



INTELLECTUAL PROPERTY AND TRADE

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OUTLINE

1. Intellectual property as a subset of international economic law – trade and investment
2. Examples of patent law, pharmaceuticals
3. Exceptions to patent rights, compulsory licensing
4. The push for IP maximalisation
5. Examples of technology transfer

CONCEPT AND FUNCTIONS OF IPRS

Create and grant legal entitlement to exclusive commercial use of information due to market failures

- “Monopoly” in form of exclusive rights limited in time as incentive for innovation (e.g. patents) and creation (e.g. copyright)
- Dissemination of innovative and creative efforts
- Renewable “monopoly” as identifier and incentive to invest in quality (trademarks, trade names, indication of origin)

IP AND TRADE LINKAGES

- IPRs are rights given to persons over the creations of their minds. They usually give the creator an exclusive right over the use of his/her creation for a certain period of time
- Linkage between IP and trade: broadly through following two premises:
 - (I) Widespread piracy, counterfeiting and infringements of intellectual property rights constituted a barrier to trade
 - (II) IPRs/technology transfer agreements

IP AND THE WTO

Negotiated in the Uruguay Round

Rationale — minimum standards on rights and enforcement obligations— IP inherent in many/most goods that are traded

Difficult Negotiations

- North v South, with unilateralism in the background (S 301)

Controversial Implementation

- raising issues about the limits countries face when they try to adopt high standards.


TRIPS & IP HISTORY

TRIPs follows up and incorporates major intellectual property treaties:

- Paris (1883) (patents/trademarks)
- Berne (1886) (copyrights)

Objectives of the TRIPS Agreement

- To reduce distortions and impediments to international trade and take into account the need to promote competition as well as adequate protection of IPRs
- To ensure that measures and procedures to enforce IPRs do not themselves become barriers to legitimate trade
- To reduce tensions by reaching strengthened commitment to resolve disputes on trade-related IP issues through multilateral procedures
- To establish a mutually supportive relationship between the WTO and World Intellectual Property Organisation (WIPO)



“[T]he field of international intellectual property law underwent a tectonic shift with the promulgation of the [TRIPS].”

- Charles McManis, Washington University of Saint Louis

WHAT DOES THE TRIPS AGREEMENT DO?

Recognizes and defines minimum standards in seven categories of IPRs:

- Patents (product and process)
- Trademarks
- Copyrights
- Trade Secrets
- Industrial Designs
- Lay-out Designs/Integrated Circuits
- Geographical Indications

STANDARD SETTING IN THE TRIPS

Territoriality – countries recognise IPRs and provide a way to grant and enforce rights—in domestic laws

Sets out minimum standards

- Term of protection
- Principles of MFN and National Treatment
- Procedural and enforcement obligations
 - Setting up of IP administrative offices
 - judicial procedures
 - border and internal measures to counter infringement — seizures
 - civil and criminal procedures

DESIGN OF TRIPS AGREEMENT

Part 1 — General Provisions and Basic Principles

- Scope; Adoption of Existing Intellectual Property Conventions; National Treatment; Most Favoured Nation

Part II — Standards (on availability, scope and use) for each of the seven IPRs

Part III — Obligations to provide procedures/remedies for IP rights

Part IV — Transitional Arrangements

Part V — Dispute Settlement

DESIGN OF TRIPS AGREEMENT

Illustration: Part II, Patents

- Art. 27 Patentable subject matter
- Art. 28 Rights Conferred
- Art. 29 Conditions on Patent Applicants
- Art. 30 Exceptions to Rights Conferred
- Art. 31 Other use without Authorization (Compulsory licensing, emergencies and response to anticompetitive uses)
- Art. 32 Revocation/Forfeiture
- Art. 33 Term
- Art. 34 Process Patents: Burden of Proof
- Section 8 — Control of Anti-Competitive Practices in Contractual Licenses. (Art. 40 recognizes the link between IP protection and anti-competitive licensing practices and gives Members the right to determine what constitutes an abuse of IPRs and to ban certain licensing practices.)

TRIPS AGREEMENT: ART 27

Patents shall be available

- “...for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application ... and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.”

Sets out several minimum standards for patent protection

- Invention (whether products or processes)
- Novel
- Inventive step (non-obvious)
- Capable of industrial application (useful)

PATENTABLE SUBJECT MATTER



TRIPS 27(2), 'Exceptions' to patentability

Members may exclude from patentability inventions ... 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...



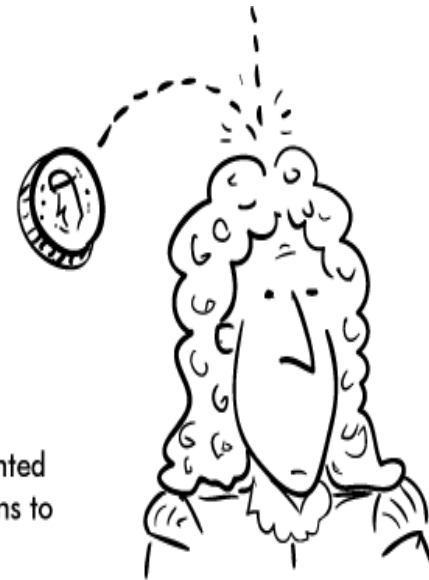
TRIPS Art 27(3)

(a) Members may exclude diagnostic, therapeutic and surgical methods for the treatment of humans or animals

(b) Members may exclude plants and animals other than micro-organisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof...



