised „jurisdictional caution“ vis-à-vis national judiciary.

Eli Lilly vs. Canada

- The standard applied by the arbitral tribunal in respect of expropriation and denial of FET was whether the Canadian courts' adoption of the promise utility doctrine in the mid-2000s was a „dramatic“ or „fundamental“ change from prior law.
 - The arbitral tribunal only found that Canada's utility requirement underwent incremental change between the time the Zyprexa and Strattera patents were granted and subsequently invalidated.
- ➔ Arbitral tribunal also exercised caution with respect to substantive law decisions which were taken by the national judiciary.

Eli Lilly vs. Canada

- Whereas the arbitral tribunal in Philip Morris vs. Uruguay only regarded Philip Morris' investment in Uruguay as a whole as the object of expropriatory measures, the arbitral tribunal in Eli Lilly vs. Canada had no problem with regarding the Zyprexa and Strattera patents as protected „investments“.
- ➔ Possibility to focus on specific public policy issues/to exclude other public policy issues

Eli Lilly vs. Canada

- The tribunal noted that its jurisdiction is limited to investment law claims under Section A of NAFTA Chapter 11.
 - The tribunal held that it has no jurisdiction to adjudicate claims for breach of other NAFTA provisions, e.g. NAFTA IP Chapter 17.
 - Nevertheless, the tribunal held that it would not ignore other rules of international law.
- ➔ Possibility to take into account public policy considerations regulated in TRIPs and the Doha Declaration on TRIPs and Public Health 2001

Conclusions

- National IP law, international investment law and international IP law can serve as gateways for public policy considerations in IP-related investment disputes.
- In the existing awards on IP-related investment disputes arbitral tribunals largely deferred to public policy decisions that are extrinsic to international investment law and IP law (e.g. public health).
- Did the arbitral tribunals struck the right balance between public policies, which are inherent to international investment law and IP law, e.g. protection of property, and other public policies, e.g. public health?

Further Reading

- Simon Klopschinski/Christopher S. Gibson/Henning Grosse Ruse-Khan, *The Protection of Intellectual Property under International Investment Agreements*, Oxford University Press (forthcoming)
- Simon Klopschinski, *Der Schutz geistigen Eigentums durch völkerrechtliche Investitionsverträge (The Protection of Intellectual Property under International Investment Agreements)*, Carl Heymanns Verlag 2011
- Simon Klopschinski, *The WTO's DSU Article 23 as Guiding Principle for the Systemic Interpretation of International Investment Agreements in the Light of TRIPs*, 19 *Journal of International Economic Law* 211 (2016)

Thank you!

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