FACT:
Newton invented
ridges on coins to
prevent theft



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INVENTIVE STEP



Inventiveness (aka non-obvious)

- protects against patents being granted for things that are already in the public domain
- protects against patents being granted for new inventions which lack creativity such that they are obvious to a person of ordinary skill in the art relative to the invention

US Patent Code, S 103

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made. ...



New forms of known substances

India excludes patents on '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...'.
Efficacy = improvement to the actual medicinal or healing effect in the body as opposed to merely allowing the medicine to be stored or handled more easily or cheaply.



In April 2013, Supreme Court of India denied Novartis a patent for cancer drug Glivec

Rejected in 2006 - Section 3(d) of the Patents Act
Appeals rejected in 2007 and 2009

NOVELTY AND INVENTIVE STEP



Utility = useful or capable of industrial application

Invention must be 'new and useful'

- 'If not useful, it is not an invention within the meaning of the Act' (*Apotex v Welcome* (CND SC, 2002))



What is the point where a concept turns from mere speculation to utility?



Is objective evidence of effect, or potential effect, needed?

UTILITY/INDUSTRIAL APPLICATION

UTILITY/INDUSTRIAL APPLICATION

Article 33(4) of the PCT states:

- “For the purposes of the international preliminary examination, a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense) in any kind of industry. “Industry” shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property.”

In the context of pharmaceuticals, see *In re Brana*, US Court of Appeals for the Federal Circuit:

- “Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.”

UTILITY AND PHARMACEUTICALS: MORE DIFFICULT CANADIAN STANDARD

Apotex v Wellcome (CND SC, 2002)

- Generic manufacturers challenge AZT patent
- Claims identification of AZT as a treatment for HIV/AIDS was speculation 'based on inadequate information and testing'
- Claims NIH should have some patent rights

Court: No patent if Glaxo/Wellcome hadn't established such utility by tests or sound prediction (constructive reduction to practice) when it applied for the patent

Apotex argues

- Glaxo/Wellcome did not "discover" the chemical compound (well-known for 20 years) for AZT
- Glaxo/Wellcome identified a new use – an unrecognised utility



Supreme Court

“Where the new use is the *gravamen* of the invention, the utility required for patentability (s. 2) must, as of the priority date, either be demonstrated or be a sound prediction based on the information and expertise then available.”



Doctrine of ‘Sound Prediction’

- (1) Factual basis for the prediction
- (2) Articulable and “sound” line of reasoning from which the desired result can be inferred from the factual basis
- (3) Proper disclosure

UTILITY AND PHARMACEUTICALS: MORE
DIFFICULT CANADIAN STANDARD

UTILITY: ELI LILLY V CANADA (NAFTA, 2012)

Eli Lilly submitted notice of its intent to file a claim under NAFTA Chapter 11 against Canada

- Court invalidated several Eli Lilly patents
- Complaint against Canada's strict patentability requirements applied since 2005 regarding 'utility' ('promise doctrine') and a 'new, non-statutory disclosure obligation'
- Claim expropriation and breach of fair & equitable treatment (FET) – invalidations 'are contrary to Canada's international treaty obligations' (i.e. TRIPS, NAFTA and the Patent Cooperation Treaty)

UTILITY: ELI LILLY V CANADA (NAFTA, 2012)

Tribunal focused on two questions

- 1) has there been a dramatic change in the utility requirement in Canadian patent law?
- 2) is the utility requirement in Canadian patent law, as applied to the Zyprexa and Strattera Patents, arbitrary and discriminatory?

Eli Lilly failed to demonstrate a fundamental or dramatic change in Canadian patent law and that the evolution of the Canadian legal framework was not arbitrary or discriminatory in accordance with NAFTA Chapter 11.

EXCEPTIONS: COMPULSORY LICENSING

Compulsory license

- a government allows the production of a patented product without the necessary permission from the patent holder

Article 31

- permits Members to grant compulsory licenses for patented products and processes under limited circumstances and upon satisfying certain conditions (a-k), including:
- prior negotiation with patent holder (waived in national emergency or other circumstances of extreme urgency or in cases of public non-commercial use).
- scope and duration of such use shall be limited to the purpose for which it was authorized
- non-exclusive, non-assignable
- authorised *predominantly for the supply of the domestic market*
- adequate remuneration
- legal validity of any decision relating to the authorization shall be subject to judicial review or other independent review by a distinct higher authority in that Member.

TRIPS: EXCEPTION TO OWNER RIGHTS

Section 84 of India's Patents Act allows for the issuance of a compulsory licence provided that three years have passed from the grant of the patent and one of the following three criteria is satisfied:

- (1) failure to satisfy the 'reasonable requirements of the public';
- (2) failure to provide the patented invention to the public 'at a reasonably affordable price'; and
- (3) failure to 'work' the patent in India.

India issues first compulsory licence in March 2012

- Nexavar, used to treat kidney and liver cancer
- Bayer 'clearly neglected India' and that it had not taken 'adequate or reasonable steps to start the working of the invention in the territory of India on a commercial level and to an adequate extent.'

FREE TRADE AGREEMENTS AND PHARMACEUTICAL PATENTS

Patents-plus, TRIPS-plus

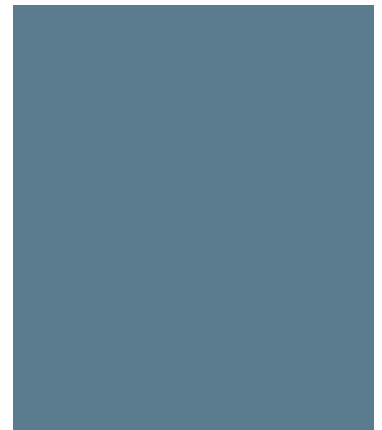
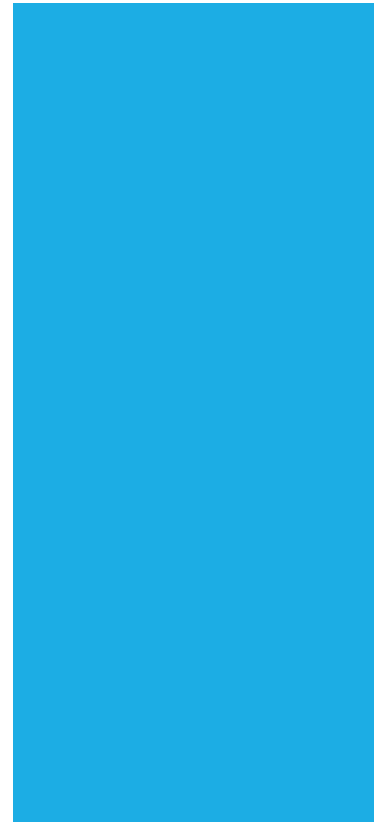
- Patent term extension
- Patent linkage
- Test data protection
- Limitations on compulsory licensing

HARMONISATION: WITHOUT CONTEXT OR EMPIRICAL BASIS

Differences in design and implementation can have a large impact on availability of generic medicines and price

Presumably designed to suit the particulars of the differing jurisdictions, most simply follow US justifications and model

No evidence that any of the systems reduce costs, increase access to medicines or promote innovation





TRIPs (Art 66.2) encourages 'technology transfer'

Directs developed countries to provide incentives to their enterprises and institutions for the purpose of promoting and encouraging technology transfer to least-developed Members 'in order to enable them to create a sound and viable technological base'.



Certain International Investment Agreements prohibit performance requirements, which include technology transfer provisions

Broad rejection of performance requirements
Framework of TRIMS, with wider coverage: export performance, technology transfer, equity participation, etc

IIAS AND THE PROHIBITION ON PERFORMANCE REQUIREMENTS

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Canada – Venezuela BIT, Annex II.6

Neither Contracting Party may impose any of the following requirements in connection with permitting the establishment or acquisition of an investment or enforce any of the following requirements in connection with the subsequent regulation of that investment ...

- (e) requirements that an investor of the other Contracting Party transfer technology, a production process or other proprietary knowledge to a person in its territory unaffiliated with the transferor, except when the requirement is imposed or the commitment or undertaking is enforced by a court, administrative tribunal or competition authority, either to remedy an alleged violation of competition laws or acting in a manner not inconsistent with other provisions of this Agreement.

IIAS AND THE PROHIBITION ON PERFORMANCE REQUIREMENTS

US-Chile FTA, Investment Chapter, Article 10.5.3(b), prohibition on technology transfer does not apply...

“when a Party authorizes use of an intellectual property right in accordance with Article 31 of the TRIPS Agreement, or to measures requiring the disclosure of proprietary information that fall within the scope of, and are consistent with Article 39 of the TRIPS Agreement”

IIAS AND THE PROHIBITION ON PERFORMANCE REQUIREMENTS

Japan-Vietnam BIT, Article 4(1)(g), prohibition on the imposition and enforcement of...

“transfer technology, a production process or other proprietary knowledge to a natural or legal person or any other entity in its Area, except when the requirement (i) is imposed or enforced by a court, administrative tribunal or competition authority to remedy an alleged violation of competition laws; or (ii) concerns the transfer of intellectual property rights which is undertaken in a manner not inconsistent with the Agreement on Trade-Related Aspects of Intellectual Property Rights ...”

A person wearing a dark blue suit jacket, a light-colored shirt, and a dark tie is holding a rectangular white sign with both hands. The sign has the word "QUESTIONS?" written on it in a bold, dark blue, sans-serif font. The background is a plain, light gray color.

QUESTIONS?